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Comparison of Body Weight Support–Assisted Balance and Gait Training With or Without Balance Perturbations in Poststroke Rehabilitation: Multisite Randomized Controlled Trial

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Abstract

Background: Impaired balance regulation after stroke puts patients and therapists at a heightened risk of injury during rehabilitation. Body weight support systems (BWSS) allow patients to safely conduct gait and balance training while minimizing risk and the fear of falling. Integrating perturbation-based balance training (PBT) modules with a BWSS may lead to further improvements.

Objective: This study aimed to evaluate the impact of a ceiling-track-mounted BWSS plus an integrated PBT (BWSS-P) module on the rehabilitation of stroke-related gait and balance impairments.

Methods: A multisite randomized active-comparator controlled trial was conducted. Inpatients with Berg Balance Scale (BBS) scores ≥21/56 were recruited from 4 sites. Participants completed 2-to-6 BWSS or BWSS-P study sessions. Both groups conducted the same balance and gait regimen, with the BWSS-P group also receiving 8 balance perturbations per session. BBS, Activities-Specific Balance Confidence, and 10 Meter Walk Test assessments were collected.

Results: A total of 126 patients were approached with 99 yielding sufficient data for analysis. With a corrected α level of .0054, both groups showed significant in-group changes over time for all outcomes evaluated ($P \leq .001$). However, the primary outcome measure, the BBS, did not show evidence of a difference between BWSS and BWSS-P groups over time ($F_{1,97}=1.57$; $P=0.21$) via linear mixed effects modeling with type III Wald F test with Kenward-Roger degrees of freedom. No significant between-group differences were noted for either secondary outcome measure, the Activities-Specific Balance Confidence scale ($F_{1,94.99}=0.36$; $P=.55$), or 10 Meter Walk Test ($F_{1,97}=4.15$; $P=.04$).

Conclusions: Although significant between-group differences were not observed, participants in both groups demonstrated similar improvements from before to after assessment. This novel PBT technology shows promise as an option for gait and balance recovery training, especially for individuals with impaired balance control or fear of falling. The BWSS-P intervention contributed positively to rehabilitation outcome overall and should be considered as a viable treatment modality when clinically appropriate.

Trial Registration: ClinicalTrials.gov NCT05110300; https://clinicaltrials.gov/study/NCT05110300.

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KEYWORDS

stroke rehabilitation; postural balance; gait; ambulation; balance perturbation; postural perturbation; body weight support system; physical therapy; long-term acute care hospital; acute rehabilitation

Introduction

Each year, more than 795,000 people experience a stroke [1]. Strokes are devastating neurological events that can lead to cognitive and physical deficits, such as the inability to ambulate, impaired balance regulation, and loss of coordination [2]. Following a stroke, many patients are admitted to rehabilitation facilities to address these deficits and maximize their independence before returning to the home setting [3]. Gait and balance dysfunction are common secondary impairments to

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stroke, usually requiring specific neurological rehabilitative interventions to regain functional independence [4,5].

As a result of these physical deficits, patients are at a higher risk of experiencing a fall following a stroke [6]. Moreover, fear of falling has also been shown to influence balance and gait control in older adults, with over 90% of survivors of stroke reporting that the fear of falling negatively impacts their performance of daily living activities [7]. These psychological factors are strong predictors of falling compared to some physical factors or the presence of pathology [8,9]. It is reasonable then to suspect that any fall that occurs during rehabilitation would either reinforce or create a psychological fear of falling that would impede patient recovery [9].

Unfortunately, falls during and outside of rehabilitation can prolong patients' inpatient length of stay, increasing the economic and financial strain on them and their families when the patient is unable to work [10]. Any falls, especially injurious falls, also increase the financial burden of an institution [11]. Focusing on balance and gait training early in patients' rehabilitation can improve their overall fall risk, reducing the need for other resources such as safety sitters and further improving the financial burden of the institution. One strategy for improving balance and gait training safely is to incorporate new and existing robotic technologies into neurological rehabilitation, including body-weight support systems (BWSS) [12].

BWSS are stationary or track-mounted suspended harnesses that support a predetermined portion of a patient's body weight. BWSS permits those with significant weakness and poor coordination to ambulate and perform more intensive therapy sessions sooner in their recovery with minimal risk of injurious falls [13]. Current evidence supports the safety and effectiveness of BWSS during rehabilitation training, showing greater improvements in patient outcomes in patients treated with BWSS versus without [14,15].

Perturbation-based balance training (PBT), the practice of purposefully unbalancing patients to rehabilitate their postural control, can also be used to improve patients' balance control following stroke or other age and disease-related balance impairments [16-21]. Where other training modalities can only provide nonreactive balance training, PBT can be used to improve both reactive and anticipatory control to unexpected and anticipated stimuli [22]. Conventionally, PBT is conducted using modified treadmills, unstable surfaces, or external force directly provided by a treating therapist [16-21]. These strategies present a risk to patients and therapists alike. Incorporating a stationary BWSS over a modified treadmill or unstable surface can decrease this risk; however, ambulation over a treadmill does not represent functional ambulation in the patients' home environment, and some patients struggle to use a treadmill. Unfortunately, there is little consensus about the optimal training regimen for PBT [23,24].

To reduce risk and replicate patients' functional ambulation, new devices have been developed that integrate PBT with an overhead track-mounted BWSS [12,25,26]. Using this "fall-free" environment, therapists can deliver PBT safely and consistently earlier in patients' plan of care. Previously, we conducted a pilot study of such a device [13].

In that study, we demonstrated that a standardized balance and gait training regimen using BWSS or BWSS plus an integrated PBT module (BWSS-P) was safe and did not negatively impact patient recovery [13]. The preliminary efficacy data from this pilot study demonstrated similar improvements in BWSS and BWSS-P groups from baseline to postintervention, but as a pilot study, it was underpowered to determine if there was a significant impact on patient outcomes between groups.

The goal of this study was to build upon this pilot study and conduct a definitively powered randomized controlled trial. We hypothesized that BWSS-P would demonstrate greater outcomes than BWSS-supported training alone.

Methods

Ethical Considerations

A multisite randomized active-comparator controlled clinical trial was conducted. The study was submitted, reviewed, and approved by each site's institutional review board for either local review or to complete a reliance agreement with the Gaylord Hospital institutional review board [27]. Enrollment began on December 15, 2021, and ended on November 6, 2023. Once approved, the study procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Declaration of Helsinki. This included maintaining the privacy and confidentiality of research participants' data and identity. Written informed consent was delivered and collected from each participant before study activities were conducted. Participants were not compensated for study participation. Before the study was initiated, the study was prospectively registered with ClinicalTrials.gov (NCT05110300) on October 26, 2021. For reporting, the CONSORT (Consolidated Standards of Reporting Trials) framework was used (Checklist 1).

Power Analysis and Interim Analysis

Referencing the early efficacy data collected in the pilot study [13], a Cohen *d* effect size of 0.39 was calculated for the observed Berg Balance Scale (BBS) change using a 2-sample, 2-tailed *t* test. Assuming a similar effect size, a 2-tailed power analysis (α=.05) and sample size estimation for 80% power were conducted. Using G*Power, an estimated sample size of 214 participants was needed for this effect size to achieve 80% power. During study development, an interim analysis was prospectively planned once 100 participants successfully completed the study activities. Given the small effect size noted in preliminary efficacy data, the goal of this interim analysis was to evaluate the study progression and to determine where there was any clear evidence of a clinically important difference between intervention groups that was or was not trending towards statistical significance.

Study Locations and Study Criteria

Participants were recruited from 1 of the 4 participating inpatient rehabilitation centers: Gaylord Specialty Healthcare,

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Wallingford, CT (site 1); MedStar National Rehabilitation Hospital, Washington, DC (site 2); Spaulding Rehabilitation Hospital Cape Cod, Sandwich, MA (site 3); and St. Luke's Rehabilitation Hospital, Spokane, WA (site 4). Site 1 was the primary coordinating site for study activities.

To be eligible, participants had to be admitted for inpatient rehabilitation following either an ischemic or hemorrhagic stroke of any laterality or location. Patients were evaluated by physical therapy within the first 72 hours of admission at each recruitment site, at which point an initial BBS was obtained as appropriate. To be eligible, patients had to have a BBS score of ≥21/56. The BBS was chosen as the primary eligibility criterion as it was the standard functional balance measure used across all sites.

Patients were ineligible to participate if they did not meet any one of these criteria or presented with one or more of the exclusion criteria shown in Textbox 1. To increase recruitment, the progression of patients with a BBS of <21 at admission was tracked; if at any point those patients later progressed to a BBS of ≥21/56, they were rescreened for study inclusion. If the patient met the study criteria, did not meet the exclusion criteria, and had a set discharge date of 10 days or longer from the time of recruitment, they were consented into the study.

Textbox 1. Exclusion criteria.

- Cognitive deficits that would disrupt the ability to provide informed consent
- Active enteric infection control precautions
- Ongoing orthostasis
- Uncontrolled hyper- or hypotension
- Active seizures
- Spinal stabilization with the use of a halo-brace or halo-gravity traction
- Unstable skin structures (ie, skin grafts)
- Chest tubes
- Unstable rib or lower extremity fractures
- Severe osteoporosis
- Subjects where pressure around the abdomen, thighs, groin, or shoulders is contraindicated
- New limb amputations
- Vestibular disorders that may impact balance
- Premorbid conditions that may impact balance
- Patients requiring more than 50% high flow oxygen as consistent with inpatient therapy guidelines.
- Subjects who weigh more than 450 pounds, per the structural limitations of the ZeroG system.
- Anyone belonging to a vulnerable population, including individuals aged <18 years and who are or might be pregnant.

Functional Outcome Instruments

The primary end point for this study was the BBS [28], with the Activities-Specific Balance Confidence (ABC) scale [29], and the self-selected 10 Meter Walk Test (10MWT) as secondary outcomes [30]. The BBS is an objective clinician-reported balance measure with a scale of 0 to 56 (0 being the lowest function and 56 being the highest function), the ABC scale is a subjective patient-reported balance confidence measure with a scale of 0% to 100% (0% being the least confident and 100% being the most confident), and the self-selected 10MWT is used to evaluate gait speed in meters per second ($m\ s^{-1}$), which has been shown to correlate to balance and fall risk [31].

The BBS evaluation that was collected within 72 hours of admission was used as the baseline assessment (ie, before assessment) during data analysis. If eligible and willing to participate, participants were consented and enrolled into the study within 48 hours of admission.

After consent was collected, and before the study-related therapy sessions began, the ABC scale and 10MWT were administered by site investigators. Within 48 hours of the last study session or prior to discharge, whichever occurred first, a post-intervention assessment (ie, after assessment) was collected for all measures.

BWSS Equipment

For this study, the ceiling-track-mounted, Food and Drug Administration–listed ZeroG Gait and Balance BWSS and the ZeroG Training Responses in Postural Rehabilitation balance perturbation module (Aretech LLC) were used to complete this study. All study locations already had the ZeroG BWSS with Training Responses in Postural Rehabilitation module installed prior to study initiation. The study sites were not sponsored or supported by the manufacturer to conduct this study.

Standard Care Protocol and PBT Interventions

To minimize disruptions to participants' standard therapy regimens, and to maximize the generalizability of the study protocol in real-world settings, the pragmatic decision was made

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to integrate study-related sessions directly into the participants' standard care routines. As part of their normal care, participants received a minimum of 3 hours of multidisciplinary inpatient physical, occupational, or speech rehabilitation appropriate for their condition, and as was prescribed by their attending physician. This standard of care did not include additional PBT.

As appropriate, participants' standard of care therapy regimen included, but was not limited to, functional mobility training targeting specific activities of daily living and instrumental activities of daily living needs, endurance training, balance retraining, coordination retraining, strengthening, high-intensity gait training, range of motion training, patient education with durable medical equipment, and family training prior to discharge. Referrals and treatment by other specialties (ie, therapeutic recreation, dietary, and neuropsychology) continued as normal.

Study-related therapy sessions were conducted individually. Each session lasted a minimum of 15 minutes and a maximum of 30 minutes. Data were collected from all participants who completed at least 2, and up to 6, study-related therapy sessions. Data from a range of completed sessions were purposefully collected to accommodate "real-world" short or unexpected changes to discharge timelines due to insurance authorization or other disturbances. This allowed us to examine the effect of sessions completed on outcome measures recorded. Based on the average length of stays of the study sites, once consented and enrolled in the study, participants received an average of 3 study sessions per week, approximately one every other day, until discharge.

During the BWSS only control group sessions, participants conducted a series of standard balance exercises, including: marching, side-stepping, retroambulation, step taps, and step-ups. Standard gait exercises were also completed, including: overground ambulation, going up and down stairs, and sit-to-stand transitions. For each participant, only 4.54 kg (ie, 10 pounds) of body weight was unloaded as this is the minimum requirement to activate the BWSS. As this is an active clinical comparison, clinical parameters and progression, other than those described earlier, were determined by the treating clinical investigator (ie, use of assistive devices and bracing) to ensure the participant's safety, success, and appropriate challenge.

The BWSS-P group completed the same balance and gait exercises as the control group; they differed only in the inclusion of 8 total balance perturbations, 2 in each cardinal direction (lateral left, lateral right, anterior, and posterior). Perturbations occurred while static (lateral, anterior, and posterior) and dynamically while ambulating (anterior and posterior). Eight perturbations were selected based on the findings of the previous pilot study [13] and to minimize fatigue effects. In that study, we found that 1 perturbation every 2 to 4 minutes during the 15-to-30 minute study-related session was enough to challenge participants without overtaxing them and allow for a wider range of participants with varying tolerances, while also allowing them to conduct other elements of their physical therapy regimen.

Perturbation intensity was determined by participants' tolerance and ability to recover from perturbations at baseline. At the start of the study, a baseline BWSS-P perturbation level was individually set for each participant by incrementally increasing the level to balance loss or near loss without recovery. The perturbation level then was decreased by 1 level for treatment. All 8 perturbations were set to this level until it was clinically appropriate to progress to maintain a sufficient challenge to the patient. The intensity of the perturbation ranged from level 1 (minimum) to level 10 (maximum), as set by the manufacturer. Note, while both groups had access to assistive devices during ambulation as appropriate to ensure participant safety, their use was minimized and was not used at all during balance perturbations. Furthermore, the BWSS group did not receive any balance perturbations, including manual perturbations delivered by the treating clinician.

Treating clinicians were licensed physical therapists who were all trained on best practices in using the specific BWSS and perturbation module. To ensure consistency, an initial virtual training session was led by site 1 to review best practices for delivering all study outcome measures. A virtual training session was agreed upon as COVID-19-related travel and visitation restrictions limited the lead site's ability to conduct in-person site initiation visits. Following this, site 1 led a monthly steering committee meeting that consisted of each study site principal investigator, representatives of the treating clinical teams, and the study's acting data and safety monitor. The goal of this meeting was to review if any safety events or harm had occurred, discuss protocol adherence, answer any clinical or technical questions, discuss recruitment, and address any other items as needed.

Participant Recruitment, Enrollment, and Randomization

Each study site was responsible for screening, recruiting, and consenting qualifying participants from their individual locations. Once consented, participants were randomly assigned to either the BWSS standard intervention (ie, control) group or the BWSS-P intervention (ie, experimental) group according to a pregenerated assignment sheet provided by the coordinating site. Each sheet was generated using block randomization using the random list generator tool found at Random.org. A block size of 4, 2 BWSS, and 2 BWSS-P assignments per block were used. Depending on anticipated recruitment numbers, 12-to-20 assignments were generated for each site at a time to allow for balancing as needed.

Given the nature of the intervention (ie, whether or not a baseline perturbation level was needed), clinical staff and participants were unable to be blinded to the randomly assigned group assignments.

Data Analysis

Data were analyzed using GraphPad Prism (version 10; GraphPad Software) and RStudio (version 4.2.2, Posit Software) using the *car*, *lme4*, and *emmeans* packages [32-34].

Descriptive data were reported as mean (SD). If hypothesis testing was done, data were reported with a *P* value, and significance was set at α=.0054 using the O'Brien-Fleming correction for interim analysis [35]. The primary outcome measure was the BBS. Secondary outcome measures included

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the ABC and 10MWT. Data were determined to be missing completely at random and were dealt with via complete case analysis for the total outcome measure change [36].

Pairwise categorical data were analyzed using chi-square testing. Unpaired 2-tailed *t* tests or Mann-Whitney *U* tests were used as necessary to evaluate pairwise between-group differences in continuous outcome variables. 2-way ANOVA or mixed-effects analysis was used to evaluate pairwise pre- and postoutcome measure data.

Intervention effect on outcome measure data was analyzed using a linear mixed effects model. In the models, outcome measures were the dependent variable, with fixed effects for timepoint, group assignment, sessions completed, study location, and timepoint x group assignment interaction term. Participant was included as a random effect. Type III Wald *F* test with Kenward-Roger degrees of freedom was used to evaluate the significance of all the fixed effects. Model assumptions were assessed through visual inspection of residual plots and model diagnostics.

Results

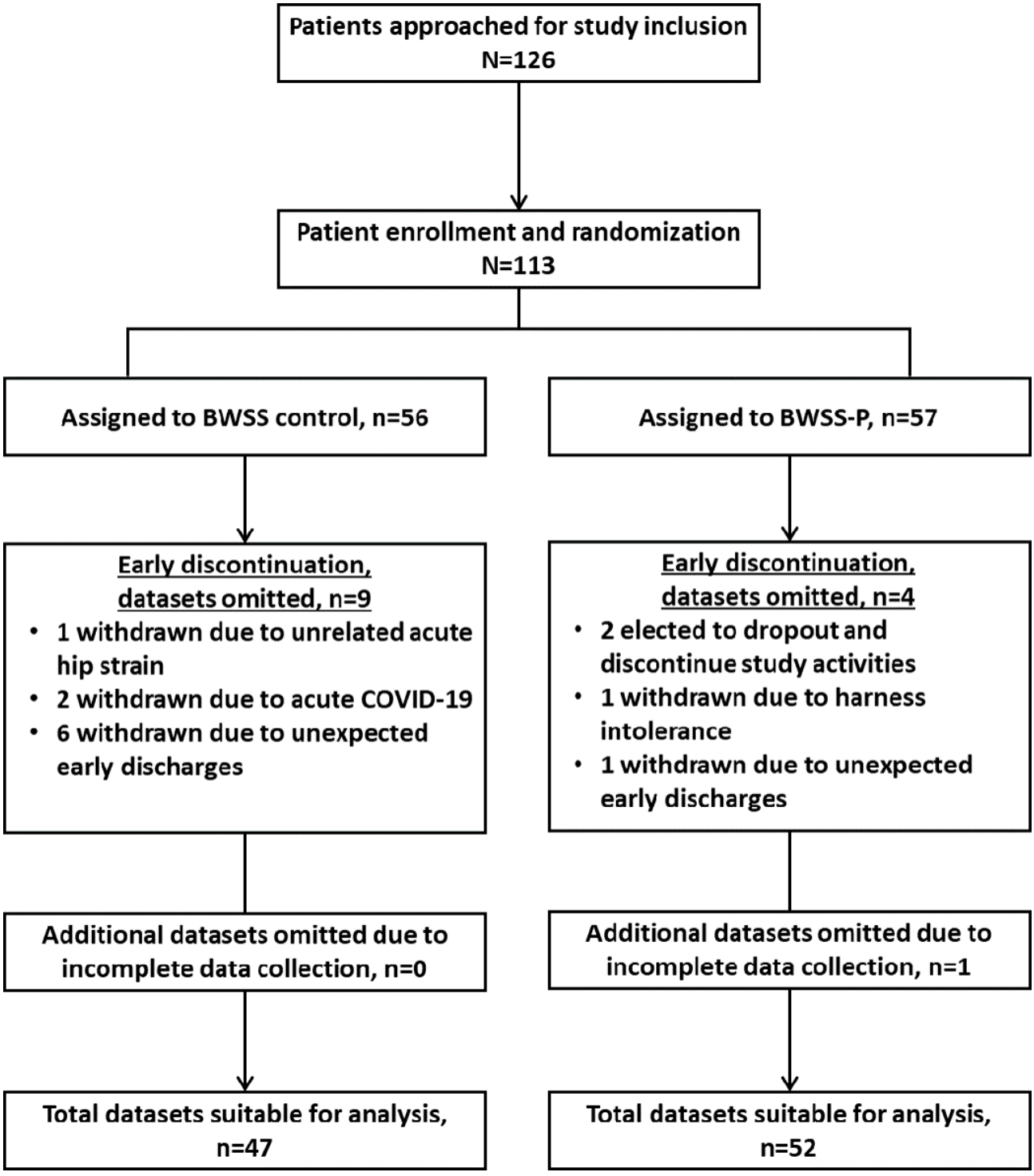
Participant Characteristics

The study's initial target was a final sample size of 214 participants. However, based on the results of the planned interim analysis following the recruitment and completion of 100 participants, the study team made the decision to end study recruitment early and proceed with full data analysis using an appropriately adjusted α. In total, 126 participants were approached for study inclusion, 113 were consented, enrolled, and randomized, with 99 participants yielding sufficient data for analysis (Figure 1). No major or serious adverse events were noted during the study period.

Of the 99 participants with complete data, 47 were assigned to the BWSS only control group, and 52 were assigned to the BWSS-P group. No trends related to sex, age, or any other demographic were observed between groups (Table 1). Participants began study activities a mean of 16.00 (SD 8.01) days following their stroke and a mean of 1.99 (SD 1.99) days following collection of the BBS preintervention assessment.

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Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram. The diagram outlines how many eligible patients were approached, recruited, and completed the study. It also indicates the number of datasets excluded from analysis and the rationale for doing so. BWSS: body weight support system; BWSS-P: body weight support system plus an integrated perturbation-based balance training module.



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Table . Patient demographics (N=114).

	BWSS[a] (n=47)	BWSS-P[b] (n=52)	*P* value
Participants, n (%)[c]			.730[d]
Site 1	21 (45)	20 (38)	
Site 2	13 (28)	16 (31)	
Site 3	8 (17)	7 (13)	
Site 4	5 (11)	9 (17)	
Age (y), mean (SD)	62.36 (14.13)	65.63 (12.55)	.229[e]
LOS (d)[f], mean (SD)	18.34 (8.45)	16.42 (7.71)	.171[g]
Sex, n (%)			.887[d]
Male	31 (66)	35 (67)	
Female	16 (34)	17 (33)	
Race, n (%)			.700[d]
African American	12 (26)	16 (31)	
Caucasian	33 (70)	35 (67)	
NR[h]	2 (4)	1 (2)	
Total sessions completed, n (%)			.476[d]
2 sessions	5 (11)	3 (6)	
3 sessions	8 (17)	11 (21)	
4 sessions	11 (23)	16 (31)	
5 sessions	10 (21)	14 (27)	
6 sessions	13 (28)	8 (15)	
Sessions completed, mean (SD)	4.38 (1.34)	4.25 (1.14)	.595[e]

[a]BWSS: body weight support system.

[b]BWSS-P: BWSS plus an integrated perturbation-based balance training module.

[c]Due to rounding, percentages may not total 100%.

[d]Chi-square test.

[e]Unpaired *t* test.

[f]LOS: length of stay.

[g]Mann-Whitney *U* test

[h]NR: not reported.

Participant Outcome Measures

The outcome measures collected included baseline and post-intervention assessments of BBS, ABC, and 10MWT (Figure 2). The effect of the BWSS-P intervention was analyzed using linear mixed effects models with a type III Wald *F* test with Kenward-Roger degrees of freedom for all outcome measures collected. With a corrected α level of .0054, the intervention did not show any significant impact on our main outcome measure, the BBS. This was shown by the *time x assignment interactions* ($F_{1,97}$=1.57; *P*=.21). Similarly, no significant intervention effects were observed in either the ABC ($F_{1,94.99}$=0.36; *P*=.55) or 10MWT ($F_{1,97}$=4.15; *P*=.04; Table 2).

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Figure 2. Participant outcomes. Primary outcome measures were collected for both groups at baseline and after completing the study protocol, including the (A) Berg Balance Scale (BBS); (B) Activities-Specific Balance Confidence (ABC) Scale; and (C) self-selected 10 Meter Walk Test (10MWT). Data are presented as box-and-whisker plots with the box representing the 25th to 75th quartiles, the midline representing the median, the (+) symbol representing the mean, the whiskers denoting the minimum and maximum of the dataset excluding any outliers, and the open circles representing individual outliers. The gray or lighter color represents the preintervention data, while the green or darker shading represents the postintervention data. BWSS: body weight support system; BWSS-P: BWSS plus an integrated perturbation-based balance training module.

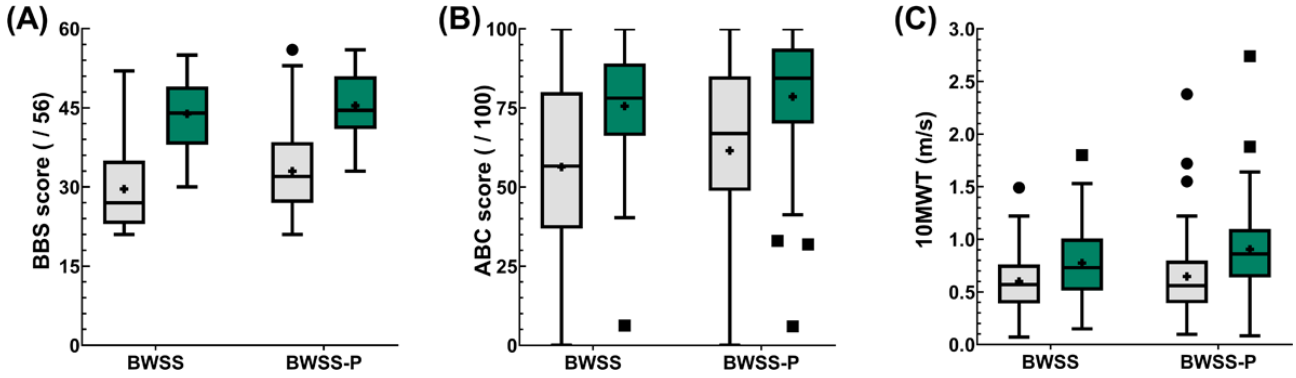


Table . Model effects.

Parameter	Fixed effects[a] of BBS[b,c]		Fixed effects of ABC[d,e]		Fixed effects of 10MWT[f,g]	
	F test (*df*)	*P* value	*F* test (*df*)	*P* value	*F* test (*df*)	*P* value
Time x assignment	1.57 (1,97)	.21	0.36 (1,94.99)	.55	4.15 (1,97)	.04
Time	181.01 (1,97)	<.001[h]	42.89 (1,95.30)	<.001[h]	23.71 (1,97)	<.001
Assignment	5.92 (1,148.14)	.02	1.09 (1,132.74)	.30	0.57 (1,110.82)	.45
Sessions completed	6.23 (1,93)	.01	3.29 (1,93.25)	.07	0.57 (1,93)	.45
Location	3.12 (3,93)	.03	0.02 (3,92.83)	.99	3.44 (3,93)	.02
Random effects[a]	Variance	SD	Variance	SD	Variance	SD
Participant	26.80	5.18	342.3	18.50	0.12	0.35
Residual	26.30	5.13	198.6	14.09	0.03	0.16

[a]Results from linear mixed effects models. Fixed effects were tested using a type III Wald *F* test with Kenward-Roger degrees of freedom. Random effects are shown as variance with SD.

[b]BBS: Berg Balance Scale.

[c]In BBS, random effects of participant: variance 26.80 (SD 5.28) and residual: variance 26.30 (SD 5.13).

[d]ABC: Activities-Specific Balance Confidence.

[e]In ABC, random effects of participant: variance 342.3 (SD 18.50) and residual: variance 198.6 (SD 14.09).

[f]10MWT: 10 Meter Walk Test.

[g]In 10MWT, random effects of participant: variance 0.12 (SD 0.35) and residual: variance 0.03 (SD 0.16).

[h]Significance was set at α=.0054 using the O'Brien-Fleming correction for interim analysis.

Time effects were significant across all outcome measures. BBS scores showed significant improvement from admission to discharge across both groups ($F_{1,97}$=181.01; *P*<.001), along with ABC ($F_{1,95.29}$=42.91; *P*<.001) and 10MWT ($F_{1,97}$=23.71; *P*<.001).

Assignment effects were nonsignificant across all outcome measures. BBS showed the most suggestive evidence of differences between groups ($F_{1148.14}$=5.55; *P*=.02), with ABC ($F_{1132.74}$=1.09; *P*=.30) and 10MWT ($F_{1110.82}$=0.57; *P*=.45) outcomes showing less evidence of a difference.

The number of sessions completed (ie, 2-to-6) did not have any evidence of a significant effect on the outcome measures. BBS showed the most difference in regards to the number of sessions completed ($F_{1,93}$=6.23; *P*=.01), with ABC ($F_{1,93.25}$=3.29; *P*=.07) and 10MWT ($F_{1,93}$=0.57; *P*=.45) showing smaller differences.

Location had similarly suggestive, but inconclusive, evidence of an effect on outcome measures. BBS ($F_{3,93}$=3.12; *P*=.03) and 10MWT ($F_{3,93}$=3.03; *P*=.03) had the most evidence of a location effect, while ABC did not ($F_{3,92.83}$=0.01; *P*=.99).

Model estimated marginal means (SE) for the BBS showed that at admission, both the BWSS (30.02, SE 1.15) and BWSS-P

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(33.44, SE 1.13) groups had similar scores. This finding was also true at discharge, with BWSS (43.45, SE 1.15) and BWSS-P (45.42, SE 1.13) ending at a similar level. Similar patterns were noted in the model estimated means of the secondary outcome measures, as well as the observed unadjusted means for all outcomes (Table 3).

Table . Outcome measure pre- and post-assessment scores.

Outcome measure and type	Before assessment, mean (SD), n	After assessment, mean (SD), n	*P* value
BBS[a] (0-56)			
BWSS[b]			
Observed	29.62 (8.58), 47	43.85 (6.62), 47	<.001[c]
Estimated[d]	30.02 (1.15)	43.35 (1.15)	<.001[e]
BWSS-P[f]			
Observed	33.00 (8.62), 52	45.40 (6.32), 52	<.001
Estimated	33.44 (1.13)	45.42 (1.13)	<.001
ABC[g] (/100)			
BWSS			
Observed	56.35 (25.26), 47	75.58 (18.12), 45	<.001
Estimated	58.18 (3.74)	76.04 (3.81)	<.001
BWSS-P			
Observed	61.53 (27.50), 51	78.54 (20.05), 52	<.001
Estimated	62.96 (3.69)	78.77 (3.68)	<.001
10MWT[h] (m s^{-1})			
BWSS			
Observed	0.60 (0.33), 47	0.77 (0.36), 46	<.001
Estimated	0.58 (0.06)	0.73 (0.06)	<.001
BWSS-P			
Observed	0.65 (0.42), 52	0.90 (0.45), 52	<.001
Estimated	0.66 (0.06)	0.91 (0.06)	<.001

[a]BBS: Berg Balance Scale.

[b]BWSS: Body weight support system.

[c]*P* values from two-way ANOVA and mixed-effects analysis as applicable.

[d]Values shown are estimated marginal means (SE) from the mixed effects model. These values are predictions estimated from the fitted model. Since they are estimates, there are no sample sizes associated with these reported values.

[e]*P* values from type III Wald *F* test for main effect of time in linear mixed effects model

[f]BWSS-P: BWSS plus an integrated perturbation-based balance training module.

[g]ABC: Activities-Specific Balance Confidence Scale

[h]10MWT: 10 Meter Walk Test.

Discussion

Principal Findings and Alignment With Literature

The goal of this study was to compare the effects of a BWSS-integrated PBT training module on poststroke balance and gait rehabilitation as compared to BWSS training alone. Specifically, participants completed a regimented neurological rehabilitation program that included 2-to-6 BWSS sessions with or without 8 balance perturbations per session. Participants in both groups demonstrated similar within-group improvements with no significant between-group differences in BBS, ABC, or 10MWT. Furthermore, there was suggestive, but inconclusive, evidence of minimal site-specific effects. While these observations are nonsignificant and confirm the null hypothesis that the BWSS-P intervention is not different than the BWSS only control, these data still provide us with meaningful observations that support past publications.

First, similar to past observations [37], the number of sessions that participants completed greatly varied due to several extenuating and pragmatic factors, including insurance continuing stay authorization [37]. While not ideal, these data and the protocol are reflective of what are feasible and realistic

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best practices in these inpatient settings in the current environment.

Our findings are also in alignment with other past studies that tested the effect of traditional PBT intervention in the poststroke population [17,19,20,38-44]. Many of these studies used the same outcome measures that were used in this study. Of these, 6 studies used the BBS to evaluate balance [19,20,39,40,42,43], 2 studies used the 10MWT to assess gait speed [17,41], and 2 studies used the ABC to measure participants' balance confidence [17,41]. Similar to our findings, little to no between-group differences were observed for each of these outcome measures.

As noted by Brown et al [44], these past studies all varied in training duration, frequency, and interventions used. Study sessions ranged from 1 to 24 sessions, and the number and type of perturbations also varied and included treadmill delivery, therapist-applied perturbations, waist pull perturbations, and slip training, in addition to other commercially available systems. Few studies, however, have examined the impact of overhead gait robotics that facilitate balance perturbation. These studies and others report encouraging results; however, the impact of PBT on stroke balance rehabilitation remains inconclusive [20,22,44].

In addition to unifying study interventions, Mcrum et al [22] have also indicated the need for further dosing studies to examine optimal dosing within sessions or within training programs in addition to examining the effect of bidirectional and multidirectional perturbation training to provide recommendations for clinicians. Following this study, 1 observation that we made is that the level of perturbation experienced by the end user can be defined in many ways, including the magnitude and duration of the applied force that disrupts the user's balance. This can be controlled by factors like the force applied, the direction of the force (eg, forward, backward, and lateral), and the timing of the perturbation during the gait cycle. In addition, the level of body weight support provided by a harness can also influence the perceived perturbation level, as less support means greater impact from the applied force, and more support may result in the patient being able to complete greater repetitions. These factors all need to be taken into account when planning future dosing studies of this technique.

Limitations and Lessons Learned

As this was the first multisite randomized-controlled trial to evaluate this novel BWSS-integrated PBT technology, we can identify several limitations that must be considered when interpreting the data and planning future studies.

First, since the study was conducted in the inpatient rehabilitation setting, the study activities were only a small part of the participants' overall treatment strategy. Several factors, including therapy outside the study and natural recovery progression, likely contributed to improvements in participants' status and function. Despite attempting to unify the delivery of the study intervention, treatment strategies outside of study activities may have been variable across study sites. For example, in seeking possible explanations of the suggestive location effect, it was found that site 2 had implemented an institution-wide high-intensity gait training program as part of their site's standard of care, which was not used by the other study sites during the study.

Second, BBS score changes may have been limited due to ceiling effects. To address this, an upper BBS score should be considered as part of the study criteria in all future studies on this topic. For example, a BBS score of 45/56 has been suggested to describe patients with normal functional ability [28]. Similarly, incorporating a dynamic gait assessment that more closely resembles functional movement patterns and reactive balance-specific outcome measures may be beneficial to understanding the full implications of this new BWSS-P module [45,46].

Third, several participants (8/99, 8%), constrained by short lengths of stay, only completed 2 sessions, the minimum number to be included in the study. This limited dose may not have been enough to elicit a clinically significant change in balance and balance confidence as may have been hypothesized. Short lengths of stay were due to several factors, including industry trends of decreasing lengths of stay in the cerebrovascular accident (ie, cerebrovascular accident, stroke, and brain injury) population; inclusion of participants with BBS scores of 45 or greater; and the impact of COVID-19. Specific to COVID-19, many patients opted to discharge home as soon as they could safely navigate the home environment with assistance, meaning some patients did not remain long enough to receive more than 2 study sessions. In addition, many patients who were eligible for the study could not participate due to a positive COVID-19 diagnosis and droplet precautions, while others were withdrawn and their data omitted from analysis due to breakthrough infections requiring isolation.

Fourth, the number of balance perturbations provided to the BWSS-P group was strictly kept to 2 balance perturbations in each cardinal direction per session (ie, 8 total). This was maintained even if the first or second perturbation in a particular direction did not elicit a strong balance response. Further, a target of 6 study sessions was based on the preliminary efficacy data collected during the pilot study; this may not have been as optimal as previously thought [13]. In future studies, it will be essential to expand upon this work and complete a dedicated dosing study to determine the optimal number of BWSS-P sessions and number of balance perturbations per session [22].

Fifth, the study end points may have been impacted by the variability in the timing of when outcome assessments were collected. To reduce the burden on the study participants from having to complete the same assessments repeatedly in a short period of time, the study team made the decision to use recently collected data to serve as study end points when available and collected in close proximity to study activities. Although some assessments were then not collected immediately prior to starting the study intervention, the authors felt the period of time between admission assessments, study enrollment, and study initiation was sufficiently short enough, and completed consistently enough, to be representative and with minimal variation.

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Conclusions

PBT therapy is an important treatment modality for the rehabilitation of gait and balance following a stroke. As it becomes more accessible and widely adopted, ceiling-track-mounted BWSS with an integrated PBT module allows therapists to more safely add PBT into patients' rehabilitation sooner and in ways that are more representative of their functional environment. Our goal was to determine if neurological rehabilitation paired with this technology could significantly improve poststroke gait, balance, confidence, and functional outcomes compared to using a BWSS alone. Ultimately, both were found to be similarly effective interventions, resulting in similar improvements in patient gait, balance, confidence, and functional outcomes. Given the safety it provides to clinicians and patients alike, conducting PBT with such a device provides a safe option for conducting gait and PBT in the inpatient setting, especially for patients who are unable to safely ambulate without assistance.

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Data Availability

Copies of the detailed treatment protocol are available upon request. Requests for copies of the deidentified datasets will be considered upon reasonable request. Please contact the corresponding author for more details.

Authors' Contributions

Conceptualization: PG, AM, KR, EM, CB, CG, HCH
Data curation: AM, JC, KR, HCH
Formal analysis: JC, HCH
Investigation: AM, KR, EM, CB, CG
Methodology: PG, AM, KR, EM, CB, CG
Project administration: PG, AM, KR, CG, HCH
Software: PG, JC, HCH
Visualization: JC, HCH
Writing – original: PG, AM, JC, KR, EM, CB, CG, HCH
Writing – review & editing: PG, AM, JC, KR, EM, CB, CG, HCH

Conflicts of Interest

KR and AM are secondarily employed by Aretech LLC as ZeroG trainers. The study was designed, and results were analyzed with no input from Aretech LLC. PG, JC, CG, CB, EM, and HCH have no conflicts of interest to disclose.

Checklist 1
CONSORT checklist.
[PDF File, 480 KB - rehab_v12i1e80525_app1.pdf]

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Abbreviations

10MWT: 10 Meter Walk Test
ABC: Activities-Specific Balance Confidence Scale
BBS: Berg Balance Scale
BWSS: body weight support system
BWSS-P: BWSS plus an integrated perturbation-based balance training module
PBT: perturbation-based balance training

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A Novel QR Code–Based Solution for Secure Electronic Health Record Transfer in Venous Thromboembolism Home Rehabilitation Management: Algorithm Development and Validation

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Abstract

Background: Venous thromboembolism (VTE) is a common vascular disorder requiring extended anticoagulation therapy postdischarge to reduce recurrence risk. Home rehabilitation management systems that use electronic health records from hospital care provide opportunities for continuous patient monitoring. However, transferring medical data from clinical to home settings raises significant concerns about privacy and security. Conventional methods such as manual data entry, optical character recognition, and dedicated data transmission lines face notable technical and operational challenges.

Objective: This study aims to develop a QR code–based security transmission algorithm using Avro and byte pair encoding (BPE). The algorithm supports the secure creation and transfer of out-of-hospital health records by enabling patients to scan QR codes via a dedicated mobile app, ensuring data security and user privacy.

Methods: Between January and October 2024, 300 hospitalized patients with VTE were recruited at the Sixth Medical Center of the Chinese PLA General Hospital. Post discharge, participants used a home rehabilitation app tailored for VTE management. The QR code–based security transmission algorithm was developed to securely transfer in-hospital electronic health records to the out-of-hospital app. It uses BPE, Avro, and Gzip for optimized data compression and uses ChaCha20 and BLAKE3 for encryption and authentication. Specifically, BPE tokenizes medical text, while Avro serializes JSON (JavaScript Object Notation) objects, contributing to data encryption. A proprietary tokenizer was trained, and compression efficiency was evaluated using a "Performance Benchmark Dataset." Comparative analyses were conducted to assess the compression efficiency of JSON serialization methods (Avro and ASN.1 [Abstract Syntax Notation One]), and tokenization algorithms (BPE and unigram).

Results: The dataset consisted of JSON files from 300 patients, averaging 240.1 fields per file (range 89 - 623) and 7095 bytes in size (range 2748 - 17,425 bytes). Using the BPE + Avro + Gzip algorithm, the average file size was reduced to 1048 bytes, achieving a compression ratio of 6.67. This was 1.82 times more efficient than traditional Gzip compression (average file size: 1907 bytes; compression ratio: 3.66; $P<.001$). For Chinese medical text tokenization, BPE outperformed unigram with a compression ratio of 4.68 versus 4.55 ($P<.001$). Avro and ASN.1 demonstrated comparable compression ratios of 2.57 and 2.59, respectively, when used alone ($P=.30$). However, Avro combined with BPE and Gzip significantly outperformed ASN.1, achieving compression ratios of 6.67 versus 5.21 ($P<.001$). Additionally, 84.7% (254/300) of patients needed to scan only 1 QR code, requiring an average of 3.1 seconds.

Conclusions: The QR code–based security transmission algorithm using Avro and BPE efficiently compresses and transmits data in an encrypted manner and authenticates the identity of the scanning users, ensuring the privacy and security of medical data. Delivered as a software development kit, the algorithm offers straightforward implementation and usability, supporting its broad adoption across various applications.

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KEYWORDS

venous thromboembolism; home rehabilitation; electronic health record; QR code; secure data transmission; data compression; authenticated encryption; tokenization algorithm; data serialization; health information exchange; Avro

Introduction

Venous thromboembolism (VTE) is a leading cause of death and disability worldwide [1,2]. Patients with VTE require prolonged anticoagulant therapy after discharge to prevent the recurrence of thrombosis, and extended home rehabilitation management effectively reduces the incidence of VTE events [3]. To enhance the efficiency of home rehabilitation management for patients with VTE, we developed a home rehabilitation mobile health app to assist doctors in managing patients' recovery outside the hospital. According to guidelines and consensus, home anticoagulation management for VTE is complex, requiring not only professional medical knowledge but also accurate patient information, such as coagulation indicators, biochemical markers (eg, liver, kidney, and heart function), underlying diseases, and bleeding risks [4]. Therefore, establishing comprehensive health records is the first step in effective home rehabilitation management. However, due to the multitude of information fields, manual entry by patients is difficult and leads to low user engagement.

Using patients' electronic health records (EHRs) during hospitalization can improve the success rate of out-of-hospital health record creation [5]. Hospital Information Systems are typically deployed within internal (intranet) environments, while out-of-hospital services operate on public internet infrastructure. Industry standards such as HL7 Fast Healthcare Interoperability Resources have been proposed to enable cross-institutional data exchange. However, in practice, the deployment of Fast Healthcare Interoperability Resources or other application programming interface–based approaches faces multiple constraints. Their implementation depends on dedicated network connections via front-end machines or network gateways. This implementation approach introduces the following significant issues: (1) high hardware deployment and maintenance costs; (2) increased exposure of hospital intranets, elevating security risks; (3) low efficiency of cross-departmental collaboration, leading to slow service response; and (4) complete incompatibility with closed-network environments. Consequently, such protocols have not been widely adopted in domestic settings.

Some alternative approaches attempt to use optical character recognition on printed reports. However, the recognition accuracy (75.86% - 92.46%) is highly affected by scan quality and layout [6], generally requiring manual validation [7], making it difficult to scale for widespread use. Other solutions use QR code–based transmission [8-14], either transmitting in plaintext—posing leakage risks—or relying solely on traditional compression algorithms such as Gzip, which offer limited compression efficiency and fail to make full use of QR code capacity. In real-world scenarios, a single QR code typically holds only 500 - 1500 bytes, further highlighting the importance of efficient encoding. Additionally, certain implementations require specialized screens and camera equipment, failing to balance medical privacy protection with end user convenience.

To address these challenges in cross-network medical information exchange, this study proposed a secure QR code–based transmission algorithm. The algorithm encrypts, compresses, and partitions JSON-formatted (JavaScript Object Notation) health records into multiple QR codes. Patients can safely, easily, and accurately complete the creation and transfer of out-of-hospital records simply by scanning the QR codes using a dedicated mobile health app.

To comprehensively demonstrate the advantages of the proposed solution in terms of recognition accuracy, data privacy, network exposure risk, and deployment cost, Table 1 presents a comparative analysis between this method and existing typical solutions (including optical character recognition–based solutions and dedicated channel solutions) in cross-network scenarios.

In this study, we have designed the algorithm framework in detail, described the compression and encryption processes, and constructed a training dataset. Finally, we validated the algorithm's performance using real-world clinical data.

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Table . Comparison of this proposal and existing medical information exchange solutions in cross-network scenarios.

Dimension	OCR-based[a] solution	Dedicated channel (FHIR[b] or other API[c])	Proposed scheme
Accuracy	Low. Affected by image quality and layout; accuracy ranges from 75.86% to 92.46%, manual verification required	High. System-level integration with clear structure and minimal errors	High. Structured data embedded in QR code; stable decoding, unaffected by image quality
Data privacy	Low. Plaintext image transmission with high leakage risk	Medium-high. Relies on physical isolation and encryption; security depends on implementation	High. End-to-end encryption and authentication; supports zero-trust access
Network exposure risk	None. Typically offline image transmission, no network exposure	High. Requires open interfaces; increases attack surface and risk of intrusion	None. Offline QR transmission; no exposed network entry
Deployment cost	Low. No system changes needed, but high manual verification overhead	High. Requires gateway systems and dedicated channels; complex implementation and maintenance	Low. Lightweight SDK integration; high compatibility and easy deployment

[a]OCR: optical character recognition.

[b]FHIR: Fast Healthcare Interoperability Resources.

[c]API: application programming interface.

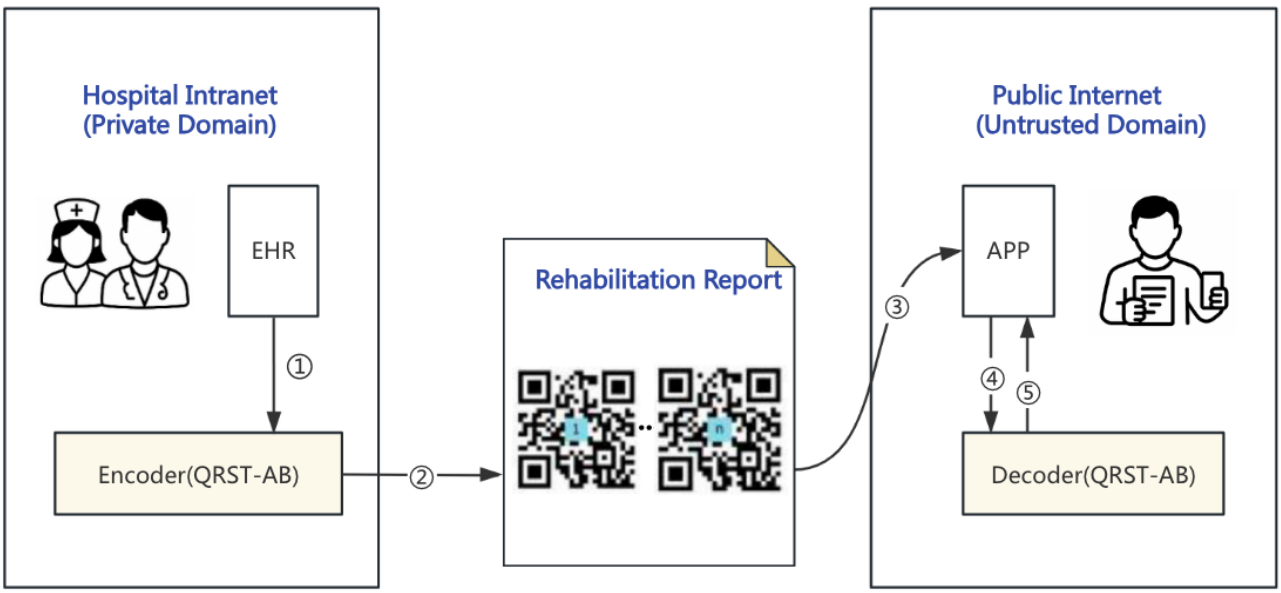
Methods

Algorithm Design

Overview

We propose a QR code–based secure transmission algorithm using Avro and byte pair encoding (BPE), which supports the secure creation and transfer of out-of-hospital health records for inpatients after discharge. The application scenario of the QR code–based secure transmission algorithm using Avro and byte pair encoding (QRST-AB), as illustrated in Figure 1, involves the following workflow: (1) health care providers access the patient's EHR; (2) the encoder module applies the algorithm to generate one or more QR codes, which are embedded into a printed rehabilitation report and physically delivered to the patient; (3) the patient scans the QR code using a mobile app; (4) the app uploads the QR code content to a server-side module; and (5) the decoder performs verification and decryption, with results presented to the user. In this process, the encoder operates within the hospital intranet (trusted domain), whereas the decoder resides in the public internet (untrusted domain), enabling secure cross-network transmission.

Figure 1. Application scenario of the proposed QRST-AB, illustrating the data flow of rehabilitation reports in cross-network environments. EHR: electronic health record; QRST-AB: QR code–based security transmission algorithm using Avro and byte pair encoding.



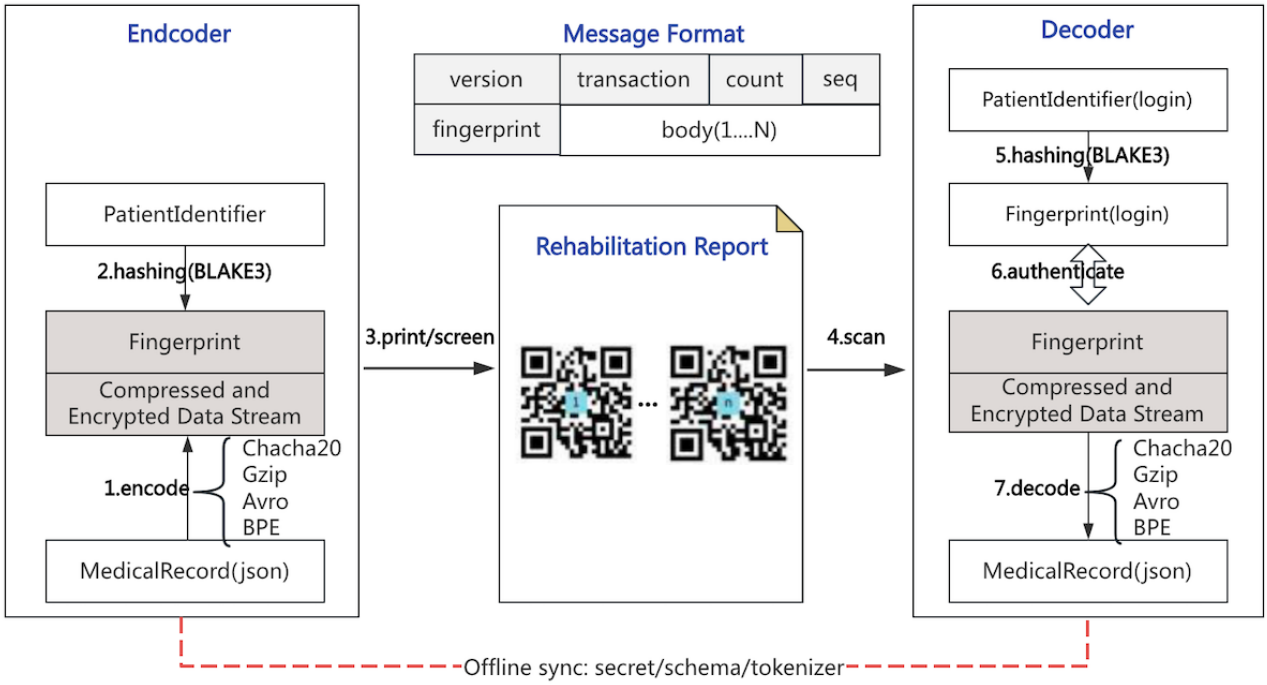
Algorithm Framework

The QRST-AB algorithm efficiently compresses and encrypts patient medical records in JSON format, divides them into multiple QR codes for secure transmission, and authenticates users through encrypted digital fingerprints, ensuring privacy and data security. The algorithm consists of 2 components: an encoder and a decoder. The encoder and decoder periodically synchronize the secret, schema, and tokenizer through offline

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methods. The details of the framework and processing flow of the QRST-AB algorithm are shown in Figure 2 and Textbox 1.

Figure 2. The framework and processing flow of the QRST-AB, illustrating how patient medical records are compressed, encrypted, split into QR codes, and securely transmitted and authenticated. BPE: byte pair encoding; JSON: JavaScript Object Notation; QRST-AB: QR code–based security transmission algorithm using Avro and byte pair encoding.



Textbox 1. Textbox 1. The processing flow of the QR code–based secure transmission algorithm using Avro and byte pair encoding (BPE).

1. The patient medical record is deidentified and separated into 2 parts: the patient identifier and the limited data set. The data is processed through a multistage encoding pipeline consisting of BPE, Avro, Gzip, and ChaCha20, to generate a compressed and encrypted data stream, which serves as the message body. The data stream is then divided into multiple subpackets (body1...N) based on the predefined maximum size of the QR code. BPE tokenizes and vectorizes the texts in the medical record; Apache Avro serializes the JSON (JavaScript Object Notation) objects into a binary format; Gzip compresses the binary data stream; Chacha20 encrypts the compressed data to ciphertext.
2. Every subpacket and patient identifier is hashed using the cryptographic function (BLAKE3) to generate a digital fingerprint and is encapsulated within the message header. This header is combined with body1..N to form multiple QR codes.
3. The QR codes are printed on A4 paper as part of the home rehabilitation report and handed to the patient, or displayed directly on a hospital computer screen for the patient to view.
4. The QR codes are scanned by a dedicated app on the smartphone, and the scanned content is uploaded to the server (decoder).
5. Upon receiving the QR code content, the decoder first generates a new digital fingerprint based on the logged-in user's identifier.
6. Next, the calculated fingerprint is authenticated against the digital fingerprint in the QR codes, and only if the authentication passes, the decoding process is executed.
7. In the presence of multiple QR codes, a merging operation is conducted to form a complete information body, which is then converted back into a JSON object through the decoding process. The specific steps include the following: Chacha20 decrypts the ciphertext; Gzip decompresses the binary data; Avro deserializes the binary data back into a JSON object; and BPE restores the string representation of the JSON object from its numerical form.

Protocol Package Format

Within each QR code, the data content is divided into 2 parts: the message header and the message body. The header consists of 5 fields: version, fingerprint, transaction, count, and seq. The specific definitions of each field are shown in Table 2.

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Table . Definition of the message header fields in each QR code of the QR code–based secure transmission algorithm using Avro and byte pair encoding.

Field	Definition	Value formula	Description	Len (bits)
Version	Version identifier, a predetermined fixed value	Constant	Used for compatibility with historical versions after updates.	8
Fingerprint	The message fingerprint	H(Message‖IdentityID)[1:n]	H() represents a cryptographic hash function. n represents the length of the digest in bytes, ranging from 1 to 64.	16
Transaction	Transaction ID for the current transmission	Tadm+Ttag	T_{adm} represents the patient's admission date, and T_{tag} is a predefined date for a specific tag, such as "2020-01-01".	16
Count	Number of QR codes the record is split into	[LbodyLqr−Lheader]	L_{body} is the total length of the compressed and encrypted body, L_{qr} is the maximum length of a QR code, and L_{header} is the fixed length of the message header	4
Seq	Sequence number of each QR code	Sprev+1	Starts from 0 and increments by 1.	4

Response Status Codes

When users receive information contained in the QR codes, the operation is simple—scanning each QR code sequentially using the dedicated app. The program provides friendly prompts based on the parsing results. The explanations for different response status codes are listed in Table 3.

Table . Response status codes and their explanations for users scanning QR codes with the dedicated app in the algorithm.

Result code	Explanation
finished	All QR codes have been successfully scanned, and decoding is complete.
waiting	Current QR code has been successfully scanned, please continue scanning others.
duplicated	Current QR code has been scanned repeatedly, please continue scanning others.
tag_error	Tag error, not a QR code format supported by the program.
auth_failed	Authentication failed, please verify authorization.
exception	Other exceptions, please contact technical support for assistance.

Algorithm Scalability

In this algorithm, each version can define the length of individual fields in the message header. Different versions correspond to different encoders, each with its own secret, schema, and tokenizer. On the decoder side, a multiversion manager enables support for various encoders, allowing compatibility with multiple data centers.

By leveraging the flexibility of the flexible structure of Avro Schema, it is easy to extend the system to support different JSON formats. In addition to the VTE electronic medical records discussed in this paper, the algorithm can be adapted to other disease types and even to nonmedical application scenarios, demonstrating strong scalability and versatility.

Data Compression

JSON Serialization

JSON serialization refers to the process of converting data structures or objects into a string or binary form for the purpose of storage or transmission. The opposite process is deserialization, which restores the serialized data back to its original structure or object.

Within serialization methods, common types include schema-driven serialization and schema-less serialization. The former includes methods such as Abstract Syntax Notation One (ASN.1) using Packed Encoding Rules, Apache Avro, Microsoft Bond, Cap'n Proto, FlatBuffers, Protocol Buffers, and Apache Thrift. These methods rely on predefined schemas to ensure the structure and type of data, typically achieving higher space efficiency. Previous studies have shown that ASN.1 and Apache

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Avro perform particularly well in compression efficiency [15,16].

After comparative validation and in combination with the Gzip method, we found that Apache Avro outperforms ASN.1 in terms of compression efficiency, and Avro's syntax definition is more compatible. Therefore, in our algorithm, we adopted Apache Avro as the serialization method.

Tokenization

Tokenization is a technique that converts text sequences into numerical sequences, serving as a foundational step in natural language processing tasks. It bridges the gap between raw text and language models. Existing tokenization methods, such as BPE, originate from the field of data compression. Some scholars believe that BPE is effective because it compresses text into fewer tokens, allowing the tokenizer to be trained more efficiently on specific datasets [17-19].

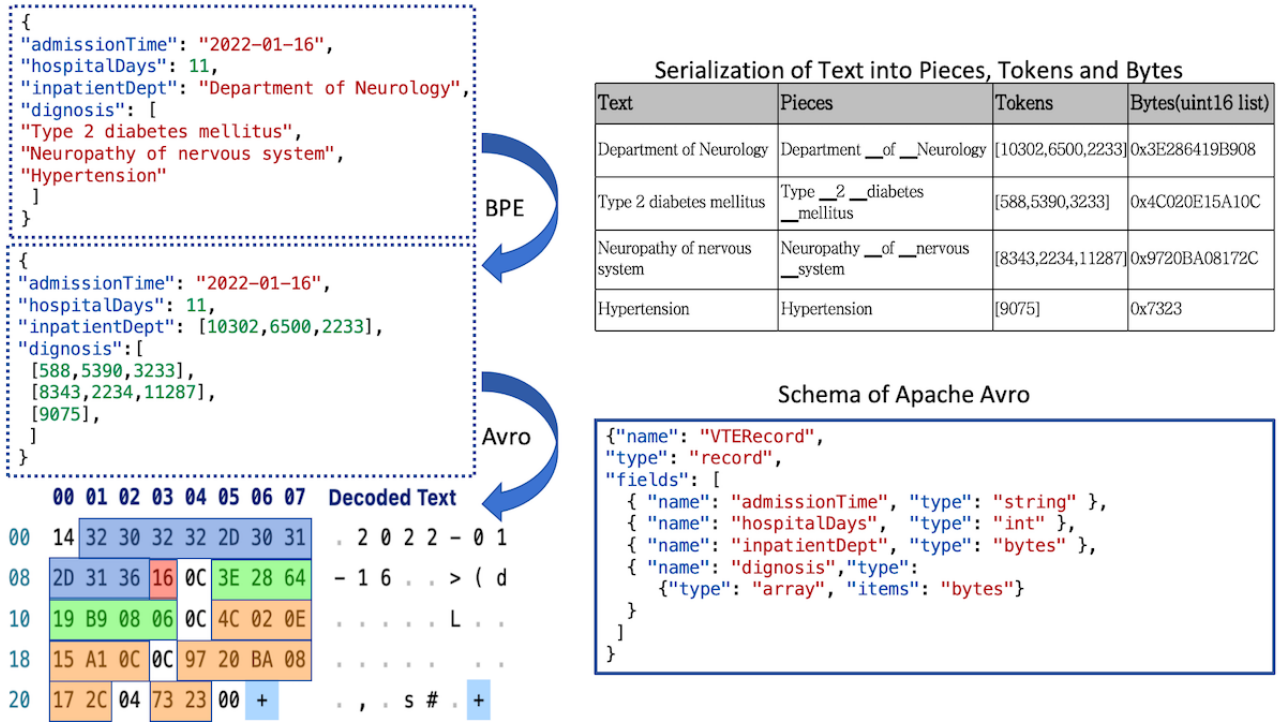
The prevalent tokenization techniques in the field of natural language processing include BPE, unigram, and WordPiece. These techniques are adopted by different large language models: BPE is used by the LLaMA series and GPT series, while unigram and WordPiece are used by bidirectional encoder representations from transformers and its variants. Given that our study focuses on Chinese medical texts, which lack explicit delimiters and cannot directly use WordPiece, we have selected BPE and unigram for comparing tokenization compression efficiency.

In our dataset, we compared the compression efficacy of 2 tokenization methods: BPE and the unigram. Experimental results indicated that the BPE method demonstrated superior compression performance within the algorithmic framework proposed in this study. Therefore, we ultimately selected the BPE tokenization strategy [20,21].

Data Compression Process

To demonstrate the proposed data compression approach in practice, we present the following illustrative example using a simplified JSON record of patient information. The JSON file contains 4 fields: admissionTime, hospitalDays, inpatientDept, and diagnosis, as shown in Figure 3.

Figure 3. Explanation of the compression process using BPE and Avro, where BPE tokenizes using the tokenizer and Avro serializes JSON based on schema. BPE: byte pair encoding; JSON: JavaScript Object Notation.



Tokenization is performed on 2 free-text fields: "inpatientDept" and "diagnosis". For example, "Type 2 diabetes mellitus" is split by the tokenizer into "Type _2 _diabetes _mellitus" and further converted into a list of numerical values corresponding to tokens [10,302, 6500, and 2233]. It is noteworthy that due to differences in training corpora and hyper-parameter configurations, different tokenizers may generate varying segmentation results and tokens. This transformation not only contributes to compression but also provides a degree of information hiding, as the original text is not human-readable without the corresponding tokenizer.

Furthermore, Apache Avro is used to transform the JSON into a binary format to complete the serialization operation. As shown in the figure, the blue-marked bytes represent the value of the admission date "2022-01-16," the red-marked bytes represent the length of hospital stay "11" (using variable-length zig-zag encoding, 11(integer)=22(zig-zag)=0×16(octet)), the green-marked bytes represent the hospital department, and the orange-marked bytes represent the 3 disease names of the diagnosis.

It is important to note that the Avro-encoded binary data does not contain type information or field names, which significantly reduces the size of serialized data. However, this also means

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that the receiving end must use the same schema as the sending end to correctly read the Avro data. In our algorithm, the Avro schema is not transmitted via the QR code, making it particularly difficult for third parties without the schema to read the Avro data.

In summary, the exclusive tokenizer and Avro schema definitions held by the server and client provide a robust defense for data security. In the example mentioned above, the original JSON data occupies 185 bytes, and after processing with the BPE tokenization and Avro serialization, the space is reduced to 38 bytes, with a compression ratio reaching 4.87, thereby demonstrating its excellent compression performance.

Encryption and Authentication

Modern authenticated encryption adopts the authenticated encryption with associated data approach. National Institute of Standards and Technology recommends standard algorithms such as AES-GCM, AES-CBC+HMAC, and ChaCha20-Poly1305, which ensure both data confidentiality and message integrity [22]. However, these methods require additional overhead, including a 16-byte authentication tag and 8/12/24-byte Nonce or IV fields. AES-CBC further requires 16-byte block alignment, leading to significant message expansion that limits transmission efficiency in space-constrained QR codes.

This work adopts a symmetric authenticated encryption with associated data scheme, where both encoder (sender) and decoder (receiver) share a 256-bit secret key. ChaCha20 is used for encryption and BLAKE3 for authentication, resulting in only 2 bytes of overhead. ChaCha20 is an IETF-standardized stream cipher that uses a 256-bit key and 64-bit nonce, producing a keystream via 20 rounds of permutation. It does not require alignment, keeps the same ciphertext size, and works fast in software even without special hardware, making it suitable for mobile and low-latency scenarios. BLAKE3 is an advanced cryptographic hash function with higher performance than Secure Hash Algorithm 256 bit and Secure Hash Algorithm 512-bit. It supports variable output lengths, allowing flexible adaptation to different application requirements [23].

Compared with other transmission methods, QR codes printed on paper are harder to steal and are difficult to brute-force due to their low propagation efficiency. In our proposed algorithm, BLAKE3 is configured to produce a 2-byte hash, resulting in a brute-force probability of 1/(2^16), which is acceptable for practical authentication. ChaCha20 encryption, with a 256-bit key, offers a brute-force resistance of 1/(2^256), meeting the National Institute of Standards and Technology Level 3 security standard.

Dataset

During the algorithm development phase, this study constructed a “Chinese Medical Text Dataset” for training a proprietary tokenizer. The dataset was sourced from the EHRs of approximately 80,000 historical patients from a hospital. The extracted fields included department names, surgical procedures, medication names, disease diagnoses, indicator names, and imaging examinations, among others, and were saved in text. The access control layer integrates time-based one-time password using a 6-digit random code, reducing the probability of unauthorized access to below 10^{-6}.format.

In the algorithm validation phase, the study built a “Performance Benchmark Dataset” to verify the overall compression performance of the algorithm. This dataset was derived from the EHRs of 300 inpatients with VTE at the Sixth Medical Center of the Chinese PLA General Hospital between January and October 2024 and was saved in JSON format. These medical records comprehensively documented the patients’ basic information, surgical history, diseases, radiological examination results, laboratory test data, risk assessments, and medication upon discharge. Specifically, the basic information included the patient’s age, gender, height, weight, department, and length of hospital stay; surgical details recorded the name and timing of the surgery; disease classification encompassed the name and category of the diseases; radiological examination results detailed the date of the examination, the name of the procedure, the body part examined, and the conclusions; laboratory test data listed the name of the indicator, its value, unit, risk indication, and the normal range; medication upon discharge recorded the name of the medication, the daily dosage, and the frequency of administration; and the risk assessment section included the assessment scale, risk level, and risk factors.

Performance Metrics and Validation Methods

The compression ratio in this study is defined by the formula: CompressionRate=OrigDataBytes/CompressedDataBytes.

In terms of algorithm design, we strive not only to optimize overall performance but also to ensure compatibility with various worst-case scenarios. Therefore, when analyzing the byte size of JSON files and the number of fields in the “Performance Benchmark Dataset,” we used statistical methods for calculating the mean, as well as the minimum and maximum extreme values.

We compared the efficiency of our compression algorithm with the traditional Gzip compression algorithm. In addition, we compared the efficiency of the 2 most effective JSON serialization technologies in real patient datasets, as well as the compression efficiency of 2 mainstream tokenization algorithms on specific datasets. All of the above comparisons used mean statistical methods and used *t* tests to calculate *P* values.

Furthermore, we used cumulative distribution function graphs to analyze the distribution of the number of QR codes scanned by patients and tested the time required for creating patient records via QR codes using various models of mobile phones.

Ethical Considerations

This cohort study was approved by the Medical Ethics Committee of the Sixth Medical Center of Chinese People’s Liberation Army General Hospital (approval number: HZKY-PJ-2022-21). A waiver of informed consent was granted because this was a retrospective, data-only study, and all data were fully deidentified in accordance with institutional and national guidelines. Patients using the home rehabilitation service app provided informed consent at registration. QR code information constitutes a deidentified limited dataset with no personally identifiable information included; personally

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identifiable information is used only locally for authentication and is never transmitted. Encrypted QR codes are accessible only by authorized patients, ensuring data security and access control. All procedures complied with institutional policies, the Declaration of Helsinki, and relevant data protection regulations.

Results

Statistical Characteristics of the Performance Benchmark Dataset

We conducted a detailed statistical analysis of the fields and their storage sizes in the JSON files of the "Performance Benchmark Dataset," which is summarized in Table 4. The average number of fields in the raw JSON files was 240.1, ranging from 89 to 623, with an average storage byte size of 7095, varying from 2748 to 17,425. In terms of the number of fields, laboratory test data constituted the highest proportion at 67.5%, followed by risk assessment data at 9.6%. Regarding storage byte size, laboratory test data also represented the largest proportion at 61.4%, with radiological examination result data following at 14.4%.

Table . Characteristics of the performance benchmark dataset in this study.

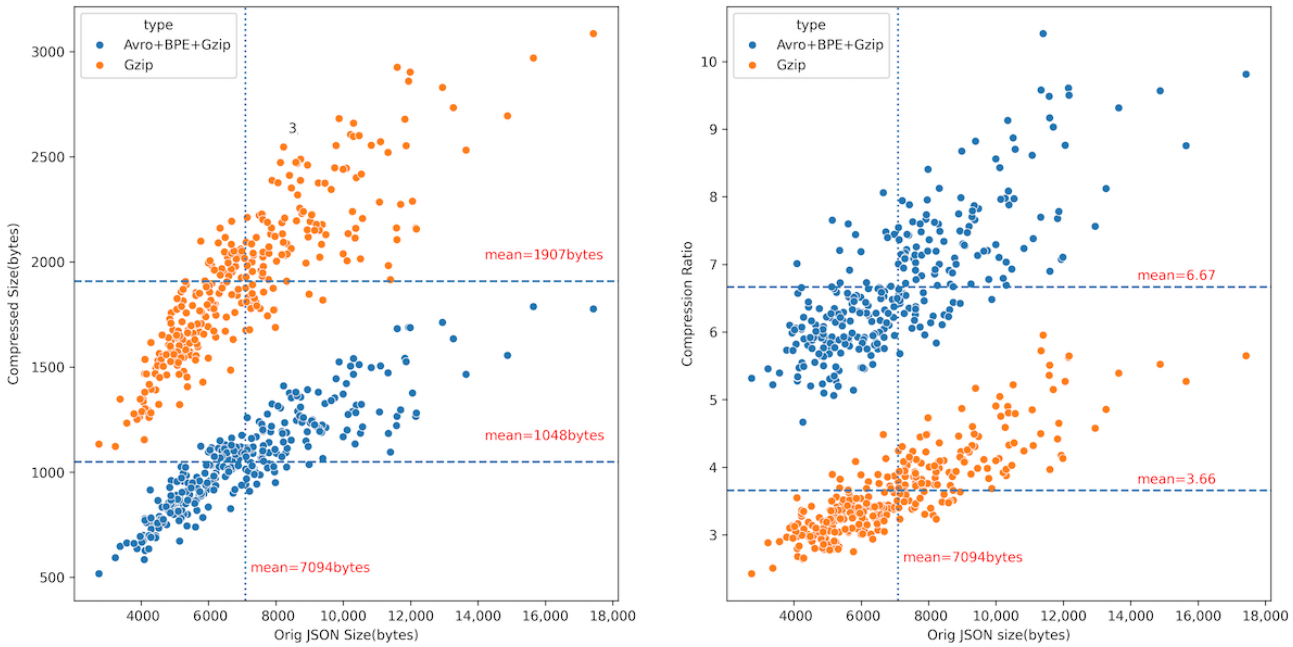
Patient (n=300)	Field (num), mean (min-max)	Field (%)	Size (bytes), mean (min-max)	Size (%)
Total	240.1 (89-623)	—[a]	7095 (2748-17,425)	—
Base	10 (10-10)	4.2	261 (242-270)	3.7
Operate	1.1 (0-32)	0.5	77 (23-1269)	1.1
Image	17.1 (4-56)	7.1	1022 (153-3944)	14.4
Lab	162 (46-496)	67.5	4354 (1269-13,365)	61.4
Ass	23 (10-35)	9.6	584 (212-1181)	8.2
Disease	12.2 (2-48)	5.1	419 (80-1537)	5.9
Drug	14.6 (0-85)	6.1	379 (28-2042)	5.3

[a]Not applicable.

Overall Compression Efficiency Analysis

The average size of the original JSON data was 7095 bytes. After compression using the traditional Gzip algorithm, the average size was reduced to 1907 bytes, with an average compression ratio of 3.66. By applying our developed BPE+Avro+Gzip combined compression algorithm, the average size was further reduced to 1048 bytes, improving the average compression ratio to 6.67. The compression efficiency of our algorithm was 1.82 times that of the traditional Gzip algorithm (P<.001). The scatter plot distribution in Figure 4 shows that the larger the original JSON file, the more significant the compression effect.

Figure 4. Comparison of the compression efficiency between our Avro + BPE + Gzip combined method and traditional Gzip in the performance benchmark dataset. BPE: byte pair encoding; JSON: JavaScript Object Notation.



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Comparative Analysis of Avro and ASN.1

According to previous research, ASN.1 and Avro demonstrated the best compression performance among JSON serialization technologies. For our "Performance Benchmark Dataset," Avro achieved a compression ratio of 2.59, while ASN.1 had a compression ratio of 2.57, with no significant difference (P=.30). However, Avro significantly outperformed ASN.1 when combined with BPE or Gzip methods (Table 5 and Figure 5). Specifically, the compression ratio for Avro+Gzip reached 4.72, compared with 4.12 for ASN.1+ Gzip (P<.001). Further, when the BPE method was introduced, the compression ratio for Avro+BPE+Gzip was 6.67, while for ASN.1+BPE+Gzip it was 5.21 (P<.001).

Table . Comparison of compression ratios between Avro and Abstract Syntax Notation One (ASN.1) in different combinations with byte pair encoding (BPE) and Gzip.

Name	Median (IQR)	Min	Max
ASN.1[a]	2.59 (2.45-2.77)	1.78	3.09
Avro	2.57 (2.43-2.75)	1.78	3.07
ASN.1+Gzip[b]	4.12 (3.63-4.46)	2.92	6.92
Avro+Gzip	4.72 (4.18-5.15)	3.35	7.73
ASN.1+BPE[c]	5.01 (4.83-5.23)	4.07	5.81
Avro+BPE	5.14 (4.94-5.37)	4.16	5.99
ASN.1+BPE+Gzip[d]	5.21 (4.95-5.45)	4.12	6.62
Avro+BPE+Gzip	6.67 (5.93-7.20)	4.67	10.41

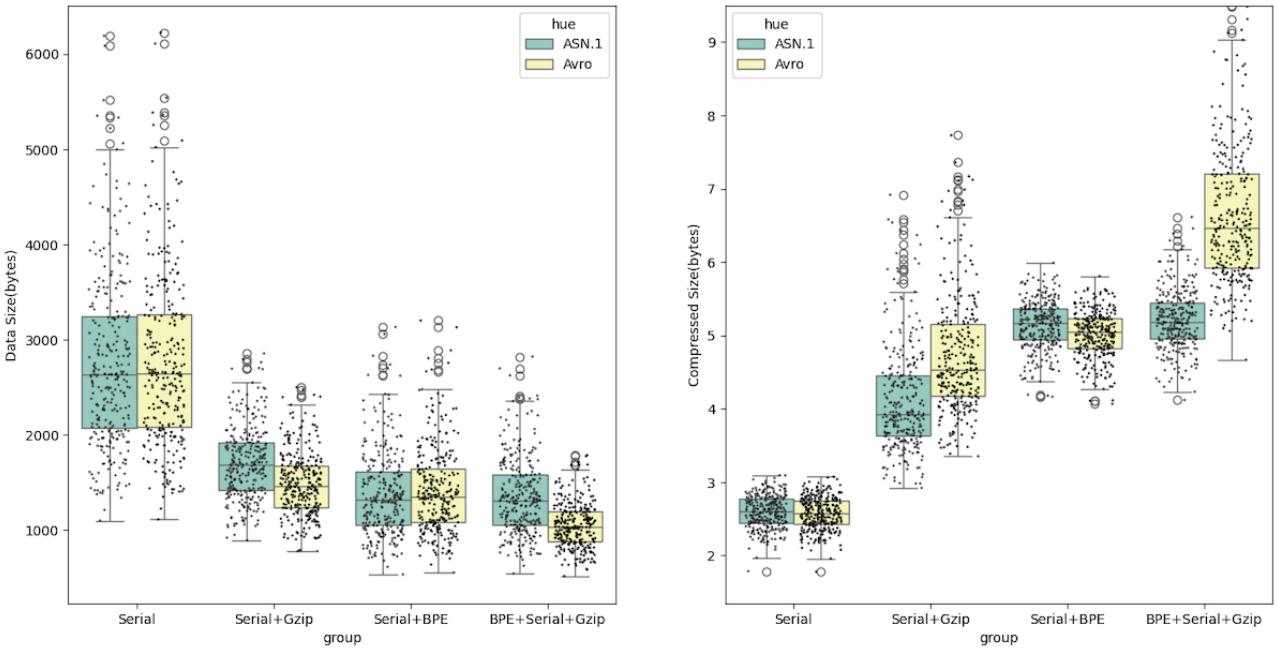
[a]ASN.1 versus Avro; P=.30.

[b]ASN.1+Gzip versus Avro+Gzip; P<.001.

[c]ASN.1+BPE versus Avro+BPE; P<.001.

[d]ASN.1+BPE+Gzip versus Avro+BPE+Gzip; P<.001.

Figure 5. Analysis of compression performance for Avro and ASN.1 in different combinations with BPE and Gzip, where "Serial" indicates the use of Avro or ASN.1 for JSON serialization. ASN.1: Abstract Syntax Notation One; BPE: byte pair encoding; JSON: JavaScript Object Notation.



Comparative Analysis of BPE and Unigram

Our constructed dataset consisted of a total of 1,146,532 records, with a total size of 122.5 MB and an average sentence length of 38.3 Chinese characters, corresponding to an average byte length of 106.8. We divided this dataset into a training set and a test set at a ratio of 9:1.

Using Google's open-source project SentencePiece for tokenizer training, we trained and validated 2 tokenization methods: unigram and BPE171819, with a vocab_size of 65,535, allowing each token to be represented by a 2-byte unit. In terms of training duration, unigram took 65.91 seconds, while BPE took 360.2 seconds, with unigram being faster. In terms of compression ratio, on the training set, unigram and BPE

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achieved compression ratios of 4.7 and 4.83, respectively (P<.001); on the test set, they achieved 4.55 and 4.68, respectively (P<.001), showing that BPE is more efficient than unigram (Table 6).

Table . Comparison of compression ratios for byte pair encoding (BPE) and unigram with different serialization methods in the Chinese medical text dataset.

Dataset	Sentences (n=1,146,532)	Unigram	BPE	*P* value
Train	1,031,697	4.70	4.83	<.001
Test	114,835	4.55	4.68	<.001

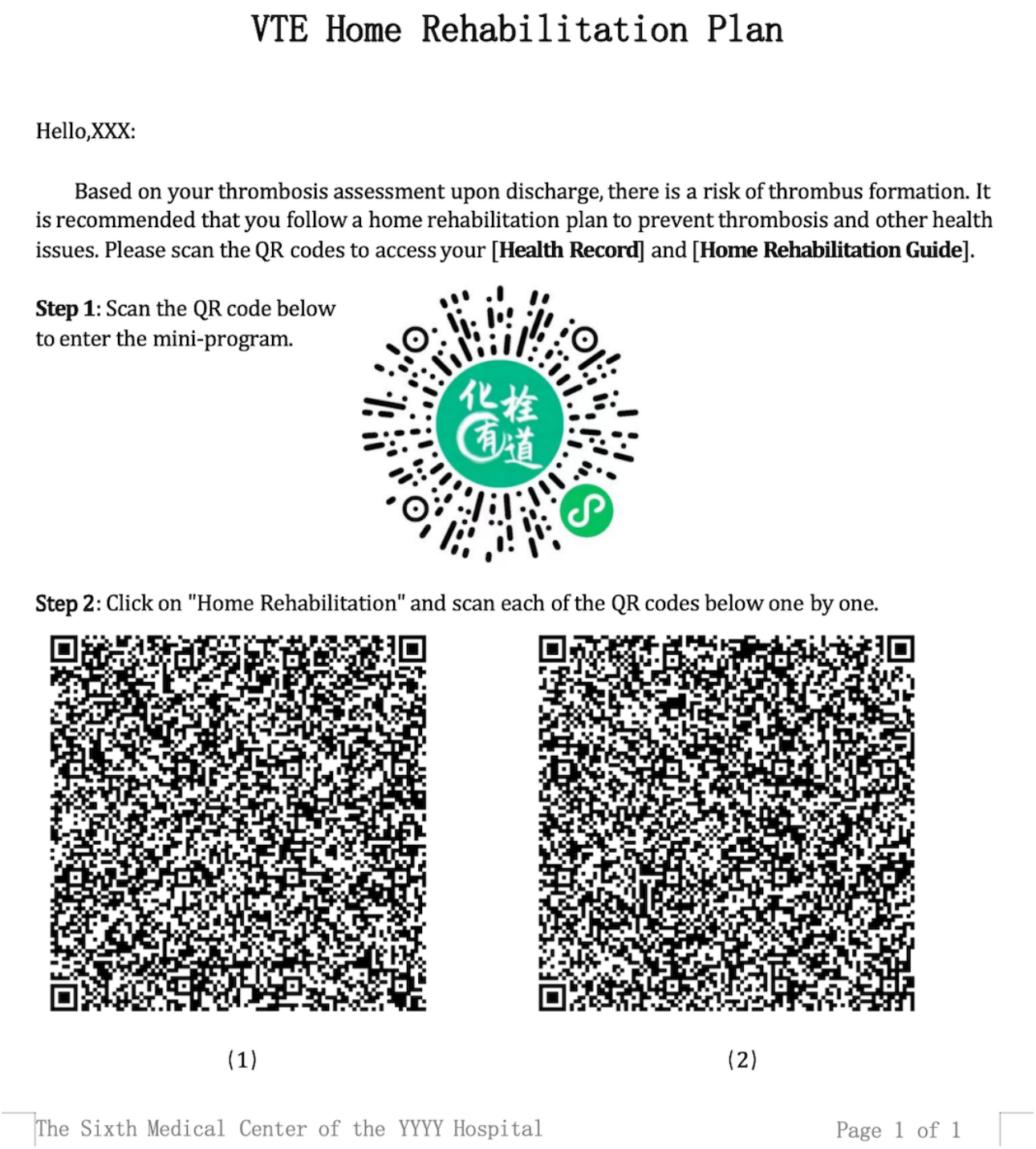
QR Code Distribution and Scanning Time

Based on previous research, when each module size is set to 4×4 pixels, 100% readability can be achieved on A4 white paper [24]. For the largest QR code size, the number of modules contained is 177×177 [25]. With a border width of 4 and an estimated resolution of 200 dots per inch for a standard printer, even the largest QR code would occupy a space of 3.7 inches (9.39 cm) in both length and width on A4 paper.

Considering the response speed of mobile phone scanning and the redundancy requirements of QR codes, we selected the version 25 QR code with 117×117 modules, which has a theoretical size of 2.5 inches (6.35 cm). Taking into account the differences in dots per inch, ink density, and default print margins across different hospital printers, we reserved a 20% redundancy, resulting in a designed QR code size of 7.62 cm × 7.62 cm (approximately 3×3 inches), with 2 QR codes per row. The specific layout is shown in Figure 6.

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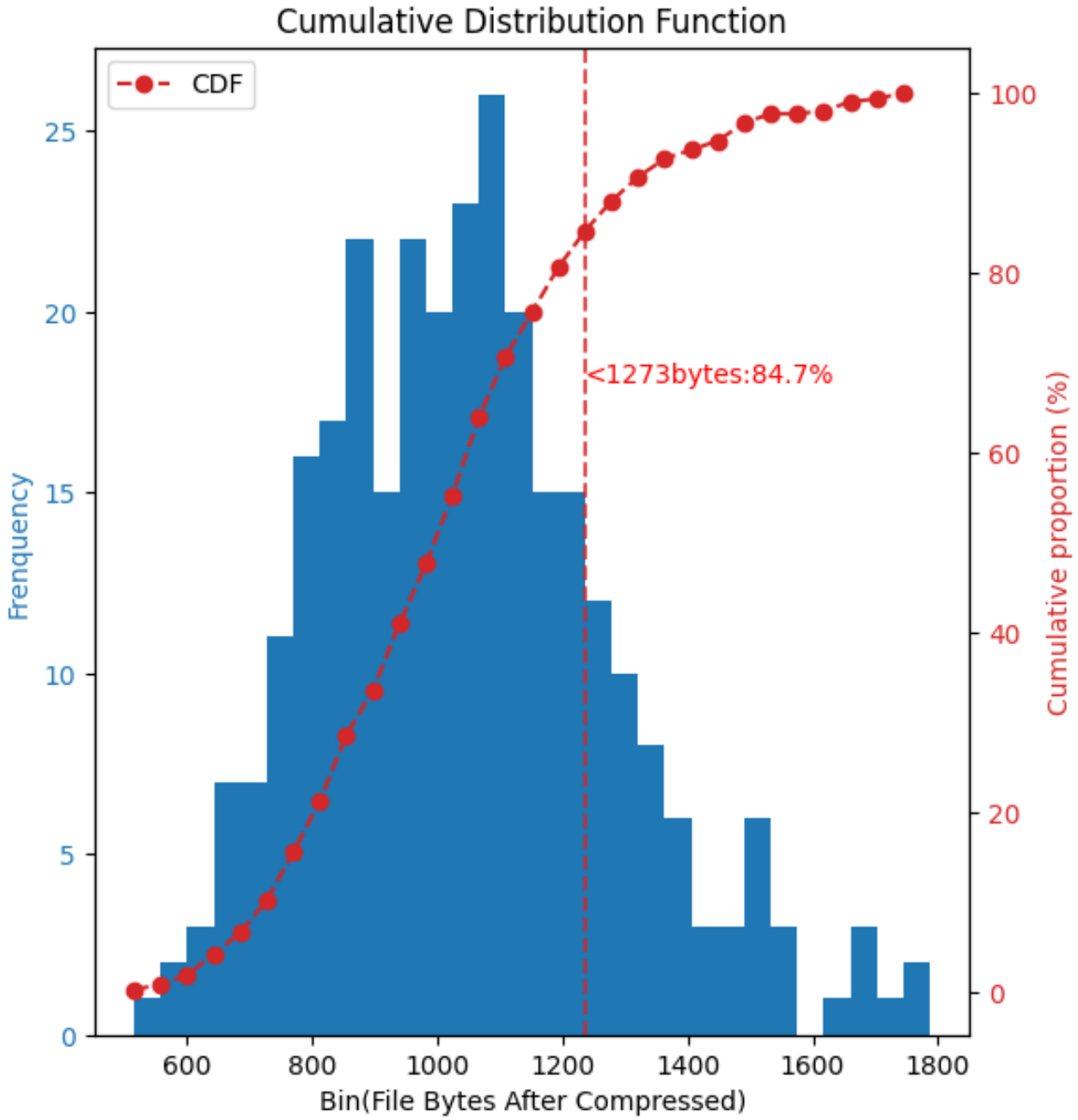
Figure 6. Example of a home rehabilitation report given to patients upon discharge for scanning QR codes. VTE: venous thromboembolism.



We used version 25 QR codes with an error correction level set to L, each supporting a maximum binary capacity of 1273 bytes [25]. As shown in Figure 7, following a cumulative distribution function [26] analysis of the compressed file sizes for 300 patients, we found that 84.7% of the patients needed to scan only one QR code, while 5.3% of the patients required scanning 2 QR codes. Only an extremely small number of patients may need to scan more than 3 QR codes.

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Figure 7. CDF analysis of file sizes for 300 patients after compression, showing that 84.7% of patients require scanning only 1 QR code with a file size less than 1273 bytes. CDF: cumulative distribution function.



Based on the size of the compressed files, we selected 3 patients for a scanning test, corresponding to 1, 2, and 3 QR codes, respectively. The test timing started when the patient clicked the scan button and ended when the record creation was completed. Testing with different models of mobile phones showed that, on average, scanning 1 QR code took 3.1 seconds, scanning 2 QR codes took 7.30 seconds, and scanning 3 QR codes took 8.73 seconds. ANOVA was used to test the differences, with a *P* value <.001.

Based on the size of the compressed files, we selected 3 patients for a QR code scanning test, corresponding to 1, 2, and 3 QR codes, respectively. The timing started when the patient clicked the scan button and ended when the registration was completed. Different smartphone models were used for the tests, and the results showed that, on average, scanning one QR code took 3.1 seconds, scanning 2 QR codes took 7.30 seconds, and scanning 3 QR codes took 8.73 seconds (Table 7). ANOVA was used to test the differences, with a *P* value <.001.

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Table . Duration (in seconds) for different types of patients to scan QR codes and complete record creation using various mobile phone models.

Phone model	Patient 1 (1 QR code)	Patient 2 (2 QR codes)	Patient 3 (3 QR codes)
iPhone 13 Pro Max	2.43	8.02	6.32
Xiaomi 13 ultra	2.18	5.95	8.79
iPhone 15 Pro	1.63	5.44	5.68
OPPO Find X5 Pro	1.94	6.50	7.70
OPPO K9s	6.03	8.83	10.54
Redmi K60	2.36	8.88	10.29
Xiaomi 10	2.98	6.28	9.37
Redmi Note 13 Pro	5.30	8.48	11.17
Mean	3.10	7.30	8.73

Discussion

Main Findings

We developed a QRST-AB, which assists patients in creating home rehabilitation records after discharge while ensuring the privacy, security, and efficiency of medical data transmission. The primary outcomes of our study are as follows. (1) We proposed a QR code authentication and encryption mechanism that leverages ChaCha20 encryption and the BLAKE3 hash function, reducing message inflation to as low as 2 bytes and enabling noninteractive cross-domain verification and data security in a zero-trust environment. (2) We developed an efficient combined data compression method, where the BPE+Avro+Gzip compression approach is 1.9 times more efficient than traditional Gzip compression, allowing a single patient's medical record to be compressed into 1 - 3 QR codes, thus improving the practicality and efficiency of QR code transmission in medical data scenarios. (3) The algorithm is provided in software development kit form, making it easy to deploy and use, which facilitates broader adoption.

Comparison With Prior Work

In previous research, there have been instances of embedding medical data, as opposed to URL information, into QR codes for transmission. Specifically, Lin et al [8] encoded patients' prescription information into QR codes, facilitating the use of these codes by patients at different pharmacies. The QR code encompassed information across 17 fields, including the patient's name, identification, age, type of disease, name of medication, and date, among other critical data. Additionally, Nakayama from Japan [9] and Mathivanan from India [10,11] have successfully embedded electrocardiogram data into QR codes. Lauriot [12] adopted the approach of directly embedding the data results of imaging reports into a single QR code. Mao et al [13], on the other hand, used a different strategy; they segmented a file containing medical data and embedded the segmented data into consecutive QR codes, which were dynamically and continuously displayed in a streaming video. Users could capture this video stream with a smartphone and subsequently recover the relevant medical data from the QR codes.

However, in previous practices, despite the use of signal sampling and private encryption algorithms to enhance security when embedding electrocardiogram data into QR codes, medical texts are still embedded in plaintext, which may expose the data to interception by unauthorized third parties, leading to potential leakage of patient privacy information. Moreover, these cases generally lack user authentication mechanisms and exhibit low compression efficiency.

Prior to this work, several studies have proposed solutions for securing data transmission in untrusted environments. For example, [27] introduces authentication and encryption measures for military communication protocols to prevent man-in-the-middle and replay attacks. In [28], blockchain technology is used to establish a decentralized trust mechanism—for instance, similar to the framework described in [29], one can refer to its on-chain authentication and consensus processes to enhance data integrity and immutability when transmitting QR-embedded information. In the health care domain, [30] emphasizes the need to balance data security and privacy protection in telemedicine interoperability, which informs our design of QR code data encryption and client authentication. Moreover, [31] addresses deepfake disinformation strategies from a holistic cybersecurity perspective, offering guidance on ensuring the integrity and trustworthiness of data embedded in QR codes. Finally, [32] presents a hesitant fuzzy decision-making approach for usable-security assessment, which can be applied to optimize the usability of our underlying authentication workflow.

To address these security risks and efficiency issues, we have taken the following improvement measures. First, we have proposed a complete solution and an end-to-end communication mechanism, defined the protocol specifications, and added authentication information to the protocol header. We use cryptographic hash algorithms to verify the identity of the scanning user, preventing unauthorized users from scanning the QR code. Additionally, we use encrypted transmission, which remains secure even if a third party understands the principles of our algorithm, as they do not possess the ChaCha20 secret key, the Avro encoding schema, and the BPE tokenizer, and thus cannot decipher the contents of the QR code.

Second, we have proposed an efficient compression algorithm for patient medical record data, organically integrating JSON

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serialization technology, tokenization techniques based on large language models (including subword tokenization methods like BPE), and binary data compression technology. The combination of BPE+Avro+Gzip has achieved optimal compression performance. To date, there is no precedent for compressing electronic medical records using this combination. Although the transmission efficiency of QR codes is inherently limited and slow, our effective compression algorithm can significantly reduce the size of medical record data, thus greatly enhancing the practicality of QR codes in the transmission of medical information. Furthermore, our solution supports the transmission of multiple QR codes in a single transaction, thereby enabling the carriage of larger volumes of medical records and information.

Through our improvements and real-world data validation, the QRST-AB possesses the characteristics of encryption, authentication, efficiency, robustness, and scalability. This makes it well-suited for home rehabilitation registration scenarios and other situations requiring the transmission of patient privacy data.

Limitations

There were some limitations to this study. First, due to the limited project timeline, validation was conducted using single-center data only. However, the algorithm was designed with flexibility for multicenter deployment and support for diverse disease types, which will be further validated in future studies. Second, when patient records are large and QR codes contain substantial data, poor network conditions may lead to delays in the decoder's real-time response. Thirdly, the solution relies on manual scanning, and the patient's digital health literacy may affect the user experience; however, most users are capable of performing scanning operations, which helps mitigate this issue.

Future Work

We plan to conduct multicenter validation and extend support to other disease types, as well as optimize the algorithm to reduce response delays caused by large patient data volumes.

Conclusions

The QRST-AB algorithm efficiently compresses and transmits data in an encrypted manner and authenticates the identity of the scanning users, ensuring the privacy and security of medical data. Delivered as a software development kit, the algorithm offers straightforward implementation and usability, supporting its broad adoption across various applications. All code is publicly available through the QRST-AB GitHub repository.

Acknowledgments

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

YG had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The study was conceptualized and designed by YG, FW, and CL. CL was responsible for the development. Data acquisition, analysis, and interpretation were performed by CL, ZJ, and YG. CL and ZJ drafted the manuscript. YG, FW, ZJ, and CL contributed to the critical revision of the manuscript for important intellectual content. Statistical analysis was conducted by CL, ZZ, and BL. YG obtained the funding for the study.

Conflicts of Interest

None declared.

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Abbreviations

ASN.1: Abstract Syntax Notation One
BPE: byte pair encoding
EHR: electronic health record
JSON: JavaScript Object Notation
QRST-AB: QR code-based security transmission algorithm using Avro and byte pair encoding
VTE: venous thromboembolism

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How AI-Based Digital Rehabilitation Improves End-User Adherence: Rapid Review

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Abstract

Background: The integration of artificial intelligence (AI) in rehabilitation technology is transforming traditional methods, focusing on personalization and improved outcomes. The growing area of AI in digital rehabilitation (DR) emphasizes the critical role of end-user compliance with rehabilitation programs. Analyzing how AI-driven DR tools can boost this compliance is vital for creating sustainable practices and tackling future challenges.

Objective: This study seeks to assess how AI-based DR can improve the end-user compliance or adherence to rehabilitation.

Methods: Following the updated recommendations for the Cochrane rapid review methods guidance and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, a systematic literature search strategy was led in PubMed, which yielded 922 records, resulting in 6 papers included in this study.

Results: The reviewed studies identified 6 key ways in which AI enhances end-user compliance in rehabilitation. The most prevalent method (in 4 studies) involves motivating and engaging users through features like exercise tracking and motivational content. The second method, also noted in 4 studies, focuses on improving communication and information exchange between health care providers and users. Personalized solutions tailored to individual cognitive styles and attitudes were highlighted in 3 studies. Ease of use and system usability, affecting user acceptability, emerged in 2 studies. Additionally, daily notifications, alerts, and reminders were identified as strategies to promote compliance, also noted in 2 studies. While 5 studies looked at AI's role in improving adherence, 1 study specifically assessed AI's capability for objective compliance measurement, contrasting it with traditional subjective self-reports.

Conclusions: Our results could be especially relevant and beneficial for rethinking rehabilitation practices and devising effective strategies for the integration of AI in the rehabilitation field, aimed at enhancing end-user adherence to the rehabilitation regimen.

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KEYWORDS

artificial intelligence; AI; rehabilitation; digital rehabilitation; compliance; adherence; PRISMA; Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Introduction

Increased population growth in the global south, aging demographics in the global north, and rising numbers of individuals in both contexts with chronic conditions highlight the growing need for multidisciplinary rehabilitation worldwide. Rehabilitation is defined as "a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment" [1]. Access to rehabilitation services plays a crucial role in providing comprehensive care and support for individuals in need. However, traditional rehabilitation services present significant limitations, including time constraints, long distances to travel, high costs, lack of human resources, and limited availability of clinical facilities, leaving a large unmet need and subsequent lack of participation [2,3].

The growing trend toward digitized health care, the use of portable technology, and events such as the COVID-19 pandemic have exacerbated the challenges that rehabilitation services face. The social distancing measures implemented during the COVID-19 pandemic provided a considerable push for the expanded use of digital rehabilitation (DR) modalities

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by numerous types of health care professionals [4]. DR has the potential to advance end-user (patient) and therapist collaboration to enhance the outcomes, improve performance challenges and quality of life, decrease health care costs, and tackle other key rehabilitation obstacles [5,6]. DR involves incorporating digital technologies into the rehabilitation process, which encompasses, but is not limited to telehealth and remote rehabilitation apps and services, a range of sensor and information and communication technologies, artificial intelligence (AI)–driven and robot-assisted tools, wearables, as well as email, video, speech, and SMS text messaging solutions [3,4].

The application of AI is revolutionizing almost all subfields of health care, including rehabilitation [7]. AI is described as the capacity of a machine to do a functional task under the intelligent supervision of humans [8]. AI tools are becoming more adept at learning from extensive and intricate data, using algorithms to acquire knowledge, analyze, and subsequently aid in different clinical and rehabilitation procedures [9].

Rehabilitation technology supported by AI signifies a groundbreaking and revolutionary method in the rehabilitation sector, which can be used to customize and complement the overall quality of traditional rehabilitation strategies [10]. AI has become a crucial component of DR, transforming and improving evaluation, screening, therapy, and monitoring through identifying patterns within vast quantities of health care data [10]. These patterns can then be used in designing tailored and personalized rehabilitation strategies and treatment regimens and comprehensive care planning [10-12]. AI tools support the automation of many rehabilitation tasks, injury prevention, prompt referral decisions, remote rehabilitation, monitoring and forecasting the end-user progress, and the creation of assistive technologies [12,13].

AI technologies provide efficient and enhanced rehabilitation access with optimized outcomes, which have the potential to improve client adherence and motivation [4,10,12]. Some of these technologies include AI-based digital and personalized rehabilitation mobile apps, AI-driven virtual reality and augmented reality rehabilitation, sensors, robotic devices, and AI-powered gamification and telerehabilitation [4,10].

Despite the key benefits of these technology-driven interventions—such as improved accessibility, affordability, and their availability from the convenience of homes—most of the AI-based rehabilitation applications are in the early stages of development [12,14-16]. However, the application of AI in redesigning rehabilitation to tackle upcoming challenges will intriguingly grow [4].

Compliance or adherence to long-term treatments, including rehabilitation, poses a significant health care challenge when managing chronic illnesses and is crucial for the success of rehabilitation and end-user recovery. While it signifies the end user's readiness to engage in and dedicate themselves to the treatment and prescribed therapeutic routine, this commitment aims to prevent complications and the reoccurrence of the disease by enhancing daily activities, quality of life, and overall outcomes [17]. Although the terms compliance and adherence are different in some ways, the 2 words are used interchangeably by medical professionals [18]. Compliance or adherence guarantees that there is willing, cooperative, and engaged interaction between the client and the health care provider [19].

Several factors and explanations contribute to the complexity of compliance or adherence to rehabilitation. In medical and rehabilitation settings, adherence refers to how well individuals follow the clinical recommendations that have been mutually established [20]. In this study, we refer to rehabilitation adherence as the end user's (patient's) compliance or adherence to, engagement in, and acceptability of the rehabilitation program. Reasons for the end user not adhering to rehabilitation plans may include skepticism about treatment benefits, concerns about side effects, financial limitations, the complexity of the treatment plan, and insufficient support from family and peers [19,21]. Prior studies have indicated that patients who adhere more closely to treatment plans tend to experience improved outcomes [22]. However, there is an overall lack of evidence in the area of compliance or adherence, and in what ways AI can improve end-user rehabilitation compliance or adherence is unknown. AI in DR is an emerging field, and considering that end-user compliance or adherence to a rehabilitation regimen plays a significant role, comprehending how AI-based DR can impact the end-user rehabilitation compliance or adherence is crucial for establishing sustainable DR practices and meeting the challenges ahead. The aim of this rapid review (RR) lies in understanding the impact of AI-based DR tools on the improvement of end-user rehabilitation compliance or adherence. This review answers the following research question: "How can AI-based DR improve end-user compliance or adherence to rehabilitation?"

Methods

Study Design

A Cochrane RR is "a form of knowledge synthesis that accelerates the process of conducting a traditional systematic review through streamlining or omitting specific methods to produce evidence for stakeholders in a resource-efficient manner" [23]. It primarily provides prompt evidence for decision-making regarding urgent and high-priority health issues [23].

RR is a type of systematic review that aims to balance time limitations with the need to address bias [24]. However, RRs may not include all elements of a systematic review, with differences in the dimensions of time, resources, and searches. For example, Cochrane RRs should take no longer than 6 months; they may be less comprehensive, and a small number of databases are selected for searches; they may exclude hand-searching and gray literature; and some limits such as years and language may be applied in RRs [24,25].

This review is in compliance with the updated recommendations for the Cochrane RR methods guidance and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) recommendations (Checklist 1) [24,26]. The Cochrane RR guidance consists of 24 specific recommendations supporting the conduct of RRs to enhance the efficiency of the review process [24].

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Literature Search

PubMed was searched in May 2024, and a combination of MeSH terms and keywords on the following themes was used: AI, DR, and end-user compliance or adherence. A copy of the PubMed search strategy is included as Multimedia Appendix 1.

Study Selection

Titles and abstracts were initially screened through applying the eligibility criteria by 2 reviewers (MM and MLW) independently. The only software that was used to facilitate this process was Microsoft Excel to aid in the display and tabulation of the information. For retained papers, full texts were obtained, and again, a subset of full texts was screened by 2 researchers (MM and MLW). Differences and discrepancies were discussed, and dual screening was continued until convergence was reached.

Studies were included when they encompassed the following elements in line with the population, intervention, comparison, and outcome framework for evidence-based practice:

- Population: Adults (≥18 years of age) undergoing formal rehabilitation.
- Intervention: Any type of AI-based applications and tools, used by end users or health care providers, in inpatient, outpatient, or community-based settings.
- Comparison: For interventional studies, the control group is defined as those not receiving AI-supported rehabilitation.
- Outcome: End-user rehabilitation compliance or adherence.
- Study types: Any study design.
- Other: English language studies published from January 1, 2012, onward.

Protocols, books, theses, editorials, conference abstracts, and non-English language studies were excluded. Studies focusing on psychiatric rehabilitation were intentionally excluded since distance- and digital-based mental health interventions have been widely available, even before the internet age with counseling being done via telephone. Studies focusing on robotics and AI were also excluded, as this is a sufficiently large field that would require a separate review. Considering the recent use of AI applications in the health care field and a surge of advancements in AI in 2012, it was deemed not necessary to review papers published before 2012.

Data Extraction and Management

Data extraction was conducted by a single researcher and then verified for consistency, accuracy, and completeness by a second independent researcher. It included population characteristics, rehabilitation field and setting, intervention details including AI subset or algorithm, purpose of the device and the technology used, the study aims and its characteristics evidencing drawbacks and advantages reported by respective authors, major findings, and the way AI impacts the end-user compliance or adherence.

Quality Assessment

The Cochrane Risk of Bias tool 2.0 [27] was used for randomized controlled trials (RCTs) to assess the quality of studies. The tool inquires about various aspects in 5 domains where bias could potentially arise. The five domains include (1) bias from randomization, (2) bias from deviations in interventions, (3) bias from missing outcome data, (4) bias in outcome measurement, and (5) bias in reported result selection.

Data Synthesis

Due to the diversity in study designs and outcome measures, the results were synthesized in a narrative format.

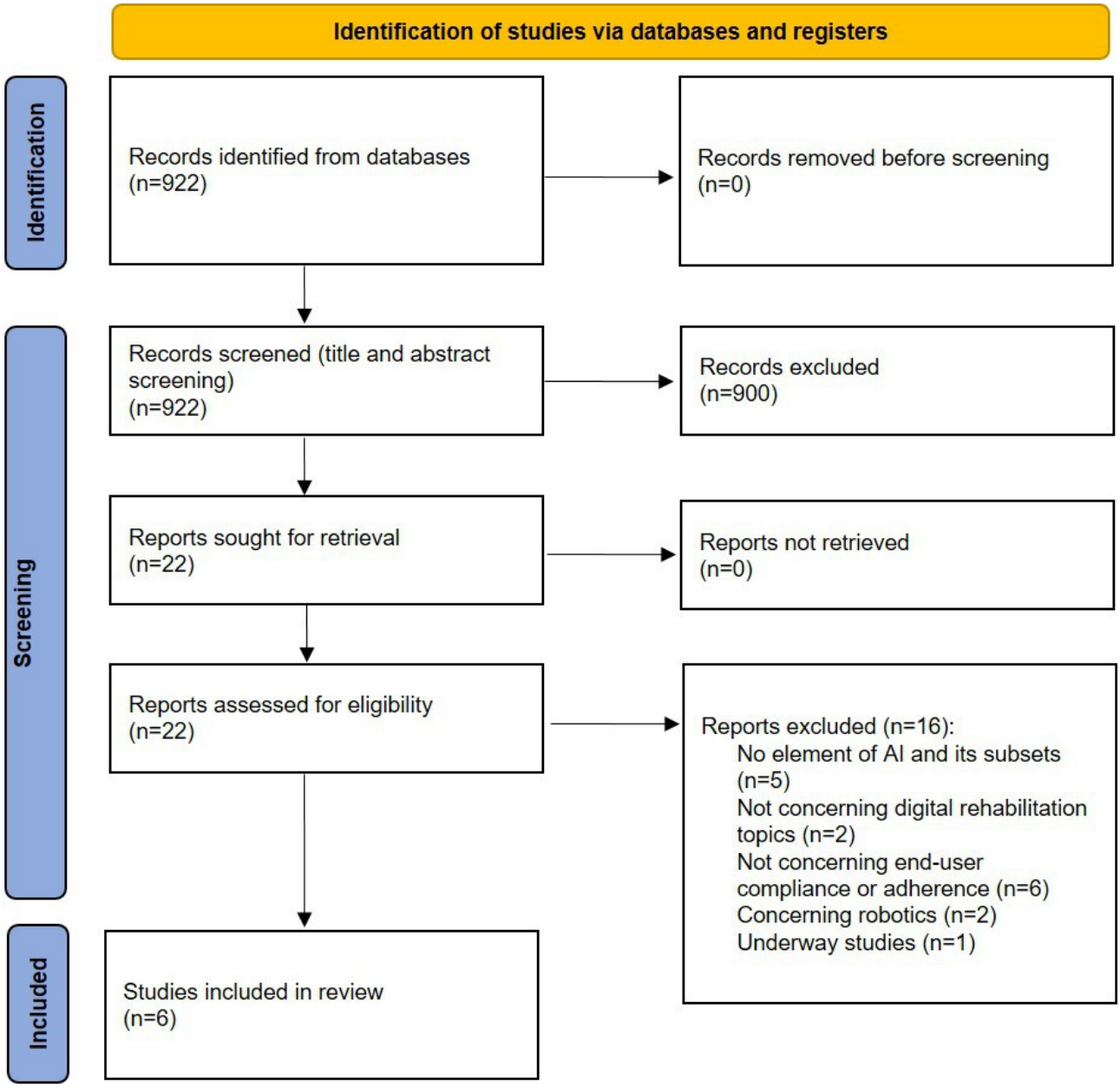
Results

Overview

In the initial paper search, 922 unique papers were identified. After screening, 6 papers met the eligibility criteria and were included (Figure 1).

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Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of the results from the literature search. AI: artificial intelligence.



Study Characteristics and Interventions

Characteristics of the included studies and their relevant interventions are presented in Table 1. Of the 6 publications, 3 were RCTs [28-30], 2 were pilot studies [31,32], and 1 was a proof-of-concept study [33]. The number of participants recruited into the included studies ranged from 6 to 500 participants. Studies were conducted in Canada (n=1), Israel (n=1), the Republic of Korea (n=1), Thailand (n=1), Italy (n=1), and the United States (n=1).

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Table . Characteristics of the included studies and their interventions.

Reference (year, country)	Study design	Rehabilitation field and setting	Sample characteristics	Intervention
Chae et al (2020) [29] (Republic of Korea)	RCT[a]	Upper limb rehabilitation, home-based	End users with chronic stroke, intervention: n=17; mean age 58.3 (SD 9.3) years; control: n=6, mean age 64.5 (SD 9.6) years	Performing the home rehabilitation exercises while using wearable sensors embedded in a commercial smartwatch
Aharon et al (2022) [28] (Israel)	RCT	Cardiac rehabilitation, clinic-based	End users discharged from a cardiovascular event, intervention: n=95; mean age 61.3 (SD 14.6) years; control: n=500; mean age 65.4 (SD 10.4) years	Using the Well-Beat system, ongoing personalized text messages for each end user were generated to create continuity and reinforce desired behaviors
Burns et al (2018) [33] (Canada)	Proof of concept	Shoulder physiotherapy, home-based	Healthy adult participants, n=20, mean age 28.9 years; range 19 - 56 years	Performing 20 repetitions of 7 shoulder exercises bilaterally while using a smartwatch device with embedded inertial sensors
Thiengwittayaporn et al (2023) [30] (Thailand)	RCT	Physical therapy, home-based	End users with primary knee osteoarthritis, intervention: n=42; mean age 62.2 (SD 6.8) years; control: n=40; mean age 63.0 (SD 9.7) years	Receiving information regarding knee osteoarthritis disease background and exercise instruction through mobile app self-directed exercise guidance
Capecci et al (2023) [31](Italy)	Prospective, pre- or postintervention pilot study	Motor and respiratory rehabilitation, home-based	Participants with post–COVID-19 condition and Parkinson disease, n=21; mean age 61.1 (SD 10.5) years	Using ARC Intellicare, a telerehabilitation solution based on the use of multiple wearable sensors, a mobile device, and algorithms of AI[b]
Ramkumar et al (2019) [32] (United States)	Pilot study	Total knee arthroplasty, home-based	End users undergoing primary total knee arthroplasty, n=25; mean age 64.3 years	Performing daily exercises and a weekly survey while using a knee sleeve paired with the end user's iPhone and a mobile app

[a]RCT: randomized controlled trial.

[b]AI: artificial intelligence.

There were diverse rehabilitation settings, and most were home-based. Only in 1 study was the rehabilitation in a clinical setting. The treated conditions included stroke, cardiovascular disease, osteoarthritis, post–COVID-19 condition, and Parkinson disease. While 4 studies used wearable sensors as an intervention, in 1 study, end users received information regarding the disease background and exercise instruction through a mobile app, and in the other study, ongoing personalized SMS text messages for each end user were generated to create continuity and reinforce desired behaviors.

Outcomes and Results Summary

Outcome measures and results summary of the included studies are presented in Table 2. The outcomes measured in the included studies fell into 3 categories: feasibility, accuracy, and usability of the rehabilitation system; end-user compliance or adherence, engagement, and acceptability; and clinical outcomes (eg, functional improvements, range of motion, and quality of life). However, our focus is on the second category of outcomes.

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Table . Outcomes and results summary of the included studies.

Reference	Outcome measures		Results summary
	Primary measures (end-user compliance or adherence)	Other measures (feasibility, accuracy, and usability or clinical outcomes)	
Chae et al [29]	Dropout rate and home exercise performance average time as measures for the end-user compliance or adherence	Accuracy of the developed rehabilitation system, functional assessment test, shoulder range of motion	A decreased dropout rate, increased home exercise performance average time, a significant increase in functional recovery and shoulder flexion
Aharon et al [28]	End-user rehabilitation adherence	None	Significant improvement in end-user adherence and participation in the rehabilitation program
Burns et al [33]	The frequency and duration an end user is engaged with exercises as measures for the end-user compliance or adherence	Classifier performance in the measurement of frequency and duration of an end-user engagement in prescribed exercises	Feasibility of robust and highly accurate classification of sensor data in the measurement of frequency and duration of an end-user engagement in prescribed exercises
Thiengwittayaporn et al [30]	Ability to correctly perform the rehabilitation exercises as measures for the end-user compliance or adherence	Range of motion, Knee Injury and Osteoarthritis Outcome Score, and Knee Society Score	Improved accuracy of rehabilitation exercises, as measures for the end-user adherence, stronger overall functional outcomes, better daily life, ability to do sports and recreation, higher satisfaction and expectation, and a significantly better quality of life
Capecci et al [31]	Adherence to the rehabilitation program	Safety, usability, and acceptability of the rehabilitation program, clinical effectiveness (disability in basal activity of daily living, respiratory outcomes, endurance and fatigue, mood, and quality of life)	Improved end users' adherence, improved system usability scale score, clinical outcome measures, and no side-effect reports
Ramkumar et al [32]	Rehabilitation compliance	Feasibility validation, mobility, knee range of motion, patient-reported outcome measures, opioid use	Improved rehabilitation compliance, the provision of a continuous stream of data without any loss, improved mobility and patient-reported outcome measures, and stopped opioid use

Risk of Bias Summary

Three of the studies [28-30], which were RCTs, were assessed using the Cochrane risk of bias tool [27]. One of the studies had an overall risk of bias of "some concerns" [30], and 2 studies had an overall high risk of bias [28,29]. In total, 1 study had a high risk of bias arising from the randomization process [29], all 3 studies had a risk of bias of some concerns in the domain of bias due to deviations from intended interventions, and in the domain of bias in measurement of the outcome, 1 study had a high risk of bias [28], and 2 studies had a risk of bias of some concerns [29,30].

The Role of AI

Summarized information regarding the system and technology used by interventions in the included studies and the role of the used AI subset is presented in Table 3.

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Table . Characteristics of the systems used in interventions: technology type, artificial intelligence (AI) subset, and role.

Reference	AI subset	System and technology type	Purpose or role of the AI-based device or system
Chae et al [29]	Machine learning (ML) algorithm implemented by a convolutional neural network ascertaining what types of sensor data can detect home exercise activities most accurately via a cross-validation test	Activity monitoring using wearables (smartwatch, smartphone, and apps [Android Studio 2.3, Google])	The AI-based rehabilitation system connected end users and therapists at a distance and made it possible to share end users' home exercise data with therapists at remote locations. The system assisted participants in the intervention group to record their exercise time, obtain their own home exercise results, and communicate with a clinician, yielding visible improvement and acting as a motivation—features that were not available to those in the control group.
Aharon et al [28]	A real-time ML algorithm processing the digital questionnaires	Well-Beat platform, which created a profile for each end user by processing a digital questionnaire assessing end users' initial state	After processing the questionnaires, the system created a profile for each end user and presented it on the health care providers' toolbar. The toolbar included the end user's persistence level, readiness for change level (maturity), self-efficacy level, main motivational driver, and barrier, as well as what the health care provider should watch out for in communication with them. Based on this information, the engine recommended the personalized end-user dialogue to use, in terms of the tone, the style, and motivation factors, as well as what to avoid saying.
Burns et al [33]	Supervised ML approach	Exercise recognition using wearables, that is, smartwatch device with embedded inertial sensors (Apple Watch [series 2 and 3] with the PowerSense app, sampling at fs=50 Hz)	The AI-based system assessed the feasibility of performing shoulder physiotherapy exercise recognition with inertial sensor data recorded from a wrist-worn device to enable objective measurement of home shoulder physiotherapy adherence.
Thiengwittayaporn et al [30]	Rule-based and AI techniques (eg, determining the disease stage based on decision tree)	Education and assessment for the stage of disease via Love-Your-Knee mobile app (Android)	The AI-based system was used as a personalized solution and recommending the appropriate exercise types and the number of sets for each end user by assessing the stage of the disease, monitoring disease progression, and promoting physical therapy and rehabilitation exercise.
Capecci et al [31]	Algorithms of AI (patent pending), a neural network was used to recognize the performed exercise and segment the data into single repetitions	The ARC Intellicare system (an AI-powered and inertial motion unit-based mobile platform) consisting of a set of 5 inertial sensor inserted in slap supports, a tablet with a dedicated app, and a charging station	The AI-based system allowed rehabilitation professionals to prescribe exercises according to specific therapeutic needs and to monitor end users' performances and progresses remotely. The counting of the number of exercise repetitions correctly performed was the output of the developed AI algorithm. Real-time feedback was provided to the end user through the app user interface.

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Reference	AI subset	System and technology type	Purpose or role of the AI-based device or system
Ramkumar et al [32]	ML algorithms	Activity monitoring using wearables (knee sleeve, personal iPhones [Apple], and mobile app termed TKR [Focus Ventures])	The system transmitted the wearable knee sleeve motion data to the smartphone, then transmitted these and all other data to the dashboard, then analyzed these data by the ML algorithms to actively record and check daily compliance in order to provide automated reminder notifications based on the end user's compliance to the program.

The Ways AI Impacts End-User Rehabilitation Compliance or Adherence

In the included studies, the role of AI in rehabilitation and how it impacts end-user compliance or adherence to rehabilitation fell into 6 categories. End-user rehabilitation compliance or adherence improvement through motivation, engagement, and encouragement of end users was the first more cited procedure that was provided by AI-based rehabilitation systems or tools in the studies [28-30,32]. This was done, for example, by exercise tracking, using interactive features, and sending motivational content to end users to keep them engaged and to motivate them to adopt more desirable behaviors.

The second most cited approach was the enhancement of end-user rehabilitation compliance or adherence by facilitating information exchange and improving health care provider-end-user interaction and communication [28-31]. Third, offering a personalized end user–tailored solution was the other strategy supported by AI-based rehabilitation systems that could influence end-user compliance or adherence to rehabilitation [28,30,31], for example, by way of identifying end users' cognition, coping styles, and attitudes. The fourth category was ease of use and simple system usability influencing end-user acceptability [31,32]. Providing daily notifications, alerts, and reminders for end users, as end users, was another procedure that AI-based rehabilitation systems used to improve end-user compliance or adherence to rehabilitation [28,32].

While 5 studies addressed the role of AI in end-user rehabilitation compliance or adherence improvement, 1 study evaluated the capacity of AI-based rehabilitation systems in objective measurement of end-user compliance or adherence [33]. Since adherence is typically assessed using subjective methods like relying on end users' self-reports for home exercises, which may lack validity due to recall bias, social desirability, and misinterpretation, AI-based solutions could more easily and objectively monitor and assess the at-home adherence of exercise protocols by measuring the frequency and duration an end user is engaged with each of their prescribed exercises.

Implications and Drawbacks

Table 4 presents summarized information on the implications for end-user rehabilitation compliance or adherence, along with the drawbacks and limitations reported within the included studies themselves.

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Table . Summary of the included studies' implications and reported drawbacks.

Reference	Implications concerning end-user rehabilitation compliance or adherence	Study drawbacks and limitations
Aharon et al [28]	A dropout rate could decrease, and home exercise performance average time could increase due to using an AI[a]-based rehabilitation device, which could be considered as measures for improved end-user compliance or adherence to rehabilitation	Small number of participants, discrepancy in the number of case and control participants, and the probability of selection bias
Chae et al [29]	To increase adherence, any intervention should be tailored to the end user's preferences and behavioral profile, and this end user–tailored intervention approach could improve adherence with no change to the therapeutic regime	The potential bias related to the unblinded nature of this study with health care providers, the possible influence of the method of recruiting participants on the results
Thiengwittayaporn et al [30]	AI-based algorithms could be used to objectively monitor and assess the end-user rehabilitation compliance or adherence by measuring the frequency and duration an end user is engaged with exercises	The limited number of participants, no participants had symptomatic shoulder disorders, significantly younger age of the participants, and how well the proposed AI-based system would generalize to adherence monitoring in a clinical population is uncertain
Capecci et al [31]	An end user's ability to accurately perform the exercises at the final follow-up reflects adherence to home exercise, which could be improved due to the role of AI-based rehabilitation regimen	The end users included in this study were able to efficiently use smartphones, which may not be reflective of a larger older adult population; according to the structure of the study, it was impossible to blind the participants to their intervention, which could potentially skew self-reported outcomes, and the majority of the end users were female participants
Ramkumar et al [32]	AI-based devices allow for real-time monitoring of several aspects of adherence: both daily adherence and repetition, based on exercise recognition	The small sample size and the absence of a control group
Burns et al [33]	The AI-based remote end-user monitoring system could offer the newfound ability to more completely evaluate the end-user rehabilitation compliance	The data represented a small cohort with no broadly generalizable conclusions, a small sample size, and the potential risk for selection and recall bias by end users

[a]AI: artificial intelligence.

Discussion

Principal Findings and Interpretation

Achieving end-user autonomy represents an important objective of rehabilitation in response to the growing population, aging demographics, and higher prevalence of chronic illnesses. The integration of AI in rehabilitation technology represents an innovative and transformative approach, offering the potential to enhance and tailor traditional rehabilitation methods also for improved overall effectiveness [10]. However, adhering to extended treatment regimens, such as what rehabilitation may often require, presents a significant health care challenge in the management of chronic conditions and is essential for the effectiveness of rehabilitation and end-user recuperation. This review showcases how technology-driven interventions affect end-user (patient) rehabilitation adherence and focuses on the use of AI in enhancing end-user rehabilitation compliance or adherence by providing a general summary of the topic. This study categorizes literature according to the combination of procedures that AI impacts end-user rehabilitation compliance or adherence to support the future challenge of implementing sustainable DR practices to address upcoming issues.

According to the findings, 6 distinct areas were found to be important in assessing the impact of AI on end-user rehabilitation compliance or adherence across the independent studies [28-33]. One method that was frequently mentioned in the studies for enhancing end-user compliance or adherence to rehabilitation involved using AI-based rehabilitation systems and tools to motivate, engage, and encourage end users [28-30,32]. Motivation is a significant personal factor that strongly affects adherence to rehabilitation [32], which can be supported by AI-based technologies. Due to the significance of establishing habits and nurturing internal motivation, AI-based rehabilitation systems could potentially promote consistency and strengthen end users' desired behaviors by exercise tracking, using interactive features, music, video instruction, alerts, and awards, and sending motivational content to end users to keep them engaged and motivated [30]. Based on the findings, various aspects of AI-driven rehabilitation could enhance end-user engagement, such as real-time feedback and self-assessment features, and showcase daily progress [32].

Promoting information sharing and enhancing communication and interaction between health care providers and end users were other specific areas that AI-based rehabilitation systems could play a role in improving end-user rehabilitation

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compliance or adherence [28-31]. Numerous authors believe that developing a strong therapeutic bond with end users and effective health care provider-end-user communication greatly influences end-user adherence [34,35]. Communication-driven features of the AI-based rehabilitation tools and services could potentially strengthen the health care provider-end-user interaction and enhance communication. This was achieved by identifying the most effective communication approach for end users, tailoring personalized communication, and inspiring them to take action [28]. End users could benefit from such interventions by conveniently retrieving relevant medical information offered by these tools [30]. By facilitating the information exchange between the end user and the health care provider, the AI-powered rehabilitation tools and services can potentially support remote interventions. This represents a significant advancement in delivering services to vulnerable end users who must refrain from visiting health care centers during events like the COVID-19 pandemic [28].

Offering personalized solutions tailored to individual end users was a strategy supported by AI-driven rehabilitation systems that could impact end-user compliance or adherence to rehabilitation [28,30,31]. End users' characteristics, values, and the variability among their requirements, lifestyle, habits, beliefs, and persistence should be taken into consideration in the development and implementation of interventions aimed at improving health [36,37]. Accordingly, in order to improve end-user adherence to rehabilitation protocols, interventions should be customized to align with the end user's preferences and behavioral characteristics. Tailoring an AI-based rehabilitation intervention for each end user was determined by a comprehensive assessment of their medical records and profile, including aspects such as personality, coping mechanisms, willingness to change, and other factors, in addition to their behavior. This was achieved through, for example, targeted screening to identify end users' cognitive frameworks, their attitudes and perspectives on the circumstances, the factors that inspire them, and the obstacles they face toward progress [28]. In the study of Capecci et al [31], AI algorithms allowed rehabilitation professionals to prescribe exercises according to end users' specific therapeutic needs and to monitor their performances and progresses remotely, which led to real-time monitoring of several aspects of adherence and improved end-user compliance or adherence to rehabilitation. Similarly, Thiengwittayaporn et al [30] used AI techniques as a personalized solution for assessing the stage of the disease for each end user, monitoring disease progression, and promoting physical therapy and rehabilitation exercise. Therefore, rather than aiming for a one-size-fits-all optimal intervention, AI-based rehabilitation services help health providers identify the most suitable intervention for each individual end user at a specific moment. What may be highly effective for one end user can be ineffective, or even detrimental, for another. Additionally, the same intervention that initially shows promise in the rehabilitation process may prove inadequate, as the end user's performance progresses.

Another category, which could be instrumental for the improvement of end-user rehabilitation compliance or adherence, was the usability and ease of use of the AI-based rehabilitation intervention [31,32]. Low usability, in terms of ease of use and suitability, and inadequate user-friendliness are primary factors leading to the neglect of technological systems, impacting individuals' willingness to accept digital solutions and adherence to the treatment [38,39]. With their availability from the convenience of homes and being readily usable, AI-based rehabilitation tools and services could potentially contribute to end-user engagement and satisfaction and consequently rehabilitation compliance or adherence [32]. Moreover, AI technologies are commonly being integrated into smartphone apps, offering a variety of health care services including rehabilitation. The availability and ubiquity of smartphones, easy-to-use experience of the mobile apps, and platforms that do not necessitate any extra hardware beyond an end user's own smart device have unleashed the possibilities of AI-driven rehabilitation tools and services to enhance end-user compliance or adherence to rehabilitation [32].

Additionally, the findings of this review suggest that the capability of AI-based tools and services in providing automated daily notifications, alerts, and reminders for end users had an impact on the improvement of end-user rehabilitation compliance or adherence [28,32]. Numerous studies have demonstrated the effectiveness of reminders, notifications, and alerts in improving health outcomes [40,41]. The AI-driven rehabilitation tools and services have the ability to remotely monitor end users' progress and compliance with rehabilitation protocols, offering automated daily notifications, alerts, and reminders for end users to enhance end-user adherence to the program. For example, in the study of Ramkumar et al [32], the AI-based system actively recorded end users' weekly data for the daily compliance check and provided automated reminder notifications whenever required, and the end users mentioned these notifications as reasons for their engagement with the system.

Another key finding of this review is the ability of AI-driven rehabilitation systems to accurately measure end-user rehabilitation adherence in an objective manner [33]. At present, there is a scarcity of tools and a lack of agreement on a standardized approach for accurately and objectively measuring end-user rehabilitation compliance or adherence, specifically in a home environment [33,42,43]. End-user rehabilitation compliance or adherence evaluated through subjective approaches, such as end users' self-reports for home exercises, may lack validity. A less unexplored alternative is to assess the effectiveness and functionalities of AI-driven rehabilitation tools and services, offering the potential to use these technologies for objective end-user rehabilitation adherence measurement. AI-powered devices have the potential to enable the real-time tracking of various aspects of end-user rehabilitation compliance or adherence, including daily compliance and repetition, through exercise recognition [31]. In the study of Ramkumar et al [32], the AI-powered remote end-user monitoring system could provide a novel capability to assess end-user adherence to rehabilitation using machine learning algorithms. However, studies have taken various approaches to the evaluation of end-user rehabilitation adherence. For example, in the study of Chae et al [29], home exercise performance average time and a decrease in dropout

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rate were considered as measures for improved end-user adherence to rehabilitation. Burns et al [33] suggest that AI-based solutions could more easily and objectively monitor and assess the at-home adherence of exercise protocols by measuring the frequency and duration an end user is engaged with each of their prescribed exercises. Thiengwittayaporn et al [30] believe that an end user's accurate performance in executing the exercises indicates adherence to home exercise; nevertheless, this may not consistently hold true.

The application of AI in end-user rehabilitation adherence is a relatively new and evolving field of study, and this topic is still in its infancy. Nevertheless, it is evident that certain features offered by AI-based rehabilitation can contribute to enhancing end-user compliance and adherence to rehabilitation protocols. Our aim was to offer a summary of the current role of AI in assessing and enhancing end-user adherence to rehabilitation programs by examining the ways by which AI can impact end-user adherence in rehabilitation. In general, the present findings indicate that AI could contribute to the improvement of end-user rehabilitation adherence by its capacity in motivating and engaging end users, facilitating information exchange and improving communication, offering personalized end user–tailored solutions, delivering convenience and ease of system use, providing automated daily notifications, alerts, and reminders for end users, and measuring end-user rehabilitation compliance or adherence with an objective and accurate approach.

Strengths and Limitations

The evidence considered in this review was sourced from publications released within a 7-year time frame from the date of this RR, thereby enhancing the importance of the findings. Notwithstanding the methodological issues, all of the studies included in the analysis were published in peer-reviewed journals. However, it is important to address a few limitations of this review. First, we refrained from conducting a systematic literature review due to the limited number of studies available on the role of AI in measuring or enhancing end-user rehabilitation compliance or adherence. Moreover, due to the wide variety of study designs, it was deemed more suitable to perform an RR with synthesized results in a narrative format to present a comprehensive summary of the literature. Finally, the potential bias related to the unblinded nature of most of the included studies and the relatively limited number of participants complicates the definitive conclusions regarding the impact of AI-based DR on the end-user rehabilitation compliance or adherence.

Future Directions

A deeper comprehension of the effectiveness of AI-based approaches in DR is required to support the improvement and objective measurement of end-user rehabilitation compliance or adherence. Future work should concentrate on implementing AI-based DR in the real world and relevant operational settings and evaluate the clinical significance of the intervention through RCTs comparing the impacts on particular demographic groups of these innovative solutions as opposed to conventional rehabilitation methods. Additionally, further research is needed to validate the use of specific AI models and use the AI's complete capacity in the improvement of end-user rehabilitation compliance or adherence to achieve constructive change in population health, policy, and genuine medical revolution.

Conclusions

This RR offers an insight into the role of AI in the DR and the approaches that AI uses to improve and measure the end-user rehabilitation compliance or adherence. Overall, the current findings suggest that AI-based rehabilitation can contribute to improved end-user compliance and adherence to rehabilitation programs by its capacity in motivating and engaging end users, facilitating information exchange and improving communication, offering personalized end user–tailored solutions, delivering convenience and ease of system use, providing automated daily notifications, alerts, and reminders for end users, and the objective measurement of end-user rehabilitation compliance or adherence. Our findings may be of particular interest and valuable in redesigning rehabilitation and strategizing the optimal integration of AI into the rehabilitation sector to address future challenges.

Acknowledgments

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Authors' Contributions

All authors contributed to the conception or design of the work. Data collection and extraction were performed by MM and MLW. Data interpretation was performed by MM with MLW. The first draft of the manuscript was written by MM under the supervision of KPM, EA, MO, KK, and MLW. MM, MLW, KPM, EA, MO, and KK contributed detailed academic input to subsequent versions. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PubMed search strategy used for literature review.
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Checklist 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File, 276 KB - rehab_v12i1e69763_app2.docx]

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Abbreviations

AI: artificial intelligence
DR: digital rehabilitation
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
RR: rapid review

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Development of Goal-Achievement Support App to Assist Children and Families in Participating in Meaningful Occupations: Content Validation Using Delphi Method

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Abstract

Background: Occupational therapy has highlighted the necessity for planning and executing interventions in collaboration with clients, families, and caregivers to facilitate their progress. Thus, in pediatric occupational therapy, it is essential to position the family as a primary client and to actively involve them in the intervention process. These interventions often incorporate tools that facilitate parental engagement in home-based activities. However, no tools have been specifically designed to support parents comprehensively in achieving their parenting goals in everyday situations. To address this gap, we developed a mobile app called the Children's Occupation Support Mobile System (COSMO) to support occupational therapists, children, and parents in a collaborative manner to achieve intervention goals in daily life.

Objective: The aim of the study is to develop the COSMO and validate its content in terms of legibility, visibility, and accessibility.

Methods: This study was conducted in two stages: (1) designing a prototype of COSMO and (2) validating its content using the Delphi method. The prototype was developed based on a conceptual model of parenting strategies, which was derived from interviews with mothers raising children with developmental disabilities. This study included 10 Japanese pediatric occupational therapists, who were selected using convenience sampling to ensure diversity and heterogeneity in attributes. The Delphi survey was conducted entirely through a web-based questionnaire emailed to the experts. Participants rated their agreement with each item on a 5-point Likert scale. A mean item score of ≥3.75 (75%) indicated consensus.

Results: The prototype was designed through a series of 13 one-hour meetings held monthly. The functional framework of COSMO was structured into four core components based on previous research: (1) collaborative goal setting, (2) home strategy—an action plan to achieve goals, (3) self-reflection—a record of implemented strategies, and (4) progress reports—data storage for tracking outcomes. For validating the content, the 2 Delphi rounds resulted in a total mean score of 4.44 for legibility, 4.86 for visibility, and 4.84 for accessibility. In the free-text responses, there were references to improvements in the wording and to the burden of writing the reflections. Therefore, the wording was revised to avoid jargon and use plain language. The burden of COSMO use was reduced by simplifying the use process by incorporating optional inputs for some of its functions.

Conclusions: COSMO was developed as a comprehensive tool to integrate functions while aiming to reduce the burden on parents. This may reduce resistance to app use and make it easier for more parents to use it. Future studies should evaluate the generalizability and effectiveness of the prototype as an intervention. Limitations of this study include the absence of end-user testing, a geographically limited expert panel, and a limited discussion of implementation challenges across diverse health care settings.

Trial Registration: University Medical Information Network (UMIN) Center 000057084; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000065080

(JMIR Rehabil Assist Technol 2025;12:e73430) doi:10.2196/73430

KEYWORDS

children's occupation support mobile system; home-centered interventions; neurodevelopmental disorders; pediatric occupational therapy; family-centered care; mobile health; mobile app; occupational therapy

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Introduction

The World Health Organization emphasizes the importance of designing interventions for children with neurodevelopmental disorders, including autism, through the active participation of all stakeholders [1]. Furthermore, these interventions should be implemented at the community and social levels to enhance accessibility, inclusivity, and support [1]. Similarly, the American Occupational Therapy Association (AOTA) highlighted the necessity for planning and executing occupational therapy interventions in collaboration with clients, families, and caregivers to facilitate their progress [2]. Thus, in pediatric occupational therapy, it is essential to position the family as a primary client and actively involve them in the intervention process.

A systematic review of pediatric occupational therapy interventions recommends an activity-focused top-down approach that prioritizes collaboration with caregivers [3]. Specifically, interventions should begin with child-centered goals, incorporate real-life activities in natural settings, and use intensive repetition and problem-solving at an appropriate difficulty level [3]. Furthermore, interventions should be seamlessly integrated into daily life environments, such as homes and schools, while ensuring active family and caregiver participation [4].

Therefore, pediatric occupational therapy should emphasize family engagement and practical activity-based support in natural living environments. Several occupational therapy interventions have adopted family-centered approaches in real-life settings. Examples include Occupational Performance Coaching [5], Home Programs [6], Cog-Fun [7], Pathways and Resources for Engagement and Participation [8], and Parental Occupational Executive Training [9]. These interventions often incorporate tools that facilitate parental engagement in home-based activities. For instance, intervention booklets outline objectives and policies [10], structured documents help record strategies [8], and diaries support tracking daily progress [9]. These tools assist in setting collaborative intervention goals, reinforcing strategies, and documenting progress. However, no tools have been specifically designed to fulfill these functions comprehensively and to support parents in achieving their parenting goals in everyday situations. Everyday situations refer to parenting behaviors that occur outside the occupational therapy room, where the occupational therapist cannot be involved. Examples include self-care activities such as eating and dressing, productive activities such as learning and playing at home, and leisure activities such as sports and socializing with friends. Various activities that individuals perceive as important in their lives are referred to as “meaningful occupations” [11]. Understanding the history, interpersonal relationships, context, and development of meaning in a client’s occupations is essential to effectively support these meaningful occupations [12]. Our scoping review of home-centered occupational therapy for children with neurodevelopmental disorders found no validated tools designed to support parental caregiving as assessed by experts for reliability and validity (K Kura, MSc, unpublished data, August 2025).

To address this gap, we developed a mobile app called the Children’s Occupation Support Mobile System (COSMO) to collaboratively support occupational therapists, children, and parents in achieving intervention goals in daily life. Recently, 71.9% occupational therapists have reported using apps as part of their clinical support, and interest is growing in expanding the use of apps specifically designed for occupational therapy [13,14]. Apps used in occupational therapy typically address areas such as education, activities of daily living, instrumental activities of daily living, and play, with the target users ranging from children to older adults [13]. Accordingly, developing and implementing COSMO as a mobile app was deemed appropriate to meet these needs. This study aimed to develop and validate the COSMO content. In addition, we outlined the basic steps of the app.

Methods

Study Design

This study was conducted in two stages: (1) designing a prototype of COSMO and (2) validating its content using the Delphi method. The Delphi method is a qualitative research approach commonly used to achieve expert consensus in areas such as medical guidelines and app development. It was selected for this study because it aligns with the research objectives of establishing expert agreement on the functional framework of the app and verifying its content validity. The first author (KK) was responsible for managing the Delphi process, including the study flow and questionnaire design, whereas the last author (KT) provided overall supervision and guidance. This study followed the 6-step Delphi framework recommended for health care research [15] and adhered to the ACCORD (Accurate Consensus Reporting Document) guidelines for reporting consensus-based studies [16].

Ethical Considerations

This study complies with COPE (Committee on Publication Ethics) guidelines and adheres to the guidelines in the Helsinki Declaration. Ethics approval was obtained from the Kitasato University Ethics Review Committee (approval 2024-020). Our protocol was registered with the University Medical Information Network Center (000057084).

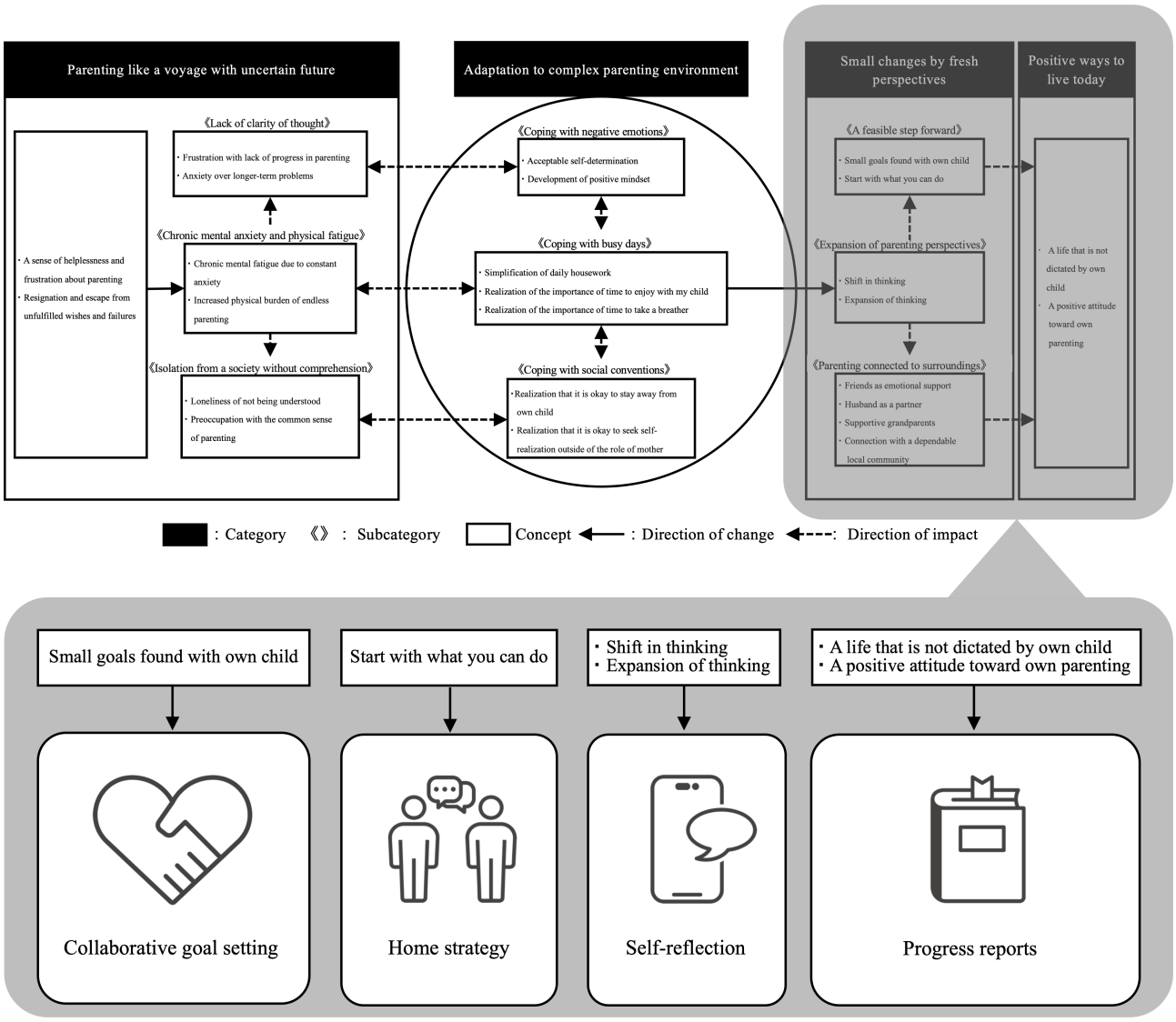
Development of Prototype Apps

The COSMO prototype was developed based on the “conceptual model of effective parenting strategies for mothers with children who experience developmental disorders” formulated from parental perspectives and previous research [17]. The conceptual model was developed on the basis of interviews with 10 mothers who had implemented an individualized occupational therapy home program. The model illustrates the process of developing parenting strategies adapted to the home environment. The relationship between the conceptual model and the prototype app is shown in Figure 1. For example, “collaborative goal setting” corresponds to the theme “small goals found with own child,” “home strategy” corresponds to “start with what you can do,” “self-reflection” relates to “shift in thinking” and “expansion of thinking,” and “progress reports” connects to themes such as “a life that is not dictated by own child” and “a

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positive attitude toward own parenting." End users were not involved in the process of deriving the prototype's functionality from the conceptual model. The first and last authors (KK and KT) collaboratively designed the prototype through a series of 1-hour meetings held monthly, for a total of 13 meetings. Initially, COSMO's vision was conceptually defined as "an app that supports children and families in achieving their goals within the context of parenting." The concept of COSMO was further operationally defined as "an app that grows with the child." It was designed to be downloaded to the parents' smartphones and used as a tool for occupational therapy. To enhance accessibility, terminology was chosen to resonate with parents caring for their children with neurodevelopmental disorders.

Figure 1. (A) Conceptual model [13] and (B) app function.



The functional framework of COSMO is structured into four core components based on previous research: (1) collaborative goal setting, (2) home strategy, (3) self-reflection, and (4) progress reports.

Nine functions were developed to align with the objectives of the 4 components. The functional framework and corresponding functions were developed based on theoretical concepts and input from parents. Finally, the user interface and user experience of COSMO were designed to support these 4 functional components and 9 specific functions. The details of this framework are presented in Table 1.

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Table . App function, items, and contents.

Function and item		Contents
1. Collaborative goal setting		
	Listing of goal setting	The goal-setting list function displays multiple goals on the screen, allowing users to quickly review all goals upon launching the app.
	Set time frames for achieving goals	The goal time limit function lists the deadlines for achieving each goal. By displaying the remaining time for each goal, this function clarifies the necessary steps from the current state to the goal deadline.
	Framework for goal setting by who, what, when, where, why, and how	The who, what, when, where, why, and how framework function for goal setting assists in defining specific, life-related goals using the who, what, when, where, why, and how approach. It is designed to support occupational therapists with limited clinical experience and caregivers in concretizing goals.
2. Home strategy		
	Setting multiple strategies for goals	The multiple strategy-setting function allows users to assign multiple strategies to a single goal. Strategies can be set flexibly to ensure that they are realistic and feasible.
	Notification of strategy implementation time	The strategy implementation time notification function sends smartphone notifications based on the scheduled execution time of each strategy at home. Given that the implementation timing varies by strategy, this feature ensures that each strategy is executed at the appropriate time.
	Framework for strategic planning by who, what, when, where, why, and how	The who, what, when, where, why, and how framework function for strategic planning helps formulate strategies in a structured and specific manner using the who, what, when, where, why, and how approach. It aims to facilitate the development of realistic and practical strategies.
3. Self-reflection		
	Diary recordings of reflections	Diary recordings of reflections function enables users to record the outcomes of home-implemented strategies. In addition to documenting the child's daily care, this function supports tracking the child's progress and provides parents with new insights.
	Caregivers' assessment of strategies	The caregiver assessment function for strategies allows parents to evaluate the efficiency and burden of implemented strategies. This function provides a quantitative assessment of parental perspectives. The assessment timing is flexible and can be adjusted based on the occupational therapy intervention's purpose and frequency (eg, weekly, biweekly, or monthly).
4. Progress reports		
	Goals, strategies, and record keeping	The goal, strategy, and record-saving function stores past records of goals, strategies, and outcomes. This function facilitates the reuse of effective strategies for other goals, enables tracking of home implementation, and allows for modifications to goals and strategies as needed.

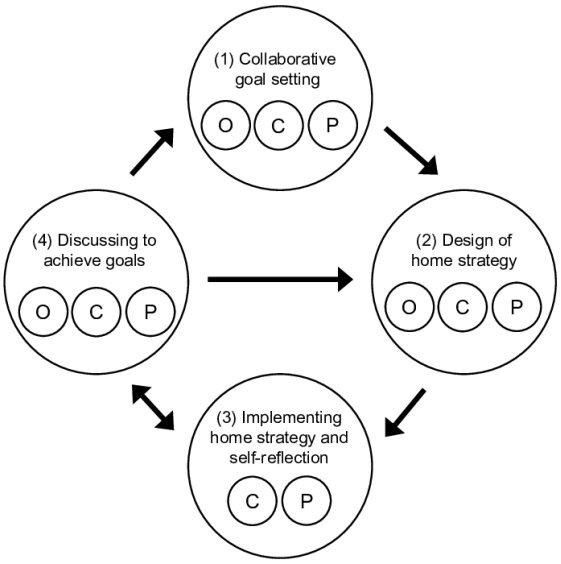
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Process of Using COSMO

Overview

The process flow of COSMO, based on 4 components and 9 specific functions determined through the development of the prototype app, is shown in Figure 2. The app was structured into four cyclical phases: (1) collaborative goal setting, (2) design of home strategy, (3) implementing home strategy and self-reflection, and (4) discussing to achieve goals.

Figure 2. Process of using COSMO. C: child; COSMO: Children's Occupation Support Mobile System; O: occupational therapist; P: parent.



Collaborative Goal Setting

Occupational therapists, children, and parents collaboratively established goals through shared decision-making. If the child could not actively participate, the therapist and parents set goals on their behalf. Goals were defined using the who, what, when, where, why, and how framework and adhered to the Specific, Measurable, Achievable, Relevant, and Timed (SMART) criteria whenever possible [18]. COSMO does not include built-in structured interview functions; therefore, complementary tools such as the Canadian Occupational Performance Measure [19], Goal Attainment Scaling [20], and Aid for Decision-Making in Occupation Choice (ADOC)—School Version [21] can be used alongside COSMO.

Home Strategy

The next step involved designing a strategy to achieve the established goals. Strategies can be linked to specific goals, and multiple strategies can be set. Intervention strategies were developed collaboratively among therapists, children, and parents. If child participation is difficult, the therapists and parents created strategies together. Each strategy was formulated using the who, what, when, where, why, and how framework to ensure that the plan is actionable and practical. Parents received smartphone notifications for each scheduled strategy.

Implementing Home Strategy and Self-Reflection

In the context of daily parenting, parents implemented strategies designed to help their children achieve their goals. For strategy implementation, it is important that the strategy is embedded in everyday situations and is easy to use. For example, regarding strategies related to changing clothes, this could mean changing the size of buttons so that it is easy to operate or supporting a stable posture for changing clothes. In other words, strategies that avoid placing an undue burden on parents and can be implemented as an extension of normal child-rearing practices promote daily use. Such a perspective is important in positioning parents as parental caregivers rather than cotherapists. Following implementation, a self-reflection process consisting of free-text reflection and a 5-point Likert-scale evaluation was conducted. The Likert scale assessed the child's efficiency in executing the strategy and the level of burden experienced by the parents. Free-text reflection allowed parents to describe what has been done, identify the difficulties encountered, note observations, and determine the next steps based on the innovations they noticed. The efficiency rating measured how smoothly the child was able to carry out the strategy from the parents' perspective,

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whereas the burden rating reflected the level of difficulty parents experienced in supporting the implementation.

The recorded goals, strategies, and reflections, including free text and Likert-scale outcomes, were stored as data that could be accessed at any time through the app. It is important to note that only this phase, in which the home strategy and self-reflection were implemented, was conducted independently by parents.

Discussing to Achieve Goals

During occupational therapy sessions, therapists reviewed progress based on the parents' recorded reflections and data. The review process emphasized that unsuccessful strategy implementation is a natural part of progress, and therapists provided coaching and guidance accordingly. If necessary, goals and strategies could be modified by returning to phases 1 and 2. If no modifications were required, the family continued to implement the strategies until the goal was achieved. Given that pediatric occupational therapy in Japan is typically provided on an outpatient basis (every 2 weeks to once a month), COSMO is designed to complement these sessions by supporting parents between visits.

Delphi Method for Content Validation

After developing the app prototype, content validation was conducted to assess the legibility, visibility, and accessibility of COSMO's 4 functional frameworks and 9 functions. The COSMO is designed for use by parents with the support of pediatric occupational therapists with diverse clinical experience. Therefore, the study participants were selected using convenience sampling to ensure diversity and heterogeneity in attributes, such as age, clinical experience, educational background, and employment status.

The sample size for the Delphi method typically ranges from 5 to 20 participants [22], with no rigid rules, depending on the study's purpose and complexity [23]. In this study, 10 Japanese pediatric occupational therapists were included based on prior research that used a similar sample size for app development in occupational therapy [24] and based on the complexity of the 4 functional frameworks and the 27-item web survey addressing 9 functions.

Participants who provided informed consent were given a 15-minute web-based briefing via a videoconferencing platform. This session covered the study background, objectives, procedures, and functions of COSMO, followed by a question and answer session to address any questions. The participants were also assured that they could withdraw from the study after receiving this explanation.

The Delphi process was conducted entirely through a web-based questionnaire (Google Forms) emailed to the experts. As the responses were collected on the web, the participants submitted their answers individually.

The questionnaire assessed the user interface or user experience design of the 9 functions within COSMO's 4 functional frameworks, comprising a total of 27 questions. These questions evaluated 3 key aspects: legibility (clarity of text expression and display), visibility (ease of viewing text and screen layout), and accessibility (ease of functional use). Participants rated their agreement with each item on a 5-point Likert scale (1=strongly disagree and 5=strongly agree). A mean score of 3.75 (75%) or higher indicated consensus on an item [15].

To allow for qualitative feedback, the questionnaire also included open-ended questions in which participants could freely express their opinions. A summary of the results was emailed to the participants, and a detailed statistical report, including summaries of questionnaire items and responses to open-ended questions, was provided in a PDF document.

Each Delphi round had a specified response deadline. If the participant did not submit a response on time, a reminder email was sent to encourage completion.

Results

Overview

The demographic attributes of the 10 study participants are summarized in Table 2. The sample included 6 male and 4 female participants. In total, 4 participants were in their 20s, 4 were in their 30s, and 2 were in their 40s. In terms of educational background, 4 participants held bachelor's degrees, 3 held master's degrees, and 3 held doctoral degrees. The occupational therapists had an average of 7.9 (SD 3.2; range 2-12) years of clinical experience.

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Table . Participant demographics.

Participants	Sex	Age (years)	Employment	Degree	Time in profession (years)
A	Male	43	Regular	PhD	12
B	Female	28	Nonregular	Master	7
C	Male	27	Regular	Master	2
D	Male	29	Regular	Bachelor	6
E	Male	33	Nonregular	Master	9
F	Female	30	Regular	Bachelor	9
G	Female	41	Regular	Bachelor	12
H	Male	31	Regular	PhD	9
I	Male	32	Regular	Bachelor	10
J	Female	29	Regular	PhD	3

Delphi Method Results

In the first round of the Delphi method, the mean score for all 27 items exceeded the consensus threshold of 3.75, with an overall average of 4.50. Research participants suggested modifying the language to make it easier for the intended users to understand and making input items optional to reduce the burden of use. These comments were reviewed and addressed by the research team, considering the degree of variation in participant feedback and outcomes of team discussions. Based on feedback from the open-ended responses, modifications were made to the app design, and a second round was conducted using the revised questionnaire. In this round, the average score increased to 4.84. Across all 27 items (comprising 9 items each for legibility, visibility, and accessibility), the mean scores for each evaluation category increased by 0.20 to 0.45 points between rounds. Furthermore, the IQR was reduced from 0.00 - 2.00 in the first round to 0.00 - 1.00 in the second round, indicating a decreased level of response variability. Because only minor revisions were suggested in the free-text comments, these were incorporated, and the Delphi process was concluded. The results of each round are presented in Table 3. Detailed comments from study participants and corresponding responses from the research team are presented in Multimedia Appendix 1. The findings are described below according to 3 evaluation criteria: legibility, visibility, and accessibility.

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Table . Results of the first and second rounds of the Delphi method (n=10).

Function and item	First round						Second round					
	Legibility		Visibility		Accessibility		Legibility		Visibility		Accessibility	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
1. Collaborative goal setting												
Listing of goal setting	4.80 (0.40)	5.00 (5-5)	4.80 (0.40)	5.00 (5-5)	4.50 (0.67)	5.00 (4-5)	5.00 (0.00)	5.00 (5-5)	5.00 (0.00)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)
Set time frames for achieving goals	4.20 (0.98)	5.00 (3-5)	4.40 (0.80)	5.00 (4-5)	4.40 (0.80)	5.00 (4-5)	5.00 (0.00)	5.00 (5-5)	5.00 (0.00)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)
Framework for goal setting by who, what, when, where, why, and how	3.90 (0.70)	4.00 (3.25-4)	4.70 (0.46)	5.00 (4.25-5)	4.40 (0.80)	5.00 (4-5)	4.70 (0.64)	5.00 (5-5)	4.80 (0.40)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)
2. Home strategy												
Setting multiple strategies for goals	4.60 (0.92)	5.00 (5-5)	4.70 (0.46)	5.00 (4.25-5)	4.60 (0.66)	5.00 (4.25-5)	5.00 (0.00)	5.00 (5-5)	4.80 (0.40)	5.00 (5-5)	4.80 (0.40)	5.00 (5-5)
Notification of strategy implementation time	4.80 (0.40)	5.00 (5-5)	4.70 (0.46)	5.00 (4.25-5)	4.40 (0.80)	5.00 (4-5)	4.80 (0.40)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)	4.70 (0.46)	5.00 (4.25-5)
Framework for strategic planning by who, what, when, where, why, and how	4.10 (0.83)	4.00 (3.25-5)	4.50 (0.67)	5.00 (4-5)	4.40 (0.80)	5.00 (4-5)	4.70 (0.64)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)	4.80 (0.40)	5.00 (5-5)
3. Self-reflection												
Diary recordings of reflections	4.50 (0.92)	5.00 (4.25-5)	4.60 (0.49)	5.00 (4-5)	4.00 (0.89)	4.00 (3-5)	4.80 (0.40)	5.00 (5-5)	4.70 (0.46)	5.00 (4.25-5)	4.80 (0.40)	5.00 (5-5)
Caregivers' assessment of strategies	4.50 (0.81)	5.00 (4.25-5)	4.90 (0.30)	5.00 (5-5)	4.40 (0.66)	4.50 (4-5)	4.60 (0.49)	5.00 (4-5)	4.80 (0.40)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)

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Function and item	First round						Second round					
4. Progress reports												
Goals, strategies, and record keeping	4.60 (0.66)	5.00 (4.25-5)	4.60 (0.66)	5.00 (4.25-5)	4.40 (0.80)	5.00 (4-5)	4.80 (0.40)	5.00 (5-5)	4.80 (0.40)	5.00 (5-5)	4.90 (0.30)	5.00 (5-5)
Overall score	4.44 (0.82)	5.00 (4-5)	4.66 (0.56)	5.00 (4-5)	4.39 (0.78)	5.00 (4-5)	4.82 (0.44)	5.00 (5-5)	4.86 (0.35)	5.00 (5-5)	4.84 (0.36)	5.00 (5-5)

Legibility

The results of the first round showed that the average score for all 9 items was 4.44. Regarding legibility, the participants suggested modifying the wording and standardizing expressions. Specifically, on the goal-setting screen, the phrase “the occupational activity you want to be able to do” was changed to “what (the activity you want to be able to do).” This adjustment avoided the use of the technical term “occupational activity” and adopted language that was easier for parents to understand. Additionally, “what” was added at the beginning of the sentence to align with the who, what, when, where, why, and how framework. There was a suggestion to change “deadline” in the goal list screen to “duration.” However, this modification was not implemented because “deadline” aligns with the time-related component of the SMART criteria in goal setting. On the strategy-setting screen, “what” was added to “in what way” to ensure consistency. In the self-reflection efficiency and burden evaluation screen, the subject of evaluation was clarified by modifying the phrasing to “How smooth was this strategy for the child?” and “How easy was this strategy for the parent or guardian?” These changes were made to enhance clarity.

The results of the second round showed that the average score for all 9 items increased to 4.82. Additionally, the terminology used to describe guardians was revised, as the participants noted that the original wording was unfamiliar to the general public in Japanese.

Visibility

The results of the first round showed that the average score for all 9 items was 4.66. Regarding visibility, the participants suggested improving the consistency of screen displays. Specifically, there was a recommendation to unify goal- and strategy-setting screens, given that the goal-setting screen provides a free-description framework for each who, what, when, where, why, and how component, whereas the strategy-setting screen lacks this feature. After discussion, the research team decided not to implement this change because the 2 screens serve different purposes. The goal-setting screen includes a who, what, when, where, why, and how framework to facilitate goal setting based on the SMART criteria, whereas the strategy-setting screen allows flexible descriptions, as the content of strategies may vary among households. This reasoning was explained to the participants during feedback. There was also a request to include example sentences on the strategy-setting screen. However, because of screen space limitations and the number of characters displayed, this suggestion was not implemented. Instead, example sentences were included in the user guide under development.

The results of the second round showed that the average score for all 9 items increased to 4.86. In addition, the participants suggested increasing the font size for better readability. Based on this feedback, the text size was adjusted to improve the readability for children and parents.

Accessibility

The results of the first round showed that the average score for all 9 items was 4.39. Regarding accessibility, participants raised concerns about the difficulty of setting goals using the who, what, when, where, why, and how framework, the burden of free-text input in self-reflection, the sequence of outcome assessments, and the need for additional data storage options. One concern was the difficulty in completing all the who, what, when, where, why, and how components on the goal-setting screen. Based on participant feedback, each who, what, when, where, why, and how framework was made optional, allowing goal setting to be completed even if some components were left blank. To reduce participant burden, free-text input and outcome evaluations were made optional, ensuring that the data could still be stored even if only one of these components was completed. The participants also suggested reordering the self-reflection process by placing free-text reflections after the outcome evaluation of efficiency and burden. However, the research team decided not to implement this change because verbalizing and reflecting on the strategies in the free-response section first was considered beneficial for conducting a structured 5-stage evaluation. Regarding data storage, there was a recommendation to store efficiency and burden evaluations along with other data. This suggestion was accepted, and these evaluations were added to the list of stored items.

The results of the second round showed that the average score for all 9 items increased to 4.84. No further modifications were made, as there were no significant concerns raised by the participants.

Discussion

Principal Findings

In this study, the content validity of COSMO was evaluated using the Delphi method. Consequently, COSMO was designed based on expert consensus regarding legibility, visibility, and accessibility in app design. Additionally, the process of using

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the developed COSMO was presented. Based on these findings, this section discusses the design of COSMO, its clinical applications, and usability.

Design of COSMO

COSMO primarily aims to support children and their families in accomplishing important tasks. More specifically, it is designed to assist parents in their daily parenting activities through practical interventions. To fulfill this purpose, COSMO was developed as a smartphone app that parents could use as part of their professional support. The coaching approach in rehabilitation emphasizes real-life activities, goal setting related to participation in daily situations, and improvements in quality of life [25]. Additionally, identifying small achievable goals with one's child and starting with what is feasible are essential steps toward reaching broader objectives [17]. COSMO facilitates goal setting through a who, what, when, where, why, and how framework, reflecting the perspectives of parents and children while ensuring that goals align with the SMART criteria [18]. The strategy-setting function allows users to develop action plans tailored to their individual goals by specifying the number of steps and content necessary to achieve them. Therefore, COSMO includes the core functionalities required for collaborative goal setting and strategy development in daily life.

Strategy implementation in real-life settings and self-reflection play crucial roles in goal attainment. A randomized controlled trial of family-centered parent-coaching interventions demonstrated that reflecting on a child's thoughts, motivations, and feelings enhanced parental self-evaluation and awareness [26]. In COSMO, self-reflection is facilitated through free-text input and a 5-point Likert scale. Free-text reflections encourage parents to verbalize their perceptions of strategy implementation, which may increase their awareness of goal progress. The Likert scale assessed 2 aspects: the efficiency of the child's actions within the strategy and the burden experienced by parents. By quantitatively measuring these aspects, COSMO helps to visualize the effectiveness of strategies and enables further refinement for improved usability.

Clinical Applications of COSMO

COSMO is expected to function as a support tool for home-centered occupational therapy. Systematic reviews of pediatric occupational therapy interventions emphasize the importance of supporting parental engagement in home settings, with collaboration between occupational therapists and parents as a key factor [3]. Existing tools used in occupational therapy include booklets outlining intervention objectives and policies [10], documents for recording strategies [8], and structured diaries for tracking daily intervention progress [9]. COSMO integrates multiple functions including goal setting, strategy development, reflection, and data storage, making it a comprehensive tool that can be flexibly applied in various intervention settings. However, careful consideration is necessary when determining whether the COSMO is appropriate for a given intervention context. A qualitative study conducted by the first author with mothers who practiced home programs suggested that using home programs and daily diaries may contribute to a positive reassessment of children's behavior and parental burden [17]. The comprehensive functions of COSMO may influence parents' perceptions of their children and themselves, motivating them toward goal achievement.

Finally, the Delphi method assessment of accessibility yielded recommendations for reducing the parental burden. Based on these recommendations, free-text reflections and Likert-scale assessments were made optional to accommodate varying levels of parental engagement. Occupational Performance Coaching, a widely used support approach in occupational therapy, sets exclusion criteria for parents with low physical or mental energy [27]. In line with this principle, COSMO was designed to minimize the parental burden wherever possible. However, some level of effort is still required for its effective use. Therefore, the decision to use COSMO should consider the physical and mental conditions of parents or guardians. Moreover, because the COSMO is only a support tool, its implementation should be assessed within the broader context of the intervention objectives, treatment plans, and social background of the target population.

If adverse effects emerge after implementation and continued use poses risks, the occupational therapist in charge should consider discontinuing its use.

Usability of COSMO

Usability for professionals and clients is essential to ensure that apps are accessible and effective. Previous studies have reported that the main purposes of using apps in occupational therapy are to enhance clients' skills, facilitate participation in daily activities, and support the therapeutic process [14]. Furthermore, apps should be matched to client needs, skills, and abilities and not the other way around [28]. The selective use of apps by occupational therapists based on individual client needs suggests that, as with other therapeutic interventions, such tools should not be uniformly applied to all clients [14,28]. Similarly, the implementation of COSMO requires the careful consideration of the intervention's goals and the unique needs of each client.

Several barriers to app usability among professionals have been identified. Prior studies have cited the most common reasons for not using apps as the inability to find suitable good apps, never thought about it, and lack of access [14]. The first 2 barriers may also apply to COSMO, highlighting the importance of building further evidence and promoting broader awareness. To address accessibility, COSMO will initially be distributed free of charge in Japan. For households without smartphones, a paper-based version offering equivalent functions will be made available via the project website. Because COSMO is intended as a supportive tool for daily life rather than a treatment device, it complies with medical app review requirements. Moreover, because COSMO is not a research app, it does not collect any personal client information via mobile networks. The app is downloaded and stored on the client's personal smartphone, minimizing the risk of data disclosure to third parties. Thus, potential concerns about data protection have been addressed.

Currently, app use in occupational therapy in Japan is generally regarded as a supplement to standard treatment. Therefore, COSMO—being freely accessible—is expected to complement existing occupational therapy and other therapeutic interventions

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based on professional clinical reasoning. In Japan, several specialized apps have been developed by occupational therapists, such as Osca Writing, a Japanese handwriting app [29], and Process Analysis of Daily Activities for Dementia, which analyzes daily occupations for individuals with dementia [30]. Additionally, goal-setting apps like ADOC and ADOC—School Version have been introduced [21,31]. Although the first 2 differ from COSMO in purpose and target populations, ADOC shares some similarities with COSMO in terms of goal setting. However, ADOC focuses on shared decision-making in goal selection, whereas COSMO emphasizes goal-sharing and achievement processes. Although this study was limited to comparisons with domestic applications due to differences in social and health care contexts, future studies should include comparisons across diverse health care systems and cultures.

Limitations

This study has some limitations. First, end-user children and parents were not included in the development process of this study; this is a significant limitation. Future usability tests should be conducted with the involved parties. Second, the Delphi method involved participants from a limited number of regions, which may have influenced the development of COSMO because of the homogeneous educational and cultural backgrounds of the participants. Third, convenience sampling—where participants were recruited through the researchers' networks—was conducted to ensure diversity and heterogeneity among participants and to enhance research feasibility; however, this limits the generalizability of the findings and may have influenced the response outcomes. Fourth, the quality of COSMO as a mobile app is currently unknown. The assessment of app quality is important for its future adoption by clients and professionals. Fifth, only the Japanese version of COSMO has been developed. Future studies should examine the cross-cultural validity, including translation accuracy and adaptation, for use in other countries. Sixth, the social implementation of COSMO was initially developed for use in Japan. Consequently, the current discussion does not sufficiently address the challenges of implementation in diverse health care settings.

Conclusions

COSMO was developed to support children and their families in achieving meaningful occupations. After 2 rounds of the Delphi method evaluation, the content validity of COSMO in terms of legibility, visibility, and accessibility was confirmed through an expert consensus. As a home-centered occupational therapy support tool, COSMO is expected to be flexibly integrated into interventions, depending on the objectives of the therapy. To optimize its use, discussions among professionals, parents, and children are essential before recommending its implementation. Ultimately, COSMO has the potential to enhance parental participation in achieving children's goals and contribute to more effective occupational therapy interventions. A dedicated website has been created, including a contact page to provide ongoing technical support. Because the app was developed for iOS, updates will be made as necessary to address technical issues arising from iOS system changes. Future studies should explore cross-cultural validity, including translation accuracy and adaptation, and should assess generalizability and effectiveness as an intervention tool.

Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Comments of the Delphi methods in 2 rounds.
[DOCX File, 34 KB - rehab_v12i1e73430_app1.docx]

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Abbreviations

ACCORD: Accurate Consensus Reporting Document
ADOC: Aid for Decision-Making in Occupation Choice
COPE: Committee on Publication Ethics
COSMO: Children's Occupation Support Mobile System
SMART: Specific, Measurable, Achievable, Relevant, and Timed

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Speech and Language Therapists' Perspectives of Virtual Reality as a Clinical Tool for Autism: Cross-Sectional Survey

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Abstract

Background: Persistent difficulties with social skills form part of the diagnostic criteria for autism and in the past have required speech and language therapy (SLT) management. However, many speech and language therapists are moving toward neuro-affirmative practices, meaning that social skills approaches are now becoming redundant. Research demonstrates that virtual reality (VR) interventions have shown promise in overcoming challenges and promoting skill generalization for autistic children; however, the majority of these focus on social skills interventions. While VR is emerging as an SLT intervention, its application for autism remains unexamined in clinical practice.

Objective: This research aimed to examine speech and language therapists' knowledge and attitudes toward immersive VR as a clinical tool for autistic children and explore the reasons for its limited integration into clinical practice.

Methods: A web-based cross-sectional survey was available from April 3, 2023 to June 30, 2023. The survey, consisting of 23 questions, focused on VR knowledge, attitudes, and the support required by speech and language therapists to incorporate VR into clinical practice. Dissemination occurred through the Royal College of Speech and Language Therapists Clinical Excellence Networks to recruit speech therapists specializing in autism.

Results: Analysis included a total of 53 responses from the cross-sectional survey. Approximately 92% (n=49) of speech and language therapists were aware of VR but had not used it, and 1.82% (n=1) had used VR with autistic children. Three key themes that emerged were (1) mixed general knowledge of VR, which was poor in relation to applications for autism; (2) positive and negative attitudes toward VR, with uncertainty about autism specific considerations for VR; and (3) barriers to adoption were noted and speech and language therapists required an improved neuro-affirming evidence base, guidelines, and training to adopt VR into clinical practice.

Conclusions: While some speech and language therapists perceive VR as a promising intervention tool for autistic children, various barriers must be addressed before its full integration into the clinical toolkit. This study establishes a foundation for future co-design, development, and implementation of VR applications as clinical tools for autistic children. This study is the first to explore clinical implementation factors for the use of VR in SLT field, specifically with autistic children. Poor autism-specific VR knowledge, and mixed attitudes toward VR, highlight that specific barriers must be addressed before the technology can successfully integrate into the SLT clinical toolkit. Speech and language therapists require support from employers, funding, a robust neuro-affirming evidence base, and education and training to adopt VR into practice. Recommendations for a SLT VR education and training program for use with autistic children, are provided.

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KEYWORDS

virtual reality; VR; autistic; ASD; speech; language; autism; speech and language therapy; speech-language pathology; SLT; immersive; voice; vocal; cross sectional; surveys; questionnaires; experiences; attitudes; opinions; perceptions; perspectives; autism spectrum disorder

Introduction

Virtual reality (VR) uses technology to digitally replicate real world scenarios [1] by providing artificial tactile, visual, and auditory feedback. This allows users to experience environments as if they were real. A VR system connects the user to the virtual environment through sensory modalities, providing sight, sound, and tactile feedback. This can be achieved through different technologies, such as Computer Automated Virtual Environments (CAVE) and immersive head mounted displays (HMDs). These facilitate different levels of interaction, presence, and immersion, such as the perception of being in the real world. In the context of this paper, VR refers to HMDs and

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CAVE, with the idea of integrating HMDs into speech and language therapists' clinical toolkits.

Research has demonstrated that VR capitalizes on visual skills, known to be a strength of autistic children, and can facilitate safe, controlled, and customizable practice environments, without negative consequences [2]. This has led to further research suggesting VR-based interventions may be effective for improving socials skills and generalization, enhancing emotional recognition, reducing anxiety, and facilitating sensory integration [3,4]. Indeed, research has demonstrated a moderate evidence base for VR with the autistic population [5]. This is evidenced by a pre-post study by George and Shakul [6], which demonstrated that a VR reality intervention for young autistic adults effectively improved their social and communication skills, and this group preferred the VR intervention in comparison with traditional methods. Furthermore, the study provides evidence that VR-based interventions can be used to complement traditional therapies for autistic service users and suggest future studies should investigate the benefits of combining VR-interventions with speech and language therapy (SLT). While VR has the potential to host communication or language-based interventions for populations such as developmental language disorder, the need to develop neuro-affirming tools to support autistic children is pressing.

As suggested above, a critical lens must be applied to previous VR research. A large proportion of studies with autistic children target social skills training, which is a neuro-affirmative shortcoming. These studies are criticized for using deficit-based interventions that aim to reduce and normalize autistic social behaviors, potentially increasing the risk of masking, negative mental health outcomes, and in some cases, trauma [7]. A growing number of professionals specializing in communication and social skills, such as speech and language therapists, are moving toward neuro-affirming practice [8]. Therefore, this paper does not use ableist language, such as autism spectrum disorder, instead adopting the term autism throughout. This reflects the authors nonpathologizing approach to autism. Neuro-affirming practice is described as support for autistic identity through strength-based, environment first approaches that promote adaptions [9]. They seek to remove environmental and societal barriers, imposed by deficit-based neurotypical standards and facilitate autistic self-advocacy [10]. Despite this, it can be difficult to know how to use resources to meet goals for autistic children. As neurotypical resources may not capitalize on autistic strengths, alternative tools, such as virtual reality (VR), should be explored to understand their application to clinical practice for autistic children [11]. As clinicians involved in the care of autistic children relating to communication and socialization, speech and language therapists' perspectives may provide insight into clinical applications of VR. Potential neuro-affirming uses have been demonstrated across literature. For example, autistic users have reported VR could help them with (1) anxiety surrounding unknown experiences; (2) concrete, literal thinking; (3) improving self-esteem and positive self-identity; (4) repetitive practice in real-life environments; and (5) making friends [11-14]. However, particularities of autism, such as sensory changes, disassociation, and indeed individualized presentations, may pose a barrier to the use of VR. Given that, VR has not been widely adopted by speech and language therapists in clinical practice, this potential remains unharnessed.

In total, 3 key papers have established a preliminary evidence base for VR as an intervention for autistic children in the SLT field. First, literature review by Bryant et al [15] provided initial support for the use of immersive VR for "communication disability" and autism, in SLT, and indicated there is some potential for every day, functional communication skills developed in VR worlds to transfer into real-world interactions. However, they suggested that technological complexities may act as a barrier to individuals with comorbid intellectual disabilities, and that VR may create ethical and safety issues that should be considered carefully. Second, systematic review by Bailey et al [16] suggested that VR could support several social communication goals for autistic children and those with an intellectual disability. However, results varied greatly, included research with low quality methodology, and outcomes were inconsistent across VR technologies. Therefore, it was difficult to compare the findings. Finally, a study by Ghanouni et al [17] examined the effectiveness of 75 speech and language therapists' social stories focused on perspective taking. While this indicates VR may be an effective medium for 'intervention' with autistic children, it is difficult to know if research is based on neuro-affirming principles. Evidence underpinning effective and affirming VR interventions in autism requires further development. Overall, Bryant et al [15] shows that VR implementation in SLT practice is still in the early stages. Therefore it is difficult to determine "which [VR] technologies work for whom, in which contexts," how VR supports SLT tasks and objectives, and the support required [18].

The precursor to using VR in clinical practice is exploring speech and language therapists' perceptions of VR and appetite for future usage. This may help to bridge the gap between technology and practice. Studies documenting clinician perceptions of VR in adult rehabilitation are positive, but knowledge and attitudes toward VR act as barriers to adoption [19]. For example, perceptions of a lack of SLT evidence, the need for training and guidelines, workplace limitations and side effects are challenging [15,20]. It is necessary to engage SLTs as one of the end users of technology, to reduce discrepancies between their needs and VR capabilities [21]. Ultimately, this may demonstrate if VR is an acceptable tool for autistic children and SLT practitioners. Despite this, there is a gap in literature examining SLT knowledge and attitudes toward VR as a tool for autistic children. Therefore, this should be explored to understand why VR has not yet been adopted into SLT practice.

In this work, we explore speech and language therapists' knowledge and attitudes toward the use of VR for autistic children. We focused on investigating knowledge and attitudinal factors that contribute to the adoption of technology, and their specific applications to an autistic population. In addition, we explored practical steps to enhance future adoption of VR by SLTs. We sought to answer 3 questions with SLTs practicing in the autism field. First, what knowledge do speech and language therapists have about VR? Second, what are speech and language therapists' attitudes toward using VR as an intervention for autistic children? Third, what do SLTs need to

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support the implementation of VR in clinical practice? With this research, we aim to create a basis for future research, co-design, and implementation of VR for autistic children in an SLT setting.

Methods

Overview

A web-based questionnaire, reported in accordance with the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist [22], was created to gather qualitative and quantitative data exploring speech and language therapists' knowledge and attitudes toward VR as a tool for autism. This was a cross-sectional study, with data representing a snapshot of speech and language therapists' perspectives at a single point in time.

Participant Recruitment

Recruitment used convenience sampling, and participants were eligible to participate if they (1) were a speech and language therapist who provided input for autistic children or had autistic children on their caseload and (2) worked in the United Kingdom or Republic of Ireland. The web-based cross-sectional questionnaire was disseminated via the first author's professional social networks, and Clinical Excellence Networks in the SLT field. Participants were encouraged to forward the questionnaire to other eligible colleagues, using a snowball strategy to increase engagement.

Recruitment flyers included information about the research, a QR code, and link to the questionnaire. Upon entering the questionnaire, participants were provided with a participant information sheet, which outlined the rationale for research, research questions, and ethical considerations. Following this, participants were presented with a consent form to participate in the questionnaire and provided informed consent.

Questionnaire Design and Data Collection

The questionnaire was created using Microsoft Forms to ensure response anonymity was upheld and was open between April 3, 2023 and June 30, 2023. The questionnaire consisted of 23 questions overall, including Likert scales, open-ended responses, and single and multiple-choice questions. Questions included 6 questions on eligibility and basic demographics, 4 on knowledge about VR, 3 regarding previous use of VR, 6 on attitudes toward VR, and 4 on future support needs.

Knowledge about VR involved a self-rating scale about knowledge of VR, multiple-choice questions about different VR technologies, which VR "brands" speech and language therapists had heard of and integration of VR into practice, This question was adapted from Khukalenko et al [23]. Questions regarding attitudes toward VR used a 7-point bipolar Likert scale, to explore SLT reasons for use or nonuse of VR. Facilitators and barriers to adoption of technology were adapted from Albudoor and Peña's study [24], and conclusions from Brassel et al [20]. Questions on future support needs are directly based on Brassel et al [20], where supporting VR into clinical practice emerged directly as a theme. Open ended questions allow speech and language therapists to consider what they need to support VR into practice, if they would benefit from training and ideas for future research. The questionnaire used display logic to direct participants to relevant questions based on whether they had used VR in clinical practice. Consequently, different numbers of participants answered questions. The questionnaire was not piloted before going live on the web but was deemed coherent by the first author and supervisor.

Data Analysis

Following questionnaire recruitment, data was exported into Microsoft Excel for analysis. This enabled descriptive analysis of quantitative data, through percentages and counts and was presented visually. Free-text questions were analyzed thematically by the first author, following an inductive thematic analysis approach [25]. This identifed key themes and facilitated a deeper immersion with speech and language therapists' personal experiences, enabling better understanding and interpretation. Identified themes were discussed and agreed with the supervisor. Following analysis, themes were compared with quantitative data to develop an overall understanding of results, and direct quotes from text were used to contextualize results, increasing confirmability of interpretation.

Ethical Considerations

This study received ethical approval from the School of Social Sciences, Education, and Social Work Ethics Committee at Queen's University Belfast (073_2223). All participants provided informed consent and participation was anonymous. No compensation was provided for participation.

Results

Overview

Overall, 60 participants gave consent to participate in the questionnaire; however, 7 were not eligible to participate and their data were excluded. Reasons for exclusion include not working within the United Kingdom or Republic of Ireland (n=3), not working with autistic children (n=3), or not completing more than half of the questionnaire (n=1).The low number of responses may reflect the limited use of VR clinically. Results will refer to those who have and have not used VR with autistic children.

Participant Characteristics

Of the 53 participants who met the eligibility criteria, 48 responses were from women, 4 were from men, and 1 was from a participant who preferred not to comment on their gender. These figures are representative of sex-based employment data which suggests 97% (n=51) of the speech and language therapy profession are female, and only 3% (n=3) are male [26]. Further data relating to age, sector and location are presented in Table 1.

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Table . Showing participant demographics factors.

Characteristic	Number of participants (N=53), n (%)
Age (years)	
21-24	11 (21)
25-34	14 (26)
34-45	13 (25)
45-54	9 (17)
55-64	6 (11)
Sector	
Public	31 (58.5)
Private	22 (41.5)
Location	
England	22 (41.5)
Northern Ireland	14 (26.4)
Scotland	7 (13.2)
Republic of Ireland	6 (11.3)
Wales	4 (7.5)

Previous Use of VR

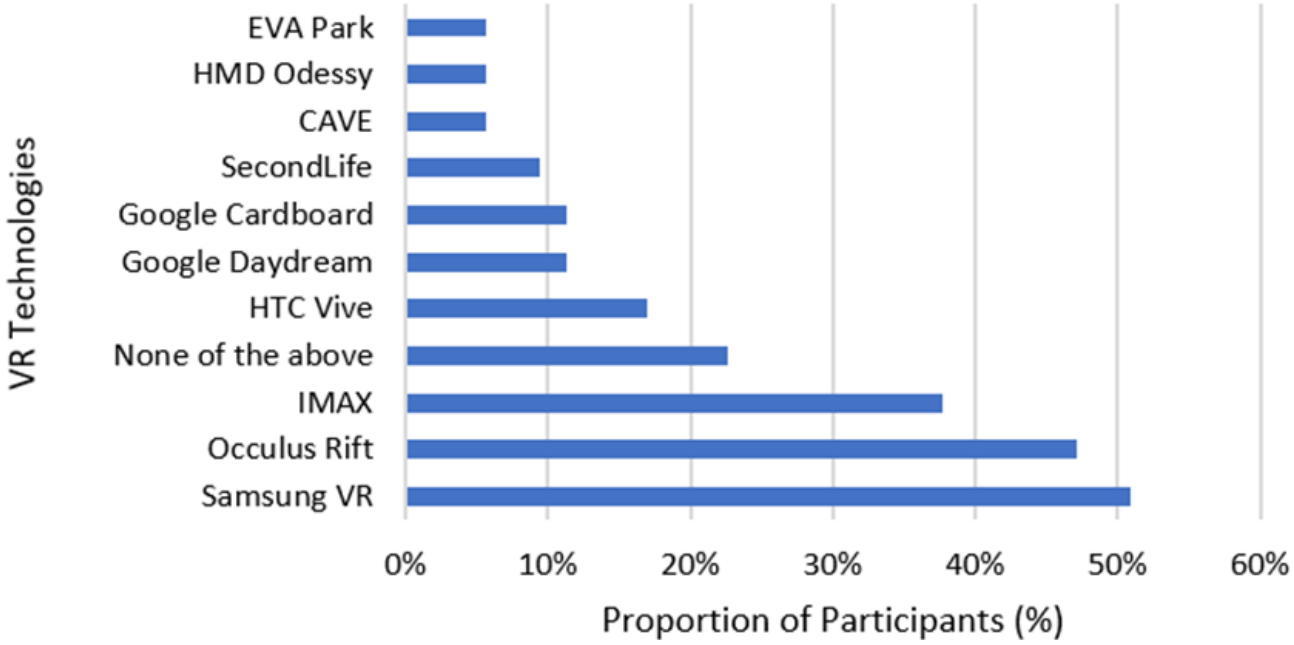
In the questionnaire, 3 questions pertained to previous VR use for SLT for autistic children. From 53 respondents, 49 had not used VR and 4 had. From the 4 VR users, 1 had used VR with an autistic child in a social skills context. In total, 3 had not used it in the context of autism but had used it to motivate children for therapy, to trial a VR Lidcombe program, and with stroke users. The Lidcombe Program refers to an SLT intervention used with dysfluency and stammering. Motivation included using gamified elements, and EVA Park had been used with people with aphasia.

Knowledge About VR

Speech and language therapists rated their knowledge on a 5-point Likert scale as excellent, good, average, poor, or very poor. Overall, they demonstrated a mixed self-reported knowledge of VR, with the majority of speech and language therapists who had not used VR, reporting poor (n=22, 41%) and average (n=20, 39%) knowledge of VR. Furthermore, a speech and language therapist exemplified this by reporting: *"My own knowledge is my main limitation."* Of speech and language therapists who had used VR (n=4), 25% (n=1) rated their knowledge as good, and 75% average (n=3). A total of 53% (n=27) of speech and language therapists who had not used VR were able to correctly identify that VR encompassed desktop computers, CAVE, and HMDs connected to smartphones or laptops. Furthermore, 70% (n=37) perceived HMDs to best describe VR. VR technology brands Samsung VR and Occulus Rift, which use HMDs, were mostly widely recognized, including by speech and language therapists who had used VR. Figure 1 outlines the recognition of various VR. Regarding the integration of VR into clinical practice, 67% (n=35) of speech and language therapists were aware of VR but had not used it in clinical practice. A further 15% (n=7) had become aware of the concept of VR from the survey and had not previously heard of it. VR was more integrated into clinical practice by those had previously used VR, with 50% (2/4) indicating their familiarity and confidence with VR, and 50% (2/4) had fully integrated VR and could creatively apply and use it in clinical practice.

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Figure 1. Showing recognition of virtual reality technologies by participants. VR: virtual reality.



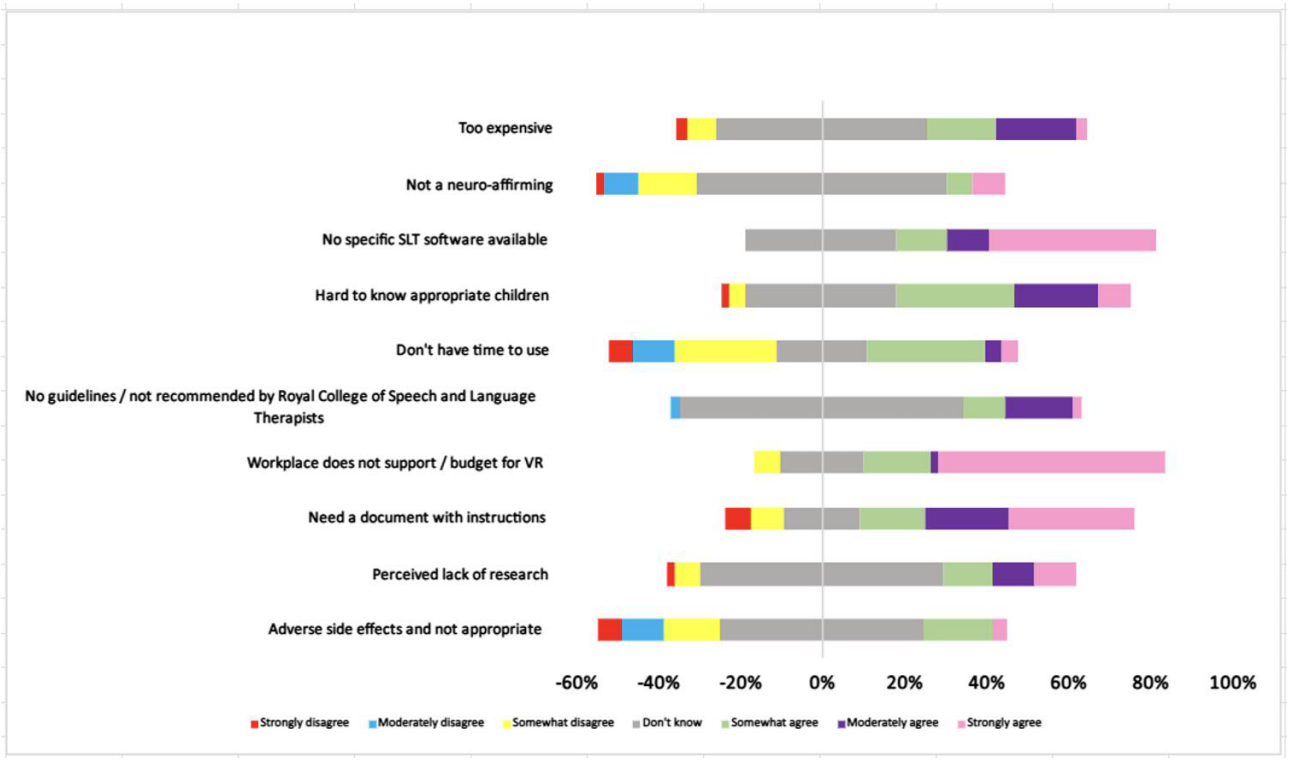
Attitudes Toward VR

Participants who had not used VR indicated that workplace budgeting and support, a lack of instruction and guidelines and a lack of specific SLT VR software acted as barriers toward the general adoption of VR into clinical practice (Figure 2).

As illustrated in Table 2, 55% (n=29) of speech and language therapists who had not used VR, strongly indicated that their workplace did not support or budget for VR.

I've never thought of this technology as an option – likely due to budgets and having access to the technology.

Figure 2. Showing speech and language therapist attitudes toward virtual reality when they had not previously used it in clinical practice. VR: virtual reality.



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Table . Showing key quotations from participants that highlight themes and subthemes of future support needs.

Theme and subtheme		Quotation
Training and **education**		• *"Knowledge, resource, time to upskill."*
	Education from specialists	• *"Someone to actually visit us in our clinics with the headsets and show us what it is, common misconceptions, how it works, all the different brands and types of VR that are actually available, with all the different features."* • *"Someone who can come in and set up a VR hub and show us what it does, and then what it does for speech therapy"*
	Information of funding	• *"There would probably need to be a funding initiative as NHS is a public service and would be unable to just purchase this off the bat."* • *"How to access affordable VR. Is there a way to get funding?"*
	An overview of research	• *"Raising awareness of the pros and cons of research"* • *"An understanding of how it would support the client group we work with."* • *"Information about case studies/evidence base/research"*
	Practice-based learning opportunities with peer support	• *"A new CEN dedicated to the use of VR in practice, where we could talk to SLT's who are already using it but promote it and can give us tips on what do to next. If they could provide workshops and like online lives or something I would really love that. Like you do it [practice] along with them on a live stream like simulated practice."* • *"Observe other specialist autism SLTs using VR."* • *"Practical based learning, get to use it and experience it, think about creative uses with other SLT's."* • *"Having someone who is an SLT and knows how to use it teaching you, so they don't neglect the nuances of the SLT role is important. Otherwise, it might not be neuro affirming for autism."* • *"Training over a few days, interactive get to experience VR, learn to theoretical side and behavioural mechanisms, opportunities to plan for made up clients like you do in university."*
Guidelines		• *"Guidelines(!!) this is a really big one I think"*

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Theme and subtheme		Quotation
Training and **education**		• *"Knowledge, resource, time to upskill."*
	VR[a] user guide and set up	• *"A guideline from using it from case history to discharge would be useful for me as an NQP."* • *"I think if a table, with VR types and efficiency for different SLT goals was put into a manual, that would be really helpful for clinical decision making as it would make it easier and way more efficient."* • *"Info on VR implementation: set up, how to support autistic children and parents."* • *"What is it, what therapy looks like, who is it for, how to set goals and measure outcomes."* • *"How to identify who it would benefit, knowing when to use it."* • *"I think an overview about VR and its uses in SLT would be super useful. eg What types of VR there are, and how you could use different software for different applications within SLT - Ax & therapy."*
	Example therapy ideas	• *"Ideas for interventions."* • *"Sample sessions/activities, how to introduce, how to include interests, what to consider from a sensory perspective."*
	Frequently asked questions	• *"Troubleshooting if technical issues arise."* • *"What to do when shit hits the fan and it all goes wrong aswell…"* • *"It needs to include 'what ifs' to help troubleshooting with autistic children, as they are all likely to react so differently."* • *"Maybe how to manage side effects because I would panic and so would most of the kids."*
Future Research		• *"Realise SLTs in NAH are still in battle mode post covid with severe shortages and whilst most SLTs are interested and can see potential for a range of applications, there are other interventions they are looking into and they have to prioritise. It may be the additional technology bugs/issues/learning curves slide VR into 2nd or 3rd place because we can't do it all."*
	Neuro-affirmative uses of VR	

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Theme and subtheme		Quotation
Training and **education**		• *"Knowledge, resource, time to upskill."*
		• *"Ensuring that the virtual reality approach to working with autistic children is neurodiversity affirmative (ie, it isn't taking a social skills approach and teaching them how to mask). The benefits to autistic children themselves should be outlined and not only to neurotypical adults in their environments."*
		• *"It would be good to see if VR could be used to explain the autistic child's perspective to others though, perhaps parents and teachers. Training up the people who work with autistic children and using it as part of advocacy as to how it feels to have social communication difficulties. I saw something similar on Chris Packhams documentary about autism. Although it was done via film, it gave first person POV of sensory differences experienced by an autistic young person."*
	Effectiveness of a specific SLT[b] VR tool	• "*Parental and SLT views on effectiveness and a range of outcome measures to assess how effective it has been."*
		• *"Increase the evidence base for different types of VR in autism, and for different goals."*
		• *"Outcome measures - depending on target of therapy, does VR help achieve these goals or hinder them?"*
		• *"Need to examine generalisation from the VR - learned experience, to the real life experience."*
	Involving autistic children and families in the design of VR tools	• *"Incorporate the ideas and needs of the individual from their own perspective. Client led - developed by clients."*
		• *"It also might be an idea to actually ask autistic children how they would like to use it when they come to therapy. The best way to understand autism is to ask and include people who have it, especially in any future design or applications."*
		• *"I think parental views? Do parents think it's an acceptable therapy when they've waited a long time. Does VR provide a new way to work on skills that are a priority for autistic clients and SLT's - comparing it to approaches being used at the minute."*
	Consideration of individual needs	

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Theme and subtheme	Quotation
Training and **education**	• *"Knowledge, resource, time to upskill."*
	• *"I would like to see if it impacts sensory differences because I find when the child used it in my clinic he got really over stimulated and had more behavior problems than he did before using it."*
	• *"It should identify children who may not benefit from it ,ie, who does it work best for."*
	• *"If there are VR worlds used for autism, I'd also like to know how to keep my young people safe, because I would be worried that their social skills may put them at risk of victimization."*

[a]VR: virtual reality.

[b]SLT: speech and language therapy.

However, 43% (22) of speech and language therapists were not sure if VR was too expensive to purchase. Overall, speech and language therapists knew that their workplace did not budget for or support VR but were unsure about the cost of VR. Most of the speech and language therapists who had used VR indicated that their workplace did support or budget for VR.

In addition, 34% (n=18) of speech and language therapists who had not used VR, did not know if they needed guidelines or a document with instructions, whilst 30% (n=15) strongly agreed that they required guidelines. Overall, most speech and language therapists either wanted guidelines or were not sure. Speech and language therapists who had used VR (n=4) had mixed views. Some did not need instructions or guidelines (2/4, 50%) and some did (n=1 somewhat agree and n=1 strongly agreed). Responses to "no specific SLT software available," suggested 41% (n=21) of speech and language therapists who had not used VR, strongly agreed that there was no SLT specific software for VR. A further 37% (n=19) remained unsure. This is illustrated in Table 2. Half of speech and language therapists who had used VR did not know (2/4, 50%) if there was or was not SLT specific VR software. Others agreed (n=13, 25%) and disagreed (n=13, 25%).

Attitudes toward using VR specifically with autistic children indicated that speech and language therapists who had not used VR, were unsure about the evidence base (n=29, 55%) and adverse side effects (over 50% [n=26]).

> *I don't know enough about the applications of it within SLT, ie, in Assessment & therapy. I would need to know this and have a strong enough evidence base before I could even approach my NHS employers.*
>
> *I would be feared to implement VR, as it may encourage some of the children in my care to disassociate from the world even further.*

In total, 64% (n=33) of speech and language therapists were unsure about the suitability and screening for use of VR with autistic children as a barrier, alongside uncertainties about the neuro-affirming status of VR (n=32, 62%) :

> *I cannot see any benefits from using it with autistic children on the grounds of teaching social skills or attempting sensory desensitisation which is harmful, and does not work!!*

Notably, VR was considered to be neuro-affirming by over 30% (n=15) of speech and language therapists who had not used VR. However, 14% (n=7) felt it was not neuro-affirming, as it, "*perpetuates harmful neurotypical stereotypes that autistic children need to change.*" Of speech and language therapists who had used VR (N=4), 25% (n=1) strongly disagreed that VR could have adverse side effects, 50% (n=2) somewhat disagreed, however 25% (n=1) remained unsure. Furthermore, 50% (2/4) of speech and language therapists who previously used VR , felt VR was neuro-affirming and 50% (2/4) did not know.

Around 80% (n=42) of speech and language therapists were willing to use VR in the future and 20% (n=10) were not. Reasons for future usage included: (1) innovation in practice:

> *Always willing to explore new ways of working*

and

> *VR is in the media ALOT at the minute with the new Apple VR headset, so I think it's important that practice reality follows these new developments and isn't stuck in the past;*

(2) the motivational nature of technology:

> *It is visual and exciting, I can see the potential for use of VR with this client group*

and

> *Because lots of my clients love to use computers/ipads,*

and (3) potential therapeutic impact:

> *Another clinical tool to add to successful therapy outcomes,*

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> *I think that it would support practicing areas such as self-advocacy and perspective taking in a more dynamic way*

and

> *If it could be used to improve social communication and language outcomes I would be willing to try it.*

Speech and language therapists who were not willing to use VR gave various reasons including (1) VR may not support neuro-affirming principles,

> *I would be worried about social scenarios created by neurotypical people to intervene in helping autistic people practice skills that don't come instinctively;*

(2) Concerns about sensory issues, and (3) ethical concerns and dissociations,

> *Virtual reality represents a disconnection from the real social interactions it [sets] out to improve.*

Support Needs

The 49 speech and language therapists who had not used VR were asked what they needed to support future research. Key themes emerged including an increased evidence base, workplace support, and training and education. Many speech and language therapists did not answer in full sentences, and this reflects the fragmented quotations used.

An improved evidence base for VR as an SLT tool for autistic children was required and "*having the knowledge to make an informed decision*," was a priority for many. An improved evidence base was also required to provide a more solid foundation for business cases for employers:

> *I don't know enough about the applications of it within SLT, ie, in Assessment & therapy. I would need to know this and have a strong enough evidence base before I could even approach my NHS employers to try and build a business case to support them purchasing it.*

Furthermore, speech and language therapists suggested future research should demonstrate clear quantitative evidence showing the effectiveness and efficacy of VR, clear, replicable outcomes measures for communication and generalization domains, and comparison of VR with standard SLT therapy.

Training and education were also identified as a theme across the data. In total, 83% (n=43) of speech and language therapists felt they would benefit from training, to include an overview of VR technology and guidelines for use. Speech and language therapists suggested a demonstration day, best described by one participant:

> *I personally would need a VR road show for autism where you can see what it can do, get to try it and talk with experts and other SLTs using it.*

Speech and language therapists wanted this to include education from specialists about the VR headsets available and appraisal of these, information on how to apply funding, an overview of research and practice-based learning opportunities, with peer support.

SLTs also reported that they needed a VR manual from VR "*procurement to [therapy] discharge.*" This would include a VR user guide and set up, example therapy ideas, and a frequently asked questions guide for troubleshooting and difficulties. Table 2 illustrates quotations which support the above findings.

Finally, specific areas for future research were also identified. This included neuro-affirmative uses of VR, effectiveness of a specific VR SLT tool and outcome generalization, consideration of individual needs, and involving autistic children and families in the designing VR tools. One speech and language therapist indicated that researchers should consider all future research in the current post–COVID-19 context:

> *Realise SLTs in NHS are still in battle mode post covid with severe shortages and whilst most SLTs are interested and can see potential for a range of applications, there are other interventions they are looking into and they have to prioritise. It may be the additional technology bugs/issues/learning curves slide VR into 2nd or 3rd place because we can't do it all.*

Discussion

Principal Findings

The aim of this study was to explore speech and language therapists' knowledge and attitudes toward the use of VR for autistic children. This questionnaire indicated that some speech and language therapists were willing to use VR, discussing barriers, potential uses, and support needed to facilitate the novel technology into practice. Key themes include considerations for VR use, attitudes toward VR and barriers to use, and supporting VR into clinical practice.

Despite being generally unsure about autism-specific considerations, most speech and language therapists were still willing to use VR as an intervention. This may be because some clinicians demonstrate an openness to innovation in practice, with some indicating that they liked to embrace new approaches and keep abreast of developments. Some advantages of VR were highlighted, including its motivational nature for autistic children and access to a range of communication environments, which are also highlighted in literature [11,12]. Despite this, speech and language therapists did not identify many of the other advantages of VR that are reported in literature, such as opportunities for repeated practice of increasing intensity in naturalistic environments, maximizing strong visual skills, or reduced negative social consequences. This indicates that SLTs may be willing to make a leap into VR adoption, relying on their own clinical judgment to evaluate how useful VR is in meeting the needs of autistic children. This demonstrates the perceived usefulness of VR is not only related to the evidence base and ability to facilitate adaptions, but also to its clinical relevance, applicability, and feasibility in the context of workplace, clinical, and individual demands [24].

Notably, some speech and language therapists in this study, who held more negative views toward VR, evaluated the technology from the perspective of autistic children themselves,

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rather than as clinicians. This may indicate that these clinicians were supportive of neuro-affirming practice, however as demographic data was not collected on approaches to practice, the authors cannot say this definitively. Responses indicated that VR was perceived to be a tool that was based on neurotypical standards, and sought to change the skills of autistic children, rather than foster strength-based approaches and promote environmental adaptions advocated for by neuro-affirming practice [9]. This suggests that neuro-affirming perspectives may be integrated into the technology acceptance model and could be a form of subjective norms, influencing perceived usefulness of VR [27]. Neuro-affirming perspectives in technology adoption, have not yet been explored in research, and this offers an avenue for exploration.

Speech and language therapists opposed to using VR as a clinical tool for autistic children also reported concerns about adverse side effects, dissociation, and sensory impacts, similar to Bryant et al [15] and Brassel et al [20]. This suggests that speech and language therapists may be considering VR in the context of specific patient profiles. Given that autism presents uniquely in many cases, it is difficult to determine optimum autism profiles for use. Although previous research has indicated that VR can be used for sensory integration therapy and reduces stereotypical behaviors in autistic children (Marco et al [28]), this deficit-based research casts doubt over both sensory impacts and use of VR for identity affirming approaches. Indeed, autistic differences in sensory regulation may heighten dizziness and cybersickness, and although autistic children reported feeling calm when using HMDs [12], sensory stimulation impacts individuals differently. VR may allow autistic children to gain access to socializing and friendships through VR that are restricted in real life, resulting in excessive usage. This prolonged emersion may exacerbate sensory and well-being risks including dissociation [29] depression and anxiety [30] and victimization, as social communication differences may increase the risk of trolling. Therefore, VR should be supported by therapist input, and future guidelines for duration safety of use.

Education surrounding the neuro-affirming potential of VR in SLT is likely to influence the attitudes of speech and language therapists and future use of VR. Although some speech and language therapists remained skeptical about the ability of VR to support a strength-based approach that affirms autistic identity, literature indicates that VR has the potential to facilitate neuro-affirmative interventions, such as perspective taking, experience of new situations, and therapeutic interventions for anxiety and phobias [11,31]. Autistic service users felt VR could affirm their identity, facilitating educational experiences, and friendships [11,14]. As VR offers a safe place to explore and practice skills without negative consequences [32], future uses of VR may use the technology to teach skills to repair communication breakdowns, and as an advocacy tool to educate neurotypicals on communication differences.

Poor knowledge of VR was cited as a barrier to adoption, which is surprising given the increased public awareness and commercial availability of VR headsets in recent years, where VR has become a mainstream technology [33]. However, it appears that speech and language therapists struggled to extrapolate the VR represented in the media, to clinical practice applications in autism. This is reflected in literature, where clinical knowledge of VR is perceived to be a barrier to VR adoption in traumatic brain injury [19,21] and indicates the gap between knowledge and practical applications must be bridged to support adoption in autism. Despite this, personal factors such as age, gender, years of experience, and perceptions of digital skills may also impact adoption. Future research should build a clearer picture of links between demographic factors and technology adoption in SLT to understand SLT behaviors that should be targeted for change to support adoption.

Negative workplace attitudes were also highlighted as barriers to adoption of VR and similarly, these risks and barriers have also been highlighted by speech and language therapists using VR for adult communication and cognitive rehabilitation [15,19,21]. This also aligns with the technology acceptance model, by demonstrating that facilitating conditions and technological and institutional factors, play a role in technology adoption [15,24,27]. This indicates that more needs to be done to improve the ability of workplaces to support VR innovation and adoption into clinical practice. For example, grant and reward schemes for managers and trusts embedding VR therapy models.

Fostering positive knowledge and attitudes toward VR in SLT for autism, to overcome barriers, should build on suggestions for education, training, and guidelines. Previous literature in traumatic brain injury has used clinical manuals, workshops, IT support, and courses to make VR easier to use and improve practitioner confidence [21]. Although these approaches are deemed appropriate to facilitate the immersive VR use by speech and language therapists [20], the current suggestions for SLT support may improve upon this previous training model. Support for speech and language therapists using VR with autistic children should target awareness of VR technology, education and practice-based learning, and VR trials and support. Education and training strategies should work in tandem with research knowledge to translate the theoretical into practical. Both speech and language therapists who had and had not used VR, advocated for the development of VR guidelines for autistic children. Bauer et al (2023) [34] has provided detailed extended reality guidelines for paediatric autism interventions, suggesting they should be considered as part of an overall intervention program. However, they also recommend that future interventions should focus on mediation, well-being, and sensorially, social, and cognitive training, which it does not appear to be neuro-affirmative. Although these guidelines provide foundational guidance which speech and language therapists may apply to practice with autistic children, recommendations should be critically appraised on a case-by-case basis. VR SLT created guidelines for traumatic brain injury [20] that may be used as a guide to modify the guidelines by Bauer et al [34] in future research. Participatory design methods should be used in additional research [35] incorporating co-design workshops with speech and language therapists, autistic children, and parents to ensure usage recommendations reflect the needs of service users and speech and language therapists, and are underpinned by neuro-affirmative frameworks.

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Overall, this research establishes emerging evidence regarding SLT knowledge and attitudes toward VR. This preliminary research is reflective of Bailey et al [16], where similar affordances and drawbacks are discussed regarding VR in SLT for communication disabilities and the technology acceptance model [27]. Knowledge of VR, subjective norms, including clinical judgment or neuro-affirming practice, and facilitating conditions such as workplace support, contributed to speech and language therapists attitudes toward VR as a clinical tool for autistic children and intention to use the technology.

Limitations and Future Directions

Limitations

Demographic variables were not analyzed in relation to adoption in this study. A fuller profile of respondents may have enabled a more nuanced discussion of VR within SLT autism practice and linked this to current practice. Studies seeking to replicate these findings should evaluate roles in autism care and professional practice. Perhaps speech and language therapists who had more clinical experience with autism, and the appropriateness of interventions, were better able to critically evaluate VR, thus reflecting their more critical attitudes toward VR. Many of these responses showed more depth than speech and language therapists who described a willingness to use VR. Future research should seek to explore the impact of previous training, years of clinical experience, location, and reflective practice on adoption of VR. A specific inclusion criterion, targeting speech and language therapists with substantial experience working with autistic children or using VR is required in future research. Authors should ensure inclusion criteria targets those aged more than 21 years as trained speech and language therapists.

In addition, the questionnaire was completed via web and self-selective, meaning respondents with adequate digital skills responded to the survey. Respondents may have an increased interest in or experience with VR, resulting in a self-reported bias. It may have been beneficial to include an adapted digital skills questionnaire to estimate SLT levels of digital competence, and how this impacted VR adoption. Results would have indicated if competence was related to technology generally, or specifically to VR. Furthermore, a questionnaire limited the depth of understanding of research questions. Focus groups may have enabled a richer exploration of clinician perspectives and future research should seek to use this methodology. Finally, it was difficult to ascertain figures for the number of speech and language therapists working with an autistic caseload in the United Kingdom and Republic of Ireland, from employment figures and therefore no power calculation was carried out. As a result, the authors are unsure if the sample size of 53 accurately sampled this population, and thus if the findings have suitable power. Given the increasing number of autism diagnoses across the United Kingdom, the number of clinicians in these roles may be higher than expected. Therefore, future research should seek to replicate this result with a larger sample size and recruit speech and language therapists from settings where they work predominately with autistic children.

Future Research

Patient specific facilitators and barriers to VR SLT interventions should be identified (eg, sensory differences, epilepsy, victimization, dissociation, intellectual disability, and gender) and external features of VR that contribute to effective SLT interventions. Given the link between epilepsy and autism, and the lack of evidence regarding seizure risk with HMDs, side effects are a pertinent area for exploration. Although the risks of HMDs are reportedly low for autistic children [12], it is necessary to establish safety protocols, such as maximum exposure time and treatment intensity required for generalization, to ensure tolerance and comfort. Limiting exposure times may also help reduce the possibility of autistic children dissociating from reality and real social interactions [15].

The neuro-affirming stance of VR was a key issue in this research. Future research should ensure VR research in autism is rooted in strength-based philosophies, given much of the current evidence base for autistic children prioritizes technology-based interventions for social skills and social cognition training [34]. This paper reiterates the need to think beyond a social skills approach, considering other linguistic, educational, and pragmatic domains within the SLT remit. This reflects the systemic change to autism management observed in the SLT literature and current practice standards [8]. However, the authors acknowledge that populations such as developmental language disorder may benefit from VR interventions designed to improve social or communication skills. Furthermore, it may be that a priority setting exercise for neuro-affirmative speech and language therapists would uncover pressing areas for research, which could guide future neuro-affirmative VR research.

SLT-specific software for autism should be designed using participatory research approaches [35] to ensure VR applications are neuro-affirmative, rooted in autistic and family priorities, and contribute to evidence-based practice in socially and ecologically valid ways [36]. This will solidify the use of VR in the care of autistic children. Frameworks such as Design Thinking [37] may facilitate future research allowing this topic to become more defined and to create new ideas to solve barriers to implementation in practice. Feasibility of VR as a clinical SLT tool may follow [38]. Additional research should compare outcomes from VR and traditional SLT clinical tools, enabling a cost benefit analysis for the benefit of clinical decision-making. Suggestions for development include VR applications that facilitate perspective changing and VR as an educational tool.

Finally, an education and training program may be developed for speech and language therapists, regarding VR as a clinical tool for use with autistic children. Key themes are outlined in Multimedia Appendix 1. Future research should explore how a SLT-specific VR training package impacts knowledge and attitudes toward VR as a clinical tool for autism and impacts adoption of VR into clinical practice. First-hand experience of and engagement with VR, may allow speech and language therapists to consider how it may be used with autistic children and for SLT goals. This may also inform future research

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questions regarding implementation of dosage, minimum and maximum immersion time, and protocols for use, which contribute toward evidence-based guidelines for VR.

Conclusion

This research demonstrates mixed attitudes toward VR as a tool for autistic children among speech and language therapists. Barriers need to be carefully considered before VR can fully integrate into the SLT clinical toolkit, and this paper makes the following recommendations: (1) future research into VR in SLT should ensure a neuro-affirming approach, including autistic children in development of new software; (2) a stronger neuro-affirming evidence base regarding the use of VR for autistic children in an SLT setting, to contribute to evidence-based practice and enable access to resources; (3) development of a VR education and training program for speech and language therapists to include neuro-affirming practice; and (4) Clinical Excellence Networks should be set up to facilitate peer support among clinicians who adopt VR. From this, working groups of "VR champions" should be formed to provide advice regarding funding procurement and to engage managerial staff using success stories and outcome driven data.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The following provides a brief outline of suggested themes for an autism specific SLT VR education and training programme.
[DOCX File, 17 KB - rehab_v12i1e63235_app1.docx]

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Abbreviations

CAVE: Computer Automated Virtual Environment
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
HMD: head mounted display
SLT: speech and language therapy
VR: virtual reality

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Effectiveness of a New Device for Hand, Wrist, and Forearm Rehabilitation: Feasibility Randomized Controlled Trial

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Abstract

Background: Forearm, wrist, and hand impairments affect many individuals and impose a significant economic burden on health care systems. The FEPSim (flexion, extension, pronation, and supination) is designed for hand and wrist rehabilitation. It could become part of the standard care for upper extremity rehabilitation, aiming to improve range of motion, dexterity, and strength during therapeutic activities. However, the FEPSim has not yet been tested in a health care setting, highlighting the need for a trial to assess its effectiveness in upper extremity rehabilitation.

Objective: We aim to assess the feasibility of conducting a definitive trial investigating the effectiveness of adding a new device for hand therapy exercises, the FEPSim, to standard care for patients with impairments of the hand, wrist, and forearm.

Methods: Thirty-eight patients with impairments of distal upper extremities were randomly assigned either to the intervention group (FEPSim and standard care, n=19) or to the control group (standard care, n=19). Therapeutic activities to increase strength, range of motion, resistance, and dexterity were delivered by treating hand therapists using the FEPSim device for the intervention group. Outcome measures included wrist passive and active range of motion, grip strength, pinch grip force, and the Patient-Rated Wrist Evaluation.

Results: The trial retention rate (36/38, 95%) and compliance (control group: 100%; intervention group: 89%) were high. The comparisons of the change-from-baseline between groups revealed that in 63.2% (12/19) of the outcome variables, the change was in favor of the FEPSim, with statistically significant improvements in passive wrist flexion (t_{34}=−0.335, P=.008) and grip strength (t_{34}=−1.841, P=.04).

Conclusions: The FEPSim was accepted as part of standard care by therapists and patients at 2 hospitals. The trial design was feasible for hand intervention using the FEPSim device. The FEPSim positively affected grip strength, an objective measure of hand functioning.

Trial Registration: ISRCTN Registry ISRCTN13656014; https://www.isrctn.com/ISRCTN13656014

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KEYWORDS

hand; upper limb; motion; movement; wrist; therapeutics; rehabilitation; musculoskeletal; musculoskeletal diseases; stroke; wrist fractures; feasibility studies; randomized controlled trial; digital health; physiotherapy; physical therapy; occupational therapy

Introduction

Impairments affecting the hand, wrist, and forearm have been found to impact everyday functioning and are associated with reduced quality of life, as well as increased levels of anxiety and depression [1]. These impairments impact a significant proportion of the global population, as they are caused by numerous etiologies such as fractures (including those caused by osteoporosis), osteoarthritis, stroke, and nerve and tendon disorders, among others [1,2].

The existing body of evidence indicates that exercise can lead to varying degrees of improvement in hand, wrist, and forearm impairments, with effects ranging from weak to moderate, particularly in cases of fractures, rheumatic arthritis, and osteoarthritis [1]. Additionally, comprehensive rehabilitation after stroke underscores the crucial role of exercising the hemiparetic hand and wrist across all stages to optimize patient

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outcomes [3]. However, intervention protocols reported in the literature for exercises as part of hand therapy exhibit significant heterogeneity in conceptualization, dosage, and delivery. This limits the possibility of designing evidence-based clinical guidelines [1,4]. One reason for the observed heterogeneity in hand exercises could be the extensive variety of equipment and materials used during therapy sessions. For example, therapy putty, resistance bands, dumbbells, and jar openers are commonly used. However, these materials typically do not enable therapists to accurately determine and measure their patients' range of motion or strength during functional hand movements and exercises, which can contribute to inconsistencies in treatment protocols across therapists and settings.

Therapists in clinical settings typically use equipment falling into two main categories to enhance strength, range of motion, and resistance in the hand, wrist, and forearm [5]:

1. Low-cost and portable devices: These devices, averaging US $100, are generally small and designed to specific exercises. Examples are wheel-like or hammer-like devices to exercise pronation and supination and squeezing balls or bars to exercise grip strength. These devices lack direct measurement capabilities during hand therapy activities and are nonadjustable.
2. High-cost electromechanical devices: This category includes both portable and nonportable commercial electromechanical devices whose cost ranges from US $10,000 to US $95,000. Examples are the Simulator II (BTE Technologies) and SaeboReJoyce (Saebo). The BTE Technologies devices have been shown to be a reliable and valid tool, comparable to standard dynamometers, for measuring grip strength in healthy individuals [6,7]. The SaeboReJoyce provides a valid, quantitative, and automated alternative to standardized hand function assessments especially for patients with stroke [8]; however, its effectiveness in improving upper limb function remains inconclusive [9].

There is a clear need for a new rehabilitation device for hand therapy. Existing devices either are low-cost but lack measurement and adaptability or are prohibitively expensive for many health care settings. A versatile, cost-effective device could bridge this gap, offering precision and accessibility for more consistent hand therapy interventions.

The FEPSim (flexion, extension, pronation, and supination [10]), developed by Karma Machining & Manufacturing Ltd, is a rehabilitation device designed explicitly for hand therapy. It targets hand and wrist conditioning through various movements and offers adaptability for different grasp patterns. The device allows therapists to monitor improvements in strength, range of motion, and endurance by enabling controlled resistance adjustments. Resistance is set using a lever on a generic scale from 0 to 1, which corresponds to a torque range of 0.1 to 3.7 newton meters. In addition to resistance, the device can record the repetitions of therapeutic exercises, and is equipped with degree scales that allow therapists to observe patients' range of motion during active movements of the hand, wrist, or forearm. Thus, although the FEPSim is not an assessment tool, it serves as a useful tool for tracking patient progress in hand therapy. Its potential advantages also include compactness and portability, making it a promising option for rehabilitation of impairments of the hand, wrist, and forearm; however, the effect of using the FEPSim on hand therapy outcomes is unknown. In addition, the device is priced at less than US $3000.

In order to investigate the areas of uncertainty regarding a future definitive randomized controlled trial (RCT), this feasibility study, of which the protocol has been published previously [5], had the following objectives: (1) to assess the methods in terms of recruitment, the eligibility criteria, the type and number of diagnoses included, the length and dosage of the intervention, the data collection methods, and the outcome variables; (2) to explore the clinical effectiveness of adding the FEPSim device to the standard of care for patients with impairments of the hand, wrist, and forearm; and (3) to gather and synthesize the data, from which the sample size of a definitive RCT can be estimated.

Methods

Study Design

A pilot or feasibility study is intended to guide the planning of a large-scale investigation. As noted by Thabane et al [11], the primary objective of pilot studies is to evaluate feasibility, mitigating the risk of potentially catastrophic consequences associated with initiating a large-scale study. This precautionary measure aims to prevent the potential "drowning" of the entire research endeavor [11]. A feasibility study serves the purpose of elucidating previously unknown information crucial for designing a definitive RCT. It plays an integral role in acquiring pertinent insights into the acceptance of a novel intervention by both clinicians and patients. Additionally, this study seeks to identify potential beneficiaries of the intervention and elucidate optimal delivery methods within the context of standard care. The decision to undertake a feasibility study is rooted in the purpose of gaining insights into the acceptance and effectiveness of a newly developed hand therapy device which has not yet been tested in health care settings. Additionally, this study aims to evaluate the suitability of the designed research protocol for the clinical settings involved in the investigation.

This study was a feasibility parallel-group RCT that followed the CONSORT (Consolidated Standards of Reporting Trials) statement for randomized feasibility studies. The CONSORT statement serves as a guideline developed to enhance the transparency and quality of reporting in feasibility RCTs [12]. The trial was registered in the ISRCTN (International Standard Randomized Controlled Trial Number; ISRCTN13656014) Registry.

Ethical Considerations

This study was reviewed and approved by the University of Alberta Health Research Ethics Board - Health Panel (Pro00095587) and the Northern Alberta Clinical Trials and Research Centre. Treating therapists identified eligible participants and invited them to participate. A member of the

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research team explained the study and obtained signed consent. Participants were able to withdraw from the study at any time, and this did not in any way affect their treatment or their rights as patients at the hospitals. Participants received a coffee shop gift card valued at CAD $25 (US $17.34) upon completing their participation. Personal data were deidentified. The participant names were replaced by numeric codes at the beginning of the study, and these codes were retained throughout data collection and analysis.

Materials

The FEPSim is an innovative device designed for the rehabilitation of the hand, wrist, and forearm. This study used the horizontal model depicted in Figure 1. This device features a central structure with an adjustable resistance mechanism, a degree-of-rotation scale for supination and pronation, and a small screen displaying exercise repetition counts. The device is tabletop secure and comprises 2 lateral shafts.

Various attachments facilitate exercises and the simulation of daily activities. For instance, a dowel grip attachment, installable on each shaft, is used for wrist flexion and extension exercises. Rotation and supination exercises involve a 90-degree unit rotation, enabling patients to grasp the dowel and perform clockwise and counter-clockwise rotations. Additional attachments include a key pinch attachment for lateral pinch exercises resembling tasks such as starting a car or turning a key, a T attachment simulating can opener use, a lever attachment for elbow extension or flexion exercises and simulating knife cutting and steering wheel use, and a doorknob attachment for door opening simulations.

Figure 1. The FEPSim device horizontal model. FEPSim: flexion, extension, pronation, and supination.



Recruitment

Patients receiving outpatient hand therapy at the Glenrose Rehabilitation Hospital and Royal Alexandra Hospital (Alberta Health Services) who met the inclusion criteria were invited to participate in the trial. The participants were outpatient adults (18 y of age and older) with limitations in their forearm, wrist, or hand function due to distal radial or ulnar fractures, stroke, osteoarthritis (ie, patients who had undergone wrist salvage surgery), Keinbock disease, ulnar shortening, perilunates dislocation, ganglion removal, tumor removals, triangular fibrocartilage complex injury repairs, ligament repair (torn ligament), or spinal cord injury. This study excluded patients with chronic regional pain syndrome, those who experienced unmanaged pain or edema, individuals with communication or cognitive impairments that hindered their ability to understand instructions, and those who were not able to participate in the outpatient hand program at least once a week. The participants were randomly assigned 1:1 to either the experimental group or the control group, using a permuted block-randomization approach with a block size of 4. The stratification was carried out based on diagnosis at each of the hospitals to ensure balance between the groups.

Procedures

Invitations to participate were posted at several locations in the 2 hospitals. Hand therapists at both hospitals who were unaware of the randomization blocks identified eligible participants. Then, the participants who met inclusion criteria and consented to participate were allocated into one of the groups (experimental group or control group) by the project coordinator who was off-site. This was a single-blinded study. Research assistants blinded to group allocation collected demographics (age, gender, ethnicity, employment status, highest degree or level of education, and medication taken) and outcome measures. Outcome measures were collected at enrollment and weeks 2, 4, 8, and 10.

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Outcome Measures

The primary outcome measures were range of motion and grip strength. Range of motion included active range of motion and passive range of motion of wrist extension, flexion, and radial and ulnar deviation, and pronation and supination were measured using a 12-inch clear plastic goniometer (Baseline 360-degree; Fabrication Enterprises, Inc); grip strength was measured using a hydraulic dynamometer (Baseline Lite hydraulic, 200 lb; Fabrication Enterprises, Inc); pinch strength (including pulp pinch, key grip, or 3 finger grip) was measured using a pinch gauge or pinch meter—60 lb. Grip and pinch strength were measured 3 times, then the mean and SD of the 3 measures were calculated. The secondary outcome variables were the patients' perceived wrist pain and disability in activities of daily living and was measured with the Patient-Rated Wrist Evaluation (PRWE) questionnaire. The PRWE is a valid and reliable assessment tool of patient-based pain and disability in 3 components: pain; function during specific activities of daily living; and functioning during usual activities (personal care, household work, work, and recreational activities) [5]. Each item is rated from 1 to 10, and the maximum PRWE score is 100. Lower values in the PRWE scale outcome variable are desirable with hand therapy interventions.

Intervention

Overview

Both groups received standard care at each hospital, which consisted of immobilization for 7 to 8 weeks after the time of the injury or surgery (if needed), followed by hand therapy sessions for about 10 weeks. Hand therapy sessions included the management of scar tissue, sensory alterations, and edema, and therapeutic activities to increase strength, range of motion, resistance, and dexterity. For both groups the sessions' length and frequency depended on the patients' individualized needs and diagnoses, as determined by their treating therapists. The length of each session was between 30 and 45 minutes, carried out once or twice per week. The sessions were provided by occupational or physical therapists with training and experience in hand therapy.

Control Group

The therapeutic activities to increase grip strength and wrist or forearm range of motion were performed using available equipment and materials at each hospital. This included using weights such as dumbbells, elastic and squeezing equipment, therapy putty, bands, and other equipment that imitated the hand patterns required for daily activities (eg, jar openers).

Experimental Group

The research team worked with a group of experts to define which equipment and materials used at each hospital for hand rehabilitation could be replaced by the FEPSim device based on its features. As a result, for the experimental group, the therapeutic activities to increase grip strength, and wrist or forearm range of motion were performed using the FEPSim device instead of the equipment and materials used in the control group as described above.

Statistical Analysis

The analysis was conducted using an intention-to-treat principle. Descriptive statistics were used to characterize the groups at the pre- and posttest. Due to variations in the lengths of the interventions, as a result of various discharge times from treatment services, posttest was defined as the last measure taken once discharge from the outpatient clinic was determined by the hand therapists. Tests of normality were carried out in within and between groups comparisons across the outcome variables as appropriate (ie, 1-tailed paired *t* test or Wilcoxon signed rank test for within group comparisons; independent *t* test or Mann-Whitney *U* test for between group comparisons). We calculated 95% CIs and interpreted the level of uncertainty based on them [13]. The α level of significance was set at $P<.05$ (1-tailed). Cohen *d* values were calculated across variables, and an overall average effect size was calculated using a fixed-effects model for continuous outcomes. All analyses were conducted using SPSS (version 28, IBM Corp). In addition, the minimal clinically important difference (MCID) was calculated. An effect size of 0.2 is commonly considered equivalent to the MCID, so we estimated it by multiplying the SD of the baseline scores by 0.2 (a small effect size) [14].

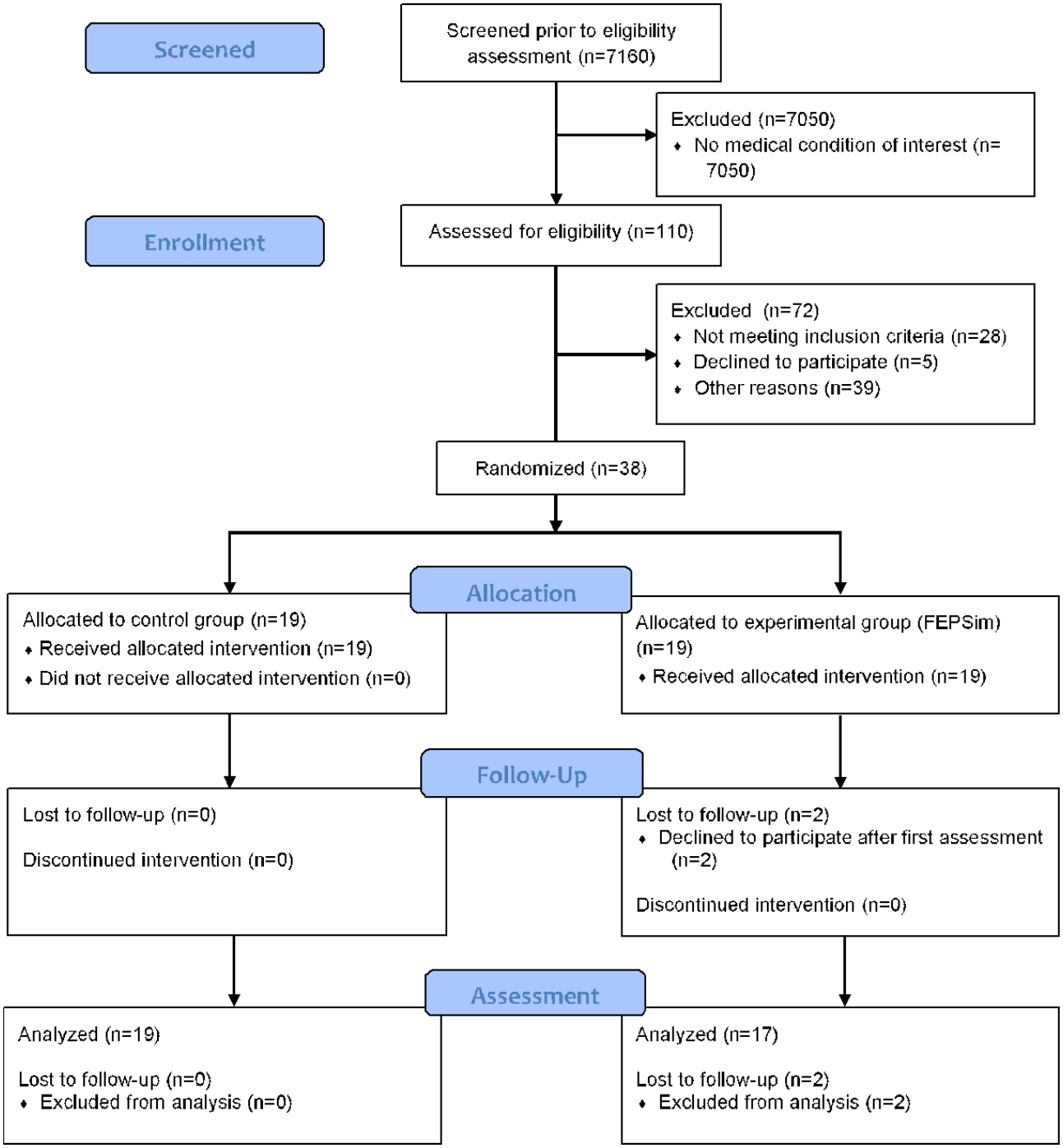
Results

Recruitment

From October 1, 2020, to August 31, 2022, a total of 7160 patients received hand therapy rehabilitation at the 2 hospitals, from which 110 were eligible to enter the trial and 38 consented to participate (participation rate of 35%). The trial retention rate was 95% (36/38). The compliance for the control group was 100%, and for the intervention group, it was 89%. Two participants declined to participate after the first assessment due to disagreement with measures in place to control the spread of the pandemic. Figure 2 presents the flow diagram of the progress during the phases of this study. Table 1 presents the demographics of the 36 participants who completed this study, and Table 2 presents the participants' baseline characteristics according to group allocation.

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Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. FEPSim: flexion, extension, pronation, and supination.



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Table . Demographic data per randomized controlled trial group.

Variable		Control group (n=19)	Intervention group (n=17)	Statistics	
				Chi-square (*df*)	*P* value
Age (years), mean (SD)		58.37 (11.09)	54.59 (15.41)	0.851 (34)[a]	.40
Biological sex, n (%)				1.3 (1)	.24
	Male	11 (57.9)	13 (76.5)		
	Female	8 (42.1)	4 (23.5)		
Ethnicity, n (%)				3.1 (4)	.53
	African-Canadian	1 (5.3)	0 (0)		
	Asian	2 (10.5)	4 (23.5)		
	Caucasian	15 (78.9)	11 (64.7)		
	Latino or Hispanic	0 (0)	1 (5.9)		
	Other or unknown	1 (5.3)	1 (5.9)		
Highest level of education, n (%)				6.6 (6)	.36
	Some high school	2 (10.5)	1 (5.9)		
	High school	6 (31.6)	3 (17.6)		
	College or trade school	2 (10.5)	5 (29.4)		
	Bachelor’s degree	7 (36.8)	6 (35.3)		
	Master’s degree	0 (0)	2 (11.8)		
	PhD or higher	1 (5.3)	0 (0)		
	Prefer not to say	1 (5.3)	0 (0)		
Employment status, n (%)				3.4 (4)	.48
	Employed	7 (36.8)	7 (41.2)		
	Self-employed	2 (10.5)	0 (0)		
	Unemployed at present	1 (5.3)	0 (0)		
	Retired	6 (31.6)	5 (29.4)		
	Unable to work	3 (15.8)	5 (29.4)		
Diagnosis, n (%)				2.0 (4)	.72
	Stroke	9 (47.4)	8 (47.1)		
	Wrist fracture	4 (21.1)	3 (17.6)		
	Osteoarthritis	5 (26.3)	5 (29.4)		
	Ligament repair	1 (5.3)	0 (0)		
	Spinal cord injury	0 (0)	1 (5.9)		

[a]*t* test (2-tailed).

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Table . Comparison of outcome variables at baseline across groups.

Outcome variables	Control group (n=19)	Intervention group (n=17)	Statistics				
	Mean (SD)	Mean (SD)	*t* test (*df*=34)	*P* value	95% CI	Effect size	Power (%)[a]
Active wrist flexion (degrees)	45.26 (24.98)	42.94 (20.69)	0.302	.38	−13.32 to 17.97	0.101	6
Active wrist extension (degrees)	34.37 (23.47)	33.12 (19.92)	0.171	.43	−13.5 to 16.09	0.057	5.32
Active ulnar deviation (degrees)	21.21 (11.48)	20.24 (11.44)	0.255	.40	−6.80 to 8.75	0.085	5.70
Active radial deviation (degrees)	14.16 (7.91)	16.41 (8.98)	−0.846[b]	.20	−6 to 2	0.266	12.10
Active pronation (degrees)	85.89 (14.18)	86.65 (15.60)	−0.67[b]	.26	−10 to 5	0.051	5.25
Active supination (degrees)	72.16 (27.43)	76.71 (16.40)	−0.127[b]	.45	−15 to 10	0.201	9.01
Passive wrist flexion (degrees)	61.95 (29.94)	55.88 (28.10)	0.624	.27	−13.6 to 25.80	0.209	9.34
Passive wrist extension (degrees)	50.16 (29.98)	51.35 (25.58)	−0.128	.45	−20.1 to 17.80	0.043	5.18
Passive ulnar deviation (degrees)	28.26 (10.96)	25.71 (13.66)	0.623	.27	−5.79 to 10.91	0.206	9.21
Passive radial deviation (degrees)	20.32 (9.29)	23.18 (10.04)	−0.888	.19	−9.41 to 3.68	0.296	13.84
Passive pronation (degrees)	96.68 (17.91)	95.82 (16.65)	0.149	.44	−10.9 to 12.62	0.050	5.24
Passive supination (degrees)	87 (26.10)	89.29 (18.82)	−0.19[b]	.43	−15 to 13	0.101	6
Grip strength (lbs)	33.83 (21.10)	35.32 (25.01)	0[b]	.50	−13.33 to 14.37	0.064	5.40
Three finger grip (lbs)	8.61 (4.25)	9.34 (4.48)	−0.502	.31	−3.69 to 2.23	0.167	7.75
Key grip (lbs)	10.54 (5.07)	11.87 (4.89)	−0.793[b]	.22	−5.20 to 3	0.267	9.05
Pulp pinch (lbs)	7.26 (3.72)	7.97 (3.30)	−0.606	.27	−3.11 to 1.68	0.202	9.05
PRWE[c] pain sum	17.16 (15.52)	14.47 (11.28)	−0.222[b]	.42	−7 to 12	0.198	8.89
PRWE function sum	57.53 (34.60)	47.47 (29.27)	0.935	.18	−11.79 to 31.90	0.314	14.99
PRWE total	74.68 (47.43)	62 (35.28)	0.901	.19	−15.91 to 41.28	0.303	14.28

[a]The power (%) is calculated using a statistical equation and reflects the probability of detecting a true effect, not a ratio (eg, n/N). As such, it is presented solely as a percentage and not in the format n (%).

[b]*z* score.

[c]PRWE: Patient-Rated Wrist Evaluation.

Eligibility Criteria

The trial protocol originally proposed to include outpatient adults with 3 specific diagnoses [5]. However, during the intervention sessions, therapists using the FEPSim device identified 8 additional diagnoses that could potentially benefit from its use. As a result, we amended the trial protocol to include patients with a total of 11 diagnoses, as outlined in the Methods section.

Length and Dosage of the Intervention

Mean numbers of treatment sessions received per group are highlighted in Table 3. We found no statistically significant differences in the number of weeks, the number of sessions, nor the number of days between the pre- and posttest between groups. All the participants in the intervention group received the treatment with the FEPSim. On average, the therapists used the FEPSim in 89% of the sessions in the intervention group.

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Table . Treatment information per group.

Treatment parameters	Control group (n=19)		Intervention group (n=17)		Statistics	
	Minimum, maximum	Mean (SD)	Minimum, maximum	Mean (SD)	*z* score	*P* value
Number of weeks	2, 11.43	7.01 (3.19)	2, 10.86	8.54 (2.75)	−0.779	.21
Number of days (between pre- and posttests)	14, 80	49.05 (22.34)	14, 76	59.76 (19.24)	−0.779	.21
Number of sessions	4, 13	7.94 (2.95)	5, 19	10.82 (4.73)	−1.649	.05
Number of sessions with the FEPSim[a]	0, 0	0 (0)	3, 18	9.76 (4.52)	—[b]	—
Compliance (%)[c]	100, 100	100 (0)	57, 100	89.34 (14.80)	−3.09	<.001

[a]FEPSim: flexion, extension, pronation, and supination.

[b]Not applicable.

[c]Compliance was calculated as the percentage of intervention sessions completed as expected for each participant relative to the total number of prescribed sessions. Since this value varies across participants, the table reports the minimum and maximum values, as well as the mean and SD for each group. Therefore, compliance is presented solely as a percentage and not in the format n (%), as this format is not applicable to the data.

Data Collection Methods

The overall missing data was very low; from a total of 3204 values across participants and variables, 2.5% of the data was incomplete. Most of the missing values occurred in the baseline data collection phase, which was largely influenced by clinical decisions made by the therapists (ie, if conducting a measurement could compromise the healing process or worsen the clinical condition of a patient). As a result, variables such as pinch strength and grip strength were not measured for 19% (7/36) of participants, while the passive range of motion was not measured for 14% (5/36) of participants at the baseline. In addition, 25% (9/36) of participants did not respond to the “lifting a heavy object” item on the pain subscale of the PRWE at baseline. Most of the missing data were from participants with diagnoses of stroke, wrist fracture, and for ligament repair. Furthermore, the percentage of participants who were discharged from therapy increased as the trial measurement progressed (6%, 25%, and 50% at weeks 4, 8, and 10, respectively); which led the team to define posttest as the last measure taken before discharge.

Effect of the Intervention

Both groups showed better values in all outcome variables at posttest compared to pretest. The differences between posttest and pretest were statistically significant in 89% (17/19) of the outcome variables for the control group and 95% (18/19) of the outcome variables for the intervention group.

Table 4 displays the change-from-baseline outcome variables for both groups. Comparing the change-from-baseline between groups revealed that in 63% (12/19) of the outcome variables, the change was greater in the intervention group that used the FEPSim than in the control group; however, statistically significant differences between groups were observed in only two of the outcome variables 11% (2/19), specifically grip strength and passive wrist flexion, both in favor of the intervention group. The MCID was 0.96 for grip strength and 1.08 for passive wrist flexion. For the PRWE scale, including the pain and function subscales, as well as the overall summative scale, the change-from-baseline was not in the desired direction (unfavorable for the FEPSim). However, no statistically significant difference was observed for these outcome variables.

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Table . Outcome variables change-from-baseline between the groups.

Outcome variables	Control group (n=19)	Intervention group (n=17)	Statistics				
	Mean (SD)	Mean (SD)	*t* test (*df*=34)	*P* value	95% CI	Effect size	Power (%)[a]
Active wrist flexion (degrees)	10.53 (15.13)	18.53 (14.21)	−1.63	.056	−17.98 to 1.97	0.545	35.46
Active wrist extension (degrees)	9.74 (14.05)	13.71 (12.80)	−0.882	.19	−13.11 to 5.17	0.295	13.81
Active ulnar deviation (degrees)	6.74 (9.92)	5.82 (11.36)	0.257	.40	−6.30 to 8.12	0.086	5.73
Active radial deviation (degrees)	4.26 (6.23)	3.12 (11.11)	−0.397[b]	.35	−5 to 6	0.127	6.57
Active pronation (degrees)	8.37 (12.81)	4.71 (10.83)	−0.682[b]	.25	−6 to 9	0.309	14.63
Active supination (degrees)	12.79 (24.72)	10.29 (13.35)	−0.365[b]	.36	−12 to 11	0.126	6.55
Passive wrist flexion (degrees)	6.74 (17.63)	22.06 (18.70)	−2.530	.008	−27.63 to –3.01	0.843	68.91
Passive wrist extension (degrees)	13.11 (19.08)	14.88 (11.30)	−0.032[b]	.49	−12 to 10	0.113	6.25
Passive ulnar deviation (degrees)	7.63 (9.04)	8.41 (11.72)	−0.365[b]	.36	−8 to 4	0.075	5.54
Passive radial deviation (degrees)	4.84 (7.17)	5.12 (9.70)	−0.098	.46	−6.01 to 5.46	0.033	5.10
Passive pronation (degrees)	9.05 (12.01)	10.06 (10.24)	−0.269	.40	−8.61 to 6.60	0.091	5.80
Passive supination (degrees)	12.00 (18.03)	13.65 (12.56)	−0.314	.38	−12.30 to 9	0.106	6.10
Grip strength (lbs)	7.26 (10.09)	16.06 (17.92)	−1.841	.04	−18.52 to 0.91	0.605	42.14
Three finger grip (lbs)	1.33 (2.67)	2.62 (2.40)	−1.515	.07	−3.02 to 0.44	0.508	31.56
Key grip (lbs)	2.02 (3.16)	2.36 (3.05)	−0.328	.37	−2.45 to 1.77	0.109	6.17
Pulp pinch (lbs)	1.43 (2.32)	2.10 (2.04)	−0.921	.18	−2.16 to 0.81	0.307	14.51
PRWE[c] pain sum	−2.00 (9.80)	−1.76 (12.20)	−0.064	.48	−7.70 to 7.23	0.022	5.05
PRWE function sum	−29.95 (25.93)	−21.47 (18.78)	−1.111	.14	−23.98 to 7.02	0.375	19.34
PRWE total	−31.95 (31.23)	−23.12 (26.42)	−0.91	.19	−28.55 to 10.89	0.305	14.42

[a]The power (%) is calculated using a statistical equation and reflects the probability of detecting a true effect, not a ratio (eg, n/N). As such, it is presented solely as a percentage and not in the format n (%).

[b]*z* score.

[c]PRWE: Patient-Rated Wrist Evaluation.

Sample Size of a Future Definitive RCT

The overall fixed-effects model calculated a small effect size. That is, we obtained a statistically significant test for Cohen *d*=0.189 (*z* score=2.450, 95% CI 0.038 to 0.340, *P*=.01) with an SE of 0.077. With a statistical power of 0.8, an α of .05, and the effect size of 0.189, the minimum sample size required for a future definitive RCT is 350 participants (174 participants in each group).

When estimating the effect size per group using a fixed-effects model for continuous outcomes, the overall average effect size for the intervention group had a higher value. That is, we obtained a statistically significant test for Cohen *d*=0.420 (*z* score=5.360, 95% CI 0.267 to 0.574, *P*<.001) with an SE of 0.070 and a *d*=0.310 (*z* score=4.092, 95% CI 0.161 to 0.458, *P*<.001) with an SE of 0.075 for the intervention and control groups, respectively.

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Discussion

Trial Feasibility

Overall, the research design is feasible for a definitive RCT and offers valuable information for ongoing and future studies. The high trial retention and compliance showed that both the therapists and participants from the 2 hand therapy services agreed to incorporate the FEPSim into their hand therapy treatments. The therapists' acceptance of this device is also backed up by the qualitative results of another study published elsewhere [15].

Clinical Effectiveness of Adding the FEPSim Device to Hand Therapy

This study provides evidence of the potential clinical benefits of incorporating the FEPSim device into hand therapy. Both groups improved with the hand therapy treatment in around 8 weeks. However, the FEPSim group showed improvement in more outcome variables, associated with a statistically and significantly higher effect size. For grip strength and passive wrist flexion, the change-from-baseline was statistically significant in favor of the FEPSim. In the intervention group, 76.4% of participants showed a change equal to or greater than the MCID for grip strength, and 88.2% for passive wrist flexion. Grip strength is a commonly used objective proxy of hand function due to its strong correlation with overall hand performance and functionality [16,17]. Grip strength is a composite measure that reflects the integrated function of various hand muscles and joints, capturing both intrinsic and extrinsic muscle function, is clinically relevant and is associated with various health outcomes [18]. Furthermore, sufficient strength in the upper limb is related to the ability to adequately perform many activities of daily living.

The significant improvements in grip strength are clinically relevant for the most common diagnoses included in our trial. Postimmobilization following a wrist fracture often results in stiffness and muscle wasting, leading to a decrease in grip strength, which in turn affects the individuals' capacity to use the affected hand in daily activities [12]. High movement dosage after distal radius fractures has been found to be critical to increasing grip strength and range of motion. For example, repetitive wrist extension exercises have been found to facilitate regaining grip strength [19]. Additionally, wrist surgical salvage procedures aimed at alleviating osteoarthritis pain have been observed to decrease wrist range of motion and grip strength, potentially leading to long-term impairment [20]. The postoperative rehabilitation goal focuses on pain-free functional wrist motion and includes isometric strengthening exercises, followed by isotonic strengthening and progressive resistive exercises. Depending on the specific surgical salvage procedure, patients can achieve between 53% and 83% of normal contralateral grip strength [21]. Finally, following a stroke, there is a substantial reduction in maximal voluntary force within arm and hand muscles, contributing to significant upper-limb weakness during acute and chronic stages of recovery. A meta-analysis proves that graded strengthening programs improve grip strength and hand function in stroke survivors [22].

The significant improvements in grip strength can be explained by physiology. The use of the FEPSim as part of the therapeutic sessions allowed patients to repeat specific movements such as wrist FEPSim, as well as different grasp patterns with a resistance appropriate to the patient's progress at each session. This promoted muscle activation and efficiency of muscle recruitment in the wrist and hand intrinsic and extrinsic muscles, leading to an improvement in grip strength. Finally, the diverse wrist and hand movements the device facilitated might improve tendon gliding and elongation, reducing adhesions or tightness and enhancing passive wrist flexion.

The findings underscore the potential efficacy of FEPSim in augmenting grip strength among individuals diagnosed with specific conditions. The device's multifaceted capabilities, including the provision of real-time repetition counts, adjustable resistance levels, and the simulation of daily tasks impacted by hand injuries (eg, knife cutting), demonstrate its ability to enable multiple repetitions, carry out graded strengthening programs, and perform hand grasp and grip patterns used in functional activities in a controlled and safe manner. These features appear instrumental in optimizing movement dosage, thereby potentially enhancing clinical outcomes in therapeutic interventions.

Recommendations for a Definitive RCT

Based on the results of this feasibility trial, the authors make the following recommendations for a definitive RCT. First, to investigate a larger sample of diagnoses, including the emerging 8 diagnoses, from the outset to promote sample size and a more robust evaluation. Second, we recommend having 3 measurement points pretest (wk 0), posttest (immediately after discharge), and follow-up at 6 months. This recommendation is based on the observation that the percentage of participants who were discharged from hand therapy services increased during the trial, and that participants may have been discharged at different points during the proposed protocol. Third, considering that the sample size calculation showed that a total of 350 participants will be required and that we had a dropout rate of 10%, a total of 385 participants will be required to participate in a definitive RCT. Considering that the participation rate of this feasibility trial was 34.5%, for a definitive trial the required accessible population will be 1116 patients. To ensure an adequate sample size for a definitive RCT that recruits participants over a 2-year period, it is recommended that recruitment is from 10 settings. This is based on the observation that the feasibility trial admitted approximately 5 patients per month who potentially met the inclusion criteria, resulting in an estimated 47 eligible patients per month (1116 patients/24 mo). It is important to note that these conclusions were reached under challenging circumstances, as the data used to inform this recommendation was collected in hospital settings during the COVID-19 pandemic.

Study Limitations

It is worth noting that this study has some limitations. Given the limited sample size and low statistical power, caution should be exercised when interpreting the results; it is important to consider these limitations in the context of its feasibility nature and the power calculation conducted for a future definitive trial. Another important consideration is that the 2 variables showing

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statistically significant differences between groups—grip strength and passive wrist flexion—had missing values in 19% and 14% of participants, respectively. These missing pretest values were imputed using the single imputation method of carrying the last observation backward. While this approach is widely used, it, as with all imputation methods, has inherent limitations. The COVID-19 pandemic had a significant impact on the trial, with different hospital policies for COVID-19 prevention and control, resulting in varying recruitment launch dates and the closure of one hospital's hand therapy service. This led to a significant reduction in the number of potential participants who met the inclusion criteria. In addition, the data collection was affected, as the trial was conducted over several months during the pandemic. A study by Ivy et al [23] investigated the pandemic's impact on hand therapy services; they reported a decrease in caseload for 98% of the 719 surveyed hand therapists, with 46% providing telehealth services. However, it is important to note that the impact of the pandemic on the results of this study may differ in a postpandemic world, where hand therapy services may have returned to prepandemic levels. Lastly, as no follow-up measurement points were incorporated in this study, the long-term effects cannot be determined; thus, the results are limited to their generalizability to the short-term.

Conclusions

To conclude, our study's findings suggest that it is feasible and acceptable to conduct a future definitive RCT to assess the effectiveness of the FEPSim device in improving impairments of the hand, wrist, and forearm. This trial had high retention and compliance, indicating that the therapists and participants from 2 hand therapy services agreed to incorporate the FEPSim in their hand therapy treatment. The FEPSim had a positive effect on grip strength, an objective measure of hand functioning. The device features appear instrumental in optimizing movement dosage, thereby potentially enhancing clinical outcomes in therapeutic interventions.

Acknowledgments

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Conflicts of Interest

None declared.

Checklist 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File, 1166 KB - rehab_v12i1e62809_app1.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
FEPSim: flexion, extension, pronation, and supination
ISRCTN: International Standard Randomized Controlled Trial Number
MCID: minimal clinically important difference
PRWE: Patient-Rated Wrist Evaluation
RCT: randomized controlled trial

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A Tablet-Based Technology for Objective Exercise Monitoring in Vestibular Rehabilitation: Mixed Methods Study

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Abstract

Background: A low-cost home exercise system called VestAid has been developed to assist participants during vestibulo-ocular reflex gaze stabilization exercises outside of clinic visits. The system includes a tablet-based app for the participant and a web-based portal for the physical therapist that provides data to make judgments about exercise accuracy and performance.

Objective: The purpose of this study was to assess the feasibility and acceptability of VestAid in a pilot study of 10 participants (mean age 45 [SD 19] years; 6 women) with various vestibular diagnoses.

Methods: All participants completed twelve 30-second horizontal vestibulo-ocular reflex exercises in a seated position (6 “easy” and 6 “hard” exercises). The exercises differed by variations in the background color, pattern, and movement. One of the exercises was repeated to assess the test-retest reliability of the measure of gaze stability accuracy and head motion compliance during the exercise. Participants rated the difficulty of the exercises (0 - 10 where 0=easy, 10=difficult) and completed usability surveys.

Results: Participants completed the VestAid session without adverse events. The responses from the usability survey demonstrate the acceptability of VestAid. The mean rating of the “easy” exercises was 2.7/10 (SD 1.9). The mean rating for the “difficult” exercises across participants was 4.8/10 (SD 2.1).

Conclusions: The consistency of the mean ratings of the participants with the exercise classifications (“easy” and “difficult”) suggests that VestAid has clinical utility.

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KEYWORDS

technology; rehabilitation; vestibular; physical therapy; vestibulo-ocular reflex; ocular; physiotherapy; vision; feasibility; exercises; mHealth; mobile health; app; tablet; digital health; telerehabilitation; e-health; web-based; clinical use; physiotherapist; home exercise; usability study; mobile app

Introduction

Completion of gaze stabilization, or vestibulo-ocular reflex, exercises, such as vestibulo-ocular reflex × 1 (VORx1), have been shown to improve vestibulo-ocular reflex gain and reduce dizziness [1-3]. Prescription of gaze stabilization exercises has also been linked to decreased risk of falls [4]. Current clinical practice guidelines recommend that people with vestibular disorders complete gaze stabilization exercises at a minimum of 3 times per day for a total of at least 12 - 20 minutes each day if they have difficulty with vision or dizziness with head movement [5,6].

A retrospective chart review of 104 participants referred to vestibular rehabilitation postconcussion found that eye-head coordination exercises were the most common exercise prescribed by vestibular physical therapists, with the most common frequency and duration being 3 times per day for 60 seconds [7]. To achieve the recommended dose for VORx1 exercise during vestibular rehabilitation, most of the exercises must be completed outside of the clinic without expert supervision, which prevents participants from receiving timely individualized feedback.

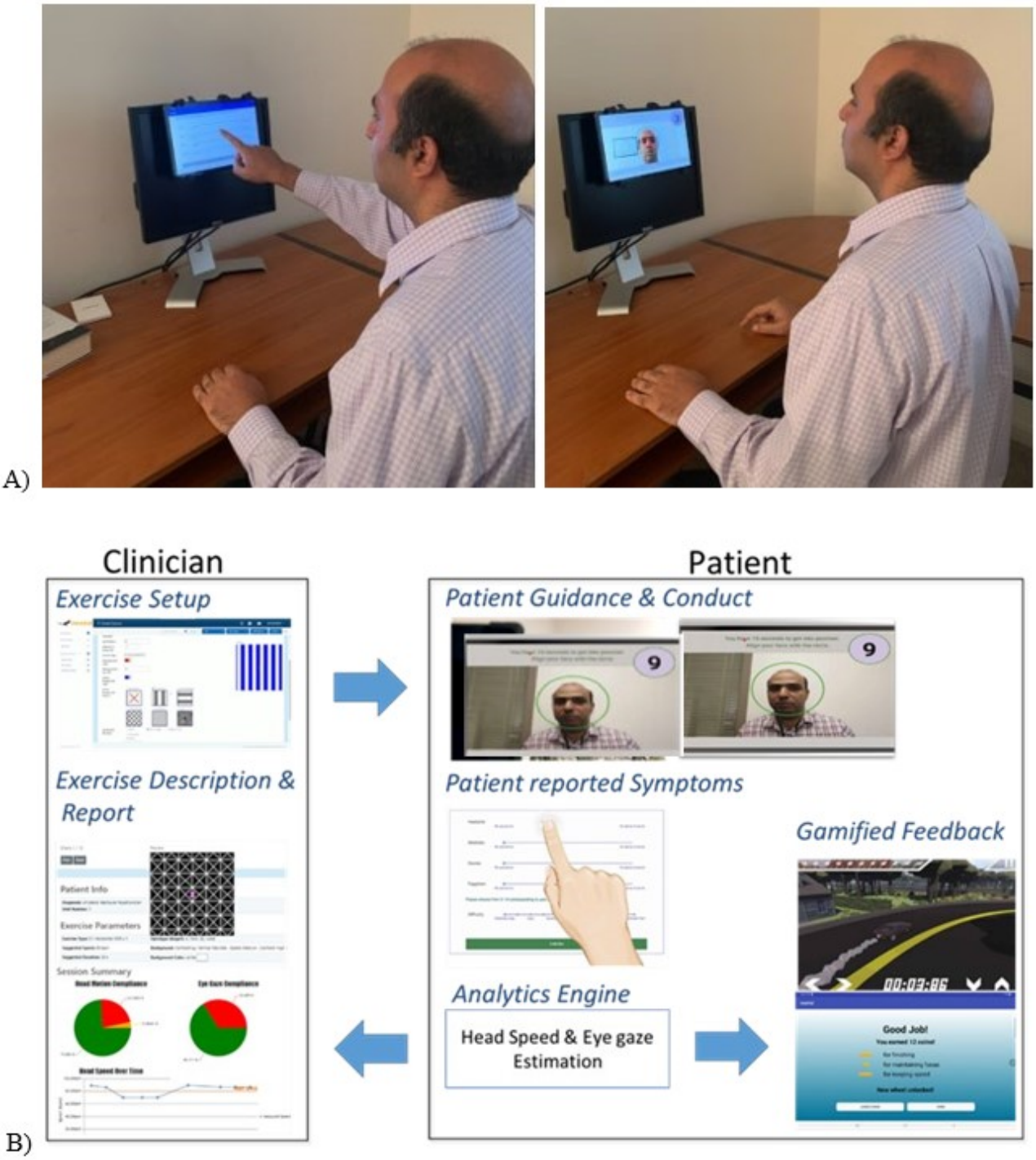
Determining VORx1 exercise compliance is challenging for rehabilitation professionals. In the clinic, evaluation of gaze compliance and head speed compliance may vary based on clinician experience, and there is currently no easy, objective method to record VORx1 exercise performance.

VestAid [8] is an innovative tablet-based app for home or clinic use to objectively track exercise compliance and provide VORx1 performance feedback to both the treating physical therapist and the participant (Figure 1). Video instruction helps participants recall how to do the VORx1 exercises and a metronome guides head speed during the exercises. With the

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tablet camera, facial and eye recognition software is used to analyze the accuracy of head and eye movement during the exercise. An unconstrained face detection method (where the face in the frame has arbitrary position and orientation variations) [9] combined with facial landmark detection and convolutional neural network models are used to determine the face image, refine landmark points (eye and nose positions), and capture face shape [8,10,11]. Head angles are computed using the filtered data from facial landmarks. A peak detection algorithm is used to determine head-speed compliance. The system classifies eye gaze direction as on- and off-target which is then used to determine eye-gaze compliance. The participant records their symptoms before and after each exercise which is then combined with the eye and gaze performance to provide feedback to the participant and the physical therapist.

Figure 1. VestAid tablet (**A**) and web portal (**B**).



While VestAid is thought to provide useful information to the participant and clinician, the feasibility and usability from a participant perspective is not yet known. The purpose of the study was to evaluate the usability of the VestAid technology from the perspective of the participant. Prior to using VestAid in a clinical trial, it was important for us to know whether the participants found the device easy and acceptable to use. We

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hypothesized that VestAid would be both feasible and acceptable to participants with dizziness who complete VORx1 exercises.

Methods

Participants

Ten participants receiving vestibular rehabilitation for dizziness were recruited in this single-site pilot study in a tertiary balance center. All participants were 18 y or older and were diagnosed with a vestibular disorder by a neurologist who specializes in otology. Participants were excluded if they had a baseline dizziness rating of >5 out of 10 on a verbal analog scale (with 10 being the worst imaginable dizziness), visual acuity worse than 20/40, loss of protective distal sensation, or less than 5 degrees of ankle dorsiflexion. Previous experience has shown that people with severe baseline dizziness might not be able to complete the study.

Ethical Considerations

Informed consent was obtained from all participants and the study was approved by the University of Pittsburgh Institutional Review Board (STUDY19050389).

VORx1 Exercise Description

Participants performed horizontal VORx1 (a yaw head movement exercise done at 80 beats per minute while focusing on a stationary target) for a total of 12 trials of 30 seconds each during the single study session. There was a 1-minute rest break between each trial and per study protocol, the next trial was not initiated until symptoms returned to baseline. The study team chose a standardized speed for this usability study and opted for a relatively slower speed that we felt all participants could complete. Twelve trials of 30 seconds provided a total of 6 minutes of gaze stabilization exercise during the study session. If the gaze stabilization exercise is completed 3 times per day as is recommended for vestibular hypofunction, the dose of 6 minutes in our study session is on target for the recommended daily dose for gaze stabilization exercises (3 times per day for 6 minutes equals 18 min of gaze stabilization).

Each exercise varied in difficulty level by manipulating the background colors, patterns, and movement of the visual scene. The study team classified 6 of the exercises as being “easy” and 6 as being “difficult.” The exercises were selected and classified as “easy” or “difficult” based on pilot testing with study team members and the clinical experience of the research team. Insights from both the pilot testing and the team’s clinical expertise informed the final categorization, supporting appropriate exercise selection for study participants. The background of the easy exercises had low color contrast with no movement whereas the more difficult exercises had higher color contrast, and all but one trial incorporated a moving background. The 6 easy exercises were completed first in a randomized order followed by a second group of 6 difficult exercises, also in randomized order. This design was planned as we were unsure if participants would tolerate the moving and busier backgrounds and we wanted to allow for adequate comparisons of exercises completed. All exercises were completed in the seated position with the tablet positioned 3 feet away from the participant. A minimum of a 1-minute rest was given between trials. The visual fixation gaze stabilization target was viewed on the tablet screen and the exercise was video-captured and recorded by the tablet. For all 12 exercises, the optotype of the target was a pink “X” with a 30-point font size. The background patterns and movement during the more difficult exercises differentiated “easy” exercises from the “difficult” (Figures 2 and 3).

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Figure 2. Background patterns of the easy vestibulo-ocular reflex × 1 (VORx1) exercises; background stationery for all 6 exercises.

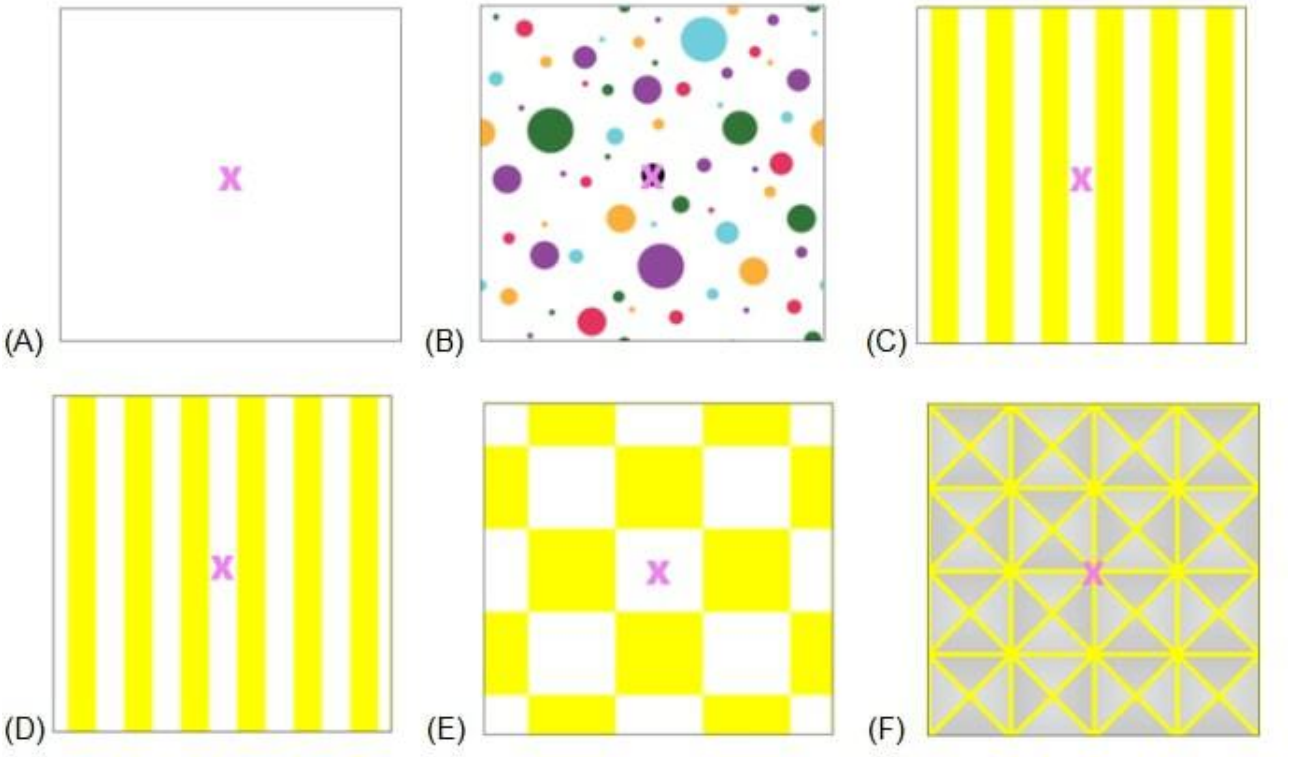
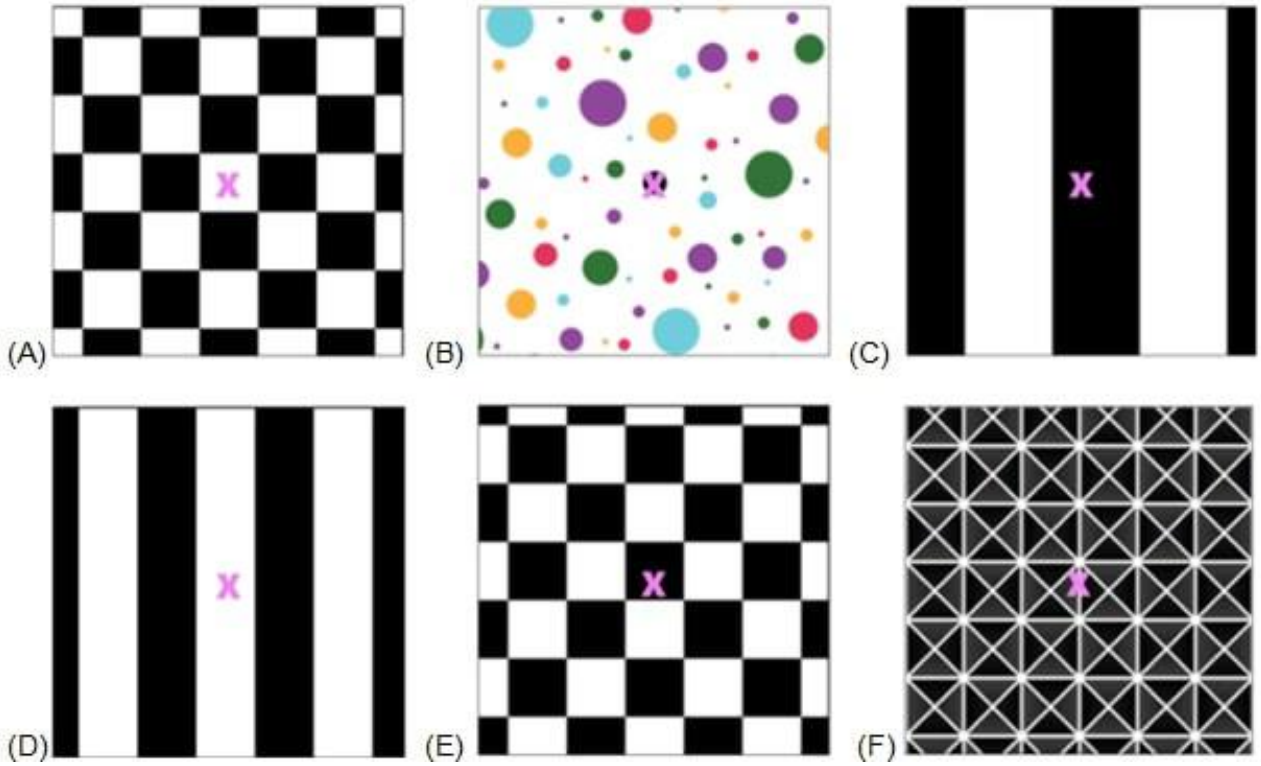


Figure 3. Background patterns and movements of the difficult vestibulo-ocular reflex × 1 (VORx1) exercises. Background movements are as follows: (A) stationary, (B) rotating clockwise, (C) moving left to right, (D) oscillating horizontally, (E) moving down to up, and (F) oscillating vertically.



Exercises are easily selected in the VestAid web portal for the desired parameters including exercise duration, head speed, target size, and background (type, color, stationary or moving speed, and direction of movement). The patient-facing tablet-based app provides written exercise instructions and an audible metronome to ensure proper head speed. Image-processing algorithms use facial recognition features from the camera in the tablet to track the patient's gaze fixation, head movement amplitude, and speed. VestAid estimates key parameters, including 3D head angles (roll, pitch, and yaw) and eye movements, in near real-time using advanced machine learning algorithms. Using these data, VestAid calculates

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compliance metrics for head and eye movements, such as the percentage of the exercise performed at the correct speed. Additionally, the app collects patients' pre and postexercise symptoms (dizziness, headache, nausea, and fogginess) along with their perceived difficulty of the exercise.

Data Collection and Analysis

All participants completed the Dizziness Handicap Inventory [12] prior to the initiation of the exercises. Participants completed a 0 to 10 visual analog score rating (where 0=no symptoms and 10=worst imaginable symptoms) of their dizziness, headache, nausea, and fogginess before and after each VORx1 exercise [13]. Additionally, after each VORx1 exercise, participants rated the difficulty of the exercise on a 0 to 10 visual analog scale (VAS) (0=no difficulty and 10=most difficult) [14]. After the participants performed all 12 VORx1 exercise trials, they were asked to complete a brief usability survey with a 10-point Likert scale to note their level of agreement with 10 statements and 6 open-ended questions. The usability survey was administered on paper and asked open-ended questions such as "What did you like most in the app?" and "What did you like least in the app?" Descriptive statistics and reliability analysis were conducted using SPSS (version 28; IBM).

Results

The 10 participants (6 females) had a mean age of 45.3 (SD 18.7) years and a mean Dizziness Handicap Inventory score of 41.4 (26.7) indicating moderate handicap due to dizziness on average (Table 1). The number of vestibular rehabilitation visits completed prior to the study session ranged from 1 to 15 (mean 6; median 5) and the vestibular diagnoses included: unilateral vestibular loss (n=4), vestibular migraine (n=3), postconcussion (n=2), and dizziness of unknown etiology (n=1).

Table . Participant demographics.

	Age (years)	Sex	Diagnosis	Vestibular physical therapy visits completed	Dizziness handicap inventory
1	31	Male	Vestibular Migraine	10	52
2	41	Male	Postconcussion	9	64
3	31	Male	Unilateral vestibular hypofunction	3	4
4	80	Male	Dizziness of unknown etiology	2	88
5	43	Female	Vestibular Migraine	1	26
6	27	Female	Postconcussion	3	28
7	70	Female	Unilateral vestibular hypofunction	7	30
8	52	Female	Vestibular Migraine	2	74
9	24	Female	Unilateral vestibular hypofunction	15	26
10	54	Female	Unilateral vestibular hypofunction	7	22

The changes in dizziness, headache, nausea, and fogginess are summarized below. There was a total of 120 exercises (10 participants each completed 12 exercises) and while symptoms often increased following the exercise trial, all participants returned to baseline within 1 minute of rest. Exercise difficulty ratings had variable distributions on the 0 - 10 scale (where 0=easy and 10=difficult). The recorded gaze stabilization and head speed compliance varied among exercises and participants. Participants were not provided feedback on the objective output from VestAid related to their gaze stabilization accuracy and head speed compliance. The distribution of difficulty ratings is illustrated in Table 2.

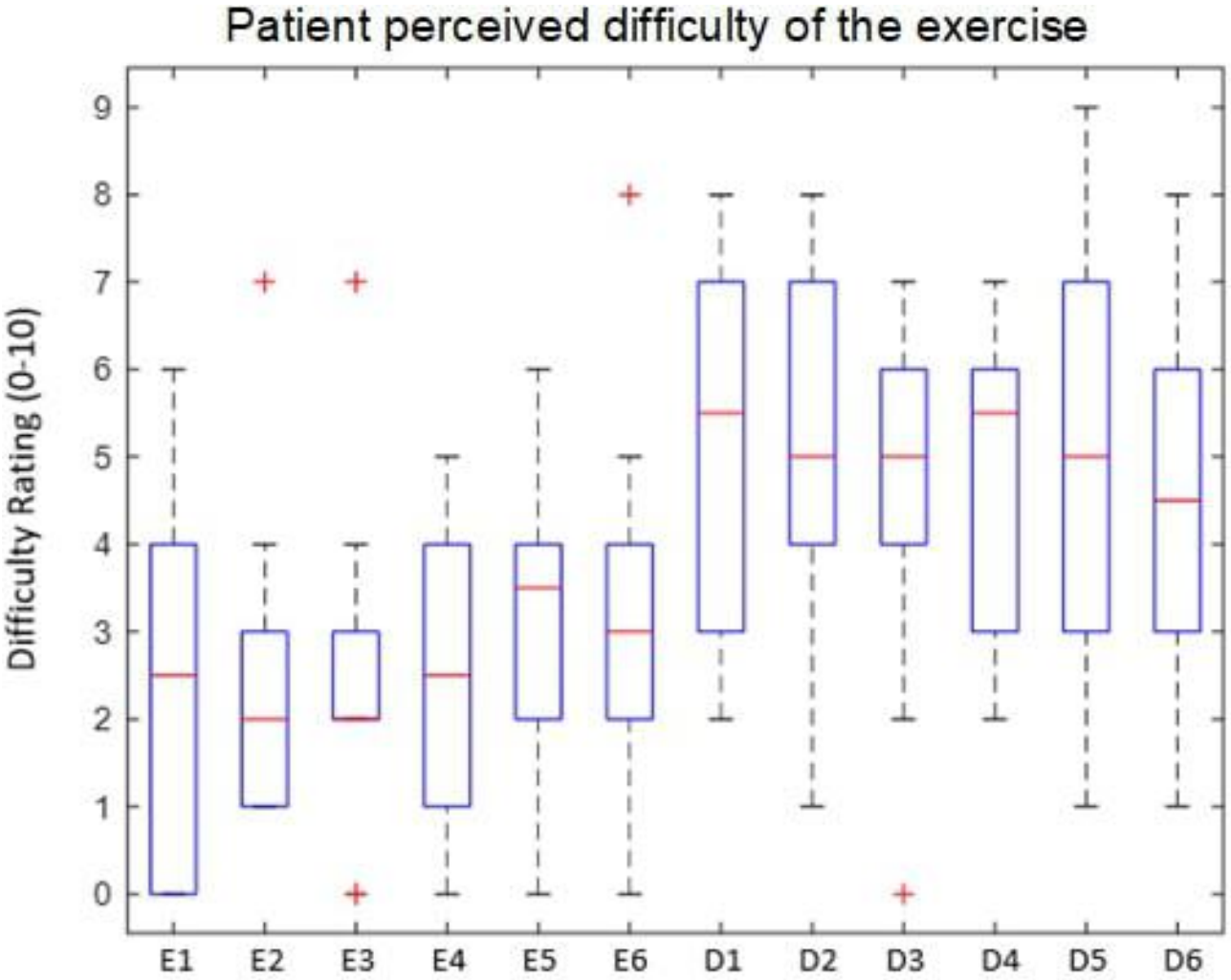
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Table . Frequency of reported exercise difficulty ratings for 120 exercises.

Reported difficulty rating (0 - 10)	Frequency, n
0	12
1	10
2	19
3	17
4	19
5	14
6	15
7	11
8	5
9	1
10	0

Prior to collecting data, physical therapists categorized 6 exercises as easy and 6 exercises as difficult. Figure 4 reveals that the participants rated the exercises categorized as difficult at higher difficulty ratings than those that were categorized as easy, validating the physical therapist's determination of exercise difficulty.

Figure 4. Participant perceived difficulty with the vestibulo-ocular reflex × 1 (VORx1) yaw exercises. D: difficult; E: easy



As illustrated in Table 3, 100% of the participants strongly agreed that the instructions were clear and VestAid was easy to use (usability study). Neutral responses were recorded from one respondent for statements about the size and color of the target being easy to see and the ease of rating the exercise difficulty. A common theme of "easy to use" was inferred from

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the responses to the question about what was liked most in the app from responses such as, “self-explanatory,” “user friendly,” “quick to navigate,” and “could be used at home.” The responses regarding what was liked least about VestAid included “user interface for reporting the symptom and difficulty rating” (n=5), “visual appeal of the user interface” (n=1), “metronome speed” (n=1), and “distance of tablet too far away” (n=1).

Table . Distribution of responses (n=10) to statements provided on the VestAid usability survey.

Statement	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The exercise instructional video was easy to understand.	—[a]	—	—	—	10
The exercise steps were easy to follow.	—	—	—	—	10
The size of the exercise target (the X) made it easy to see.	—	—	1	2	7
The color of the exercise target (the X) made it easy to see	—	—	1	2	7
The metronome sound made it easy to turn my head at the right speed.	—	—	—	1	9
It was easy to rate my symptoms using the scales.	—	—	—	5	5
It was easy to rate the difficulty of the exercises.	—	—	1	3	6
Thirty seconds of exercise was easy to complete.	—	—	—	3	7
The break between exercises was enough.	—	—	—	3	7
The exercises I did using the app were similar to ones I have done before.	—	1	—	4	5

[a]Not applicable.

Discussion

Principal Findings

In this study, participants with vestibular disorders were able to complete the gaze stabilization exercise trials using VestAid without adverse events or complaints. Our sample was heterogeneous which is representative of the range of patients that are seen in vestibular rehabilitation clinics. The study sessions were tolerated by the participants without any major increases in visual analog symptom ratings. Only 7% of the exercises caused a greater than 1-point increase in the VAS for symptoms of dizziness. Of the 7% of the exercises that caused greater than a 1-point increase in dizziness, all but one were exercises from the “difficult” category and the ratings were from 3 unique participants. Only 3%, 4%, and 6% of the exercises caused an increase of greater than 1 point on the VAS for headache, fogginess, and nausea respectively. This provides us with information that displaying the gaze stabilization target and background on an electronic tablet (compared with being displayed on paper) is feasible. In this study, we chose to use an optotype that was pink as it was visible against white, black, and yellow backgrounds. We currently do not know how contrasting colors impact the difficulty of a gaze stabilization exercise and future work should explore this research question.

Overall, the feedback from the participants was positive and VestAid was well received. Participants reported that performing exercises with moving backgrounds was more difficult than backgrounds that did not move, and they indicated that increasing the speed of the background made the exercise more difficult. Participants reported that the exercises were easy to perform and that the instructions were easy to understand. We believe that the speed of head movement (80 bpm) and the completing the exercises while seated contributed to the ability of all participants being able to complete all 12 trials which was a goal of our study. It is important for new investigations to explore the optimal ways to increase the challenge and difficulty of the exercise. The participant’s perceived exercise difficulty data combined with symptom rating and the objective information about head speed and gaze stability may have clinical utility in determining when exercises should be

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progressed, stay the same, or be made easier in future trials or sessions. While exercise prescription was not a goal of this study, the ease of inputting symptom ratings and perceived difficulty were important for our research question examining the acceptability and usability of VestAid.

Many barriers currently exist to the completion of gaze stabilization exercises at home. Inherent to all home exercise programs, the understanding of the exercise and the motivation to complete the exercises present barriers to completion. In a systematic review, Essery et al [15] identified factors that predict whether participants will adhere to physical therapy exercise programs. They reported that self-motivation, social support, self-efficacy, and previous adherence to physical therapy exercises were positively correlated with exercise adherence in the home. Not all participants adhere to physical therapy home-based programs without social support (including supervision and encouragement from friends, family, or a physical therapist) [15].

The VestAid vestibular exercises simulate supervised exercises because they provide the physical therapist with access to performance and symptom data. Recording and tracking exercise performance makes the participant accountable to the physical therapist, and this may increase exercise adherence with VestAid. Outside of the clinic, participants do not receive feedback as to whether they are successfully completing gaze stabilization exercises (ie, maintaining visual fixation on the target and moving their head at the correct speed). Additionally, it is difficult for physical therapists to discern whether participants are completing the exercise at the appropriate level of challenge outside of clinic visits. Programs such as VestAid can make it possible for physical therapists to track participant progress and provide feedback based on performance outside of in-person sessions.

There are regions of the world where access to specialized expert care is not available [16]. VestAid may assist in the telehealth management of people with vestibular disorders, similar to other conditions that physical therapists manage via telehealth [16-23]. Internet-based vestibular rehabilitation blended with face-to-face rehabilitation and in-clinic vestibular rehabilitation were superior to usual care which was provided by a general practitioner [23]. VestAid could be used exclusively via telehealth or via a blended telehealth and face-to-face vestibular rehabilitation program.

Acceptance of technology is a consideration with people with vestibular disorders. In a systematic review [24], older adults were more adherent to technology-based programs than traditional exercise programs when provided feedback. Using VestAid, exercises can be performed sitting or standing, depending on the clinician's judgment. There are obvious fall concerns with older adults performing balance exercises in the home unsupervised, so a clinician's judgment is required to ensure participant safety. In a recent meta-analysis of randomized trials on the effects of exercise on fall injuries, exercising older adults showed very low injury rates, and exercise compliance was good [25]. This meta-analysis [25] appears to support the use of at-home standing or sitting balance exercises as low-risk activities in older people with vestibular disorders.

Motivation and understanding of the exercise can impact the completion of gaze stabilization exercises at home. VestAid has the capability to monitor gaze stabilization exercise performance digitally and performance can be reviewed with the participant in face-to-face interactions. In older people post stroke, remotely connecting the physical therapist and the participant via technology improved exercise adherence [26]. Technology features within VestAid might motivate and promote adherence to the prescribed home exercise program. Additionally, technology has the potential to enhance the participant's understanding of how to complete their exercise program and should be explored in future work.

Future work should also explore the efficacy and effectiveness of using technology in vestibular rehabilitation. Clinical trials should investigate the optimal dose of gaze stabilization exercises and specific parameters that vary the challenge of the exercise [27]. Future work should also investigate the use of technology to progress or regress a customized vestibular exercise program based on symptoms, perceived difficulty, and objective performance with gaze stabilization accuracy and head motion compliance. The reliability of VestAid in recording gaze stabilization should be assessed. Additionally, the determination of acceptable scores for gaze stabilization accuracy (the ability of the eyes to stay focused on the target during VORx1 exercise) and head speed compliance (percentage of time that the head moves at the prescribed speed) need to be determined.

Conclusion

VestAid is feasible to use in a clinical setting and acceptable to people with vestibular disorders. By monitoring exercise performance and providing near-immediate feedback, the VestAid app may improve exercise compliance and increase motivation to complete home exercises. With access to detailed performance data, clinicians can better manage participant progression between visits, thus potentially optimizing vestibular rehabilitation outcomes and speeding recovery.

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the Army's position, policy, or decision unless so designated by other documentation. BNK is receiving grant funding from National Institutes of Health/National Institute on Deafness and Other Communication Disorders (#1K23DC020215-01).

Conflicts of Interest

One or more of the investigators conducting this research has a financial interest in “Intelligent Automation, a BlueHalo Company”, a company with rights to intellectual property being evaluated and developed as part of this study.

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Abbreviations

VAS: visual analog scale
VORx1: vestibulo-ocular reflex × 1

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Original Paper

Evaluation of a Game-Based Mechatronic Device for Rehabilitation of Hand-Arm Function in Children With Cerebral Palsy: Feasibility Randomized Controlled Trial

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Abstract

Background: Children with neurodevelopmental disorders, such as cerebral palsy (CP), often experience motor impairments in manual dexterity, which hinder daily tasks and social interactions. Traditional rehabilitation methods require repetitive task practice, which can be difficult for children to sustain due to low engagement. Game-based rehabilitation devices and robots offer a promising alternative by combining therapy with digital play, improving motivation and compliance. However, many systems fail to incorporate actual object manipulation, which is essential for motor learning through sensory feedback. To address this limitation, a low-cost, easy-to-use robotic manipulandum device (RMD) was developed. The RMD enables real-time object manipulation during gameplay while providing assistive force, allowing the practice of a wide range of manual dexterity skills beyond gross reaching. This system offers an engaging and effective rehabilitation approach to enhance hand function in children with CP.

Objective: This study aimed to provide evidence for the feasibility and therapeutic value of the RMD game–based exercise program for children with CP.

Methods: In total, 34 children with CP, aged 4 to 10 years, were randomly assigned to the experimental group (XG) or the control group (CG). The XG received a computer game–based exercise program using the RMD, focusing on object manipulation tasks, while the CG received task-specific training similar to constraint-induced movement therapy. Both groups received their respective therapy programs 3 times per week for 8 weeks. Semistructured interviews with parents and children, along with qualitative analysis, were conducted to evaluate their experiences with the exercise program. The following outcome measures were used: (1) the Peabody Developmental Motor Scale-2 (PDMS-2) grasping and visual-motor integration subtests and (2) the computer game–based upper extremity (CUE) assessment of manual dexterity.

Results: No dropouts occurred during the 8-week program. Both groups showed significant improvements in the PDMS-2 subtests (P<.001) and the CUE assessment of manual dexterity, including success rates (tennis ball: P=.001; cone: P<.001; medicine ball: P=.001; and peanut ball: P<.001) and movement errors (tennis ball: P=.01; cone: P<.001; medicine ball: P=.04; and peanut ball: P<.001). The XG outperformed the CG, showing greater improvements in PDMS-2 grasping (P=.002) and visual-motor integration (P=.01). In the CUE assessment, the XG demonstrated higher success rates (medicine ball: P=.001 and peanut ball: P=.02) and fewer movement errors (cone: P<.001). Parents reported an increase in the children's independence in daily tasks.

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Conclusions: This study demonstrates the feasibility, acceptability, and positive outcomes of the RMD game–based exercise program for improving hand function in children with CP. The findings support further research and development of computer game–assisted rehabilitation technologies.

Trial Registration: Clinical Trials Registry - India CTRI/2021/07/034903; https://ctri.nic.in/Clinicaltrials/pmaindet2.php?EncHid=NTc4ODU

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KEYWORDS

cerebral palsy; computer game–assisted rehabilitation; manual dexterity; repetitive task practice; robotic manipulandum

Introduction

Children with cerebral palsy (CP) often experience motor impairments in the upper extremity, particularly in manual dexterity [1,2]. These motor deficits make it challenging for children to handle and manipulate objects, which are essential for many daily life activities, play, and social interactions [3,4]. Such impairments in fine motor control can limit their independence and hinder participation in a variety of activities that require precision and coordination [5].

Traditional therapeutic approaches, such as constraint-induced movement therapy [6-8] and hand-arm bimanual intensive therapy [9,10], have been shown to be effective in improving hand-arm function through repetitive task practice (RTP). These therapies focus on task-specific exercises and a high volume of practice [11,12]. However, maintaining children's engagement in these therapies can be challenging due to the monotonous nature of the exercises, making it difficult to sustain motivation and adherence [13-15].

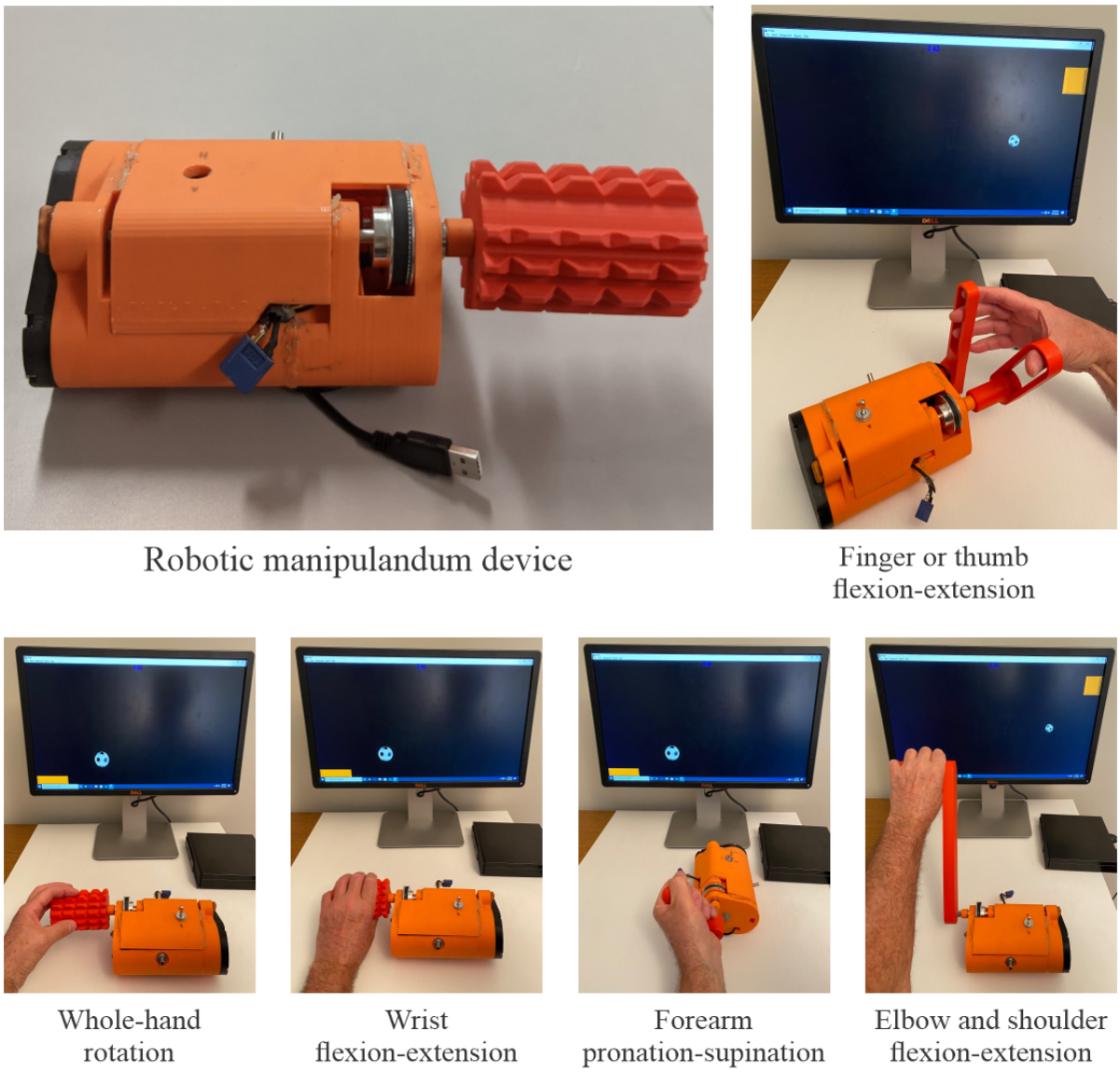
In recent years, there has been growing interest in integrating video games with rehabilitation programs to enhance engagement and motivation. These systems combine therapeutic exercises with digital gameplay, making the experience more enjoyable and encouraging adherence [16-18]. Devices like the Nintendo Wii, Kinect, Leap Motion, and inertial motion sensors have been used to track hand or arm movements and control digital avatars or objects in games [19-23]. Similarly, several studies have explored the effects of assistive robotic systems aimed at improving upper extremity function in children with CP. While many robots target the shoulder, elbow, and wrist range of motion [24-29], some focus on finger or thumb movements [30-32]. These systems use motion signals from robotic linkages (ie, body segment movements) to control digital avatars or manipulate a game paddle. However, both video game–based devices and robots often lack actual object manipulation, which provides critical tactile sensory information for detecting slip and maintaining stability, a key factor for effective motor learning [3,5,33-35].

To fill the gap in object manipulation, a game-based rehabilitation system using an inertial-based (IB) computer mouse was developed in previous studies, and its proof-of-principle was established [36-40]. The IB mouse is a miniature, wireless computer mouse that can be easily attached to any object, enabling interaction with video games through object manipulation [41]. This system allows children to practice manual dexterity tasks using real objects, with real-time feedback from video games. While effective for many children, this system does not provide movement assistance for those with limited active range of motion or poor motor control.

Taking the next step, a game-based robotic manipulandum device (RMD) was recently developed, which not only directly links object manipulation with computer games but also provides assistive force. As shown in Figure 1, the RMD consists of a small enclosure (15 cm by 10 cm by 8 cm) housing electronics, a motor, a controller, and a rotary drive shaft. A variety of 3D-printed handles of different shapes and sizes snap onto the RMD rotary drive shaft, as presented in Figure 1. These handles and their corresponding movements are designed to practice a broad range of manual dexterity skills involving (1) thumb or finger flexion-extension, (2) wrist flexion-extension and ulnar-radial deviation, (3) forearm pronation-supination, (4) elbow flexion-extension, and (5) shoulder flexion-extension and internal-external rotation. A microprocessor interfaces the RMD with computer games by reading the optical encoder on the shaft, which provides real-time angular position data to emulate mouse input. The angular position of the shaft (handle movement) is used to control the position and movement of the computer cursor or game sprite. This allows children to enjoy and engage with modern computer games, with varying levels of difficulty, speed, and accuracy, as part of a personalized exercise program. Many commercially available games also engage key visuomotor, perceptual, and cognitive skills. Specific therapeutic value can be derived from both the types of handles used (ie, different manipulation tasks) and the choice of computer games.

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Figure 1. General view of the robotic manipulandum device and examples of various handles used in game-based rehabilitation for manual dexterity.



The RMD can provide unidirectional assistive force during gameplay, with the motor programmed to apply a constant force to the output shaft in a single direction. Both the magnitude and direction of this force are configurable. For many children with CP affecting the upper extremity, finger and wrist function may be more impaired in 1 direction of motion, for example, limited extension. This limitation can prevent children from positioning and opening the hand to grasp objects of varying diameters. The force assistance of the RMD allows the child to make larger game movement responses, making the system accessible to children with very limited active range of motion or poor motor control.

The purpose of this exploratory randomized controlled trial (RCT) is to enhance the development of the RMD and provide evidence of the feasibility of conducting a full-scale RCT. The objectives were to evaluate the usability, acceptance of therapeutic value, and treatment effect size of an exercise program using a game-based approach with the RMD in children with CP. The hypothesis is that an upper extremity exercise regimen using the experimental intervention will result in equal or greater improvements in hand-arm function compared to the usual outpatient physical therapy program. In parallel with this quantitative analysis, a qualitative analysis was conducted to explore the experiences of the children in the study and investigate both the difficulties with the exercises and using the technologies as well as the engagement and motivational value of the computer games.

Methods

Ethical Considerations

The study was conducted in accordance with international standards of Good Clinical Practice. Ethics approval was obtained from the institutional ethical committee at Shri Dharmasthala Manjunatheshwara University, Dharwad, Karnataka, India (approval number: 2021/Physiotherapy/MPT/07). The study was registered with

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the Clinical Trials Registry - India (CTRI/2021/07/034903) before the onset of participant enrollment. Both parents and children were provided with a clear explanation of the study's objectives and methods. Written consent was acquired from the parents, while the children provided their assent to participate. All participants were informed of their right to opt out at any point without any repercussions. To ensure confidentiality, all data were anonymized, and no identifying information was published without explicit consent. No financial compensation was offered to the participants, and no images of the participants were included in the paper or any supplementary materials.

Participants

Children diagnosed with CP were recruited for this single-blind randomized clinical trial with an active control arm. For the full CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) V1.6 checklist, see Multimedia Appendix 1. Participants were recruited from the Pediatric Physiotherapy Outpatient Department of SDM College of Medical Sciences & Hospital.

Inclusion criteria included (1) children with a confirmed medical diagnosis of CP, a neurodevelopmental disorder, by a medical practitioner or pediatrician; (2) age 4-10 years; (3) Gross Motor Function Classification System (GMFCS) from levels 1 to 3 [42]; (4) Manual Ability Classification System (MACS) from levels 1 to 3 [43]; (5) Modified Ashworth Scale indicating spasticity in finger and wrist flexors rated from 1 to 1+ [44]; and (6) the pediatric version of the Mini Mental State Examination scored 17 and above [45].

Exclusion criteria included (1) visual or auditory impairment, such that they cannot see and interact with the computer; (2) secondary orthopedic complications due to the neurodevelopment disorder like fixed deformities of upper extremities; (3) recent botulinum toxin therapy (less than 6 months); (4) recent surgical intervention of upper extremity; (5) moderate or severe spasticity, that is, Modified Ashworth score of grade 2 and higher; (6) cognitive impairment; and (7) uncontrolled seizures.

All parents and children were informed about the purpose and protocol of the study before enrollment; written informed consent was obtained from parents and assent from the children. Successfully screened participants were randomized to the experimental group (XG) or the control group (CG) by choosing 1 sealed opaque envelope containing a letter signifying the group assignment. A graduate student not involved in the study produced the envelopes, which contained a letter for either the XG or CG. The envelopes were thoroughly shuffled before each selection.

Interventions

Participants attended 24 treatment sessions, 3 times a week for 8 weeks, at a university clinical rehabilitation research facility. Each session lasted 45 minutes.

Experimental Group

The experimental exercise program using the RMD was established based on the participants' personal goals, the degree of their hemiparesis, and functional status. Figure 1 shows a variety of 3D-printed "therapy" handles of different shapes and sizes that snap onto the RMD rotary shaft. These were designed to practice a broad range of hand function skills. A typical session involved exercises with 4-5 different handles, several computer games, and assistive forces of different magnitudes. Each handle-game-force combination was practiced for 2- to 3-minute intervals and repeated 2-3 times. Different handles required different modes of manipulation, that is, game movement responses produced by thumb, finger, wrist, forearm or elbow, and shoulder movements. Task demands were adjusted by changing mouse sensitivity, movement range, etc. Different games were also selected to adjust movement speed and precision. Progression was achieved by using a variety of commercial computer video games. Many readily available and inexpensive computer video games have therapeutic value. For example, the commercial internet website "Big Fish" games contains hundreds of arcade-style computer games in several genres, many of which are appropriate for the game-based RMD exercise program. In addition to speed, target, and accuracy movement requirements, these games include several cognitive elements, such as games with different types of distractor objects to avoid, matching activities, and those that require ordering objects. See Multimedia Appendix 2 for several examples of commercial computer games from the Big Fish website, which were used in this study. These computer video games offer sufficient diversity to appeal to a broad range of individual preferences. Progressing the difficulty levels regularly and introducing different computer video games to sustain the challenge and provide new experiences will facilitate the psychological feedback required to maintain interest and participation.

Control Group

This included a goal-directed, physical therapy program. The protocols were based on RTP-based principles of modified constraint-induced movement therapy and hand-arm bimanual intensive therapy for fine and gross motor skills. Training tasks were individualized for every child according to their level of impairment and preset goals. Individualized exercises such as reaching for objects, removing rings and putting them back, ball throwing (under and overarm), turning a doorknob, clay activities, picking marbles from sand, putting pellets, rings, and pegs into sockets, opening bottle caps, manipulating objects such as a toy car, crumbling paper, hand-arm bimanual activities such as holding the ball with both hands and transferring, rolling bolster, writing, and self-feeding were chosen as part of the conventional protocol in a one-on-one therapy session.

Quantitative Analysis

The following outcome measures were obtained prior to and following the 8-week intervention.

Computer Game–Based Upper Extremity Assessment of Manual Dexterity

A miniature, wireless IB computer mouse (Therapy Mouse, Mobility Research) was secured to 4 test objects with different physical properties and functional demands. When the IB mouse is attached to a "test" object, the manipulation of the object is

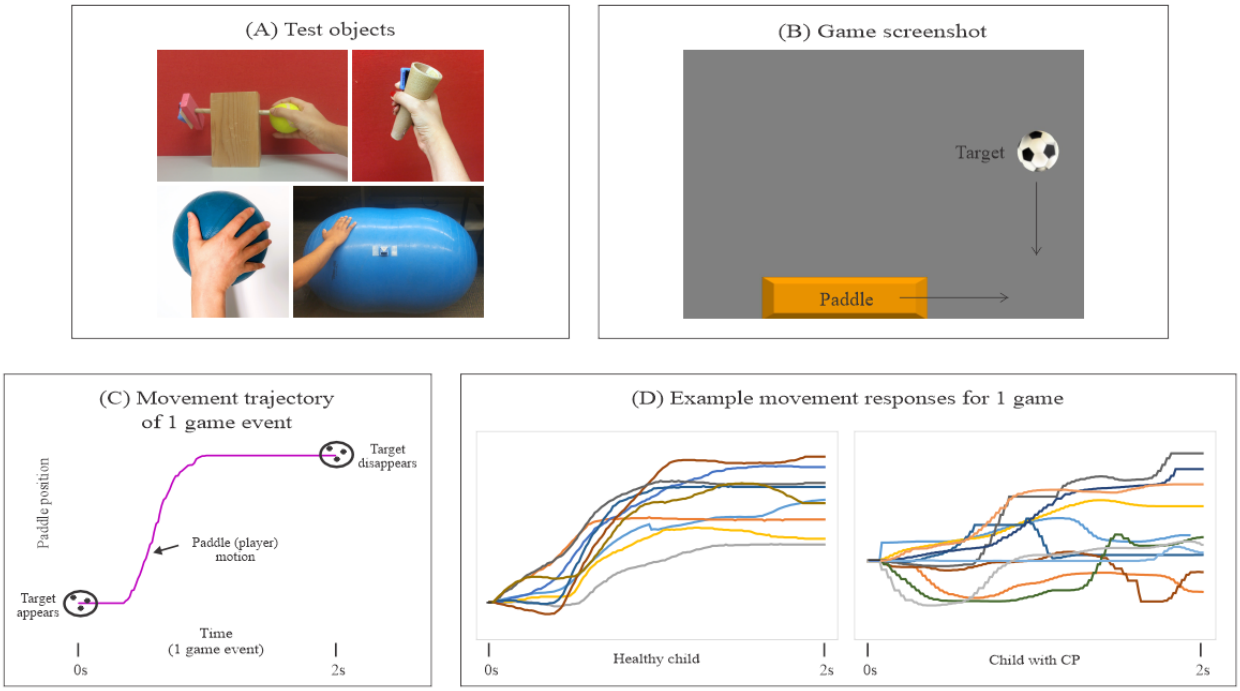
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used to control the motion of a game paddle of a purpose-built rehabilitation assessment application. For a full description of the computer game–based upper extremity (CUE) assessment, data recording, and analysis, see references [5,29,32].

Figure 2A presents the features of the four test objects:

1. Tennis ball rotation: It is a simple crafted object consisting of a wooden block and dowel. A hole was drilled in the wooden block and the wooden dowel was inserted. The IB mouse was attached to one end of the wooden dowel, and the other end was inserted into a tennis ball. Children grasped the tennis ball between their thumb and fingers and rotated the ball leftward and rightward to move the game paddle during gameplay.
2. Cone: The children grasped the cone and used pronation and supination to move the game paddle during gameplay.
3. Medicine ball (20 cm diameter): The children placed their hands on top of the medicine ball and used ulnar and radial deviation to rotate the ball and move the game paddle during gameplay.
4. Peanut ball: The children placed their hands on top of the peanut ball and moved it forward and backward using a combination of elbow flexion-extension and shoulder flexion-extension during gameplay.

Figure 2. Illustration of the computer game–based upper extremity assessment setup and data recording. Panel (A) displays 4 pictures of different test objects, each instrumented with an inertial mouse. Panel (B) shows a screenshot of the computer game–based upper extremity assessment game, featuring the target object (computer-controlled) and the game paddle (controlled by the rotation of the tennis ball). Panel (C) presents a single game movement trajectory (game paddle coordinates) for 1 game event, from target appearance (time 0) to target disappearance (time 2 seconds). Panel (D) depicts overlay plots of segmented and sorted game movement trajectories for a 60-second game trial. The plots illustrate the rightward rotation of the tennis ball, with the left plot showing data from a healthy child and the right plot representing data from a child participating in this study. CP: cerebral palsy.



A custom-designed rehabilitation assessment game, the RTP game software developed by the University of Manitoba, was used to evaluate the object manipulation tasks. The children were seated at a table with adjustable height. The test objects were placed on the table at a comfortable reaching distance. A standard computer monitor was used to display the RTP computer game tasks. The monitor was placed 1 meter in front of the children at eye level.

As illustrated in Figure 2B, a game target object (soccer ball) appears at the top edge of the display and moves to the bottom edge of the display. When the target object reaches the bottom, it disappears. The children were instructed to rotate the IB mouse on each of the 4 test objects to control the game paddle and catch the moving target object. Each game event from target appearance to its disappearance took 2 seconds. Each game trial was 60 seconds in duration; therefore, 30 game movement responses were obtained for analysis, with half of the game movement responses in each direction. The position of each successive target appearance was randomized. The RTP game software logs the coordinates of the game paddle (object rotation) and target game objects at 100 Hz for offline analysis.

Figure 2C presents the trajectory of a typical single game movement response. Figure 2D presents overlay plots of all game movement responses in 1 direction for 1 game trial. In this illustration, when using the cone as the game controller in the right hand, upward traces (rightward paddle movements) would represent supination.

The following outcome measures of structure and function were derived from the recorded game movement responses of each test object manipulation task:

- Success rate: It is the percentage of the total number of target objects that were caught in 1 game trial.

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- Movement error: When a target is missed, the magnitude of the error (distance between paddle and target position) is calculated. The average value for all misses is then computed as the movement error. Units are the percentage of screen width.

The CUE assessment has shown moderate to high test-retest reliability [32].

Two Subtests of the Peabody Developmental Motor Scale-2

The two subsets of the Peabody Developmental Motor Scale-2 (PDMS-2) are as follows: (1) grasping subtest includes 26 items that measure a child's ability to use their hands and (2) visual-motor integration (VMI) subtest includes 72 items measuring a child's ability to use visual perceptual skills. Both the PDMS-2 grasping and VMI subtest scores have shown high test-retest reliability and good construct validity [46,47].

Qualitative Analysis

Upon completion of the 8-week exercise program, parents and children enrolled in the XG were invited to participate in an interview. The following open-ended questions were asked of all participants, and their responses were recorded: (1) When you agreed to participate, how did you hope your child would benefit from the therapy program? (2) What did you like about the therapy program? (3) What was challenging about implementing the therapy program for your child and you? (4) What did you think about the exercises or games or RMD your child was asked to perform? (5) How did your child respond to the exercises or games? Was there any exercise that your child did not seem to enjoy? (6) Would you want your child to continue with the same type of therapy program? Why or why not?

Parents and children who participated in the interviews were requested to share their ideas, thoughts, opinions, and personal experiences. The inductive analytical framework of interpretive description was used for qualitative analysis [17,48].

A staff physiotherapist who was blinded to the intervention conducted all the interviews. Interviews were conducted in the local preferred language (Kannada or English), and audio recordings were later transcribed into a written format. Transcripts were translated professionally, and then one researcher developed the thematic system by coding and categorizing the written transcripts of each interview. A second researcher reviewed the categorized data, identified any additional unique responses, and finalized the codes organized into final themes and subthemes.

Statistical Analysis

Descriptive statistics, including means, 95% CIs, and percentages, were used to summarize demographic variables and outcome measures. The Shapiro-Wilk test was used to assess the normality of the data [49]. Comparisons between groups were evaluated using the independent samples 2-tailed *t* test for continuous variables and the chi-square test for categorical variables. To analyze the effects of time (pre- to postintervention), group (XG and CG), and the time×group interaction on the CUE assessment, PDMS-2 grasping, and VMI, a mixed model ANOVA with repeated measures was used. Effect sizes for the ANOVA were computed using η^2, with the thresholds for small, moderate, and large effects defined as 0.01, 0.06, and ≥0.14, respectively, following Cohen guidelines [50]. All statistical analyses were conducted using SPSS (version 24; IBM Corp).

Results

Overview

The recruitment target of 34 children was achieved within 8 months. All enrolled children completed both pre- and postassessments and attended all exercise sessions, resulting in a compliance rate of 100%. There were no adverse events or technological issues reported during the exercise programs. These findings demonstrate excellent feasibility. Figure 3 presents the CONSORT (Consolidated Standards of Reporting Trials) diagram, illustrating the participant flow throughout the study.

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Figure 3. CONSORT (Consolidated Standards of Reporting Trials) diagram for the randomized clinical trial.

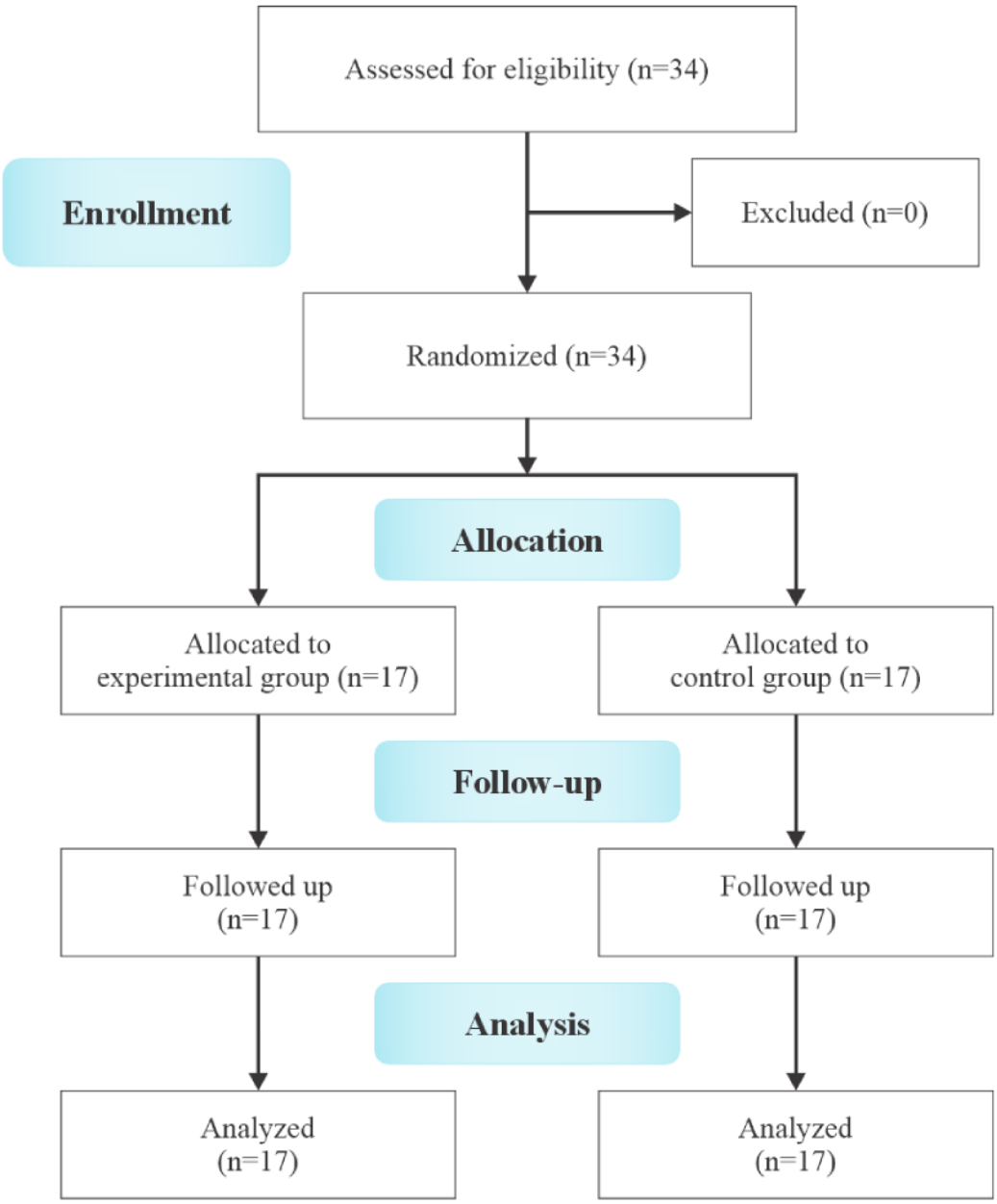


Table 1 presents demographic and clinical data categorized by group. The data were normally distributed, and there were no significant differences between groups at baseline in terms of age, sex, height, weight, GMFCS or MACS level, or treated hand. The majority of children were classified as GMFCS level II and MACS level II. The XG exhibited significantly higher scores in PDMS-2 grasping and VMI compared to the CG.

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Table 1. Demographic and clinical data.

	XG[a] (n=17)	CG[b] (n=17)	*P* value[c]
Age (years), mean (SD)	7.2 (2.8)	8.4 (2.5)	.21
Height (cm), mean (SD)	112.2 (14.7)	120.1 (18.9)	.19
Weight (kg), mean (SD)	19.6 (5.8)	23.5 (10.4)	.18
Sex, n (%)			>.99
Female	8 (47)	8 (47)	
Male	9 (53)	9 (3)	
Treated hand, n (%)			.28
Left	3 (18)	2 (12)	
Right	12 (71)	15 (88)	
Left and right	2 (12)	0 (0)	
GMFCS[d], n (%)			.42
Level I	2 (12)	5 (29)	
Level II	11 (65)	8 (47)	
Level III	4 (23)	4 (23)	
MACS[e], n (%)			.21
Level I	6 (35)	6 (35)	
Level II	9 (53)	5 (29)	
Level III	2 (12)	6 (35)	
PDMS-2[f] grasping, mean (SD)	45.7 (5.2)	39.5 (7.3)	.01
PDMS-2 VMI[g], mean (SD)	115.7 (19.4)	87.1 (19.3)	.001

[a]XG: experimental group.

[b]CG: control group.

[c]Statistical significance was assessed using the independent samples 2-tailed *t* test for continuous variables (age, height, weight, PDMS-2 grasping, and PDMS-2 VMI) and the chi-square test for categorical variables (sex, treated hand, GMFCS, and MACS) to compare differences between the XG and the CG.

[d]GMFCS: Gross Motor Function Classification System.

[e]MACS: Manual Ability Classification System.

[f]PDMS-2: Peabody Developmental Motor Scale-2.

[g]VMI: visual-motor integration.

Tables 2 and 3 present the ANOVA results for success rate and movement error, respectively, analyzing the effects of time, group, and the time×group interaction. Figure 4 illustrates line plots of group means and 95% CIs before and after the intervention for success rate and movement error. Significant time and group effects were observed with moderate to large effect sizes across all 4 object manipulation tasks. Figure 4 highlights greater improvements in success rate and movement error for the XG compared to the CG, particularly evidenced by significant interaction terms in 3 of 4 object manipulation tasks for success rate and 2 of 4 tasks for movement error.

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Table 2. ANOVA results for time, group, and the time×group interaction on success rate.

Test objects	Time of the assessment (within-group)			XG[a] vs CG[b] (between-group)			Time×group		
	F test (*df*=1)	*P* value	η^2	*F* test (*df*=1)	*P* value	η^2	*F* test (*df*=1)	*P* value	η^2
Tennis ball	12.66	.001	0.28	30.77	<.001	0.49	1.50	.23	0.05
Cone	17.11	<.001	0.35	21.73	<.001	0.40	3.93	.056	0.11
Medicine ball	12.07	.001	0.27	10.74	.003	0.25	13.74	.001	0.30
Peanut ball	18.13	<.001	0.36	8.85	.006	0.22	6.11	.02	0.16

[a]XG: experimental group.

[b]CG: control group.

Table 3. ANOVA results for time, group, and the time×group interaction on movement error.

Test objects	Time of the assessment (within-group)			XG[a] vs CG[b] (between-group)			Time×group		
	F test (*df*=1)	*P* value	η^2	*F* test (*df*=1)	*P* value	η^2	*F* test (*df*=1)	*P* value	η^2
Tennis ball	7.11	.01	0.18	6.68	.02	0.17	3.62	.07	0.10
Cone	18.42	<.001	0.37	8.62	.006	0.21	26.40	<.001	0.45
Medicine ball	4.49	.04	0.12	63.02	<.001	0.66	0.10	.75	0.003
Peanut ball	24.83	<.001	0.44	17.23	<.001	0.35	2.16	.15	0.06

[a]XG: experimental group.

[b]CG: control group.

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Figure 4. Group means and 95% CIs of success rate and movement error for the 4 test objects before and after the intervention. Solid line indicates XG, and dashed line indicates CG. CG: control group; XG: experimental group.

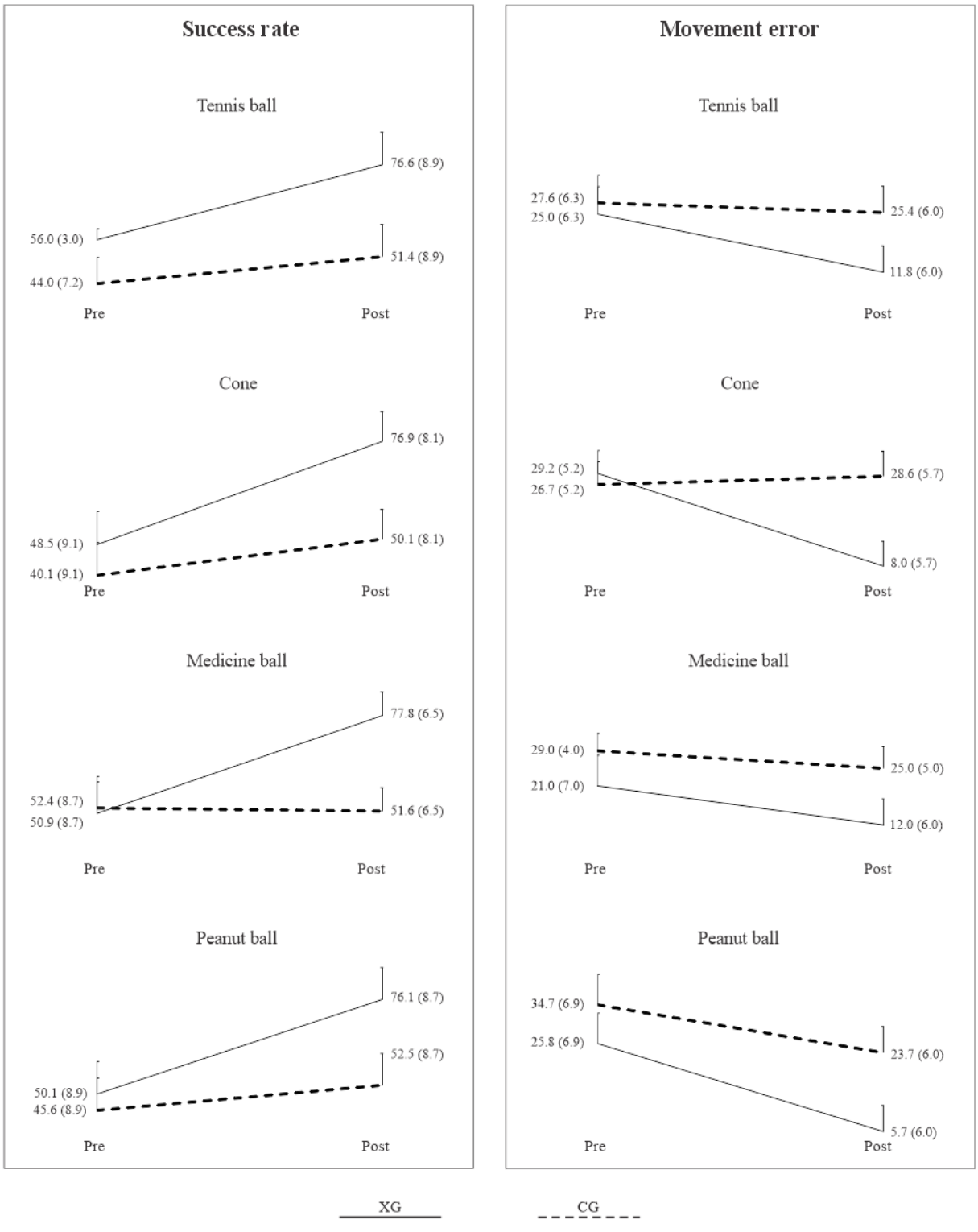


Table 4 displays ANOVA results for the grasping and VMI subtest scores, examining time, group, and the time×group interaction effects. Significant effects of time, group, and the time×group interaction were observed for both PDMS-2 grasping and VMI test scores. Figure 5 depicts line plots of group means and 95% CIs before and after the intervention for these scores. It illustrates significantly greater improvements in PDMS-2 test scores for the XG compared to the CG, accompanied by moderate to large effect sizes indicating substantial improvements from pre- to postintervention assessments.

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Table 4. ANOVA results for time, group, and the time×group interaction on Peabody Developmental Motor Scale-2 (PDMS-2) subtest scores.

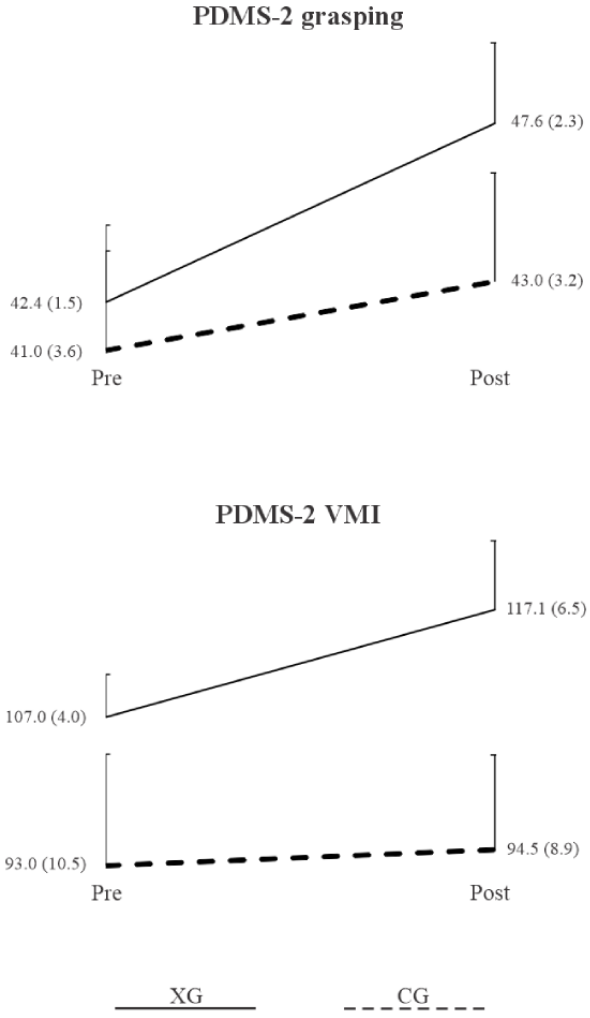
PDMS-2 subtests	Time of the assessment (within-group)			XG[a] vs CG[b] (between-group)			Time×group		
	F test (*df*=1)	*P* value	η^2	*F* test (*df*=1)	*P* value	η^2	*F* test (*df*=1)	*P* value	η^2
Grasping	132.26	<.001	0.81	6.51	.02	0.17	11.87	.002	0.28
VMI[c]	43.68	<.001	0.59	26.31	<.001	0.46	7.28	0.01	0.19

[a]XG: experimental group.

[b]CG: control group.

[c]VMI: visual-motor integration.

Figure 5. Group means and 95% CIs of PDMS-2 subtest scores before and after the intervention. Solid line indicates XG, and dashed line indicates CG. CG: control group; PDMS-2: Peabody Developmental Motor Scale-2; VMI: visual-motor integration; XG: experimental group.



Qualitative Analysis

Overview

In total, 10 parents and children from the XG agreed to participate in interviews following the 8-week intervention. The following 5 themes captured the range of parents' and children's experiences and opinions about their child's exercise program. Textboxes 1-5 present parents' direct quotes for each theme.

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Textbox 1. Parent quotes on issues encountered.

"We didn't face any type of problem during the therapy, although my child had faced little challenging at first while playing the games, he didn't understand the idea of gaming, but later he got to know how to play properly" [Parent 1].

"Some games involved one more person to assist the game as in to release the ball or bird to start the game, if even simpler games were included in treatment where child can only start the game and play easily would be really helpful" [Parent 5].

"Can improvise games, can add other interesting games specially cartoon ones which they watch regularly on TV, this will help them in playing the games even more interesting" [Parent 6].

"There were no serious problems faced, but my child had little issues with holding the handles properly, he had no idea about how exactly to hold the handles to move them to play. The main device keeps sliding a little while playing, so one person had to always hold the main device so that child can play without any problem, if the device can be fixed in one place or with better grip below it would be nice" [Parent 7].

"My child had difficulty in understanding what movement she should perform to play the games, such as catching the fish, she had little confusion with moving the handles left and right" [Parent 8].

"My child had difficulty in understanding the rules of the game" [Parent 9].

Textbox 2. Parent quotes on expectations for therapy outcomes.

"I thought that my child will be able to do hand movements better and she will get better" [Parent 3].

"I hope that his concentration, eye hand co-ordination may improve with this therapy" [Parent 4].

"I thought that my child's hand movements will improve also concentration will improve which will help him to use laptop" [Parent 5].

"I thought that my child's mind will get sharp, she can see properly with her eyes while playing" [Parent 6].

"I thought that my child's hand will get stronger with the help of this therapy" [Parent 7].

"Initially I have not predicted that this kind of therapy could help the child as I have no idea about this computer based therapy but later on I realized its very nice as it is based on game as well as work on multiple approaches in improvement by hand movement with eye co-ordination" [Parent 9].

"I thought because of this game therapy my child's concentration would improve" [Parent 10].

Textbox 3. Parent quotes on motivation and engagement with the computer game–based protocol.

"My child cries a lot while doing exercises, she would come to therapy after saying that she will be allowed to play computer games, because of this her therapy also used to happen. This I liked very much" [Parent 3].

"It's more interesting for children, my child is doing very interestingly and happily, it helps to improve concentration and eye- hand co-ordination. My child was playing happily, he likes the fish game most" [Parent 4].

"My child used to do other exercises fast while thinking that he is playing games which I liked and, he was playing games very enthusiastically" [Parent 5].

"If she plays computer games, her mind will get sharp. She got to know that what fish, ball birds look like, and she used to play well with happiness" [Parent 6].

"I liked that because of this computer game therapy my child's hand improved, she started using her hands for doing activities like to draw lines, coloring etc., which I liked about this therapy so much. She played well, she started to learn to play better later, and my child played all the games well" [Parent 7].

Textbox 4. Parent quotes on improvements in hand function and eye-hand coordination.

"I feel technology is useful. It will help to improve my son's hand problems and I liked it" [Parent 1].

"My child was not watching TV much, so I thought because of this computer games she might develop interest in watching TV and that her hand will gain strength and get better" [Parent 3].

"I liked that because of this computer game therapy my child's hand improved, she started using her hands for doing activities like to draw lines, coloring etc., which I liked about this therapy so much" [Parent 7].

"At first my child was feeling very difficult to play the games, later he improved better, hence I was satisfied. Now he is using his hand better than before" [Parent 8].

"This therapy program basically improves the eye co-ordination with hand movement. It is nice therapy as it is done in game manner" [Parent 9].

"I thought because this game my child's hand movement will improve this I liked very much. we can implement this technology based treatment for children, now my child is making his hand straight while playing games" [Parent 10].

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Textbox 5. Parent quotes on suggestions for future implementation of computer game–based therapy.

"If we could make them play for more time it would benefit them even more, this treatment should be added to regular exercise regimen" [Parent 1].

"My child had difficulty in understanding the speed and technique of the game at first and was not playing that well at first, which was the difficulty" [Parent 2].

"Some games involved one more person to assist the game as in to release the ball or bird to start the game, if even simpler games were included in treatment where child can only start the game and play easily would be really helpful" [Parent 3].

"Can improvise games, can add other interesting games specially cartoon ones which they watch regularly on TV, this will help them in playing the games even more interesting" [Parent 4].

"Kids who need this kind of treatment will be benefitted well, hence this treatment should be available to as many children as possible" [Parent 5].

"My child enjoyed playing games, but when my child was not well or due to some other issues when we were not able to go to therapy problem, my child would really miss this treatment, so if this game device was available for purchase it would really help" [Parent 6].

"If it could play for a greater number of times it would be even more helpful" [Parent 7].

"My child had difficulty in understanding the rules of the game" [Parent 8].

Issues

Parents found the computer game–based platform promising; however, they noticed that children initially found it hard to understand how the RMD device works and how to play games while using it. The RMD allows only 1 degree of freedom in any movement being practiced. The protocols for children were planned to repetitively practice challenging movements while performing a goal-directed task.

Parents' Expectations

All parents participated in the study with the expectation of improvement in hand function for their child. Most parents also expected improvements in eye-hand coordination and better concentration. Due to socioeconomic barriers, 2 parents also hoped that their child would get better exposure to computers. A few parents hoped that the computer game–based protocol would motivate their child to stay focused during therapy sessions.

Motivation

All 10 parents and children found the computer game–based protocol engaging, challenging, and extremely motivating. All 10 parents would like the computer game–based protocol to continue as regular therapy and suggested that the games should be incorporated in more ways during therapy. Children responded well to the types of games chosen for their individualized protocols; however, it was necessary to use a wide variety of games to maintain their interest in the protocol.

Improvements in Hand Function and Eye-Hand Coordination

All 10 parents observed improvements in their child's hand function and eye-hand coordination, consistent with the quantitative data. Many parents also noticed positive changes in their child's overall level of participation in daily activities and their ability to concentrate on tasks.

Plans for Future

Parents observed that there was difficulty in the initial stages of their child's participation and understanding in the computer game–based therapy program. However, after crossing the learning curve, children found the protocol engaging and fun. They suggested that this protocol should be available more frequently in clinical settings or at home to facilitate continuous improvement.

Discussion

Principal Findings

This study demonstrated the feasibility and therapeutic benefits of a game-based RMD for improving manual dexterity in children with CP. Both the XG and the CG showed significant improvements in the PDMS-2 subtests and the CUE assessment of manual dexterity. In addition, the XG outperformed the CG, with greater improvements in PDMS-2 grasping and VMI as well as higher success rates and fewer movement errors in the CUE assessment. Additionally, parents reported an increase in their children's independence in daily tasks, reflecting the positive impact of the game-based exercise program on functional hand use.

The RMD's design and functionality are crucial to achieving the observed therapeutic benefits. Various handles of different sizes and shapes were used, which could be handled with a 2-finger grip, 3-finger grip, or whole-hand grasp, and manipulated during gameplay using thumb-finger motion, wrist motion, or a combination of elbow and shoulder motions. Both the types of handle motions and the choice of computer games have specific therapeutic value. Many inexpensive commercial computer games that can be played with the RMD require different levels of movement amplitude and precision, that is, speed and accuracy. Regular introduction of new games and progression through difficulty levels are crucial to maintain the interest and participation of the children.

Several researchers and clinicians emphasize the importance of high repetition and task-specific training in facilitating the recovery of hand function [12,51,52]. One main feature of the RMD game–assisted exercise program was to increase the number of repetitions of goal-directed movements, that is, graded speed and accuracy. Each game was played for 2-3 minutes, with each game event lasting approximately 2 seconds, resulting in 60-90 goal-directed game movement responses per game. Typically, each child played several computer games for 30 minutes. Thus, during each exercise session, the children

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made several hundred game movement responses. This high number of repetitions involved goal-directed, precision movements with random directions, variable amplitudes, and speeds. Additionally, visual feedback of the game paddle relative to various moving game objects was always available. Continuous visual feedback guided the position and motion of the game paddle or sprite rather than the object being manipulated. This type of practice promotes implicit learning of eye-hand coordination [53,54].

Initially, children with severe impairments succeeded in games that involved slow movements and low precision, such as large paddle sizes, large game target objects, few distractor objects, and limited cognitive demands. Children with moderate to mild impairment could engage in a larger variety of games that had faster movement speeds, greater movement precision, and added cognitive demands.

There are no published reports that have calculated the minimal clinically important difference (MCID) for either grasping or VMI subtests. However, the MCID for the total motor quotient has been reported to be 8.3% [55]. In this study, the percentage improvement in grasping and VMI subtests for the XG was 12% and 9.3%, respectively, exceeding the MCID reported for the total motor quotient. The improvements observed for the XG were significantly greater than those observed for the CG, that is, 4% for grasping and 2% for VMI. In the previous study [3], a randomized clinical trial evaluated the effects of a game-based exercise program using an IB computer mouse on manual dexterity in young children with CP aged 4-10 years. The CG received task-specific training similar to that used in constraint-induced movement therapy. Each group received 16 weeks of therapy, 3 times per week. They observed an 18% improvement in PDMS-2 grasping and a 12% improvement in PDMS-2 VMI for the group that received the game-based exercise program. Improvement in the CG was 12% for PDMS-2 grasping and 9% for PDMS-2 VMI. In the previous study [3], the intervention lasted 16 weeks, twice as long as the duration of this study. This discrepancy likely explains the variation in percentage improvement observed in grasping and VMI between the 2 studies: 18% versus 12% for PDMS-2 grasping and 12% versus 9.3% for PDMS-2 VMI.

The PDMS-2 grasping measures daily activities involving the fingers of both hands, such as picking up small objects, buttoning and unbuttoning, stringing beads, and using hand tools. Significant improvements in PDMS-2 grasping were observed despite these tasks not being practiced during the game-based manipulation exercise program. The PDMS-2 VMI assesses an individual's ability to use visual perceptual skills for various eye-hand coordination tasks, including stacking blocks and drawing figures. In this study, the RMD game tasks required precise movements based on visual feedback from the moving game objects. This requirement is reflected in the substantial improvements seen in both the PDMS-2 tasks and the CUE object manipulation tasks.

Most parents expressed their willingness to join the trial because therapy focused on manual dexterity and addressed the lack of eye-hand coordination in their children. Both the XG and CG showed significant improvements in success rate and a decrease in movement error in all 4 object manipulation tasks, with moderate to large effect sizes. There was a significant time×group interaction, demonstrating that improvements in success rate were significantly greater for XG compared to CG.

The improvements observed in the CUE assessment of function, as well as in both the PDMS-2 grasping and VMI, were consistent with the quantitative data. Parents reported positive changes in their child's hand function, eye-hand coordination, overall level of participation in daily activities, and concentration levels. They agreed that the addition of computer games was motivating and encouraged their children to actively participate and have fun during exercise sessions. Most parents from the XG commented that the game-based exercises were challenging yet engaging and that their children enjoyed playing them. During the initial stages of the protocol, some parents observed reluctance due to a lack of understanding of the computer games and difficulty with producing precision movements. However, after 2-3 sessions, most parents felt that the computer game–based platform provided a promising way to improve children's compliance with the therapy program. Other studies incorporating computer games in therapy have also reported that children enjoyed the games used in their exercise programs [13,15,34,35].

Future Enhancements

The unidirectional force mode, while assisting movement in 1 direction, does not ensure that the handle movements will successfully interact with the target game objects. Additionally, 1 movement direction may receive resistive force, which may not be desirable. A real-time intelligent control scheme is under development, involving communication between the manipulandum and the RTP game. The controller will receive the coordinates of both the game targets and the game paddle. This knowledge about movement directions and amplitudes will be used to determine the direction and magnitude of the force required to rotate the handle and assist the subject in moving the game paddle as needed to interact effectively with the game target objects. This closed-loop assistance can be provided in both movement directions during gameplay, amplifying limited and small voluntary movements of those severely affected while allowing opportunities for progression with increased movement demands.

It is also common for children with paralysis to experience sudden, uncontrolled movements and difficulty managing their strength. To address this, a design change was made after the study to allow the device to be securely attached to a table, preventing unwanted movement during use. The modified device can now be easily attached to a table, providing greater stability and control during gameplay.

Conclusions

The results of this feasibility study demonstrate the feasibility, acceptability, and positive outcomes of the RMD game–based exercise program for the rehabilitation of hand function in children with CP. The findings indicate that computer game–assisted exercise programs can improve manual dexterity in children with CP. The results support further research and development related to the effects of computer game–assisted

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rehabilitation technology. The long-term effects of computer game–based training on hand function will need to be confirmed in future RCTs.

Acknowledgments

This study was supported by grants from the Research Manitoba Innovation Fund.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT (Consolidated Standards of Reporting Trials)-EHEALTH V1.6 checklist.
[PDF File (Adobe PDF File), 708 KB - rehab_v12i1e65358_app1.pdf]

Multimedia Appendix 2
Example computer games used in the experimental exercise program.
[DOCX File , 14 KB - rehab_v12i1e65358_app2.docx]

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Abbreviations

CG: control group
CONSORT: Consolidated Standards of Reporting Trials
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
CP: cerebral palsy
CUE: computer game–based upper extremity
GMFCS: Gross Motor Function Classification System
IB: inertial-based
MACS: Manual Ability Classification System
MCID: minimal clinically important difference
PDMS-2: Peabody Developmental Motor Scale-2
RCT: randomized controlled trial
RMD: robotic manipulandum device
RTP: repetitive task practice
VMI: visual-motor integration
XG: experimental group

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Original Paper

Exploring the Perceptions of Voice-Assisted Technology as a Tool for Speech and Voice Difficulties: Focus Group Study Among People With Parkinson Disease and Their Carers

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Abstract

Background: People with Parkinson disease (PD) often report low volume and reduced intelligibility of speech. Common household devices that use voice-assisted technology (VAT) require users to speak slowly, clearly, and loudly for the technology to function. For people with PD, this can be challenging, but this also suggests that VAT may have potential as a therapeutic tool. While VAT is an emerging health care technology, it is important to better understand the thoughts and experiences of people with PD who are already using it despite having speech and voice difficulties.

Objective: This study aimed to explore experiences of using VAT to address hypokinetic dysarthria secondary to PD, based on the perspectives of people with PD and family carers.

Methods: People with PD experiencing mild to moderate speech changes who were smart speaker users, and their carers, were invited to participate in 1 of 4 in-person focus groups. Between September and December 2024, focus groups were audiovisually recorded. A semistructured topic guide informed by published evidence was used to guide discussions. Results were transcribed and analyzed through a framework analysis approach (managed using NVivo software).

Results: A total of 15 participants, including 8 (53%) people with PD and 7 (47%) carers, participated in 4 in-person focus groups. Findings revealed shared experiences with VAT that were marked by its therapeutic potential and practical challenges. Five main themes were identified: (1) therapeutic potential for speech and voice, with subthemes of changes in volume, intelligibility, and clarity of speech; the role of VAT feedback; and VAT as an everyday device; (2) distrust of technology, with concerns surrounding data privacy, the listening nature of devices, and measures users take to protect themselves; (3) frustrations with devices, including devices not understanding, devices timing out, and the lack of conversation; (4) support needs, including the impact of a lack of knowledge and the need for education and guidance; and (5) design considerations for a future VAT tool in speech and language therapy (SLT).

Conclusions: This study extends on previous research findings, demonstrating that VAT may be acceptable to people with PD to create changes in volume, clarity, and intelligibility. However, attention must be given to users' privacy concerns and frustrations with devices before VAT can used as a tool in SLT. Future research should design solutions to address current usability challenges with people with PD and professionals in three ways: (1) co-designing education and guidelines for people with PD, describing the use of VAT for speech and voice difficulties; (2) refining commercial VAT for use in SLT; and (3) establishing the feasibility of a therapeutic VAT intervention for people with PD with speech and voice difficulties.

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KEYWORDS

Parkinson disease; voice-assisted technology; smart speakers; speech and voice; dysarthria; speech and language therapy

Introduction

Background

Parkinson disease (PD) is a progressive neurodegenerative condition that presents with rigidity, slowness of movement, and tremor [1]. In the United Kingdom, approximately 145,000 people are living with PD, including more than 4200 in Northern Ireland [2]. One of the most prevalent effects of PD is a change in speech and voice, affecting up to 90% of people with PD [3]. Also known as hypokinetic dysarthria [4], reduced volume and unclear speech worsen over time, impacting intelligibility and clarity of speech. These changes impact activity, social participation, and well-being [5].

Despite these figures, 48% of people with PD in the United Kingdom do not access speech and language therapy (SLT) [6], which may be due to long waiting lists, regional clinician shortages, and barriers related to the resource-intensive nature of therapy programs such as Lee Silverman Voice Treatment. Therefore, there is a need to explore therapy alternatives to make SLT accessible to more people with PD [7].

Voice-assisted technology (VAT) is defined as a device that uses natural language processing or automatic speech recognition (ASR) to interpret words and convert them into actionable requests. The most common commercially available VAT devices are Amazon Alexa and Google Home. Amazon Alexa is manufactured by Amazon. People with PD have been identified as a population likely to benefit from using VAT therapeutically [8]. However, VAT systems currently demonstrate poor recognition of dysarthric speech, with error rates increasing alongside speech severity [9,10]. This results in the device giving auditory or visual feedback using the recognition light, which prompts some participants with speech difficulties to change their speech to enable interaction with VAT [11-13]. Duffy et al [13] highlighted the potential of VAT to improve speech of people with PD. This study used an online survey to explore the knowledge and experiences of people with PD with VAT, in addition to reporting effects of using VAT on speech and language. In total, 290 participants reported making a deliberate effort to improve their speech clarity when interacting with VAT by specifically speaking “slower, clearer, and louder.” Similar speech changes have been reported across literature in other conditions [14,15], and this is strikingly similar to the goal of traditional SLT for people with PD. However, this survey did not solely investigate the impacts of using VAT on speech and voice in an SLT context and any reported impacts were limited by the constraints of survey methodology. Therefore, this study builds on the study by Duffy et al [13], using focus groups to provide a more in-depth and nuanced understanding of what factors contribute to this effect of increased volume and intelligibility, specifically with people with PD who use VAT regularly and report speech and voice difficulties. Focus groups may provide richer insights into experience of speech and voice difficulties, including facilitators and barriers to using VAT. Therefore, an exploration of how VAT is being used by people with PD with speech and voice difficulties and their carers is required to provide an understanding of how to use VAT to improve speech and voice outcomes as part of SLT. This ensures new technologies, such as VAT, can be used in a way that meets end user needs and may lead to a higher chance of uptake in the future [16]. An additional paper describes the perspectives of speech and language therapists regarding VAT as a tool for speech and voice difficulties in PD.

This study explores the experiences of using VAT to address hypokinetic dysarthria, secondary to PD, from the perspectives of people with PD and carers.

Objectives

This study had the following objectives: (1) to understand the type, extent, and nature of VAT use while experiencing hypokinetic dysarthria secondary to PD; and (2) to understand experiences of those who are facilitating people with PD to use VAT with hypokinetic dysarthria.

Methods

Qualitative research methods such as focus groups allow individuals to reflect on their own experiences in a supportive environment while also developing novel contributions though group discussions [17]. In-person focus groups were used for data collection to encourage conversations among participants and create richer data.

Ethical Considerations

This study was reported in accordance with the Consolidated Criteria for Reporting Qualitative Research checklist [18] and is part of a larger PhD study that received ethical approval from the Ulster University Research Ethics Committee in July 2024 (approval number FCNUR-24-016-A). All participants provided informed consent. Privacy and confidentiality were ensured—only the research team were able to see personal demographic data, and data will only be held as long as the university guidelines and General Data Protection Regulation require. Following transcription, all participants’ data were anonymized. Participants were reminded that if they knew another participant at the focus group they were to respect their right to confidentiality in their participation. No participants in the research were given payment.

Patient and Public Involvement

Before study development, a partnership was created between third-sector organization Parkinson’s UK Northern Ireland and the research team to provide a voice for people with PD and their carers throughout the research. A person with PD and a caregiver were recruited through Parkinson’s UK Northern Ireland and a speech and language therapist was recruited through research connections as “experts by experience” to co-design the research. These 3 patient and public involvement representatives influenced and informed various aspects of the study design, including participant information sheets, interview

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guides, and consent forms. They also contributed to the study's conduct and dissemination through input during online meetings, advising on recruitment strategies, focus group location, and duration. Experts by experience were asked to provide feedback on information sheets via email, indicating that complex language should be avoided. Consequently, the information sheets were revised to include more patient-friendly language. Furthermore, feedback on the interview schedule was also provided, with experts by experience suggesting that focus groups should be conducted in-person rather than online, as they felt it could limit technological barriers to participation. They also suggested that introductions from researchers should include an informal preamble about smart speakers, emphasizing the technology's relevance for people with PD and for the speech and language therapists working with this population. As a result, focus groups began with personal stories about PD and the professional journeys and provided background on what smart speakers are, why they might work to improve speech and voice, and included the lead author's personal experience using her own Alexa device. The experts by experience offered valuable lived experience insights to the academic team during data collection and charting, including suggestions to offer the option of individual interviews to speech and language therapists who were unable to attend focus groups, to maximize data collection.

Study Recruitment

Recruitment advertisements were posted on the research portal, featured in the Research Support Network monthly emails, and distributed as flyers to Parkinson's Support groups local to Northern Ireland. Some of the participants had established a relationship with the lead researcher (JM) due to work with Parkinson's UK in Northern Ireland and knew about her reasons for conducting research.

The population size could not be determined due to a lack of up-to-date data on the number of people with PD experiencing speech and voice difficulties in Northern Ireland. Therefore, 2 focus groups per each population, each comprising 3 to 4 participants, were chosen to better support people with communication disorders and provide variations in opinion while allowing data saturation. This is a smaller number than the 6 to 8 participants typically recommended in the literature, and was purposefully planned to allow discussion of ideas without discouraging quieter voices, as can happen in large groups. Participants were asked to contact the research team to express their interest in the study and were screened via telephone by the primary researcher according to predefined inclusion and exclusion criteria (Textbox 1). Potential participants were sent study information and consent forms by email or post, depending on their preference, and were asked to indicate their suitability for participation in a focus group. Once consent was gained a demographic survey, the Voice Handicap Index (VHI) [19] and a Digital Health Readiness Questionnaire was sent to participants. The VHI was included as it is a standardized tool used by speech and language therapists to measure clients' self-reported changes in voice and is commonly used with the PD population to ensure a person-centered approach to treatment, rather than focusing solely on the disease or impairment [20]. Carers did not receive the VHI.

Textbox 1. Study inclusion and exclusion criteria for people with Parkinson disease (PD) and carers.

Inclusion Criteria for People with PD

- Adult aged >18 years
- Mild to moderate dysarthria or voice difficulties (to include users of augmentative and alternative communication
- Diagnosis of PD
- Current or previous use of voice-assisted technology (VAT)
- Able to participate in a focus group up to 90 min

Exclusion Criteria for People with PD

- Moderate or severe cognitive impairment
- History of other neurological disorders

Inclusion Criteria for Carers

- Adult aged >18 years
- Live with or care for a person with PD
- Experience of facilitating use of VAT with a person with PD

Procedure

Each focus group or interview was facilitated by a female speech and language therapist (JM), with a researcher present (qualified speech and language therapist or health care professional with a PhD), and lasted between 1 hour, 9 minutes, and 1 hour, 21 minutes. Focus groups were conducted in person at the Ulster University Belfast campus. A semistructured topic guide informed by literature was prepared in advance to ensure methodological consistency across focus groups, and the lead author attended focus group training before conducting the research. The topic guides were differentiated to reflect the slight differences in lived experience between people with PD and their carers when using or facilitating VAT. Prompting

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questions encouraged equal participant contributions and topic guides were differentiated to reflect the perspectives of each stakeholder group. This was reviewed by patient and public involvement representatives, including a person with PD, a carer, and a speech and language therapist, and refinements were made to the phrasing of questions. A summary of the questions posed to people with PD and carers is provided in Multimedia Appendices 1 and 2. Participants were invited to discuss their experiences of using VAT to address the main research question: to explore the experiences of people with PD and their carers in using VAT to address hypokinetic dysarthria. Field notes of key ideas were taken during the focus groups.

Data Analysis

Focus groups were audiovisually recorded and transcribed using Microsoft Teams. To ensure methodological rigor and ensure contextual accuracy, transcriptions of videos were completed within 24 hours of the focus groups. All transcriptions were manually checked, and any errors were corrected before analysis. All personal and identifiable information was anonymized before analysis.

Framework analysis was used to structure the work as it enables an in-depth analysis of themes across a dataset and allowed researchers to collaborate [21]. In addition, given the lead researcher's involvement with the Parkinson community, it allowed awareness of any biases and improved transparency [22]. The five stages of framework analysis were followed [23,24]: (1) familiarization and data immersion, (2) develop theoretical framework, (3) indexing and data charting, (4) data summary in analytical framework, and (5) data mapping and interpreting. The group discussion further refined the initial theoretical framework. The initial draft framework was developed using published evidence [8,25].

Data recordings were transcribed before being imported into qualitative data management software NVivo (version 14; Lumivero) for analysis. Following data familiarization, initial ideas were documented on a mind map with a reflexive journal by the primary researcher (JM) and shared for discussion with coauthors (GK, OD, and KP). The reflexive journal noted authors' initial thoughts during transcription of each dataset and allowed the lead author to consider connections, similarities, and differences between data. Upon first reading, the lead author created a mind map to group these ideas together and create initial codes for analysis. Further discussion and data immersion allowed creation of draft themes, where the lead author created a second mind map considering connections between the codes, and how they could be grouped into overarching categories. Using a mind map allowed the researchers to reflect upon biases and assumptions and explore alternatives in data interpretation to ensure results accurately represented participants' lived experiences. The framework was refined to reach consensus at further meetings with coauthors. Data indexing was completed by the primary researcher (JM). Summarization of indexed data into codes and thematic charting was completed by JM and discussed with coauthors (GK, OD, and KP) and used to formulate the final theoretical framework [21]. Original data extracts from transcriptions are included, alongside the participant number, to enhance trustworthiness and credibility of findings. Furthermore, the results were sent to all participants for member checking to ensure that the written findings reflected their lived experiences and to enhance rigor of the research. Most participants responded that they were satisfied with the reporting of research. One participant reported that they appreciated that the researchers stayed true to the "Northern Irishisms" and sentence structure used during focus groups, as this accurately represented how ideas were expressed. Changes made included checking the anonymization of quotes and incorporating headings for subthemes, as some participants felt that these changes made it easier to follow for lay readers.

Results

Participants

People with PD and their carers (n=16) were recruited via Parkinson's UK in Northern Ireland, a third-sector organization. A total of 16 participants were recruited, of whom 15 (n=8, 53% people with PD and n=7, 47% carers) participated in focus groups. One carer dropped out after recruitment due to scheduling conflicts. Each group consisted of 3 to 4 participants per focus group across the 4 focus groups (Table 1). Our experience of holding separate focus groups for people with PD and their carers and not involving professionals was positive. People with PD provided open and honest reflections [21], with each contributing to the conversation, which likely would have been constrained in a mixed group. However, this resulted in a distribution of participants by sex, with mostly male people with PD and female carers. People with PD and their carers who were familiar with each other from the wider Parkinson community encouraged each other in conversations providing the richest insights and the longest focus groups. One participant in a group whose members did not know each other reported the following: "I think discussing then with each other...you learn from each other. I've learnt things from this group tonight." [P5].

A total of 16 participants were recruited to the study; however, only 15 participated. People with PD (n=8) and partners or carers (n=7) attended in-person focus groups at Ulster University Belfast (Tables 2 and 3). Most of the people with PD were male (7/8, 87%) and ranged in age from 57 to 77 years. Most of them (7/8, 87%) had been diagnosed for over a year, while one had been diagnosed more recently.

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Table 1. Format of qualitative data collection focus groups and number of participants in each group.

Population and format	Number of participants	Length of time
People with Parkinson disease		
In-person focus group 1	4	1 h 21 min
In-person focus group 2	4	1 h 12 min
Ca rers or partners		
In-person focus group 1	3	1 h 9 min
In-person focus group 2	4	1 h 12 min

Table 2. Demographic characteristics of people with Parkinson disease (PD) in in-person focus groups.

Person with PD ID	Gender	Age (y)	Year of diagnosis	Voice Handicap Index severity
P1	Male	59	2012	Moderate
P2	Male	61	2013	Normal
P3	Male	57	2023	Severe
P4	Male	73	2020	Moderate
P5	Male	77	2022	Moderate
P6	Female	70	2019	Normal
P7	Male	77	2014	Moderate
P8	Male	68	2017	Mild

Table 3. Demographic characteristics of carers in in-person focus groups.

Carer ID	Gender	Age (y)
P9	Female	55
P10	Female	65
P11	Female	67
P12	Male	72
P13	Female	74
P14	Female	66
P15	Female	57

The VHI is a subjective self-rating questionnaire for people with voice problems, where people with PD self-rated the impact of their voice disorder on their quality of life. The VHI uses statements about voice problems, which are ranked from 0 to 4 on frequency: 0=never, 1=almost never, 2=sometimes, 3=almost always, and 4=always. There are 10 questions across 3 sections, with 30 questions in total [19]. This covers the functional, emotional, and physical impacts of voice disorders, with a total score of 120. Scores between 0 and 30 show mild impairment, 31 to 60 moderate impairment and 60 to 120 severe impairment. On average, the participants reported a moderate impairment on the VHI [19] between 42 and 52, with 2 reporting very mild impairment (5 and 21) and one within the severe range (87).

The Digital Health Readiness Questionnaire required participants to rank 20 statements about technology use and ability using a 5-point Likert scale: 1 represented never or strongly disagree; 2 represented rarely or disagree; 3 represented sometimes or neither agree nor disagree; 4 represented often or agree; and 5 represented daily or strongly agree. Statements covered digital access, use of digital technology, digital literacy, digital health literacy, and learnability. Although 6 people with PD had good digital access, that is, they used the internet, a laptop, and a smartphone or tablet daily, only 3 used health-related applications, and the majority lacked digital health literacy. Participants had mixed digital skills. While 5 could complete basic tasks such as sending emails, sharing pictures, and video-calling, 3 indicated experiencing more difficulties. Moreover, 7 were motivated to learn about technology, and 5 agreed that digital skills could positively impact their health. Complete results from the Digital Health Readiness Questionnaire can be found in Multimedia Appendix 3.

Of the 7 carers or partners, 6 (86%) were female and 1 (14%) was male and ranged in age between 55 and 74 years. All carers had good digital access and 5 used health-related applications. Overall, carers had strong digital skills and almost all could complete basic tasks such as sending emails, sharing pictures, and video-calling confidently. All 7 carers were motivated to

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learn about technology and 6 agreed that digital skills could positively impact their health.

There were five main themes identified across the groups and datasets: (1) therapeutic potential for speech and voice, (2) distrust of technology, (3) frustrations with devices, (4) support needs, and (5) design considerations for a future VAT tool in SLT. Table 4 presents on overview of the themes and subthemes. The main and subthemes identified by each group are outlined with appropriate quotes in the subsequent sections to enhance credibility of results, without identifying the speaker.

Table 4. Results from research with themes and subthemes listed.

Themes	Subthemes
Therapeutic potential for speech and voice	• Changes in volume, intelligibility, and clarity, as well as role of feedback • Can act as a communication partner • A useful or everyday device
Distrust of technology	• Data privacy • Listening nature • Measures to protect themselves • A more pragmatic approach
Frustrations with devices	• Repetition, timing out, or error scaffolding • No conversation or generalization • No therapeutic relationship
Support needs	• Impact of lack of knowledge • Need for education
Design considerations for a future voice-assisted technology tool in speech and language therapy	• Develop a speech and language therapy program • Monitoring speech and voice changes • Additional feedback

Theme 1: Therapeutic Potential of VAT

Participants reported several facilitators of VAT that indicate its potential use as a clinical tool for the management of speech and voice difficulties.

Changes in Volume, Intelligibility, and Clarity and the Role of VAT Feedback

VAT promoted positive changes in volume, clarity, and intelligibility of speech. Positive implications for activity, participation, and well-being were also reported. Interacting with VAT caused people with PD to use adaptive strategies to change their speech.

For example, participants reported increased volume when talking to VAT:

> *She raises her volume and very deliberately, and says "Alexa television on."* [P12, carer]
>
> *I'm a bit like you; I would shout at it. Raise my voice.* [P5, person with PD]

Others described increased clarity of speech and a slowing down their pace:

> *I would say "Alexa play me Mozart the marriage overture," and it comes out with some pop tune, and then I'll shout back, and then I catch myself on, and speak slowwwwly and then it would work.* [P8, person with PD]
>
> *I have to step back and compose myself, I suppose mentally, and speak out slower and clearer because I realised it's my voice that's not really getting to her.* [P5, person with PD]

One participant summarized their interactions with VAT as follows:

> *I find myself speaking much louder, slower and clearer, and then it finally pumps out the record!* [P8, person with PD]

The feedback provided by VAT created awareness and prompted people with PD to adapt their speech using strategies. This feedback was seen to be key to changes in volume, clarity, and intelligibility as participants indicated the following:

> *It doesn't respond, maybe the first time. OK, you know that she hasn't either heard you or you need to speak slower and louder.* [P6, person with PD]
>
> *You should learn if Alexa doesn't hear you, Alexa won't respond. You learn to repeat yourself a bit more clearly.* [P12, carer]

VAT as a Communication Partner

Carers reported that VAT could also act as a communication partner for people with PD with speech and voice difficulties, providing opportunities to rebuild confidence in using their voice:

> *There aren't a huge amount of opportunities during the day for him to have a really good conversation until I come home. So... its another avenue for him to use his voice.* [P9, carer]
>
> *There's a benefit, because if it's given him more confidence to use his voice then, that's important.* [P9, carer]

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A Useful Everyday Device

In addition, people with PD and their carers reported everyday functional uses of VAT, ranging from basic requests, such as asking for the date and time, weather updates, setting reminders and timers, and playing music, to more complex requests such as finding recipes and cooking, searching for facts, checking sports scores, singing, participating in quizzes, and controlling smart home appliances.

Most participants reported using an Amazon Alexa Echo Dot device, (third or fifth generation), or a Echo Dot Kids. Only a few participants reported using a Google Home or Google Nest device. Participants owned between 1 and 3 devices in their homes, and their frequency of use varied widely from once or twice a day to more than 10 times daily. They reported having a VAT device in their kitchen, living room, or bedrooms. Playing music and listening to the radio or news were popular requests among participants in addition to medication reminders and controlling smart home appliances:

> *I want to get a news programme, I want music, whatever. Sit back and listen to the news or just to music and updates.* [P5, person with PD]

> *I think it's great for the alarm because we're both forgetting. I say ', Did you take your tablet?' It's the always forgetting.* [P10, carer]

> *It controls everything else in the house. We have to have one upstairs at night so we can get into bed at night and turn off the landing lights because the switch for the landing lights is under a picture, a big, big heavy pictures so we can't get at it.* [P14, carer]

In addition, participants used their VAT devices for entertainment, for example, games and singing:

> *Games! You ever played games on the Alexa Party game? They all have to be speaking ones.* [P2, person with PD]

In addition, people with PD suggested that VAT was easy to use because of voice interaction and carers explained how this overcame the physical limitations associated with PD:

> *Well, I'm so used to the convenience of Alexa and not physically going and turning the radio on...You use the voice, you've got it.*" [P8, person with PD]

> *You can set that up where she can phone your contacts, and that'll probably be good for my husband because he can't use his phone. Tremor.* [P10, carer]

Theme 2: Distrust of Technology

A distrust of VAT devices, with concerns surrounding data privacy, General Data Protection Regulation compliance, and governance, was reported frequently by participants. The inhuman nature of VAT, perceptions of the device as an outsider, and sometimes fear of the technology contributed to distrust. Other participants were less concerned about these risks.

Data Privacy

People with PD and their carers expressed caution about VAT devices eavesdropping on their conversations, as the devices are always listening. These concerns resulted from media reports and a lack of transparent communication from VAT companies regarding data privacy:

> *I just worry about it being a listening ear in the room. Too many people know too much about you sometimes I think.* [P13, carer]

> *Adverts start popping up and you're going that's spooky, because that's what we were talking about.... They are there and they are listening, you know that.* [P15, carer]

The Listening Nature of Devices

This listening nature of devices contributed to participants' suspicions and distrust of VAT, particularly regarding hacking:

> *I suppose I'm one of these people that will sit back and say how does this work. Is it all OK? Is there anything about this that's sinister?* [P11, carer]

Protection Measures

Furthermore, privacy concerns with VAT devices meant that participants did not openly welcome devices and were distrusting, with some taking measures to protect themselves:

> *I still regard it as an intruder. Handle with care.* [P5, person with PD]

> *You know the way you can programme your sat NAV to have a voice from Northern Ireland? I would really like her to be one of us. I think that would just, maybe it wouldn't feel as if it was so much of an intruder in the house.* [P9, carer]

> *I would switch it off, whenever it's not being used. Because of this—we got a warning, we got a message from the police, Watch smart phones, watch Amazon Alexa's because they monitor everything.* [P5, person with PD]

Pragmatic Attitudes

Despite this, some participants took a more pragmatic approach to VAT and their privacy. For example, one participant felt that VAT devices did not pick up sensitive information:

> *You've got to be sceptical to some extent of the conspiracy theorists who say that Alexa is listening to you...what are they going to do? What benefit do they get out of it?... They're welcome to listen to our conversation! Very exciting. "You want a cup of tea?" "Yeah." That's it!* [P12, carer]

Theme 3: Frustrations With Devices

Participants described frustrations with VAT devices, including not being understood, having to repeat themselves, devices timing out, and difficulties with error scaffolding. However, these issues did not necessarily prevent them from using the technology. Challenges with having a conversation or developing therapeutic relationship with VAT were also highlighted.

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Frustration

Frustration when interacting with VAT was widely reported by people with PD. This was often linked to VAT not understanding people with speech and voice difficulties and them having to repeat their requests:

> *Hm, yeah I curse at it every time.* [P4, person with PD]

> *He'll say something and his voice is so low, that it doesn't catch it. And then he says it again and then he gets frustrated and he just says to me "tell that thing to do it."* [P14, carer]

VAT devices often timed out before participants finished speaking, which further contributed to frustration. One person with PD reported the following:

> *If I do, longer sentences usually the gap in between it starts going and answering half the questions, and I go hadn't finished yet!* [P2, person with PD]

Another partner described that VAT "just runs out of listening time" [P14, carer].

Feedback in this paper refers to both the blue light on the VAT devices that turns on when the device is listening, and the verbal feedback the devices may give when trying to action a request. Participants reported some difficulties taking action following VAT feedback:

> *And also Alexa, because I don't know what it's heard, it's really hard.* [P2, person with PD]

> *He will ask her to play a song or something and she'll play something completely different. And I say you have to speak louder or she didn't hear you, she didn't understand what you said.* [P10, carer]

Lack of Conversation

VAT's limited conversational ability in standard settings was considered as unreflective of real-life communication and posed a challenge for delivering therapy. One person with PD reported the following:

> *To me if I'm doing anything with Alexa its either a game or your perfunctory task, you're saying do this, do that or ring somebody. It's not something you're having a conversation—it's when you get into that conversation flow, it's trying to remember to keep your voice going sometimes.* [P2, person with PD]

> *If I'm at the kitchen sink and she's putting stuff away with my back turned to her, you know, and she wants to say something she doesn't want to say, "HUSBAND, I'm going to say something. Now, listen to me." Okay? That does not happen.* [P12, carer]

In addition, this partner expressed skepticism of regarding VAT's ability to help with therapy generalization:

> *Well, I mean if she has to raise her voice and enunciate clearly and speak slowly to Alexa, that doesn't feed through to speaking with me.* [P12, carer]

Lack of Therapeutic Relationships

The perception that VAT might replace real speech and language therapists may be considered as a potential barrier. The therapeutic relationship developed between speech and language therapists and clients was considered missing with VAT with participants considering human clinical decision-making as an integral part of therapy:

> *You know you can't be left to your machine and yes, with no humanity to it, you know? You need that person.* [P11, carer]

> *It's face to face, it's a person, it's somebody that's giving you visual feedback and giving you auditory feedback all the time and is setting the pace of the of the lesson OK. And that's got to be important.* [P12, carer]

Theme 4: Support Needs

Impact of a Lack of Knowledge

Participants explained that a lack of adequate knowledge about VAT capabilities and limited experimentation prevented them from fully using the potential of the devices and understanding how VAT could be a useful tool for PD:

> *I think there is a lot of potential in Alexa. The problem for us is, you don't know what you can and can't do with Alexa.* [P2, person with PD]

> *We don't really know what he can do with it.... We've never done anything else with it except control the things around the house.* [P14, carer]

Need for Education and Guidance

People with PD and their partners suggested education and guidance were priorities. Suggestions included practical and technical support and layman's explanations about how VAT use could impact speech and voice to help people with PD understand why they were using the devices during therapy:

> *Most importantly for us, we need to know why we're doing it as well. I think people have Parkinson's need to know.* [P2, person with PD]

> *I want to, I suppose, maybe to learn to use it for its available uses.* [P5, person with PD]

> *It just frightens me to go into it and start fiddling about with settings. So maybe some sort of training or help.* [P13, carer]

Participants discussed various methods for this education, including workshops with demonstrations, videos, reference manuals, and leaflets. Overall, it was clear that more than one delivery format of guidance would cater to varied abilities and should, "take Parkinson's into consideration. And everyone at different level, you know, different abilities and different changes" [P13, carer].

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Theme 5: Design Considerations of a Future VAT Tool in SLT

Develop an SLT Program

Participants provided design considerations for the future therapeutic use of VAT for people with speech and voice difficulties in SLT, including developing an SLT "program" with interactive features, the ability to monitor speech and voice progress, and additional prompting and feedback.

Some participants embraced the idea of SLT delivered predominantly through VAT while others indicated they preferred a more hybrid approach of "speech therapist plus programme":

> *If there was a built-in programme, you could interact with Alexa.* [P3, person with PD]
>
> *So it could be some kind of speech exercises.... Like an app even that you could put on it.* [P14, carer]
>
> *If there was maybe an initial speech and language session for guidance, for training and then you're set off on your own to manage yourself.* [P9, carer]

Despite this, a minority of carers felt, "it is hard to see it work," or simply preferred in person speech therapy.

Prompts and reminders could be useful to help facilitate home practice of exercises with VAT and may help people integrate everyday practice:

> *So he gets into the habit of remembering to take a breath, remembering just. Y'know, here's a reminder for you, do this or do that, practice these breathing exercises in and out and projecting your voice.* [P14, carer]

Participants suggested numerous ideas for how an SLT Alexa skill might function or contain, including exercises, reminders to complete therapy tasks, conversation practice, feedback and prompting, and the ability to monitor progress or maintenance across tasks. For example, exercises could be delivered through an Alexa skill, which could target articulation, breath support, phonation, singing, and reading:

> *If your pronunciation is wrong, you look at your pronunciation before and after a game.* [P1, person with PD]

Maybe have Alexa read it first and then you read it. Or you read it and then have her read it back. [P9, carer]

Monitoring Speech and Voice Changes

The ability to track changes and measure progress in speech and voice was a common suggestion, aimed at supporting the maintenance of these skills over time:

> *The thing is that you're competing against your voice of yesterday. And if you can keep it the same as your voice of yesterday, we're ahead.* [P2, person with PD]
>
> *You could do, y'know your exercises at the start, and then some word work, and then go onto reading paragraphs in the second week.* [P1, person with PD]

Percentages and scores were suggested as feedback methods provide a measure of speech and voice when using VAT:

> *So if you did Alexa, and said to Alexa "Count to ten today" and it said "You counted to ten and six numbers were good, 4 numbers weren't."* [P2, person with PD]

Some people with PD described the positive impact this would have, while others felt differently, suggesting that feedback could be demotivating, counterintuitive, and negatively impact well-being:

> *What you would hopefully learn was, "I was better today than I was yesterday" and you'd realise where you put the emphasis or where you slowed down, and it'd guide you.* [P5, person with PD]
>
> *I don't want it to be a diagnosis to say your voice is getting weaker. I want it to be, "If you keep this going for Alexa, your voice will get stronger."* [P2, person with PD]

People with PD proposed using VAT's feedback light as an alternative to scores:

> *Alexa is going playing the music and you're singing along, and it goes "You're red because you're not high—we can't hear you." And then you sing high and it goes to yellow. And then you go to green. Green means your singing it properly.* [P2, person with PD]

A feedback feature to facilitate self-awareness of speech and voice difficulties may also be included. People with PD suggested that hearing how VAT interpreted their speech could help facilitate the use of adaptive speech strategies.

> *You say that, it records and sends it back, "Oh, that's not right." That's what she heard, you know. That's what it's hearing, and then you pronounce it right.* [P1, person with PD]
>
> *And the programme would go, "You're going too fast. You're going too slow. I don't understand." Yeah. So just give you feedback because see, once you've got feedback you can go, ok right it says slow down. So you go slooooower.* [P2, person with PD]

In addition, more specific feedback from VAT on speech and voice was suggested:

> *If it could interact with you and say you're not speaking clearly enough. I'm speaking at it and "You're not clear enough, you're better now."* [P5, person with PD]

Discussion

Principal Findings

The aim of this study was to explore the experiences of using VAT to address hypokinetic dysarthria, secondary to PD, from a range of stakeholder perspectives. People with PD and their carers discussed the therapeutic potential of VAT for speech and voice difficulties, with it being regarded as a novel technology that could promote louder speech with increased clarity and intelligibility. However, challenges such as

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frustrations with devices and distrust of technology must be addressed. By meeting participants' support needs and integrating feasible design considerations, the use of VAT as a tool in SLT may be considered in future research.

Evaluating the Therapeutic Potential of VAT

People with PD reported that using VAT made them speak clearer and raise their volume. This indicates that VAT can facilitate unlimited practice attempts and prompt participants to adapt their speech [14,15,26], resulting in a therapeutic benefit. These findings build on existing research that highlights VAT's potential role in improving and maintaining speech volume, clarity, and intelligibility [8,11,13,25] and the role of VAT feedback in shaping improvements in self-awareness, which led to self-reported improvements. In addition, VAT could facilitate practice of articulation, clarity, and volume exercises—the speech subsystems commonly targeted by speech and language therapists during therapeutic management of PD [27]. Thus, VAT could maximize therapeutic outcomes, while reducing health care resource demands associated with intensive interventions such as Lee Silverman Voice Treatment.

While this research focused on people with PD, previous research has also emphasized a gap in knowledge regarding potential for VAT as a therapeutic support for people with motor neuron disease with speech and voice difficulties [12]. Given the aforementioned findings, this warrants further research into therapeutic potential of VAT for neurodegenerative conditions as a tool for speech and voice difficulties. This study builds upon the findings by Duffy et al [13] to inform the design of a feasibility trial that meets the needs of users and integrates use solutions current difficulties. To inform practice, future research should consider the studies by Quinn et al [28], who used interviews and device logs to evaluate the acceptability and feasibility of a smart speaker–delivered physical activity program, and Smith et al [10] and Makin et al [29] who used before and after measures to examine if a VAT intervention could improve speech clarity for adults with intellectual disability. Future research may seek to extend the work by Smith et al [10] with people with PD, focusing on volume, clarity, and intelligibility with before and after measures.

Although VAT has therapeutic potential, there are potential caveats that require further exploration. ASR models, which underpin VAT, can be variable in their understanding of speech for reasons other than speech clarity, volume, and intelligibility [30]. For example, device updates, user ethnicity, and regional accents can impact word error rates. Indeed, research indicates that black speakers had a higher word error rate than white speakers when using common commercial VAT systems such as Apple, Amazon, and Google [31]. In addition, VAT users may adapt nonstandard accents to facilitate interactions with VAT [32], which is likely to have implications for users from ethnic minority backgrounds or with regional accents. People who use VAT might change their accents, if they do not have a standard English accent, as well as increasing their volume and speaking more clearly. Therefore, users should be careful that they do not begin to use westernized accents in favor of regional or international accents when using VAT to help the device to understand them better.

The wider literature has also indicated that VATs' limited conversational abilities was a usability issue [33]. It may be suggested that the transactional nature of VAT requests means that using VAT to practice speech may not carry over into real-life conversations [30]. While VAT may be useful to isolate practice of impaired volume and intelligibility across word, phrase, and sentence level, it may be difficult to generalize practice into conversation and create meaningful change in activity or participation. Furthermore, research investigating the error rates of ASR, which underpins VAT, has shown that error rates are higher for conversational speech than for short phrases or read speech in people with speech disorders [34,35]. Therefore, it is difficult to know if VAT could facilitate meaningful conversation practice for people with PD that generates increased real-life conversational participation. Future research should seek to establish how features of commercial VAT could be used to promote more conversational engagement with VAT for people with PD. This would build on the current research, solving the reported barrier of a lack of conversational engagement with VAT, and may enable conversational practice with VAT in the context of SLT.

Turning Distrust of VAT Into Reassurance

Concerns for data privacy, security, and unwanted surveillance are well documented in relation to VAT use among older adults and in therapeutic interventions [8,28,36]. Previous research with people with PD indicated that between 9% and 33% of people expressed privacy concerns regarding VAT [8]. Similar concerns emerged in this study, potentially influenced by significant and rising media discourse about artificial intelligence in the media [37], and perceptions of VAT as an artificial intelligence device. However, other factors may contribute, such as varying levels of digital literacy, as reported among people with PD and their carers in this study, and less frequent use of VAT, which for some resulted in fear toward technology—a pattern observed with the older population [38]. Others were actively embracing VAT, potentially due to a high level of digital capabilities, personal innovation, habit, positive attitudes to technology, or less aversion to risk [39]. While privacy pragmatism and cynicism concur with wider literature [40], other people with PD have previously reported that they are actively embracing new technological advances [8] with high levels of ownership and use of VAT reported among older adults. This builds on previous research [8] by highlighting the role of digital skills and habit in shaping privacy concerns and trust in technology and emphasizing the need for digital literacy education. Future research may build on current findings by collaborating with people with PD and their carers to discuss the best delivery method for digital skill upskilling.

Despite these concerns, privacy concerns alone do not deter people with PD and their carers from using VAT. Efforts should be made to upskill the digital skills of people with PD, increase their knowledge of privacy protection, and promote active security measures to mitigate risks. This concurs with results from the Digital Health Readiness Questionnaire, where people with PD lacked digital literacy and had mixed digital skillsets, but were motivated to learn about technology. Although efforts may also upskill carers, participants in this research had strong digital skills and literacy. Future research should seek to reassure

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people with PD and their partners about the integrity of VAT's privacy policies and surveillance concerns and develop tailored guidance to support users with diverse digital skill levels and age groups. This would build on the current research by using specific privacy concerns and providing solutions that directly address user needs and may positively impact use.

Navigating Frustrations With VAT

Technological limitations of VAT and resulting frustrations were discussed, including issues with VAT not understanding speech; devices timing out; and a lack of meaningful feedback, conversation, and relationship. Similar frustrations surrounding the inconsistency of VAT have been reported by people with dysfluent speech [41] and neurological disabilities in wider research, particularly where VAT did not understand them, or provide meaningful feedback on errors [42].

In addition, VAT should be used cautiously for feedback on speech and voice due to potential well-being implications and users should be careful not to assign responsibility for all VAT inaccuracies to speech and voice [30]. Speakers can blame themselves for ASR errors and link this to their sense of identity, including racial, regional, and location identity. Therefore, participants may modify their dialect and word choice to be understood by ASR [32], which may negatively impact their sense of self. Despite acknowledged limitations, subjective improvements in confidence, self-awareness, accessibility, and well-being have been reported when using VAT. Wider literature has also demonstrated increased independence, well-being, and quality of life for older adults following the use of VAT [43]. This paper provides the foundations for future research to cocreate solutions to the use barriers identified by people with PD and their carers. By using ideation methodology, such as design thinking, and participatory design methods, future research could integrate multistakeholder collaboration to create solutions that are rooted in user needs, as identified by this study.

Supporting Adoption and Use of VAT

Although people with PD and their carers were at varying stages on their journey with VAT adoption, increased use generally corresponded with greater integration into their daily routines. This pattern mirrors broader trends observed in the general population [44]. However, participants frequently reported a lack of awareness of VAT's full functionality and capabilities, which they identified as a barrier to wider adoption. Given that smart speakers ownership approximately doubled during the pandemic, from 22% of households in 2020% to 39% [44], this knowledge gap is somewhat unexpected.

The level of VAT use and integration by participants appeared to shape their attitudes toward its usefulness and ease of use. This aligns with established technology adoption models, such as the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) [45], which suggest that factors such as performance expectancy (perceived usefulness) and effort expectancy (ease of use) can impact technology acceptance. In this context, people with PD who perceived VAT as beneficial and easy to use were more likely to integrate it into their routines. This highlights that future refinement of a VAT tool should aim to show why VAT is easy to use and useful for speech and voice to increase adoption by people with PD. However, those unfamiliar with VATs' capabilities struggled to extrapolate their everyday uses of VAT to speech and voice therapy. Furthermore, the privacy-personalization paradox [46] offers insights into VAT adoption, as it suggests that while users appreciate that personalized technology can enhance their everyday lives, concerns about data privacy can create hesitation around its use. Indeed, some people with PD and their carers reported reluctance to use VAT due to uncertainty about data privacy and security. Addressing these concerns through education and structured guidance on VAT's therapeutic applications could facilitate greater adoption and integration into SLT practices and extend on this study's findings.

In addition, participants indicated that they would benefit from education and training. This reflects findings from previous research surrounding therapeutic use of VAT in SLT and with older adults [25,36], indicating that digital health interventions should include education in how to use technology effectively and provide technical support throughout. While Cave [30] recommended development of a clear and accessible guide to using ASR tools, no research to date has created or examined an educational intervention for VAT as a therapeutic tool for speech and voice difficulties [47]. Future research may use facilitators and barriers to VAT use, identified by this study, to cocreate training and educational resources for people with PD and their carers, by using solution focused idea generation workshops and integrating behavior change frameworks [48]. This may also include identification of best methods for delivering training effectively to encourage increased confidence, adoption, and use of VAT for speech and voice difficulties.

Design Considerations for a Future VAT Tool

Participants in the study made various suggestions about a future VAT tool for therapeutic management of speech and voice, including a specific skill for VAT, extended feedback on speech and voice, and the ability to measure progress. Esquivel et al [42] indicated similar suggestions for use of VAT for people with neurological disabilities, including a voice assistant hub with suggested skills, training, and a repository with personal stories. Duffy et al [13] and Kulkarni et al [25] also suggested that additional research may include user experience in a therapeutic VAT tool. Wider research advocates for including the lived experiences of people with PD using VAT for speech and voice in the potential design, development, and testing of VAT tools [13,42].

Therefore, future research should build upon these identified uses, facilitators, and barriers, using participatory co-design methods with speech and language therapists, people with PD, carers, and technology experts to brainstorm solutions to some of these perceived barriers with VAT. Co-design is an established way to develop health care technology and supports people with communication difficulties [49]. This ensures that VAT reflects the needs of people with PD and their carers, reducing abandonment of VAT and digital exclusion for people with PD [29].

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Limitations

This study was conducted exclusively with people with PD and their carers in Northern Ireland. While this may be identified as a limitation, it is likely that their views are representative of experiences of people with PD across the United Kingdom and beyond with some variation in technology adoption globally. Technology use and adoption varies across countries and the findings may not represent the global experiences of people with PD who are VAT users. Furthermore, the sample of people with PD recruited in this study were White. This poses a question of how results may vary with potential cultural and regional differences. Future studies should seek to replicate findings to understand the generalizability of results, recruiting a range of people with PD from diverse cultural and ethnic backgrounds.

Inclusion in the study required participants to be actively engaging with VAT. Therefore, this indicates that people with PD and their carers were self-selecting participants and may have already had the basic digital skills that facilitated the adoption of VAT. As such, they may have been biased toward the use of technology and have a positive outlook toward its use. This is a limitation in any qualitative work that explores a particular subject. Other people with PD and their carers who may not have adequate digital skills may have had a different outlook and a less favorable attitude toward VAT use.

Recommendations

Our study highlights several suggestions for future research, as outlined in the Discussion section. The following recommendations are suggested to develop the therapeutic use of VAT:

1. Refinement of commercial VAT, specifically for targeting volume, clarity, and intelligibility of speech as part of SLT, using user-led co-design: this may include feasible solutions to technological limitations, which do not redevelop the technology, and extended conversational abilities, which meet the needs of people with PD and their carers and improving their experience.
2. Co-design of clear and accessible education and guidelines to help meet the needs of people with PD and their carers: this may include realistic expectations of how VAT can benefit speech and voice, a summary of VAT's capabilities and information on privacy. Future work must also identify the optimal route for delivery of education and training, particularly for those who lack basic digital skills.
3. Establishing the feasibility of a therapeutic VAT intervention for people with PD with speech and voice difficulties, including pre- and postacoustic analysis of voice or self-reported impacts in volume, clarity, and intelligibility.

Conclusions

This study builds upon the findings of Duffy et al [13] by exploring the experiences of people with PD and their carers using VAT with speech and voice difficulties. Participants reported positive therapeutic changes in volume, clarity, and intelligibility; however, frustrations with technology and privacy concerns may need to be addressed before VAT can be integrated into SLT. The next step will explore the role of multistakeholder collaboration to co-design feasible solutions to VATs' usability challenges with people with PD, their carers, speech and language therapists, and technology experts. Furthermore, additional work is needed to trial commercially available VATs as a tool for improving speech and communication changes in people with PD, as well as to explore potential generalization and maintenance effects.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group discussion guide for people with Parkinson disease.
[DOCX File , 187 KB - rehab_v12i1e75316_app1.docx]

Multimedia Appendix 2
Focus group discussion guide for carers.
[DOCX File , 180 KB - rehab_v12i1e75316_app2.docx]

Multimedia Appendix 3
Digital Health Readiness Questionnaire results.
[DOCX File , 29 KB - rehab_v12i1e75316_app3.docx]

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Abbreviations

ASR: automatic speech recognition
PD: Parkinson disease
UTAUT: Unified Theory of Acceptance and Use of Technology 2
VAT: voice-assisted technology
VHI: Voice Handicap Index

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Original Paper

Exploring Speech and Language Therapists' Perspectives of Voice-Assisted Technology as a Tool for Dysarthria: Qualitative Study

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Abstract

Background: People living with Parkinson disease (PD) often experience low speech volume and reduced intelligibility. Research suggests that common voice-assisted technology (VAT) devices, like Amazon Alexa and Google Home, can encourage individuals to modify their speech, speaking more clearly, slowly, and loudly. This highlights the potential of VAT as a therapeutic clinical tool in speech and language therapy (SLT). However, while VAT is emerging as a novel health care technology, gaps exist regarding understanding speech and language therapists' (SaLTs) experiences using these devices in clinical practice for PD-related speech and voice difficulties.

Objective: This research set out to explore various experiences of using VAT to address hypokinetic dysarthria, secondary to PD, from a range of stakeholder perspectives. This paper specifically focuses on clinical insights from SaLTs.

Methods: SaLTs with prior experience of using smart speakers in clinical practice with people with speech or voice difficulties were invited to participate in focus groups or interviews. Between September and December 2024, seven SaLTs participated in semistructured focus groups or interviews using a topic guide. Discussions were informed by published evidence. Results were transcribed and analyzed using a framework analysis approach and were managed through NVivo software (Lumivero).

Results: Four main themes were identified across the groups: (1) potential for VAT in SLT, (2) managing therapeutic beige flags, (3) empowering SaLTs to become digitally enabled practitioners, and (4) envisioning the future of VAT in SLT.

Conclusions: This study recognizes VAT's potential as a therapeutic tool that may improve volume, clarity, intelligibility of speech, and facilitate at-home practice for people with PD. However, before VAT can be widely implemented, considerations around data privacy, device limitations, and practical integration into clinical care must be addressed. Future research is proposed to design solutions to address usability challenges for both clients and clinicians. Finally, this paper offers key clinical recommendations for the development of a therapeutic VAT tool for speech and voice difficulties in SLT.

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KEYWORDS

smart speakers; speech and language therapy; Parkinson disease; dysarthria; voice disorder

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Introduction

Up to 90% of people with Parkinson disease (PD) develop hypokinetic dysarthria [1], characterized by masked facial expression, reduced range of motion and volume, imprecise articulation, accelerated speech rate, prosodic insufficiency, reduced stress, rapidly repeated phonemes, and, in some cases, palilalia [2]. These speech impairments worsen over time due to the progressive nature of PD, resulting in low volume, which contributes to poor intelligibility and clarity of speech. This can lead to embarrassment, reduced well-being, social participation, and a loss of identity [3,4].

Early speech and language therapy (SLT) intervention is recommended during the management of PD [5], with guidance suggesting that therapists use compensatory strategies, external aids (eg, pacing boards, voice amplifiers, and augmentative alternative communication devices), or evidence-based treatments. The gold-standard therapy for hypokinetic dysarthria is Lee Silverman Voice Treatment (LSVT) LOUD [6,7], which targets vocal loudness and recalibrates internal monitoring mechanisms, using principles of motor learning and neuroplasticity. This focuses on the cue "BE LOUD," aiming to target volume, and often has subsequent positive implications for articulation. Therapy is comprised of four areas: (1) daily exercises including a sustained phonation, pitch glides and functional phrases, salient speech hierarchy tasks across words, phrases, sentences, and conversation; (2) recalibration using feedback tools and education around changes in speech in Parkinson; (3) daily homework exercises; and (4) carryover exercises to promote use of loud voice in everyday life. However, LSVT is resource-intensive, and four sessions each week, for a month, are recommended to promote lasting changes. Often, there is a shortfall between these evidence-based recommendations and the real dosage provided during face-to-face therapy. This limits the accessibility of LSVT in the United Kingdom. Furthermore, regional speech and language therapist (SaLT) shortages and postpandemic waiting lists exacerbate difficulties accessing SLT [8], leaving a large percentage of people with PD without therapy access. Given these barriers, alternative therapeutic approaches are required to facilitate increased access to SLT for people with PD.

Voice-assisted technology (VAT) uses natural language processing and automatic speech recognition (ASR) to interpret speech and translate it into actionable requests. These devices are consumer-facing apps of artificial intelligence, and help the devices to provide interactive, contextually aware responses. VAT is more commonly known by commercial names such as "Amazon Alexa" and "Google Home," or as a smart speaker. VAT has potential as a therapeutic tool in SLT for people with speech and voice difficulties [9-11]. However, dysarthric speech is often misinterpreted by VAT, with recognition accuracy decreasing as speech severity worsens or sentence length increases [12,13]. Despite this, error feedback can prompt some participants with speech difficulties to adapt their speech to enable interaction with VAT [14,15]. For example, people with PD have reported increasing their vocal effort, loudness, and clarity when interacting with VAT [10]. This is similar to the aims of LSVT, and findings are supported by wider literature [9,11]. Additionally, some SaLTs have integrated VAT into therapy for individuals with dysarthria, finding that it provides objective and impartial feedback on speech clarity and fosters improvements in volume and intelligibility [16]. However, it is important to note that the outcomes in this literature are self-reported, perceptual changes in speech and voice, rather than objective, quantifiable changes. This highlights a gap within the literature regarding the acoustic outcomes associated with VAT use for speech and voice.

While research has not yet established functional outcomes of VAT use in clinical practice, research indicates potential positive functional implications. VAT can create communication opportunities with others in the household [14,17] and contributes to increased speech confidence [10,16]. This is because VAT is perceived to provide objective, unjudgmental feedback on speech, which can reduce social barriers for users and the anxiety and embarrassment associated with repeating themselves [9,10]. Furthermore, the everyday nature of VAT avoids the stigma associated with bespoke SLT communication tools [10,16]. Notably, research also indicates potential functional risks when using VAT: communication avoidance due to increased awareness of difficulties [9] and frustration with speech not being recognized and subsequent error recovery [10]. VAT has also been recognized as a motivational tool for encouraging home-based SLT practice, addressing a recognized limitation of LSVT, where practice is described as repetitive and lacking real-world validity [18]. However, despite a growing evidence base for the use of VAT as an emerging therapeutic technology in SLT, to date, there is limited exploration of SaLTs' experiences of using VAT therapeutically with people with speech and voice difficulties. Understanding SaLTs' experiences of VAT ensures that future developments can meet their clinical needs and may reduce technology abandonment [19].

Therefore, this study aimed to explore the experiences of using VAT to address hypokinetic dysarthria, secondary to PD, from the perspectives of SaLTs.

The objectives of this study are as follows: (1) to understand how SaLTs are using VAT to support those with dysarthria; (2) to explore the therapeutic potential of using VAT for speech and voice outcomes, from SaLTs' perspectives; and (3) to establish how to support the implementation of VAT in SLT.

Methods

Study Design

A qualitative methodology using online focus groups and individual interviews was used to explore SaLTs' experience. Both SaLTs and researchers participated online via videoconferencing in their own respective homes, and no nonparticipants were present. Engaging in focus group discussions fosters dynamic conversations, often leading to fresh insights and idea generation [20], which is particularly valuable when evaluating the use of emerging technology. Notably, online focus groups have been found to produce a greater variety of novel ideas compared to traditional in-person discussions [21], as participants are described to be more

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"professional," taking time to listen and consider their contributions before responding to questions or suggestions during online interviews and focus groups.

Individual interviews were used to supplement focus groups due to SaLTs' scheduling conflicts. Online videoconferencing software (Teams; Microsoft Corp) was used, enabling data collection across a wider geographical area [22]. The lead author is a SaLT who has current and ongoing experience with the Parkinson population. It is acknowledged that this position could lead to potential bias in the interpretation of findings. Several measures were taken to address this, including transcription of focus groups and interviews within 24 hours and the use of a reflexive diary, which are further discussed within the data analysis section.

Ethical Considerations

This study was reported in accordance with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [23] and is part of a larger PhD study that received ethical approval from the Ulster University Research Ethics Committee in July 2024 (FCNUR-24-016-A). All participants provided informed consent. Privacy and confidentiality were ensured: only the research team was able to see personal demographic data, and data will only be held as long as the university guidelines and General Data Protection Regulation (GDPR) require. Following transcription, all participants' data were anonymized. Participants were reminded that if they knew another participant at the focus groups, they were to respect their right to confidentiality in their participation. No participants in the research were given payment.

Patient and Public Involvement

A patient and public involvement steering group was established prior to study commencement to provide a voice for key stakeholders and ensure they played an active role in shaping the research. This group included a SaLT with firsthand experience using VAT in clinical settings, a person living with PD, and a caregiver. These three "experts by experience" helped to co-design the project, influencing and informing this work's aims, methodology, and dissemination. Experts by experience were asked to provide feedback on information sheets via email, indicating that complex language should be avoided. Consequently, information sheets were revised with more patient-facing language. Furthermore, feedback on the interview schedule was also provided, with experts by experience suggesting that focus groups should build in time for participants to discuss their personal or professional journeys. They also suggested that introductions from researchers should include an informal preamble about smart speakers, which emphasized the technology's relevance for people with Parkinson and the SaLTs working with this population. As a result, focus groups began with a summary of professional journeys, gave background to what smart speakers are, why they might work to improve speech and voice, and the lead author's experiences of using her own personal "Alexa" device. Experts by experience also offered valuable insights of lived experience to the academic team during data collection and charting, including suggestions to offer the option of individual interviews to SLTs who could not attend focus groups, to maximize data collection.

Recruitment

SaLTs were recruited purposively in the United Kingdom through the Royal College of Speech and Language Therapists, including the Parkinson's Clinical Excellence Network and Bulletin Magazine, to participate in online focus groups and interviews. The anticipated sample size was difficult to determine without concrete and up-to-date figures of SaLTs working with adults in the United Kingdom. This study had a smaller number of participants than the suggested six to eight in the literature [24] due to pragmatic considerations and challenges with recruitment and scheduling. To balance diverse perspectives with data saturation, a range of 2-4 focus groups was proposed. Ultimately, two focus groups and two individual interviews were conducted.

Participants were asked to express their interest in the study, and following initial contact, they were screened via email or phone, according to study inclusion criteria, by the lead researcher (JM). Participants were unknown to the research team before participating. Eligible SaLTs were required to be older than 21 years of age, as this is the earliest age at which clinicians can be qualified, and were required to have prior experience of using VAT in clinical practice, with individuals experiencing dysarthria. It should be noted that four of the seven SaLTs directly worked with people with PD, and the others with populations experiencing dysarthria. Additionally, participants required access to an internet-enabled device with a camera for videoconferencing. There was no minimum clinical practice experience or experience of using VAT in clinical practice required to participate. Given that VAT use in the United Kingdom is still deemed to be emerging, this is a small, niche population. Increased inclusion criteria may have further limited the sample size. SaLTs meeting the inclusion criteria received an information sheet and consent form via email. Once consent was obtained, participants completed a digital health readiness questionnaire (Multimedia Appendix 1) and a demographic survey (Table 1). They then provided their availability for scheduling focus groups. SaLTs unable to join a focus group were offered the option of an individual interview. No background information was gathered relating to the severity of dysarthria of clients the SaLTs worked with, due to the exploratory nature of the study. Additional research may seek to investigate this further.

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Table 1. Demographic data for SaLT[a] participants.

SaLT ID	Gender	Age (years)	Clinical experience	Current clinical population	Location
P1	Female	46	23 years—specifically Parkinson	PD[b]	England
P2	Female	33	12 years	Adult disability or TBI[c]	England
P3	Female	41	11 years—specifically Parkinson	Adult community—Parkinson, MND[d], MS[e]	Scotland
P4	Female	24	6 months	Adult community, including Parkinson	England
P5	Female	36	2 years	Adult community, including Parkinson	England
P6	Female	38	17 years—5 years of acute experience with Parkinson	TBI	Northern Ireland
P7	Female	43	18 years—specifically Parkinson	TBI	England

[a]SaLT: speech and language therapist.

[b]PD: Parkinson disease.

[c]TBI: traumatic brain injury.

[d]MND: motor neuron disease.

[e]MS: multiple sclerosis.

Procedure

A total of 7 SaLTs were recruited and participated in either a focus group (n=2 groups) or an individual interview (n=2 interviews). No participants dropped out of the study. The sample size and duration of each focus group or interview are shown in Table 2.

This study was conducted as part of a larger study with people with PD, carers, and SaLTs, participating in six focus groups and two interviews. This paper only reports findings from seven SaLTs, and findings from focus groups with people with PD and carers are presented in another paper [25].

Data collection was facilitated online by the lead author (JM), a female SaLT, and a coresearcher (a qualified SaLT or health care professional with a PhD), and lasted between 38 minutes and 1 hour 30 minutes. The lead author participated in training on leading focus groups prior to conducting this research. To ensure methodological consistency, a semistructured topic guide (Multimedia Appendix 2), informed by literature, was used, and SaLTs had access to this in advance of their focus group or interview. This included prompting questions to encourage reflection and elaboration by clinicians and was reviewed by the experts with experience before use. Participants were invited to share their experiences of using VAT as a tool to address speech and voice difficulties with adults, and field notes were made during the focus groups or interviews.

Table 2. Format of qualitative data collection and number of participants for each.

Format	Number of participants	Length of time
Online focus group 1	3	1 hour 30 minutes
Online focus group 1	2	1 hour 7 minutes
Online interview 1	1	38 minutes
Online interview 2	1	1 hour

Data Analysis

Focus groups were recorded audio-visually using Teams and were transcribed by the lead author (JM). To ensure methodological rigor and to ensure the accuracy of contextual memory, transcriptions of videos were completed within 24 hours of the focus groups. Before analysis, transcripts were anonymized, removing personally identifiable details, to ensure confidentiality.

Framework analysis was used to synthesize the results, as it facilitated understanding of results across a wider dataset [26]. Given the lead researcher's background in SLT, framework analysis also supported reflexivity, encouraging critical reflection on biases and assumptions to promote analytical rigor [27]. The analysis followed the five-step process outlined by Ward et al [28]: (1) data familiarization, (2) framework development, (3) systematic coding, (4) synthesis within an analytical structure, and (5) interpretation.

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The initial theoretical framework was created using published VAT evidence [13,16]. Once transcriptions were completed, data were imported into NVivo (version 14; Lumivero) for systematic organization and qualitative analysis. The researcher engaged in repeated readings of the transcripts, using mind mapping and a reflexive journal to document emerging themes. Preliminary themes were noted and discussed with coauthors (OD, KP, and GK). This led to further data immersion and refinement by the lead author (JM) before creation of draft themes. A consensus was reached by the team following further reflection on the data. The finalized framework was developed by systematically indexing data, summarizing this into codes, and charting findings into a structured analytical model [26]. Direct participant quotations are presented to provide context, to link data with interpretations, and to enhance the credibility of findings. Furthermore, results were sent to all participants for member checking to ensure written findings reflected their lived experiences and to enhance the rigor of the research.

Results

Overview

The Digital Health Readiness questionnaire required participants to rank 20 statements about technology use and ability, using a 5-point Likert scale. Statements covered digital access, use of digital technology, digital literacy, digital health literacy, and learnability.

Although seven SaLTs were recruited, 1 (P5) did not return the digital health readiness questionnaire. All 6 SaLTs who responded had good digital access: they all used the internet, a laptop, and a smartphone or tablet daily, 5 used health-related apps, and all indicated digital health literacy. All were motivated to learn about technology and strongly agreed that they would learn quickly when offered personal guidance about digital technology. Multimedia Appendix 2 provides further details.

There were four main themes identified across the groups and datasets: (1) VAT as a potential driver of positive speech therapy outcomes, (2) managing therapeutic beige flags, (3) empowering SaLTs to become digitally enabled practitioners, and (4) future design and features of a VAT tool (Textbox 1).

Textbox 1. Results from research with themes and subthemes.

Theme 1: Voice-assisted technology (VAT) as a potential driver of positive speech therapy outcomes

1.1 Enabling speech practice and self-management

1.2 VAT reduces practice stigma as an everyday device

Theme 2: Managing therapeutic beige flags when repurposing commercial technologies

2.1 Usability barriers to therapeutic benefit

2.2 Need for monitoring and human interaction

Theme 3: Empowering speech and language therapists to become digitally enabled practitioners

3.1 Limited device knowledge for therapy

3.2 Suggestions for education and guidance

3.3 Navigating governance, data storage, and confidentiality

3.4 Smart speaker implementation concerns

Theme 4: Future design and features of a VAT tool

4.1 Develop a program or skill

4.2 Lee Silverman Voice Treatment through VAT

4.3 Additional feedback for self-awareness

Theme 1: VAT as a Potential Driver of Positive Speech Therapy Outcomes

Uses of VAT for managing dysarthria were reported by SaLTs, including therapeutic uses for speech and voice, VAT-supported self-management, and perceptions of VAT as an everyday, nondisability device.

1.1 Enabling Speech Practice and Self-Management

SaLTs discussed the role of VAT in therapy and supporting home practice for carryover, with most considering VAT to be functional as part of their toolkit:

> *It's used as a tool, as an adjunct ... It comes part of a massive part of treatment.* [P7]
>
> *I would almost separate it into two different roles ... The input would come from the therapy and the practice would come from the Alexa.* [P5]
>
> *You have all these like little homework tasks to do with LSVT. Alexa is kind of being your homework buddy, like a virtual assistant homework buddy for voice work.* [P7]

VAT was also identified as a practice tool for integrating volume, articulation, rate, and general intelligibility strategies:

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> *I just ask them to use [it] in conjunction with strategies. So, we've got strategies we call SLOP strategies so slow, loud, over pronounce pause and making sure you take that deep breath.* [P4]
>
> *It's like the whole needing to, remembering to breathe, activating it and then breathing again quickly and then really, really clear speech. So, it's been a really good tool for him to try and remember to articulate the words quite clearly.* [P2]

SaLTs also indicated that VAT provided feedback on volume, clarity, and intelligibility of speech, and helped to develop self-awareness. Feedback can be a light on the device, or simply the device not responding to speech. This could prompt clients with dysarthria to adapt their speech using strategies:

> *They could be using it ... and getting that feedback themselves and thinking why is Alexa not understanding me. You know, if I raise my voice, will that help? If I be clear, will that help?* [P6]
>
> *So, he would ask, quite detailed biology questions ... then he would receive feedback if Siri understood him first time or not. It was, primarily for intelligibility feedback.* [P6]
>
> *It's an alert for your kind of clear speech strategies: to speak louder, to go slower.* [P7]

SaLTs also explained that this feedback, including how well clients were understood by the VAT device or how well it completed their functional requests, was often central to their goals:

> *The other goal was for her to get feedback on her intelligibility ... So, when Alexa didn't understand her, she had to repeat it and try and reduce the amount of time she would have to repeat it.* [P6]
>
> *With the speakers, you know, just being understood ... That's quite a quick good way of monitoring their volume and their clarity I suppose if the speaker can understand them the first time.* [P3]
>
> *I'll probably kind of set clearer goals within that report and say that we had a goal to kind of use Alexa, to be able to wake Alexa and kind of ask Alexa various questions and for that to work 70% of the time.* [P7]

This objective and unjudgmental feedback from VAT devices was seen as a factor in encouraging the use of adaptive speech strategies and reportedly reduced the client's reluctance to speak out:

> *We call it high challenge, low threat. Those activities that people ... they really want to have a go at, but that fear of failure, that fear of social rejection, isolation is taken away. Because the Alexa's, you know, it's going to respond to neither it'll tell you "Oh sorry I didn't understand that" or it will give you what, what you want.* [P5]
>
> *She really liked the idea of practicing with the Alexa to build her confidence.* [P6]

SaLTs also reported that VAT could be used to integrate functional phrase practice in the context of everyday requests whilst also promoting an increase in practice intensity for working-age clients:

> *Speech sounds on cue, or something like that ... they're repeating random sentences that mean nothing to them. Whereas using Voice Assistant Technology they can ask whatever they want and get an actual outcome.* [P6]
>
> *We then developed kind of ten phrases that he could use for Alexa, to kind of say to Alexa and get Alexa to do various things ... So it'd be things like Alexa, what's the weather today, Alexa, what time it?* [P7]
>
> *If people are working ... I think the intensity and the dosage would be good as well if they had access to that on a smart speaker and it would kind of do the role that we wouldn't be able to offer.* [P4]

Furthermore, SaLTs reported that VAT could act as a communication partner for people with dysarthria:

> *I always go back to the means, reasons and opportunities model ... It's when they don't really have the opportunities to interact that often face-to-face with people, I tend to use that as their interaction opportunity.* [P1]

Although this research focused on VAT as a therapeutic tool for speech and voice rather than a tool for environmental control, SaLTs indicated that VAT devices were often used for accessibility and environmental control, including clients interacting with VAT via augmentative alternative communication devices. The following quotes see SaLTs draw on wider experiences of working with clients with dysarthria, who did not have Parkinson:

> *He now has that set up at home in terms of turning on his lights and TV and things.* [P2]
>
> *They can use their eye gaze or their touch and have the computer speak on their behalf, and then it can turn on the lights or it's connected to a smart plug so they can turn on their kettle to make a cup of tea.* [P7]

Furthermore, by facilitating self-management of speech and voice difficulties, VAT could reduce reliance on ongoing therapy input and transfer responsibilities onto patients themselves:

> *Our aim is to deliver the strategies to people to self-manage, which, again is something that an Alexa could really help with ... It's kind of moving patients away from that almost dependency on therapy and how can I self-manage.* [P5]

SaLTs also considered how VAT could be combined with SaLT-made resources to maintain speech and voice prior to SaLT, and following discharge:

> *We could always post it out to people as soon as they come on the waiting list and say, you know, if you've got a smart speaker. It's worth a try. Just to maintain your functionality.* [P5]
>
> *Post therapy yeah, definitely. You could use it as a kind of maintenance tool to keep your kind of dysarthria strategies up.* [P6]

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1.2 VAT Reduces Practice Stigma, as an Everyday Device

SaLTs discussed the nature of VAT devices, which meant that they were widely integrated in households, and clients were motivated to practice with them. This also brought about a societal acceptance that VAT devices may reduce the stigma of using a speech-aiding device:

> *It is something that they're familiar with and it's in their home ... They are really excited to try and give that a go.* [P4]

It's *not like a specialist piece equipment.* [P2]

> *They're normal to integrate as part of your life, it's much more acceptable ... It's not like you're singling them out and giving them some specialist equipment that doesn't look or feel like the general population ... My clients often they hate to be reminded of their disability. They're desperately trying to kind of live the life they lived before.* [P7]

Theme 2: Managing Therapeutic Beige Flags

Overview

Participants reported several factors that must be considered before VAT can be implemented as a tool for managing dysarthria, including therapeutic and practical concerns and challenges posed by VAT devices. These considerations are termed beige flags, unlike red flags, as the barriers do not prevent the use of therapeutic VAT but can make it more difficult.

2.1 Usability Barriers to Therapeutic Benefit

VAT devices not understanding clients, frustration, difficulty with error scaffolding, and devices timing out were reported as challenges when using VAT, although they did not necessarily preclude use.

Clients becoming frustrated when interacting with VAT was a concern for all the SaLTs:

> *At home, when we ask it something and then what it gives us is something completely random, it's hilarious. But if you've got difficulty with speech intelligibility, I can imagine that's not funny at all. It's actually really frustrating and just another thing that confounds the fact that you're struggling with your speech.* [P1]

> *I'm just aware of frustration as well: if they can't access the Alexa and they are working so hard at it, depending on the severity of their dysarthria. It is important that it's accessible to them and that they are getting success.* [P3]

SaLTs also explained that VAT often did not understand people, even when the clinician perceived their speech to be intelligible, and they highlighted how frustration could impact confidence. Additionally, it was recognized that fatigue and self-awareness could impact how well participants were understood by VAT:

> *It doesn't matter how clear their speech is, sometimes the smart speakers just don't get it ... It's frustrating when my client sounds really clear to me but still isn't picked up by the smart speaker. And trying to reassure them that it's not them, it's the speaker.* [P7]

> *Fatigue would also be an issue because they're dysarthric. So, in the evenings, the girl who's using it functionally would always say it's harder to do it in the evenings.* [P6]

> *They're not very good at changing their strategy, so they'll just repeat the same sentence again and again.* [P7]

SaLTs also highlighted that additional factors, such as VAT timing out and difficulties with error scaffolding, hampered the therapeutic value of VAT. Error scaffolding related to feedback, both from the blue light on VAT devices that turns on when the device is listening, and the verbal feedback that devices may give when trying to action a request:

> *It didn't actually give that feedback of "I didn't understand that" the blue light just went off.* [P4]

> *When he is pausing, if it's for too long, the device is stopping ... We've kind of had to start from scratch even though pausing is a really good strategy that I think is helpful in conversation.* [P4]

2.2 Need for Monitoring and Human Interaction

SaLTs discussed their reflections on therapeutic and practical concerns about using VAT in practice. Most clinicians indicated that they were unable to monitor clients' use of VAT during therapy and following discharge:

> *I don't want them to be unsuccessful either, and I'm not there to monitor that. I can't see what happens at home.* [P3]

Another SaLT indicated that monitoring required extra support or additional staff:

> *I've been relying on either myself going in and monitoring that, a speech therapy support worker or, know a spouse or a carer of some sort.* [P1]

Furthermore, VAT's challenges in providing conversation, with standard settings, were considered as a barrier for the delivery of therapy. SaLTs indicated that VAT was not reflective of real-life communication challenges:

> *All we've been practicing is you ask a question; it gives a response. But we want to, you know, get back to conversations with people. And so, it's kind of bridging that gap between these one-word responses to that device and how are you going to get back to the conversation?* [P4]

> *That sort of flow, the spontaneity and the flow of conversation is what patients need. It's great for them to practice their speech with short questions and one-word answers, but actually that's not what happens in communication and in conversation. It's much more of a flow, and you do have to think on your feet.* [P5]

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Theme 3: Empowering SaLTs to Become Digitally Enabled Practitioners

Overview

Participants explained how a lack of adequate knowledge about what VAT can do, privacy, and practical and technical concerns prevented them from fully using the potential of the devices. They also suggested they needed guidance and education to help them further integrate VAT into clinical practice.

3.1 Limited Device Knowledge for Therapy

SaLTs discussed their uncertainties about what VAT can do, and all described a need for education about what Alexa can do:

> *I think it would be really interesting to know all of the other different services that a smart speaker offers, apart from just playing your favorite, your music or setting a timer.* [P2]

> *It depends on the therapist's experience really with these smart speakers ... There's those gaps as well if you've not used it in a specific way in your own home life, then you won't know about it.* [P3]

SaLTs indicated that they required education and guidance about using VAT as a tool for dysarthria:

> *I think it would be really useful to have like a guidance booklet on kind of what a smart speaker is, how it's used, like how the general population uses it, why people like it.* [P7]

3.2 Suggestions for Education and Guidance

SaLTs also gave several suggestions about what they would like guidance and education to include. For example, resources, evidence-based practice, goal setting, and outcome measurement. Table 3 highlights and elaborates on these key ideas, using quotations.

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Table 3. SaLT[a] suggestions for education and guidance surrounding the therapeutic use of VAT[b] for dysarthria therapy.

Suggestions for education and guidance	Supporting quotation
Resources and example therapy plans	• "Even just like kind of therapy ideas pack. You know, this is what you could use it for. This is how you can use it, would be really nice because it's hard when your kind of thinking about things to do sometimes." [P6] • "So, I think, I think so, just having those sorts of those ideas and even something that you know, you could, you could, you could print off for that that person as well. Anything that can just help generate ideas and then having the guidance is good." [P3] • "And then to have some ideas of things to try because I had to kind of look outside the speech therapy population for ideas on things to try with it ... I couldn't come up with those on my own. So, I think just kind of showing people the different applications that you can use with smart speakers." [P7] • "Maybe also just kind of having like a little crash course into what people have found the best questions to ask are or some interesting ones that can prompt." [P5]
Scripts	• "So, we're sort of saying the same sort of thing, to the patients. A wee script is always good." [P3]
Idea sharing network with other clinicians	• "Like a sharing of practice in terms of what works, what hasn't worked, why hasn't it worked? And is there, you know, is there something that we can do differently, better perhaps to, to get that?" [P5]
Goal setting	• "How can you aim it to people who are working on different levels and different things? ... I think because everyone will use it in such a different way as well, depending on the severity of your dysarthria. And you know what, what your goals are as well. It would be really quite difficult currently." [P4]
Outcome measurement	• "Yeah, to measure that. What does progress look like? Because it will look very different for different patients depending." [P5] • "We're always working on is strategies, it's harder to sort of capture it when someone's got a progressive condition, isn't it?" [P3] • "What about the sort of goal setting and evidencing, evidencing it in that sort of way? I think that's always super, super useful. Not necessarily percentages, but if there was some sort of guidance." [P3]
Evidence-based practice relating to dosage and maintenance	• "I think it'd be useful in terms of knowing a bit of how much maybe you'd have to use it to improve speech ... I think there would be benefit from research to know, if you did this five times a day then your speech would increasingly get more intelligible." [P2] • "Evidence in terms of can they actually meet the levels of practice that you might need for maintenance, that would be something that I would find quite important." [P4]
Evidence-based practice relating to therapeutic impacts	• "If you've got that research behind it then you've got an easier sell to the rest of the team, and particularly with budget cut that we've had and the financial constraints, I think we do need this this sort of thing." [P3] • "If you were to do it purely from a data perspective, I wouldn't be overly interested because we don't work with data, we work with people ... if the data is telling me, yes, but the person is telling me no, then I'm not going to." [P5] • "I wouldn't be overly worried about the evidence being like, really clear cut, I would be thinking instead, is this accessible to the patient? Is this something that they would find motivating? Do I think they would enjoy and benefit from it? Is it something that they would have to go out of their way to do?" [P5] • "Because we don't offer LSVT[c], I think compared to another service that maybe do offer LSVT, they may want the research to be you know more developed." [P4]

[a]SaLT: speech and language therapist.

[b]VAT: voice-assisted technology.

[c]LSVT: Lee Silverman Voice Treatment.

3.3 Navigating Governance, Data Storage, and Confidentiality

SaLTs discussed common client concerns about privacy and their clinical reflections on this:

> *I think that is a concern with a lot of people, isn't it? And it might be more of a concern with patients' kids than patients themselves. You know, it would be ... Who's listening?* [P3]
>
> *Maybe people being concerned about the device is always on and always listening to them ... How much information is it storing as well and what's happening with that information.* [P4]

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One SaLT discussed how VAT's recording of clients' requests could be used in legal cases and described the measures she took to protect clients:

> *You can hear like domestic violence and things on the Alexa. People have kind of gone back and picked up arguments that have happened. You know, in police cases and thing ... I tried to make sure that when clients are kind of talking, their phrases are kind of pretty benign phrases and not giving away too much information.* [P7]

Furthermore, SaLTs indicated that GDPR and governance policies could act as barriers to VAT use. GDPR refers to guidance about how patients' personal information is collected and stored, and is considered part of clinical governance. In the United Kingdom, the National Health Service has strict governance policies about how technology used in clinics must align with GDPR guidance:

> *We've had a lot of barriers from IT, from information governance ... IT security is a really, really big thing ... It's all about GDPR.* [P3]

> *The huge amounts of red tape within the hospital trust just made it impossible.* [P1]

As a result of these concerns, SaLTs indicated that support was required:

> *I think [we need] all of the information that we just spoke about to do with risk information, governance, GDPR. All of those sort of guidelines around it.* [P1]

SaLTs also indicated that a clear, but realistic, view of risks and benefits from a clinical perspective would support the integration of VAT:

> *Information Governance is incredibly important, but I kind of feel like the risk benefit is skewed somehow? They need to be balancing it a lot better, whereas all they see is risk.* [P1]

> *We always chat to them about, you know, just about the information, keeping it safe and absolutely the benefit totally outweighs the risk. They're like, I don't care, like, I just want to communicate with people.* [P3]

3.4 Smart Speaker Implementation Concerns

Participants discussed technical and practical concerns about using VAT, as well as making suggestions for support.

VAT devices' requirement for an internet connection meant SaLTs were unable to set up their own VAT for therapy, and therefore, most were only able to use VAT therapeutically if clients in the community owned a VAT device personally:

> *You can't just take your smart speaker and plug it in in someone else's house onto their Wi-Fi network, because immediately it knows it's on a different Wi-Fi and it needs to set up an account and things.* [P5]

> *The barrier would be access, if the person has one or not ... I only use it when people have already got it set up.* [P1]

> *Neither myself or others are recommending they get smart speakers. We're just going on the back of the fact that they already have them in the house and already using them.* [P3]

Furthermore, SaLTs expressed skepticism regarding VAT's reliability for therapy and the unpredictability of responses. Variations in responses due to personalization and differences in plug-in features were also problematic:

> *I have no idea if this Alexa is going to answer me or not or what it's going to say ... I can't guarantee that it will continue to do that once I leave ... You know, it's Harry Potter, isn't it where they say, "Don't trust something that can think for itself, if you don't know where it keeps its brain."* [P5]

> *"I don't know what's coming and that's a difficulty for like therapy planning. It's like you ask it to play some music and it says "you are not linked up to Amazon Music." Well ... that's a barrier because I don't know what they have access to and what they don't.* [P4]

Most SaLTs expressed a lack of clarity around SaLT roles when using VAT as a therapy tool. However, independent SaLTs had more role flexibility:

> *Thinking about our remit, the tech setup is not a speech therapy job! So again, that raises its own challenges.* [P5]

> *A lot of what we do is troubleshooting. So, we turn up at our client's house, the Wi-Fi is down, and we've got time to call the Wi-Fi company or to switch the booster on or you know, that's the way that we work. We're really integrated into client's homes.* [P7]

Given this, SaLTs explained that technology-specific guidance may help to overcome gaps in knowledge that were beyond clinical skills and would also help them with using VAT straight out of the box:

> *We're speech therapists. We're not technicians, we're not clinical scientists. So, I think any support along those lines is, is always really useful.* [P3]

> *A set of instructions that you follow with your client in their house for the first set up, and then any other set up that they want to do, which might have to be done by someone else.* [P5]

> *Maybe also some tech support ... If it is just not responding to you, is there anything you can try?* [P4]

Furthermore, SaLTs also had practical worries about using VAT. A lack of consensus around how VAT is currently used therapeutically, dosage requirements, measurement of therapy outcomes, and maintenance or generalization was discussed:

> *I haven't really done any sort of, anything formal with smart speakers.* [P1]

> *I don't know ... I don't give a particular dosage.* [P1]

> *Everyone's doing something different in my team ... We've not been super specific in how we do it and actually in I suppose how we're measuring our success as well.* [P3]

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SaLTs indicated that future support may improve evidence-based practice using VAT, including demonstrating therapeutic impacts and required dosage to improve and maintain speech. Additional supporting quotes are found in Table 3.

> *It would be so exciting to strip everything away and just see if there's parameters of speech and voice got better just on smart speaker treatment.* [P7]
>
> *I think I'd be really keen to hear about that more sort of qualitative ... the data that from that perspective, you know the stories of how is it helping, and is it helping, and to what extent is it helping, I think more so than the numbers.* [P5]

Theme 4: Future Design and Features of a VAT Tool

Overview

Participants provided considerations for the future therapeutic use of VAT for people with speech and voice difficulties in SLT. This included developing VAT skills, delivering LSVT through VAT, increasing the ability to monitor speech and voice changes, and increasing levels of feedback to promote increased self-awareness.

4.1 Develop a Program

Participants indicated that they would like VAT to have a program for speech and voice therapy. This was described in various terms:

> *I think it would be amazing if there was an Alexa skill that dealt with therapy.* [P1]
>
> *There are all sorts of apps that you can link to Alexa. So, there might be something where you could work on your pitch and Alexa would give you some feedback.* [P7]

4.2 LSVT Through VAT

SaLTs also made suggestions regarding how a SLT VAT skill might function or features to include. For example, increased feedback, LSVT style exercises, conversation practice, and reminders to complete therapy tasks.

Participants described how LSVT-style exercises could be delivered through an Alexa skill, which could target articulation, breath support, phonation, singing, and reading:

> *I can see the 10 functional phrases. I can see that being practiced with a smart speaker. If you could think of things that you would say to Alexa where you get a response back where you know whether you've been clear enough, I can see that really working.* [P7]

SaLTs also suggested how reading aloud tasks could be facilitated by VAT:

> *You could get the lyrics to come down the screen ... could you do that with a reading passage? Could you get it to scroll a poem through in front of you?* [P1]
>
> *You could ask Alexa to listen to you whilst you read a passage for the kind of extra practice at the end.* [P7]

Furthermore, conversation was also highlighted as a beneficial feature for a VAT tool to incorporate:

> *I think just having those modelled conversations and actually having it answer you back with something that might be unexpected and you having to then formulate your response kind of like a conversation would be really helpful at the moment.* [P4]

SaLTs felt these exercises could form part of home practice, and prompts and reminders could be useful to help clients integrate their everyday practice:

> *I'd use it for that, reminding them to do it as a routine. And then maybe you know a bit later ... "Have you done it yet?"* [P1]

4.3 Additional Feedback for Self-Awareness

An enhanced feedback feature to facilitate self-awareness and recalibration of internal monitoring was suggested. More specific feedback from VAT on speech and voice was suggested. For example:

> *That wasn't clear enough. Can you say it again? Louder.* [P1]
>
> *Oh, I didn't quite understand what you said ... Could you slow down your speech?* [P4]
>
> *[VAT] could ... repeat back what they did understand* [P3]

One SaLT indicated that this may help to overcome difficulties with communication partner prompting:

> *I find that quite a challenge to get communication partners to actually do that whole repeating back ... If a smart speaker could do that would be amazing!* [P1]

Furthermore, SaLTs also indicated that scored feedback on intelligibility may be useful:

> *Sort of 6 weeks ago, I had to repeat myself 50% of the time, whereas now I'm only repeating myself 5% of the time.* [P6]
>
> *I mean, even better would be kind of being able to ... kind of give some feedback on percentage intelligibility or something, but I can imagine that would actually be very, very hard to develop.* [P3]

Finally, one SaLT suggested that this auditory feedback from VAT could be supplemented with visual displays and biofeedback:

> *If they've got that decibel meter in front of them and they could see that they're hitting the red part of it. That's the thing that helps ... I think some sort of biofeedback through a smart speaker would be really useful.* [P7]

Discussion

Principal Findings

This study aimed to explore SaLTs' experiences of using VAT to address hypokinetic dysarthria. Focus groups and interviews indicated the potential of VAT for improving volume and

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intelligibility and supporting home practice. However, concerns about privacy, practical use, and device errors were noted. Key themes include VAT's therapeutic use and potential, managing technical and practical challenges, supporting SaLTs to become digitally enabled using VAT, and the design and features of a future VAT tool.

Therapeutic Potential as a Self-Management Tool

SaLTs discussed using VAT to support practice of volume, articulation, rate, and general intelligibility strategies, and reported using VAT as a biofeedback tool to provide feedback on speech clarity. This suggests that clinicians have experience of using feedback from VAT as an objective measure of intelligibility and to prompt increased self-awareness surrounding speech and voice. Kulkarni et al [16] reported similar findings, where SaLTs indicated that VAT could improve the accuracy of word productions for people with speech and voice disorders and increase clients' motivation to practice at home. Indeed, several studies have indicated the potential for VAT as an SLT practice tool with participants, reporting a need for clear speech when interacting with the devices [12,14,29]. Furthermore, Smith et al [14] found improved speech intelligibility related to VAT use and device-related phrases and reported a smaller, but positive effect, for unrelated generalization phrases. This was echoed by Duffy et al [10], where people with PD reported speaking "slowly, loudly, and clearly" when using VAT. Findings from this study offer a foundation for collaboratively designing a VAT tool to support home practice and management of speech, voice, and self-awareness changes in neurodegenerative conditions.

Speech subsystems of articulation and phonation are commonly targeted by SaLTs during the therapeutic management of PD [30]. Although LSVT is the optimum, gold-standard therapy for people with PD [7], with clearly quantifiable improvements in volume [31], difficulties meeting intensity requirements, practice abandonment, and poor self-reported maintenance of therapy gains for people with PD can act as barriers [18,32]. VAT may have the potential to overcome these challenges by supporting the delivery of LSVT and facilitating home practice, shifting the focus from direct SLT input to self-management of longer-term conditions [33]. This is consistent with previous literature, which has suggested leveraging technology to facilitate practice of SaLT exercises and maintain therapy for people with PD or dysfluent speech [12,34]. Indeed, research has used technology at home following LSVT, known as LSVT Companion, and demonstrated gains in volume similar to in-person follow-up [35]. Literature reports that LSVT Companion can help to overcome constraints of treatment delivery, such as mobility and geographical constraints, while maintaining treatment efficacy, and may enable self-management of speech and voice difficulties for certain clients [35]. While Companion is specific to LSVT therapeutic tasks, it promotes digital use for therapeutic outcomes, particularly beneficial for providing biofeedback and outcome measures to reflect on the success of the tasks the clients have performed. Although Companion refers to laptop software, future research may consider how features of the LSVT Companion may be adapted and implemented by VAT.

However, SaLTs should be cautious that VAT is not used in isolation, but rather as a tool "to add to therapists' toolboxes," requiring SaLT-mediated support and check-ins. Current findings also overlap with wider literature regarding technology use in SLT (apps), where advantages such as increased practice frequency and intensity, alongside improved therapy motivation and engagement, are reported [36,37]. Given that improved vocal loudness, sensory recalibration, and intensive, high-effort practice are targets of traditional LSVT in SLT, future research may examine if and how VAT could host an alternative delivery of standard LSVT protocols or create "skills" for commercial VAT devices. Future research also may examine the quantitative impact of a VAT intervention to improve volume, clarity, and intelligibility for people with PD, using a combination of pre- and postmeasures and user self-reports.

Despite this, the technological caveats of VAT must be considered carefully by SaLTs. ASR errors are often higher than expected for dysarthric speech, and device inaccuracies may be attributed to ASR models and utterance complexities [38], as well as phonemic distortions associated with dysarthric speech. As discussed by SaLTs in this research, this creates concerns about a lack of consistency when using VAT for therapeutic tasks where there will be different devices, different rates of error, and even different environments. Furthermore, proper nouns, names, and locations may not be recognized by ASR [39]. Therefore, it may be difficult to use VAT to practice personalized, functional phrases, and it may limit use to basic interactional requests for some clients. Furthermore, the commercial technology exhibits an ethnocentric bias, with ethnicity and regional accents negatively influencing device recognition rates with commercial VAT systems like Apple, Amazon, and Google [40,41]. Additionally, high word error rates have also been found where individuals speak English as a second language [42]. SaLTs should therefore be mindful of attributing all device errors to clients, as other factors may be at play. Therapeutic use of VAT should ensure that users with speech and voice difficulties do not change nonstandard accents to more westernized accents to facilitate interactions with ASR [43], as this may perpetuate inequalities and racial bias at odds with person-centered practice in SLT.

Balancing Therapeutic Considerations With Technical Challenges

SaLTs indicated that the use of VAT in SLT required careful balancing of facilitators and barriers during implementation.

SaLTs reported that device timing out, not understanding disordered speech, and a lack of meaningful feedback contributed to clients' frustrations when using VAT. These difficulties were also reported in a recent scoping review examining the utilization of smart speakers by clients and staff in health care [33] and in wider literature [44-48]. Indeed, wider literature also indicates the impacts of using VAT on well-being. Decreased confidence, frustration with increased repetition, security anxieties, and avoidance of communication with smart speakers due to increased awareness of speech difficulties were noted [11-13]. Additionally, these error rates contributed to clinician perceptions that VAT was unpredictable, and SaLTs were hesitant to use VAT with participants who had more severe

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speech and voice difficulties, as they did not feel it would be beneficial. Literature examining SaLTs' attitudes toward VAT reported the same clinical implementation concerns [15]. Similarly, SaLTs in Kulkarni et al [16] who had not used VAT, also perceived clients with severe speech impairment to be unable to use VAT effectively, with perceived negative implications for confidence and motivation.

Despite this, findings from this study also saw SaLTs report that VAT practice enabled clients to improve self-confidence and independence. Particularly, the everyday nature of VAT devices and acceptability had a motivational impact for clients. This suggests that VAT may be a socially acceptable tool for therapy, with the potential to reduce the stigma of practicing with an assistive device. This shows promise in reducing barriers to use and developing motivation to practice. VATs' inclusivity as a therapy tool has been reported in literature, with studies indicating that VATs' removal of social barriers and autonomous motivation may improve intelligibility [14] and contribute to feelings of inclusion for people with communication and cognitive differences [46]. This concurs with wider literature, which has also reported subjective improvements in confidence, self-awareness, accessibility, and well-being for clients when using VAT [45,48,49]. Increased independence, well-being, and quality of life for older adults and people with disabilities following VAT use were also shown [45,49,50].

Therefore, clinicians should exercise clinical judgment and balance risks against benefits on a case-by-case basis when implementing VAT with people with PD. While there is emerging evidence relating to VAT use with people with PD in SLT and general social benefits of VAT for older adults, much of the cited evidence is based on populations without neurodegenerative conditions. Subsequently, this represents a current gap in the literature, which this study begins to fill. VAT use is likely to impact people with PD differently due to the nature of the neurodegenerative disease, and prolonged unsupervised use of VAT could potentially have negative emotional consequences. Future research should explore VATs' impact on motivation and therapy dosage in comparison to traditional SLT interventions.

Support Needs

SaLTs indicated that they had gaps in their knowledge about VATs' capabilities, as well as organizational barriers and privacy concerns. Therefore, participants highlighted that they would benefit from education and training, which would include technical education and reference material, privacy and security information, and therapeutic implementation guidance and resources. This aligns with previous research regarding the adoption and implementation of novel health care technologies, which frequently touches on privacy, GDPR, and confidentiality [13,51,52] and previous research surrounding the therapeutic use of VAT by SaLTs [16]. Future research must develop VAT standards specific to a health care context, establishing robust privacy and data security features with governance requirements in mind [33]. In the UK-based context, this should ensure VAT meets National Health Service GDPR collection and storage requirements.

While a lack of experience and training can contribute to frustration with technology [51], increased experience and knowledge can positively impact attitudes [53]. SaLTs' opinions of information and communication technology in therapy were impacted by perceived performance outcomes, benefits to their work, and support in terms of education and training [54], and wider research indicates that promoting positive SaLT attitudes to technology and digital media is vital to supporting adoption [55]. It may be that increased knowledge of VAT's capabilities in an applied SLT context could positively impact clinicians' perceptions of VAT's usefulness in SLT and lead to increased adoption. This is supported by technology adoption models such as the unified theory of acceptance and use of technology [56] and the technology acceptance model [57].

Despite this, no literature has examined education and training or knowledge translation interventions for clinical use of VAT as a tool for speech and voice difficulties. Literature regarding clinical applications of virtual reality in occupational therapy and SLT indicates that several education methods have been implemented, including manuals, web-based courses, and workshops [58,59]. Support for SaLTs using VAT with people with PD may include basic training about the range of technologies available, education regarding VATs everyday uses, skills and abilities, potential benefits, and information about applying the tool in practice, such as providing specific application examples with practice-based learning, information around privacy and GDPR, and linking to alternative delivery of known therapies such as LSVT [16]. Education and training strategies should work in tandem with research knowledge to translate the theoretical into practical and seek to empower SaLTs to become digitally enabled practitioners [60]. Future research should seek to create an educational VAT resource for SaLTs, using co-design methodology and behavior change frameworks to support the use of VAT as a therapeutic tool for the management of speech and voice disorders.

Design and Features of a VAT Tool (A Vision for the Future)

SaLTs indicated that a future VAT tool for therapeutic management of dysarthria may take the form of an Alexa skill, with practice exercises for various speech subsystems, functional phrases, and conversation, as well as increased feedback on speech and intelligibility. Given that commercial VAT is a widely available technology, using available features to overcome the described limitations would facilitate increased accessibility and ease of use for SaLTs. Wider research has created physical activity and exercise interventions, based on recognized guidelines, and self-management instructions using Amazon Alexa Skills [17,61-63]. This indicates the potential for an Alexa Skill for SLT, which adapts standard LSVT protocols to facilitate alternative delivery and potential self-management as part of therapeutic management. Developer kits such as Alexa Blueprint and Alexa Skills Kits may be used. Research indicates that skills should be scalable, cost-effective, and customizable, with a focus on increasing motivation and engagement [33]. Alternatively, there may be skills available that can be repurposed for SLT purposes, and a voice assistant hub with suggested skills [24] may also be beneficial for SaLTs. Overall, to ensure VAT tools meet SaLTs' clinical needs, future

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research should involve SLT end users in the cocreation of a VAT tool for the therapeutic management of dysarthria. This may use frameworks such as Design Thinking or ideas to focus on designing solutions to barriers suggested in this research, as well as ideating and refining suggested features.

Limitations

This research was conducted with SaLTs based in the United Kingdom. Whilst participants work in a range of geographical locations across the United Kingdom, their experiences may not reflect the more diverse attitudes and experiences with VAT globally. Future work should replicate findings to ascertain result generalizability.

Second, to be eligible for participation, SaLTs had to be actively engaging with VAT already. These participants are likely to have positive attitudes to VAT and may have self-selected for participation. Furthermore, these SaLTs may also have adequate digital skills to use technology that may not have been evident in SaLTs who were not users of the technology. Given that the aims of the review focused on users of VAT, this is an expected limitation with the target population required to fully answer the research question.

Finally, due to scheduling conflicts, additional interviews to focus groups had to be completed. Given that there is a more transactional interaction during interviews, richer data may have been generated by the inclusion of these SaLTs in focus groups. However, this reflects the pragmatic considerations of conducting research with working clinicians and is a point of consideration for future studies.

Additionally, given the novel nature of the VAT technology, a low number of clinicians are actively implementing the technology in clinical practice. Therefore, this study had a smaller number of participants than the suggested 6-8 in the literature [24] due to pragmatic considerations and challenges with recruitment and scheduling. Therefore, individual interviews were completed with two SaLTs. As artificial intelligence will undoubtedly play a larger role in health care in the coming years, replication of this research in the future may yield interesting results.

Recommendations

This study makes recommendations for future research to develop the therapeutic use of VAT:

- Co-design of a therapeutic VAT tool for hypokinetic dysarthria, which may include feasible solutions to technological limitations, to meet the clinical needs of SaLTs.
- Co-design of applied education and guidelines for therapeutic use of VAT, technology upskilling, and privacy and governance applications. Future work must also identify the optimal route for the delivery of education and training based on behavior change frameworks.
- A feasibility trial of a therapeutic VAT intervention for people with PD with dysarthria, including pre- and postacoustic analysis of voice or self-reported impacts.

Conclusions

This study builds upon Kulkarni et al [16] by exploring SaLTs' experiences of using VAT as a therapeutic tool for speech and voice difficulties. Positive therapeutic outcomes for intelligibility, volume, and clarity of speech are reported, with the potential for VAT to facilitate home practice and self-management of dysarthria. However, clinicians must balance this with well-being implications, device errors, practical implementation factors, and privacy concerns. These difficulties should be addressed in future research to enable the integration of VAT as a therapeutic tool.

Future research should use participatory research with clinicians using VAT to create achievable and practical solutions to VAT's usability challenges and consider the adaptation of the standard LSVT protocol to facilitate the development of an Alexa Skill. The feasibility of a VAT tool for SLT may be established by adapting Smith et al [14]. By examining quantitative outcomes relating to intelligibility and volume and self-reported changes, as well as potential generalization and maintenance effects, an initial evidence base may be established for the use of this novel technology in SLT.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Showing the Digital Health Readiness Questionnaire results (number 1 in paper).
[DOCX File , 22 KB - rehab_v12i1e75044_app1.docx]

Multimedia Appendix 2
Discussion guide for focus groups and interviews.
[DOCX File , 710 KB - rehab_v12i1e75044_app2.docx]

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Abbreviations

ASR: automatic speech recognition
COREQ: Consolidated Criteria for Reporting Qualitative Research
GDPR: General Data Protection Regulation
LSVT: Lee Silverman Voice Treatment
PD: Parkinson disease
SaLT: speech and language therapist
SLT: speech and language therapy
VAT: voice-assisted technology

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Original Paper

AI-Based Gait Analysis System for Rehabilitation: Usability Evaluation of Human-Technology Interaction

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Abstract

Background: Artificial intelligence (AI)–based gait analysis systems are increasingly applied in rehabilitation settings for objective and quantitative assessment of gait function. However, despite their potential, clinical adoption remains limited due to insufficient consideration of usability, user experience, and integration into actual clinical workflows.

Objective: This study aimed to conduct a formative evaluation of a prototype AI-based gait analysis system (MediStep M).

Methods: A mixed methods formative usability evaluation was conducted with 5 licensed physical therapists. Qualitative data were collected through focus group interviews, and quantitative usability was measured using the system usability scale (SUS). A scenario-based usability assessment was applied to identify user interface challenges, workflow issues, and potential design improvements.

Results: Participants identified major usability barriers, including limited accessibility of the power button, absence of battery status indicators, burdensome manual calibration, and insufficient clinical detail in the gait analysis reports. They also emphasized the need for wireless operation, improved portability, and integration with hospital electronic medical record systems. The mean SUS score was 57 (grade D), indicating suboptimal usability and the need for iterative design refinements.

Conclusions: Although AI-based gait analysis systems hold promise for enhancing rehabilitation outcomes, key usability challenges must be resolved before clinical implementation. Improvements in hardware portability, automated calibration, data management, and user interface design are essential to ensure safety, efficiency, and clinical applicability. These findings provide evidence-based insights to guide iterative development and promote user-centered innovation in AI-based rehabilitation technologies.

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KEYWORDS

usability evaluation; AI-based gait analysis; focus group interview; system usability scale; rehabilitation

Introduction

Gait analysis plays a critical role in the rehabilitation of individuals with neurological or musculoskeletal impairments [1-4]. Quantitative assessment of gait function enables clinicians to objectively evaluate motor performance, establish evidence-based treatment plans, and monitor functional recovery over time [2,5]. However, conventional gait analysis systems such as treadmill-based or marker-dependent motion capture platforms require specialized laboratories, trained operators, and controlled environments [6,7]. These limitations restrict their feasibility for routine clinical application and hinder broader accessibility in diverse rehabilitation settings [6,8].

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Recent advancements in artificial intelligence (AI), computer vision, and depth-sensing technologies have facilitated the development of markerless, AI-driven gait analysis systems capable of automatically estimating joint coordinates and computing spatiotemporal gait parameters [9-12]. Such systems have the potential to make gait analysis more portable, cost-effective, and clinically scalable [6,10,13]. Compared to conventional systems such as Zebris, which rely on treadmill-based assessments within constrained spatial setups, emerging overground AI-based systems are designed to enable natural walking conditions with minimal setup requirements [9,14].

Despite these technological advancements, many AI-based gait analysis systems continue to face significant usability challenges that limit their integration into real-world rehabilitation environments. Reported issues include labor-intensive calibration procedures, unclear user feedback interfaces, hardware nonportability, and poor alignment with clinical workflows. Previous research in human factors and digital rehabilitation has emphasized that usability—particularly intuitiveness of the user interface, workflow efficiency, and error prevention—is a primary determinant of successful clinical adoption and user satisfaction [15].

To address these challenges, we conducted a formative evaluation of a prototype AI-based gait analysis system, MediStep M. The evaluation was performed with physical therapists, who represent the primary end users of gait analysis technologies in clinical practice. A mixed methods approach was employed, combining qualitative focus group interviews (FGIs) with quantitative assessments using the system usability scale (SUS). This approach aimed to identify use-related problems, interface limitations, and potential design improvements to guide iterative enhancement of AI-based rehabilitation technologies and to ensure their alignment with clinical usability requirements.

Methods

Study Design

This study employed a formative evaluation design to identify use-related problems and interface improvement needs of a prototype AI-based gait analysis system (MediStep M). The evaluation followed the usability engineering framework described in IEC 62366-1:2020, focusing on user-system interaction and workflow alignment.

Materials

MediStep M is a prototype AI-based gait analysis system commissioned by the manufacturer for formative evaluation. The system was designed to enable objective assessment of gait deterioration in older adults and to monitor functional recovery following therapeutic interventions. Currently, in the prototype stage, the system consists of general-purpose hardware (a tablet device) running the MediStep M software (Figures 1-2).

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Figure 1. Artificial intelligence–based gait analysis system hardware: tablet and gait mat.

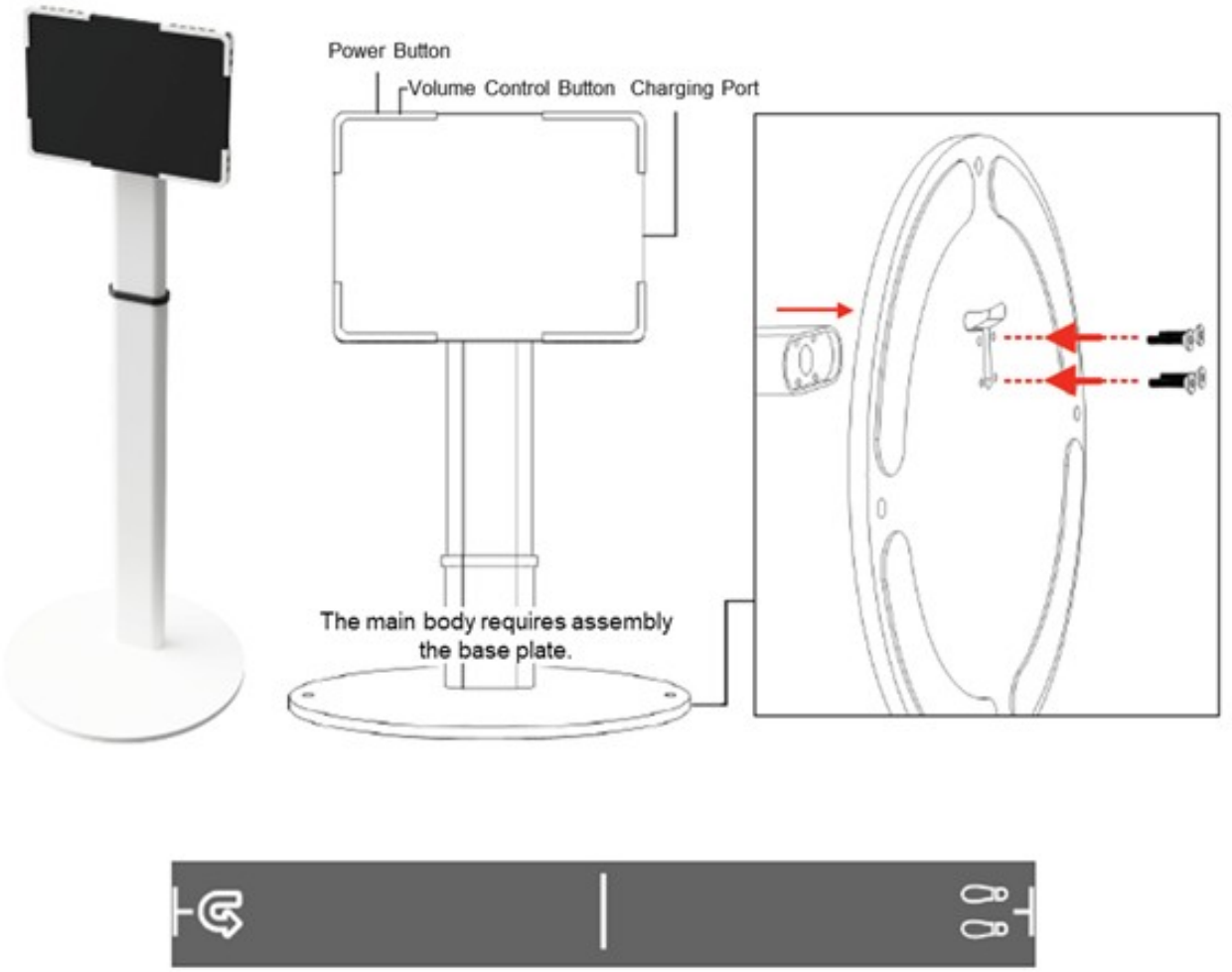
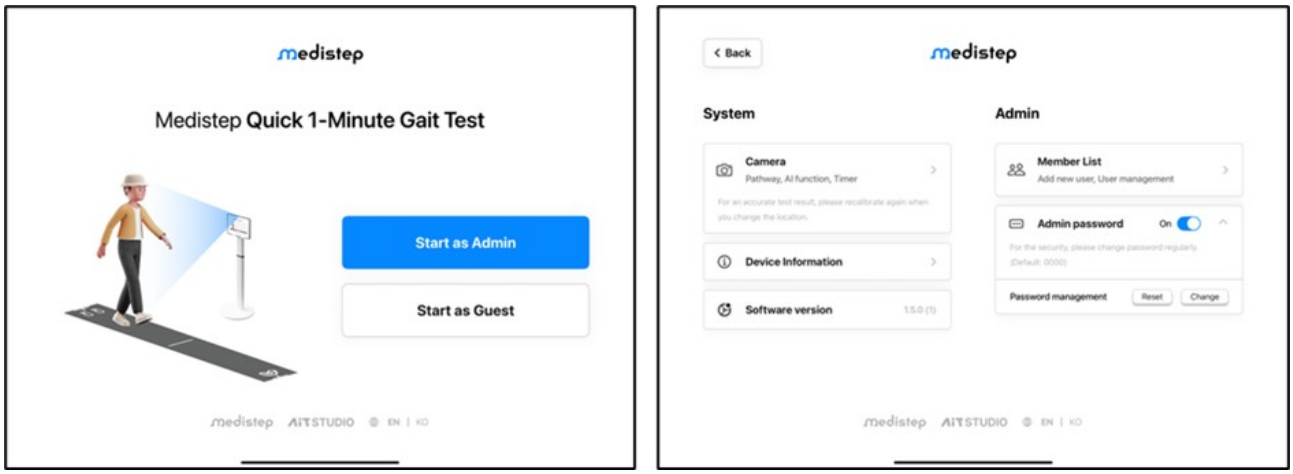


Figure 2. Artificial intelligence–based gait analysis system software interface (start user interface and settings user interface).



Using the tablet's built-in camera, the system captures side-view videos of participants performing back-and-forth walking tasks. Through markerless pose estimation technology, the software automatically extracts full-body joint coordinates and computes spatiotemporal gait parameters. These parameters are visualized and quantified to generate comprehensive gait reports, including stride length, walking speed, arm swing amplitude, upper-body inclination, and gait asymmetry. The generated reports are intended to assist clinicians in evaluating gait characteristics and identifying deviations from normative patterns.

Participant Recruitment

Five licensed physical therapists participated in the study. All participants had a minimum of 5 years of professional experience in gait assessment and rehabilitation. Recruitment

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was conducted through the National Rehabilitation Center via an internal call for participation.

The inclusion criteria were as follows: (1) licensed physical therapists with clinical experience in gait analysis or rehabilitation, (2) current engagement in gait-related clinical practice, and (3) prior exposure to gait analysis systems or equivalent medical devices.

Participants who were not actively involved in patient treatment or who performed administrative duties only were excluded. The final sample consisted of 4 male therapists and 1 female therapist, reflecting diverse experience levels across inpatient and outpatient rehabilitation contexts.

Procedures

Formative Evaluation Procedures

The formative evaluation was conducted at the National Rehabilitation Center in Seoul, Republic of Korea. Each session was conducted in a controlled clinical environment and lasted approximately 90 minutes (Table 1).

Table 1. Formative evaluation procedures, involving practitioners and evaluators, conducted for 90 minutes under the guidance of a facilitator.

Composition	Details	Time (min)
Orientation	• The moderator introduced the focus group interview to the participants (physical therapists) and provided an explanation of the product to be discussed, including its purpose, an overview, and the methods involved.	10
Guidance on consent	• The moderator informed participants about the video and audio recording procedures. • After confirming that the physical therapists fully understood the details of the study, written informed consent was obtained voluntarily. • Prior to the interview, the moderator conducted a survey to collect general demographic information from the participants.	10
Perform focus group interview	• The moderator conducted user training, demonstrations, and interviews according to a predetermined script. • The participants (physical therapists) observed the demonstrations, responded to interview questions, and were allowed to operate the product if necessary. • An observer documented the entire interview process.	50
Perform SUS[a]	• Following the focus group interview, SUS was administered, followed by an additional interview to gather further feedback from the participants.	20

[a]SUS: system usability scale.

The evaluation consisted of 3 main stages:

1. Product demonstration: The facilitator conducted a live demonstration of MediStep M according to predefined clinical use scenarios. This included device setup, calibration, gait data acquisition, and report interpretation. The demonstration followed the manufacturer's standard workflow and was intended to simulate typical clinical usage conditions.
2. Participant interaction and observation: Participants observed the demonstration, and when appropriate, were given the opportunity to interact with the system interface (eg, initiating data capture, reviewing gait reports) to better understand its functionality. During this phase, the facilitator encouraged participants to verbalize their thoughts and perceptions regarding usability issues and potential improvements.
3. FGI and SUS assessment: After the demonstration, participants took part in a 60-minute FGI to provide detailed feedback on user interface intuitiveness, workflow integration, and areas for improvement. Subsequently, SUS was administered to quantify perceived usability. Reverse-scored items (2, 4, 6, and 8) were appropriately adjusted before calculating individual and mean SUS scores.

Task Scenarios

Table 2 shows the different scenarios in product demonstration, including device setup, calibration, gait data acquisition, and report interpretation.

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Table 2. Task scenarios.

	Task	Subtask
1	Powering on the device	• Connect the charging port and check whether the indicator light turns on. • Press the power button located at the upper left on the front panel to turn on the device.
2	Camera calibration	• Open the calibration settings window and perform the camera calibration before starting. • While monitoring the screen, position the device so that the entire walking path is centered within the camera's field of view. • Adjust the device's position and orientation to ensure the vertical guideline aligns with the centerline of the walking mat. • Resize the guidelines so that both ends of the horizontal guideline align with the T-marks at either end of the walking path.
3	Using the MediStep application	• Click the "Start as Administrator" button. • Enter the user information into the designated fields on the software interface. • Review the displayed information, and then click the "Start AI[a] Gait Assessment" button.
4	Gait analysis	• Select the recording standby timer. • Touch the record button.
5	Interpretation of results	• The gait analysis results and corresponding gait videos can be reviewed through the report screen.
6	Member management	• Adding/deleting members • In the member list under the settings menu or on the examiner selection screen, tap the "Add New Member" button. • Enter the member's name, the first 6 digits and the first digit of the last 7 digits of their resident registration number, and their height. • Then tap the "Add" button. To delete a member, select the member from the list. A pop-up window will appear with options to edit or delete the information. Tap the "Delete" button. • Editing member information • This function is accessible only via the member list in the settings menu. • Select the desired member; a pop-up window will appear with options to edit or delete their information. After making the necessary changes, tap the "Complete Edit" button.

[a]AI: artificial intelligence.

FGI Method

An FGI is a qualitative research method that collects data through in-depth discussions with intentionally selected participants on a specific topic [16,17]. This approach encourages individuals to openly share their experiences and engage with others' insights, thereby providing diverse perspectives and rich, detailed information on the subject matter [18]. FGIs are considered an appropriate research method for analyzing and identifying areas for improvement in gait analysis software interfaces from the perspective of clinicians with experience in using similar medical devices (Figure 3). The FGI questionnaire (Table 3) was structured based on the type of questions, including introductory, transitional, key, and closing questions [17].

Figure 3. Conducting the focus group interview session.



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Table 3. Focus group interview questionnaire.

Stage	Questions
Opening questions	• General characteristics: (eg, age, gender, clinical experience, experience with similar medical devices) • Interview question: Are you currently using gait analysis products or similar medical devices to assess or treat patients?
Transition questions	• Could you describe your experience using similar products or medical devices? • What types of assessments or treatments have you performed using gait analysis products or similar medical devices? Please include the purpose and methods of the assessments or treatments. • In your opinion, what are the advantages of using gait analysis products or similar medical devices for clinical assessments? • What key aspects should be considered in the development of gait analysis software?
Key questions	• Based on the user manual provided, do you have any comments on the product's composition (eg, contents, structure, or layout)? • Following the verbal explanation and demonstration, do you anticipate any user interface errors or potential hazards when using the MediStep M interface? • Are there any elements of the user interface that you believe should be improved? (demonstration provided according to the product scenario.) • Do you have any additional comments or suggestions regarding this product?
Ending questions	• If you have any further opinions on aspects to consider in the development of gait analysis software, please share them.

SUS Evaluation Tool

The SUS is a quantitative evaluation tool used to assess how users perceive system usability [19]. The SUS comprises 10 items rated on a Likert scale (1=strongly disagree to 5=strongly agree) (Table 4). The total score was converted to a range of 0-100 points to evaluate overall system usability. Moreover, the SUS scores were assigned a letter grade from "F" (0-60 points) to "A" (91-100 points) according to a standardized grading system [20,21].

Table 4. System usability scale questionnaire.

Items	Statement
Utility	I think that I would like to use this system frequently.
Complexity	I found the system unnecessarily complex.
Simplicity	I thought the system was easy to use.
Professionalism (technician support)	I think that I would need the support of a technical person to be able to use this system.
Integration	I found the various functions in the system were well integrated.
Unity	I thought there was too much inconsistency in this system.
Learnability	I would imagine that most people would learn to use this system very quickly.
Convenience	I found the system very cumbersome to use.
Satisfaction	I felt very confident using the system.
Professionalism (prior learning)	I needed to learn a lot of things before I could get going with this system.

Data Analysis

Qualitative data from FGIs were transcribed verbatim and analyzed using an inductive thematic analysis approach. Two independent researchers coded the transcripts to identify recurring patterns, usability barriers, and improvement suggestions. Themes were derived through iterative comparison and consensus discussions.

Quantitative data from SUS were analyzed descriptively to calculate mean scores, standard deviations, and percentile rankings based on established SUS benchmarks. Both qualitative and quantitative findings were triangulated to derive comprehensive insights into the system's usability and user needs.

Ethical Considerations

The study protocol was reviewed and approved by the institutional review board of the National Rehabilitation Center (government-affiliated national rehabilitation center in Seoul, Republic of Korea; NRC-2024-06-046). All participants provided written informed consent prior to participation and were informed that participation was voluntary and that they could withdraw from the study at any time without any penalty or disadvantage. Participants received a nonmonetary gift with a value of up to KRW 50,000 (US $34.05) as a token of appreciation for their participation. To ensure confidentiality,

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all identifiable personal data were removed, and all photographic materials were anonymized prior to analysis and publication.

Results

Participant Characteristics

Five licensed physical therapists participated in the evaluation, with clinical experience ranging from 7 to 23 years (Table 5). All participants had prior experience using similar gait analysis systems (eg, Zebris, Joynt, or Morning Walk) and reported a usage frequency of 1-3 times per week.

Table 5. General characteristics of the participants.

ID	Sex	Experience	Similar medical device			
			Used before	Model name	Experience of use	Frequency of use
P1	Female	8 y 8 mo	Yes	Zebris	1 y	1 time/wk
P2	Male	18 y 9 mo	Yes	Zebris	1 y	3 times/wk
P3	Male	23 y	Yes	Joynt	1 y	1 time/wk
P4	Male	7 y 8 mo	Yes	Morning Walk	2 y 2 mo	3 times/wk
P5	Male	15 y 7 mo	Yes	Zebris	1 y	2-3 times/mo

Qualitative Findings (FGI)

FGIs revealed several key themes regarding usability, functionality, and areas for improvement of the AI-based gait analysis system.

Theme 1: Importance of Real-Time, Quantitative, and Understandable Feedback

The participants (P1-P5; as indicated in Table 5) appreciated the ability of gait analysis devices to provide quantitative assessments, particularly for aspects that are difficult to measure visually, such as gait symmetry and alignment. They emphasized that real-time feedback not only enhances clinicians' evaluation capabilities but also motivates patients by enabling them to monitor their own gait patterns. However, some participants noted that complex setup procedures and spatial constraints could limit the practical utility of such devices in busy clinical environments.

> *…The advantage is that machines can accurately measure what we cannot visually quantify, such as distance and symmetry, without requiring large spaces.* [P1]
>
> *…Real-time visualization of movements could help patients self-correct during therapy sessions.* [P2]

Theme 2: Necessity for Simplified and Portable Hardware Design

Although the hardware components and instructions were generally understandable, several participants stressed the need for wireless operations to enhance portability and convenience. The participants recommended minimizing wired connections, incorporating a wireless printer, and adding basic features such as a built-in level gauge for easier setup on uneven surfaces.

> *…The product should be portable. Wireless operation would greatly improve usability.* [P2]
>
> *…Adding a leveling tool on the device would help ensure proper setup on uneven floors.* [P3]

Theme 3: Challenges Related to Power Button and Battery Display

Many participants expressed frustration with the placement of the power button, which was obscured by the device frame. They suggested relocating it for easier access and improving the visibility of the battery status, either through a larger indicator light or by displaying the battery percentage on the screen.

> *…The power button is hidden behind the frame, making it very inconvenient to press.* [P1]
>
> *…It would be helpful to see the battery level on the main screen.* [P2]

Theme 4: Calibration Process Needs Automation

The participants criticized the manual calibration process, noting that it could introduce human error depending on the user's expertise and environmental factors. They recommended an automated calibration to enhance the reliability and usability of the system.

> *…Manual calibration can vary the results based on a user's skill. AI-based automatic calibration would significantly increase reliability.* [P1]
>
> *…It should not rely on the inspector's height but rather on more objective standards like leg length.* [P2]

Theme 5: User Interface and Patient Management System Improvements

Participants generally found the software interface to be user-friendly but identified specific areas for improvement. They requested enhancements to the patient management system, such as the introduction of an auto-complete search, ID-based patient identification, and simplified patient registration procedures.

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> *…When selecting patients, it's inconvenient to search by full name. An auto-complete or list view would help.* [P3]
>
> *…It would be better if patients were identified by number rather than name for privacy and speed.* [P5]

Theme 6: Enhancing the Gait Analysis Reporting and Interpretation

Participants appreciated the effort to make the results accessible but criticized the oversimplification of the analysis outputs. The authors called for more detailed and clinically meaningful metrics and stronger reference explanations, particularly for cases involving pathological gait patterns.

> *…Simple statements like slow walking speed aren't enough. Specific advice is required, such as suggesting an increase in stride length by 10 cm.* [P4]
>
> *…The report distinguishes between normal and pathological gait patterns.* [P1]

Theme 7: Additional Requirements for Clinical Usability

Finally, the participants highlighted the need for expanded language support for international use, improved data extraction features (eg, exporting to Excel), and improved integration with hospital electronic medical record (EMR) systems. Some participants suggested adding remote-start features to minimize device manipulation during testing and prevent device tilting.

> *…If the device is intended for hospital use, data should be easily exportable and integrated with the EMR.* [P3]
>
> *…Remote control start could prevent tilting issues during test initiation.* [P2]

Quantitative Findings (SUS)

The mean SUS score was 57, corresponding to a grade of "D" on the SUS grading scale (Figure 4, Table 6).

Figure 4. System usability scale (SUS) results.

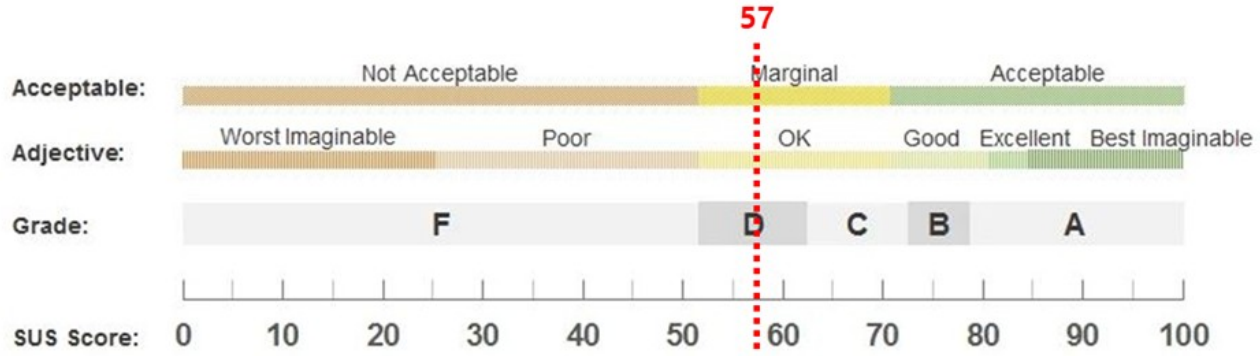


Table 6. System usability scale evaluation results (N=5).

Item	Min (point)	Max (point)	Mean (SD)	Scaled mean (SD)
Total	—[a]	—	2.88 (0.44)	57.00 (17.98)
Utility (Q1)	1.00	3.00	2.40 (0.89)	35.00 (20.00)
Complexity (Q2)	1.00	3.00	2.00 (0.71)	75.00 (15.81)
Simplicity (Q3)	4.00	5.00	4.20 (0.45)	80.00 (10.00)
Professionalism (technician support) (Q4)	2.00	4.00	3.40 (0.89)	40.00 (20.00)
Integration (Q5)	1.00	3.00	2.00 (0.71)	25.00 (15.81)
Unity (Q6)	1.00	4.00	3.20 (1.30)	45.00 (29.15)
Learnability (Q7)	3.00	5.00	4.00 (0.71)	75.00 (15.81)
Convenience (Q8)	1.00	4.00	2.20 (1.10)	70.00 (24.49)
Satisfaction (Q9)	3.00	4.00	3.20 (0.45)	55.00 (10.00)
Professionalism (prior learning) (Q10)	1.00	3.00	2.20 (0.84)	70.00 (18.71)

[a]Not applicable.

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Discussion

Principal Findings

This formative usability evaluation identified key strengths and limitations of the prototype AI-based gait analysis system MediStep M from the perspective of clinical end users. Overall, the findings demonstrate that while the system shows strong potential to support objective gait assessment in rehabilitation, several usability issues must be addressed to enable efficient integration into clinical practice. The mean SUS score of 57 (grade D) indicates below-average usability, aligning with qualitative feedback obtained through FGIs.

Participants acknowledged the clinical value of quantitative gait analysis enabled by AI-based systems, particularly the ability to objectively visualize spatiotemporal gait parameters that are difficult to assess through observation alone. However, multiple usability barriers were identified across both hardware and software components. Hardware-related issues included limited portability, poor accessibility of the power button, and lack of a battery status indicator. Software-related challenges involved the need for automated calibration, improved patient management features, and more detailed gait reporting to support clinical decision-making. These findings highlight that usability and clinical applicability depend not only on algorithmic performance but also on the intuitiveness and efficiency of the overall user interface and workflow design.

The results of this study are consistent with prior usability research on AI-driven and markerless gait analysis systems, which similarly reported barriers such as setup complexity, calibration burden, and limited interoperability with EMR systems. Previous studies have also emphasized that successful implementation of AI technologies in rehabilitation requires a user-centered approach that reflects real-world clinical workflows [22-25]. Compared to treadmill-based systems such as Zebris, MediStep M offers an overground and portable configuration that allows a more natural gait pattern to be analyzed. Nonetheless, iterative refinement remains necessary to enhance user experience, workflow compatibility, and data management efficiency.

The findings from this study suggest several priorities for future development. First, hardware design should improve ergonomics and mobility through compact structure, wireless operation, and automated leveling mechanisms. Second, calibration procedures should be automated using AI-assisted alignment algorithms to reduce operator variability. Third, software feedback should evolve beyond raw numerical data to include graphical trends, interpretive summaries, and actionable recommendations for rehabilitation. Finally, interoperability features such as secure EMR integration and standardized data export formats are essential for broader clinical adoption.

Importantly, several of the usability issues identified in this formative evaluation were subsequently addressed by the manufacturer. As of March 2025, the finalized version of MediStep M incorporated significant hardware and software refinements, including a redesigned rear magnetic detachable cover, removal of the front frame obstructing the power button, and addition of a main-screen battery status indicator. Wireless printing capability using Apple AirPrint, an AI-based automated calibration algorithm achieving 97% accuracy compared to the manual process, and a CSV-based data export function were also implemented. This iterative process underscores how formative usability evaluations can directly inform product improvement and regulatory readiness.

Limitations

Several limitations should be acknowledged. The small sample size (N=5) limits the generalizability of our findings, and the predominance of male participants (4 out of 5) may introduce gender bias. As a formative study, the evaluation did not measure long-term usability or clinical efficacy outcomes. Future studies should include larger and more heterogeneous samples, repeated testing cycles, and longitudinal assessments to validate the system's usability and clinical performance after iterative refinement.

Conclusion

This study provides evidence on the usability of an AI-based gait analysis system from the perspective of clinical end users. Although the prototype demonstrated technical feasibility and clinical potential, several usability challenges were identified that require further optimization. The subsequent improvements implemented by the manufacturer exemplify how formative feedback can guide user-centered development of rehabilitation technologies, supporting safer and more effective integration of AI systems into clinical workflows.

Acknowledgments

This study was supported by grants (NRCRSP-24TB01 and 25TB01) from the Rehabilitation Research & Development Support Program, Korea National Rehabilitation Center, Ministry of Health & Welfare, Korea.

Data Availability

The datasets generated and/or analyzed in this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
EMR: electronic medical record
FGI: focus group interview
SUS: system usability scale

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A New, Portable Orofacial Manometer for Measuring Tongue Strength and Endurance in Children: Laboratory-Based Validity Study

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Abstract

Background: An accurate tongue strength and endurance assessment is necessary for pediatric dysphagia. TongueFit is a new, portable orofacial manometer for measuring tongue strength and endurance and a game-based training app for children.

Objective: This study aimed to test the validity of TongueFit compared with a standard manometer as the current gold standard for measuring air pressure.

Methods: This laboratory study compared TongueFit and a standard manometer as the gold standard for measuring air pressure. This study was conducted in 3 different experimental conditions. The first experiment compared TongueFit and the standard manometer using a force tester (MCT-2150), with pressure controlled by MSatLite software. The second and third experiments involved 2-cm and 3-cm bulbs between the 2 devices. This study used Lin concordance correlation to measure the level of agreement.

Results: There was a mean absolute difference of 0.005 kilopascals (kPa) between the TongueFit and the standard manometer (n=35, ρC=1). Statistical analysis showed perfect agreement correlation (ρC=1). By using the 2-cm bulb, TongueFit's mean was 0.007 kPa lower, also showing perfect agreement (ρC=1). Furthermore, using the 3-cm bulb, results showed almost perfect agreement (ρC=0.999) with the TongueFit's mean, which was 0.044 kPa lower.

Conclusions: This study confirms the high validity of TongueFit as an orofacial manometer compared with a standard manometer, with negligible mean differences, as well as near-perfect and perfect agreement in the experiments. These results confirm that TongueFit is a valid and accurate tool for assessing tongue strength.

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KEYWORDS

pediatric swallowing; tongue strength; tongue endurance; orofacial manometer; validity

Introduction

Eating and swallowing are dynamic processes essential for children's growth and development [1]. This complex mechanism involves the coordination of more than 30 nerves and muscles in the oral cavity, pharynx, larynx, and esophagus [2,3]. Typically, the swallowing process is divided into 3 distinct phases based on the passage of the bolus through different anatomical regions: the oral phase, the pharyngeal phase, and

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the esophageal phase. Each phase is critical in facilitating food and fluids' safe and efficient passage from the mouth to the stomach, ensuring proper nutrition and hydration for optimal growth and function [3-5].

The tongue comprises bundles of highly flexible, vascularized, and innervated muscles that play a critical role in the oral phase of swallowing. Tongue movements, controlled by the intrinsic and extrinsic muscles, include protrusion, retraction, elevation, depression, rotation, lateralization, cupping, and twisting [6,7]. Tongue dysfunction can result in reduced tongue strength and endurance, potentially compromising swallowing function and leading to difficulty eating and swallowing, a condition commonly referred to as oral dysphagia [8]. Reduced tongue strength can significantly impact several aspects of tongue function, including chewing, bolus control, and bolus clearance. Previous research suggests that reduced tongue strength may contribute to oral and pharyngeal dysphagia [9]. Tongue muscle weakness could decrease intraoral pressure during swallowing, thereby increasing pharyngeal residue and risk of aspiration in the pharyngeal phase [6,10].

The early diagnosis of dysphagia is important for the prevention of malnutrition, dehydration, and aspiration pneumonia, in addition to allowing adequate treatment [11]. Previous studies evaluating neurological pathologies that affect swallowing disorders have observed a positive association between tongue strength and dysphagia. Dysphagic patients had significantly reduced tongue strength and endurance compared with patients with preserved swallowing [11-13]. Therefore, evaluation of tongue strength and endurance is critical, especially in populations of children who have feeding difficulties and are at increased risk for eating and swallowing disorders, such as children with cerebral palsy, Down syndrome, and other related conditions [14,15].

Assessment of tongue strength is essential because of its important role in eating and swallowing [16]. Various orofacial manometers have been developed to measure tongue force objectively and continue to evolve. One of the most widely used orofacial manometers is the Iowa Oral Performance Instrument (IOPI). The IOPI is a portable device designed to measure tongue strength and endurance, using an air-filled bulb as a sensor to measure the maximum isometric force of the tongue in kilopascals (kPa). The IOPI provides biofeedback in the form of a vertical light indicator that illuminates when the target pressure is reached. It also includes a training mode designed to improve tongue strength and endurance [17-19]. It has been used extensively in numerous studies and has shown reasonable validity and reliability. However, the IOPI has limitations. It is unavailable in the Indonesian market, and users reported problems slipping the air-filled bulb during measurements.

There was no tool specifically designed for children to measure and train their tongue strength and endurance. Therefore, we developed a device called "TongueFit" that is designed for both clinical and home use. It features a nonslip surface on the air-filled bulb sensor and incorporates a game-based biofeedback for exercise. The biofeedback was created as an Android-based app to complement the device. This app allows users to access measurement results, historical data, and game-based exercises. Integrating game-based biofeedback in TongueFit enhances dysphagia treatment by providing real-time feedback and rewarding good performance with scores. This approach transforms therapy into an engaging experience, fostering greater participation, particularly in pediatric patients.

Although TongueFit can also be used as an exercise tool to improve tongue strength and endurance, the focus of this study was solely on assessing the validity of TongueFit as a measurement tool. By focusing solely on the validity of TongueFit's measurement capabilities, we seek to provide empirical evidence to support its efficacy as a tool for assessing tongue strength and endurance. This study aimed to determine the accuracy of TongueFit in quantifying tongue muscle performance in kPa. In addition, by confirming the validity of TongueFit's measurements, we aimed to establish TongueFit as a valuable tool in clinical settings, facilitating more accurate diagnoses and tailored treatment plans for individuals with tongue-related impairments.

Methods

Overview of TongueFit

TongueFit consisted of 2 essential components: hardware and software, both of which were interdependent for operation. The hardware included a manometer device along with 2 variations of bulb sizes. The bulbs and tubes were made of biobased polyurethane and polylactic acid—food-grade materials that had undergone rigorous toxicity testing in the laboratory to ensure their safety (Figure 1). The tests were performed at the Stem Cells and Tissue Engineering Research Centre, Cluster Indonesian Medical Education and Research Institute Fakultas Kedokteran Universitas Indonesia, using human stem cells. A material was declared toxic if the percentage of stem cell death exceeded 30% of the total stem cells within the control group in the tests. Based on the toxicity tests conducted on the bulb and hose materials, which were repeated at 15, 30, and 60 minutes, the percentage of cell death was less than 16%. Therefore, it can be concluded that the bulbs and tubes are nontoxic.

The software component included a mobile app that allows users to measure tongue strength and endurance, access measurement results, review historical data, and participate in game-based exercises in Bahasa (Figure 2). Tongue strength is assessed by positioning the bulb anteromedial on the tongue and instructing the patient to elevate the tongue against the palate with maximum effort. This measurement is performed 3 times, and the highest recorded value is used as the reference target for endurance assessment and exercise therapy. Tongue endurance is evaluated by having the patient sustain tongue elevation against the palate at 40% - 60% of their maximum strength for as long as possible.

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Figure 1. The hardware components of TongueFit. (A) The manometer; (B) the body of the TongueFit comprises the manometer hardware, an on/off button, a tube connector, and a charging port; and (C) the tongue bulb has two different sizes, consisting of the 2-cm bulb (right) and the 3-cm bulb (left).

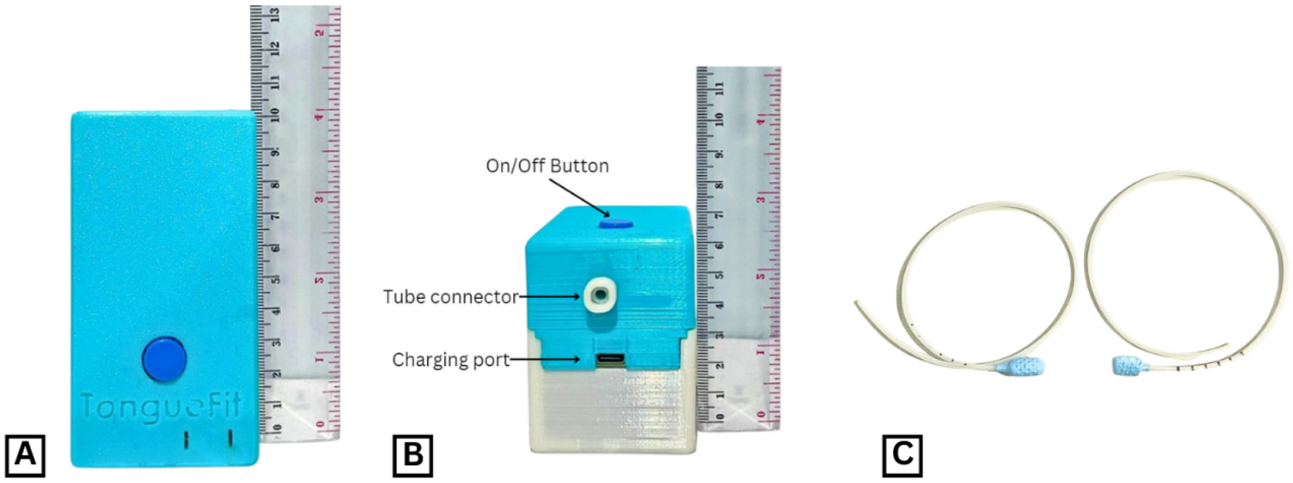
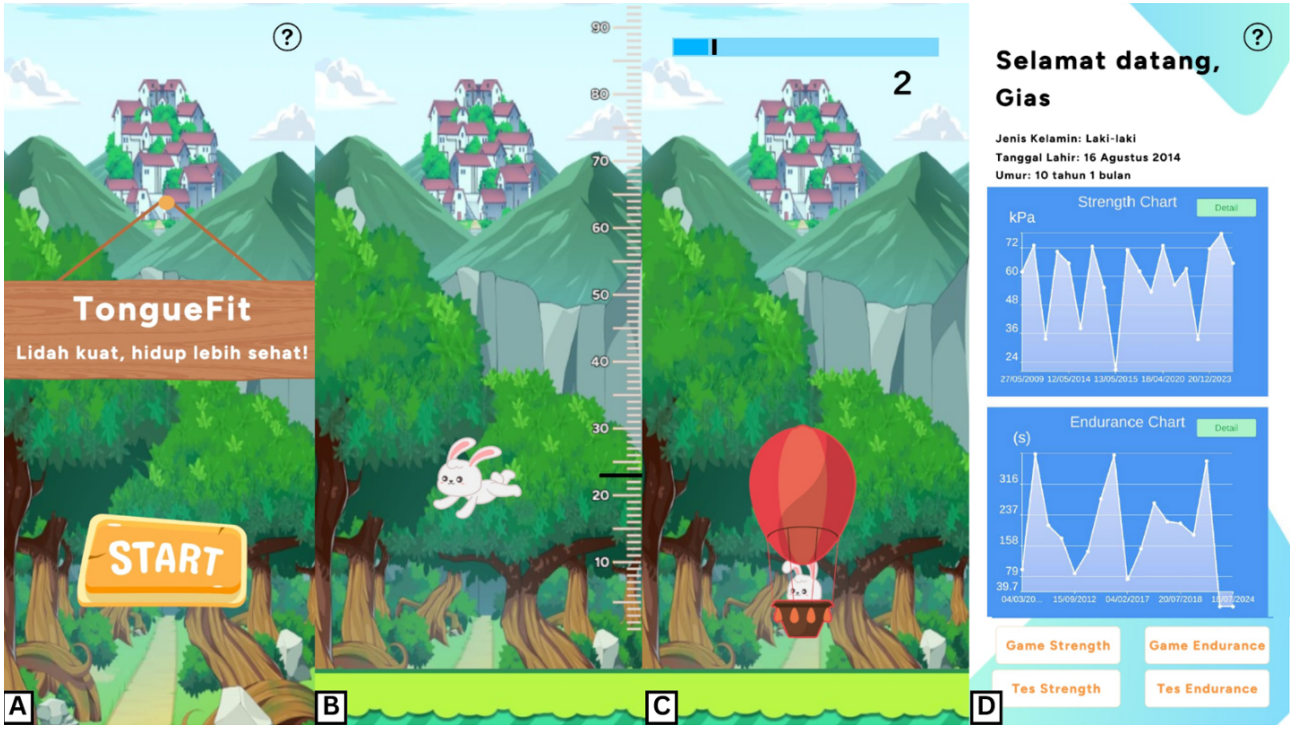


Figure 2. The TongueFit app. (A) Opening page; (B) tongue strength test; (C) tongue endurance test; and (D) tongue strength and endurance chart result.



Tongue strength and endurance measurements were conducted before therapy to establish baseline values, which served as a reference for the exercise prescription using "TongueFit." The strengthening and endurance exercises targeted the anterior tongue, considering its muscle fiber composition, primarily type IIa fibers, which exhibit fast contraction properties while maintaining a degree of endurance [9,20]. As a result, the exercise protocol incorporated both strengthening and endurance components. The exercise prescription adhered to the FITT (frequency, intensity, time, and type) principle, with strengthening exercises performed at an intensity of 60% - 80% and endurance exercises at 40% - 60% of maximum tongue strength. Each session lasted for 15 minutes per exercise type, with 30 repetitions per session.

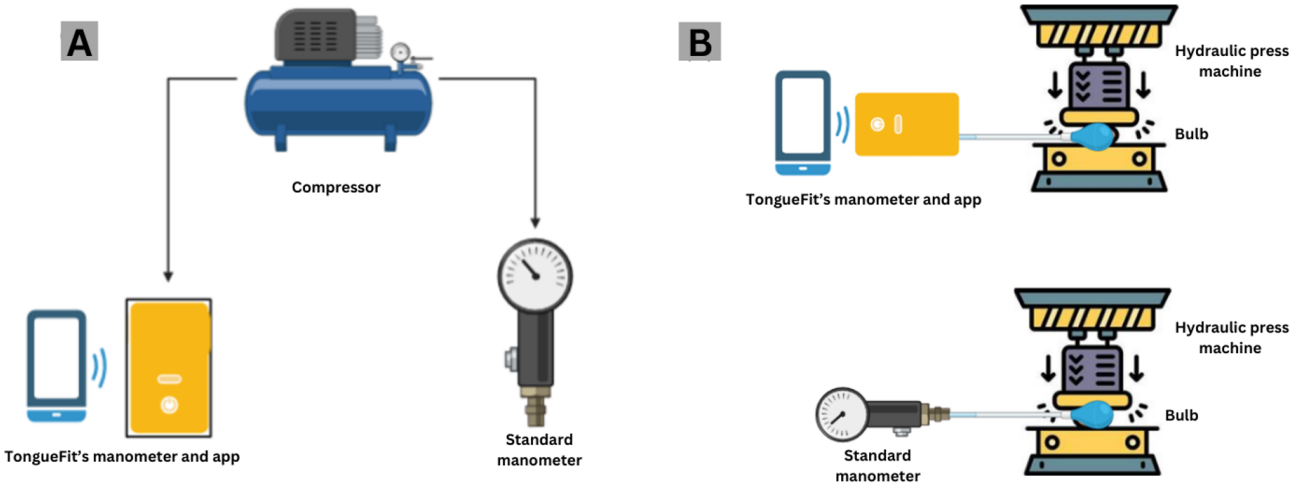
The development of TongueFit's device and app underwent user experience testing through the creation of a mock-up [21]. The mock-up of the tool was tested on a group of medical doctors experienced in pediatric rehabilitation representing potential users to ensure the quality and comfort of the final product. The testing process for the mock-up of TongueFit's device focused on evaluating comfort and ergonomics and identifying potential design improvements. In parallel, TongueFit's app mock-up trial assessed navigation, design consistency, and user interface comprehension. Based on the test results, the mock-up was improved and adjusted to better meet the needs of the target users.

In this study, we compared measurements obtained from TongueFit and a standard manometer (SNDWAY SW-512C, Dongguan Sndway Electronic), considered the gold standard

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for measuring air pressure differences. TongueFit offered two different bulb sizes: a 2-cm bulb for children under 6 years of age and a 3-cm bulb for children over 6 years of age and adults. Our experiment included the evaluation of both bulb sizes and the TongueFit device itself. This study was conducted in 3 different experimental conditions (Figure 3). The first experiment compared TongueFit and the standard manometer using a compressor. The second and third experiments involved 2-cm and 3-cm bulbs between the 2 devices.

Figure 3. Validation test scheme. (A) TongueFit versus standard manometer with compressor, and (B) TongueFit versus standard manometer with bulb validation test.



TongueFit Versus Standard Manometer

This experiment was designed to validate the ability of the TongueFit to provide accurate pressure measurements compared with the standard manometer. Each device was connected to a universal high-performance force tester (MCT-2150, A&D), which acted as an air compressor and controlled air pressure source. This connection was made alternately through a polyurethane tube. The air pressure given to each device was controlled by MSatLite software (A&D). The pressure was gradually increased, starting at 2 kPa and increasing by 2 kPa for each measurement to a maximum of 70 kPa. Each measurement started from 0 kPa.

TongueFit With 2-cm Bulb Versus Standard Manometer With 2-cm Bulb

This experiment aimed to ensure the consistency of measurement results between the TongueFit and the standard manometer when each device was connected to a 2-cm air-filled bulb that we developed. To maintain a controlled pressure on the bulb, the previously used force-tester device (MCT-2150, A&D) was configured as a computer-controlled hydraulic press machine in the laboratory, using software called MSatLite (A&D) to apply pressure on the bulb.

To conduct this experiment, TongueFit was connected to the air-filled bulb via a tube, and the bulb was positioned under the hydraulic press machine with a fixture. The machine applied pressure to the entire surface of the bulb to ensure uniform pressure distribution. The compression of the bulb was carried out by using a hydraulic machine, starting from 0.6 mm and increasing by 0.2 mm for each measurement until 5 mm was reached, each measurement starting from 0 kPa. The same procedure was then performed with the 2-cm bulb connected to the standard manometer.

TongueFit With 3-cm Bulb Versus Standard Manometer With 3-cm Bulb

This experiment followed identical procedures to the 2-cm bulb experiment. Maintaining consistency in the experimental protocol ensured that the methodology, conditions, and variables studied remained consistent throughout the investigation. This approach allowed for a direct comparison between the results of the 2 experiments, facilitating a comprehensive evaluation of the effect of different bulb sizes.

Statistical Analysis

The obtained measurement data were recorded and processed using Microsoft Excel. Data analysis was performed using SPSS software (version 27; IBM Corp). The validity test used the Lin concordance correlation coefficient to assess the degree of agreement between the standard manometer and TongueFit. Lin concordance correlation coefficient (ρC) results of <0.9 indicate poor validity, the range of 0.9 - 0.949 indicates moderate validity, 0.95 - 0.99 indicates substantial validity, and values >0.99 indicate almost perfect validity.

Results

Overview

This study was a laboratory-based study that compared TongueFit and a standard manometer in 3 different experiments.

TongueFit Versus Standard Manometer

The sensor readings obtained by TongueFit (Table 1 and Figure 4) show a slightly higher mean value of 0.005 kPa compared with those recorded by the standard manometer when the compressor administered air pressure. Upon further statistical analysis, a perfect agreement value (ρC=1) indicates a precise agreement between TongueFit and the standard manometer readings.

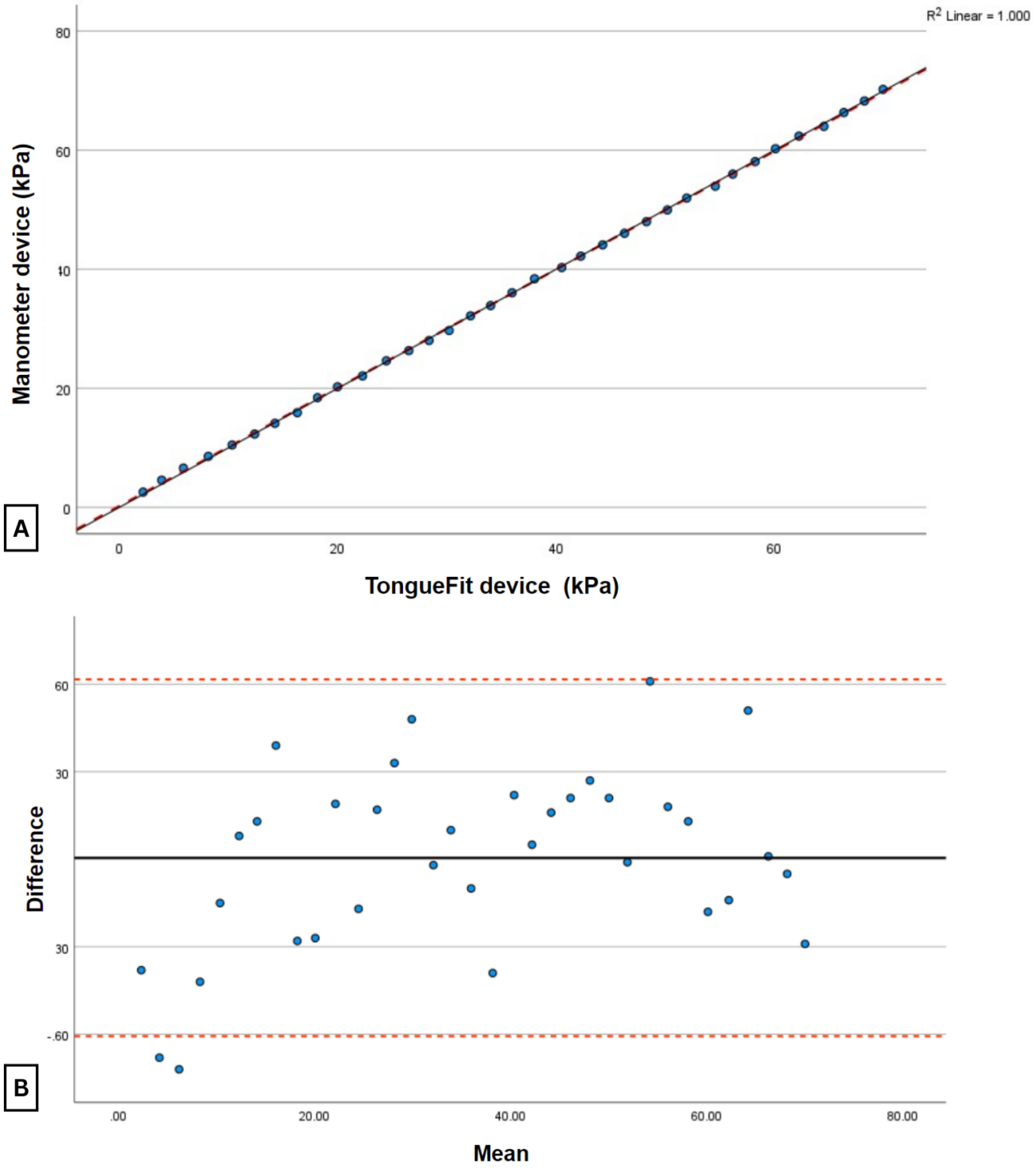
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Table . The degree of conformity between TongueFit, the standard manometers, and the compressor.

Compressor (kPa)	TongueFit (kPa)	Standard manometer (kPa)
2	2.18	2.56
4	3.88	4.56
6	5.87	6.59
8	8.15	8.57
10	10.33	10.48
12	12.39	12.31
14	14.25	14.12
16	16.30	15.91
18	18.15	18.43
20	19.98	20.25
22	22.27	22.08
24	24.45	24.62
26	26.51	26.34
28	28.36	28.03
30	30.20	29.72
32	32.16	32.18
34	34.00	33.9
36	35.96	36.06
38	38.02	38.41
40	40.51	40.29
42	42.25	42.2
44	44.26	44.1
46	46.26	46.05
48	48.27	48
50	50.18	49.97
52	51.95	51.96
54	54.57	53.96
56	56.17	55.99
58	58.22	58.09
60	60.08	60.26
62	62.23	62.37
64	64.52	64.01
66	66.34	66.33
68	68.23	68.28
70	69.93	70.22

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Figure 4. Relationship between TongueFit device readings and standard manometer device readings. (A) The graph of the TongueFit device is a scatter plot with a black solid line representing the best line and a red dashed line representing the perfect line, and (B) the Bland-Altman plot of the difference between the 2 devices, with the black solid line representing the mean difference between the measurements and the red dotted line representing 1.96 SDs above and below the mean difference.



TongueFit With 2-cm Bulb Versus Standard Manometer With 2-cm Bulb

When tested with the 2-cm bulb (Table 2 and Figure 5), TongueFit showed a perfect agreement value (ρC=1), with its mean value being 0.007 kPa lower than that of the standard manometer. This indicated a consistent trend of TongueFit readings being slightly lower than the standard manometer across different bulb sizes.

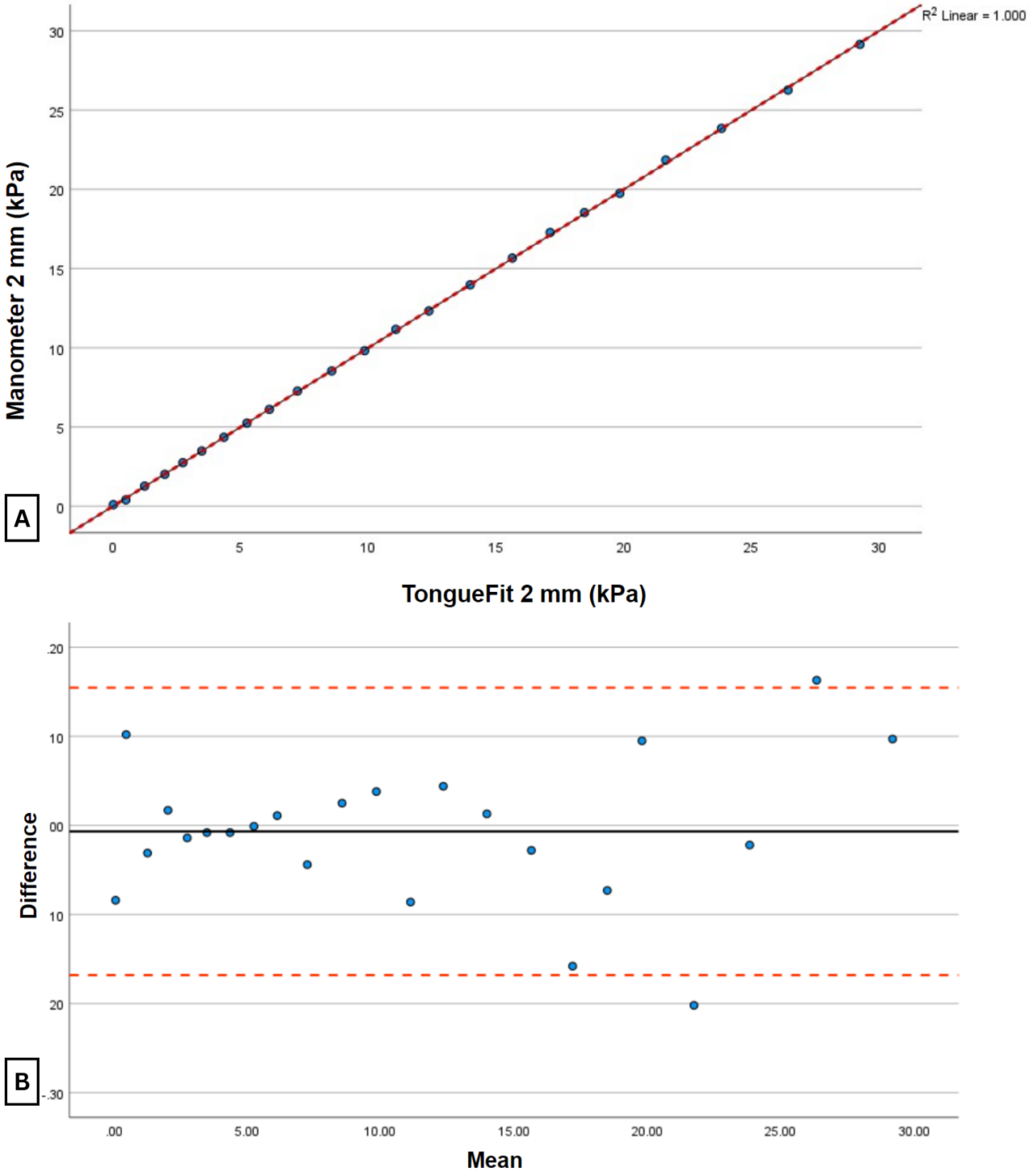
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Table . The degree of conformity between TongueFit and standard manometers with the 2-cm bulb.

Hydraulic (mm)	TongueFit (kPa)	Standard manometer (kPa)
0.6	0.02	0.1
0.8	0.51	0.41
1.0	1.24	1.27
1.2	2.03	2.02
1.4	2.74	2.76
1.6	3.48	3.49
1.8	4.35	4.36
2.0	5.25	5.25
2.2	6.13	6.12
2.4	7.23	7.27
2.6	8.57	8.54
2.8	9.86	9.82
3.0	11.08	11.16
3.2	12.37	12.33
3.4	13.99	13.98
3.6	15.64	15.67
3.8	17.12	17.28
4.0	18.46	18.54
4.2	19.85	19.75
4.4	21.65	21.85
4.6	23.83	23.85
4.8	26.43	26.27
5.0	29.25	29.15

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Figure 5. Relationship between TongueFit and standard manometer pressure readings connected to the same 2-cm bulb. (A) The scatter plot with the black solid line representing the line of best fit and the red dashed line representing the line of perfect agreement. (B) The Bland-Altman plot of the differences between the 2 devices, with the black solid line representing the average differences between the measurements and the red dashed line representing 1.96 SDs above and below the average differences.



TongueFit With 3-cm Bulb Versus Standard Manometer With 3-cm Bulb

The test results using the 3-cm bulb (Table 3 and Figure 6) showed almost perfect agreement (ρC=0.999), with a 95% CI ranging from 0.998 to 0.999. In this scenario, the average TongueFit reading was significantly lower than the standard manometer by 0.044 kPa.

Overall, TongueFit showed strong validity across all experiments, as indicated by ρC values greater than 0.99. This means an almost perfect agreement between the TongueFit measurements and those obtained with the standard manometer.

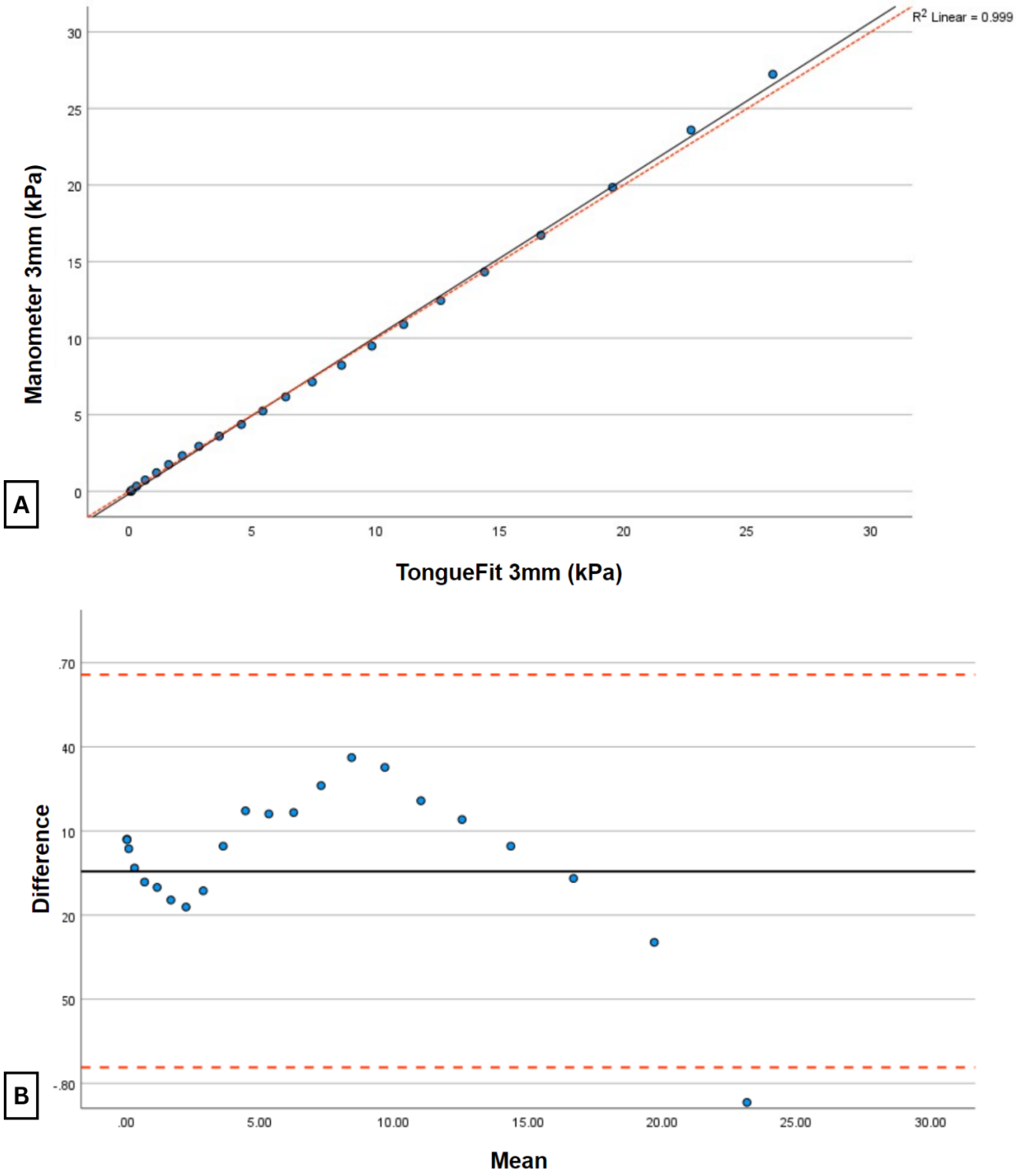
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Table . The degree of conformity between TongueFit and standard manometers with the 3-cm bulb.

Hydraulic (mm)	TongueFit (kPa)	Standard manometer (kPa)
0.6	0.07	0.00
0.8	0.08	0.01
1.0	0.12	0.09
1.2	0.31	0.34
1.4	0.66	0.74
1.6	1.11	1.22
1.8	1.6	1.75
2.0	2.16	2.33
2.2	2.83	2.94
2.4	3.65	3.6
2.6	4.55	4.37
2.8	5.41	5.25
3.0	6.34	6.17
3.2	7.41	7.15
3.4	8.6	8.24
3.6	9.82	9.49
3.8	11.11	10.9
4.0	12.61	12.46
4.2	14.38	14.33
4.4	16.66	16.73
4.6	19.56	19.85
4.8	22.73	23.59
5.0	26.03	27.24

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Figure 6. Relationship between TongueFit and standard manometer pressure readings connected to the same 3-cm bulb. (A) The scatter plot with the black solid line representing the line of best fit and the red dashed line representing the line of perfect agreement. (B) The Bland-Altman plot of the differences between the two devices, with the black solid line representing the average differences between the measurements and the red dashed line representing 1.96 SDs above and below the average differences.



Discussion

Principal Findings

Assessment of tongue strength is essential because of its important role in eating and swallowing [13]. Over time, several methods have been developed to measure tongue strength to evaluate tongue function. The orofacial manometer is a widely used tool for quantifying tongue strength, with the IOPI being one of the most commonly used devices. When lingual force is applied to the air-filled bulb, this measures the pressure difference against a predetermined air volume. It then digitally displays the pressure inside the bulb in kPa [10,11]. The TongueFit device, which we developed, works on the same principle. In addition, we integrated game-based biofeedback into the exercises to increase the children's engagement and participation in the process. This study provided evidence of

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the satisfactory validity of TongueFit compared with the standard manometer. In the first experiment, the comparison between TongueFit and the standard manometer showed a negligible mean difference of 0.005 kPa, indicating a high level of agreement between the measurements obtained by both devices. In addition, the analysis showed a perfect agreement value (ρC=1), further emphasizing the accuracy of the TongueFit measurements. The analysis of the Bland-Altman plot also suggested a consistent, perfect agreement using the 2-cm bulb (ρC=1) and the 3-cm bulb (ρC=0.999). This study confirms the high validity of TongueFit as an orofacial manometer compared to the standard manometer, with near-perfect and perfect agreement in 3 experiments.

Previously developed tongue measurement devices, such as the Tongueometer and the Tongue Pressure Meter (TPM-01; JMS), had used the IOPI as a gold standard to validate or compare their measurement results [22,23]. Unlike previous studies, we refrained from this approach primarily due to its unavailability in Indonesia and the lack of published validation studies for the IOPI. Instead, we used the standard manometer, a standard device used for measuring pressure differentials, similar to the IOPI's air-filled bulb principle. Consequently, we considered the standard manometer an accurate and valid alternative for assessing air pressure differentials, similar to the IOPI's tongue force measurement method.

In contrast to this study, where the TongueFit was compared with a standard manometer, other studies have used the IOPI as a reference tool for comparison. Gibbons et al [24] compared the Tongueometer and the IOPI in measuring lingual pressure. Statistically significant, positive correlations were found between the mean values measured by the 2 devices for anterior isometric lingual pressure (concordance correlation coefficient=0.74, P<.001), demonstrating the concurrent validity of the Tongueometer with the IOPI. The independent samples t test revealed no statistically significant difference in the means for anterior isometric lingual pressure (t_{74}=−0.5, P=.65), suggesting similar performance between the Tongueometer and IOPI in this regard. However, a study by Curtis et al [22] found that Tongueometer pressure readings under controlled conditions (without using a bulb) were typically 7 kPa lower on average than IOPI pressure readings. Lin concordance correlation was used to assess the validity of Tongueometer readings compared with the IOPI and showed substantial validity (ρC=0.97, 95% CI 0.961 - 0.977). In addition, analysis using a Bland-Altman plot showed that only 16.8% of the data points were in agreement.

Yoshikawa et al [23] used the Pearson correlation coefficient to compare the measurement results of the TPM-01 and IOPI. Their results showed significant correlations between TPM-01 and IOPI measurements in both female participants (R^2=0.74, P<.01; IOPI PRO=TPM-01×1.21+11.2) and male participants (R^2=0.64, P<.01; IOPI PRO=TPM-01×1.07+15.4). Compared with the Tongueometer and the TPM-01, TongueFit showed better measurement validity than both devices. Thus, TongueFit can be considered a valid tool for assessing tongue strength, providing accurate measurements comparable with those obtained with the standard manometer under different experimental conditions. However, it was important to note that TongueFit was validated using the standard manometer, not the IOPI.

Most studies on tongue measurement devices focus on adult populations, while only a few target pediatric populations. Potter and Short [25] used the IOPI device to measure tongue strength in typically developing children aged 3 - 16 years old using a standard IOPI bulb. One concern in Potter and Short's study was whether younger children could tolerate the IOPI bulb since it contacts more than 50% of the tongue surface in a 3-year-old child compared with only 30% in adults. While they found that most younger children tolerated the bulb well, there were still a few who did not. Given the small sample size of the age group in the study (n=28), it was possible that with a larger sample size, more children would not be able to tolerate the light bulb. To the best of our knowledge, no device has been specifically designed for children. Previous studies used commonly available tools, whereas the TongueFit used in this study was specifically designed for children and incorporated a specialized app tailored to their needs. Therefore, this study is essential for advancing future clinical applications. Furthermore, assessing the validity of the orofacial manometer and the bulb is important.

Curtis et al [22] evaluated the tongue bulb of the Tongueometer against that of the IOPI, using both the IOPI and Tongueometer devices for separate measurements. In both sets of measurements, the Tongueometer consistently registered higher pressure readings. Specifically, when measured with the IOPI, the bulb of the Tongueometer had a median pressure of 1 kPa higher than that of the IOPI, increasing to 4 kPa higher when pressures exceeded 40 kPa. Analysis using Lin concordance correlation underscored substantial validity between the bulb of the tongueometer and the bulb of the IOPI (ρC=0.987, 95% CI 0.982 - 0.991). Conversely, the pressure readings of his bulb exceeded those of the IOPI's bulb by 2.7 kPa when measured with the tongueometer, with the discrepancy increasing with increasing pressure. Lin concordance correlation between the bulb of the tongueometer and the bulb of the IOPI (ρC=0.992, 95% CI 0.988 - 0.9914) indicated substantial to excellent agreement. Although the exact cause of this variance remains unclear, it is speculated to be due to differences in the size and shape of the tongue bulbs. In this study, the TongueFit showed better results according to Lin concordance correlation, showing a perfect agreement value for the 2-cm bulb (ρC=1) and an almost perfect agreement value for the 3-cm bulb (ρC=0.999).

To our knowledge, no other studies have evaluated the validity of tongue bulb measurements. A previous study compared the performance of the Tongueometer bulbs and the IOPI bulbs [22]. In contrast, our investigation sought to elucidate the differences in pressure determinations between a standard manometer and the TongueFit when using the TongueFit bulb. This thorough investigation was conducted to verify the consistency of pressure readings between the TongueFit and the standard manometer, with both devices connected to the 2-cm and 3-cm air-filled bulbs developed in our study.

Since the TongueFit bulb would directly contact oral cavity structures, ensuring its safety is paramount. Therefore, we conducted a toxicity assessment using human stem cells to

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evaluate the raw materials comprising the bulb, tongue bulb, and tube. Our results indicate that the raw material, bulb, and tube have nontoxic properties, confirming their safety for intraoral use. This tool and app also passed preliminary testing and evaluation of the mock-up to identify potential improvements and enhancements to increase the functionality of both the device and the app. Therefore, the final tool and app are well-aligned with user needs, incorporating the findings from the mock-up evaluation. As we mentioned earlier, this study focused solely on the validity of TongueFit's measurement capabilities. The effect of TongueFit as a tool for tongue strength and endurance exercises will be investigated in future studies.

Conclusion

In conclusion, this study underlined the satisfactory validity of TongueFit compared with the standard manometer. The first experiment showed a negligible mean difference between TongueFit and the standard manometer, with a perfect agreement value, indicating high accuracy in TongueFit measurements. In addition, in the 2-cm and 3-cm bulb experiments, TongueFit showed a perfect agreement value compared with the standard manometer. This consistent trend suggests that TongueFit measurements are slightly lower across different bulb sizes. In addition, the test results using the 3-cm bulb showed an almost perfect agreement value. Furthermore, TongueFit has passed preliminary testing and toxicity assessments, ensuring it is safe, comfortable, and suitable for users. These results established TongueFit as an accurate and valid tool for assessing tongue strength and endurance, providing results that closely match those obtained with the standard manometer.

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Data Availability

All data analyzed for this study are included in this manuscript. For further information regarding the data, please contact the corresponding author.

Conflicts of Interest

None declared.

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Abbreviations

FITT: frequency, intensity, time, and type
IOPI: Iowa Oral Performance Instrument
kPa: kilopascals
TPM: Tongue Pressure Meter

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Patients' Expectations for App-Based Therapy in Knee Osteoarthritis: User-Centered Design Approach

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Abstract

Background: Knee osteoarthritis (KOA) requires long-term treatment that faces significant barriers, including inadequate physiotherapy services, especially in Slovenia and comparable European countries. Mobile health apps offer a promising solution to improve accessibility and adherence to KOA treatment.

Objectives: This study aimed to identify expectations of patients with KOA for app-based therapy, determine the functional requirements, and assess the main barriers and benefits of using mobile apps for KOA management. It also examined these factors about demographic data (gender, age, and education level) and motivation to perform knee exercises.

Methods: A mixed methods approach was used, integrating quantitative data from a structured questionnaire and qualitative data from in-depth interviews. The purposive sample comprised 82 patients with symptomatic KOA graded 1‐3 on the Kellgren-Lawrence scale, excluding those with cognitive impairments, wheelchair dependency, significant comorbidities, or language barriers.

Results: The analysis revealed that 53.7% (44/82) of patients preferred smartphones, while 40.2% (33/82) favored PCs for remote KOA management, citing accessibility and convenience. Exercise videos received the highest rating (μ=9.45), followed by goal setting and tracking (μ=8.95) and regular e-messages (μ=8.83). Telephone consultations with physiotherapists were also highly valued (μ=8.41). Significant differences were observed in the perceived importance of key disease information (F_9=2.077; P=.04) and exercise videos (F_9=2.788; P=.05) based on motivation levels but not by gender, age, or education. Perceptions of the appropriate duration of physical activity varied with motivation levels (F_9=2.490; P=.02) but not with demographic factors. Men rated ease of use (4.93 vs 4.71; F_1=3.961; P=.05) and the clarity of the exercise flow display higher than women. The most significant barrier was inaccurate disease information (μ=3.96), with notable differences across age groups. Younger participants (younger than 40 years) and those aged 51‐60 years expressed concerns about time management and information accuracy. Patients highlighted the ability to rewatch exercises as a key app feature, while time efficiency and improved access to physiotherapists were highly valued for convenience. Enhanced communication and accurate information were essential for building trust and ensuring effective treatment.

Conclusions: Mobile health apps for KOA management should be designed with a user-centered approach, prioritizing accessibility, motivation, and effective communication. Key functionalities include high-quality exercise videos, goal setting, symptom tracking, and regular electronic reminders. Mitigating user-reported barriers and integrating age-specific adaptations can enhance adherence and therapeutic outcomes. The findings highlight the potential of mobile health technologies to optimize KOA self-management and improve patient quality of life, particularly in health care systems with limited physiotherapy accessibility, such as those in Slovenia.

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KEYWORDS

knee osteoarthritis; experience; opinion; perspective; mHealth; app; user-centered design; patient engagement; preference; physiotherapy; exercises; motivation; functional requirements; barriers and benefits; digital health; chronic disease management; joint; arthritis; osteoarthritis; rheumatology

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Introduction

Knee osteoarthritis (KOA) is a prevalent degenerative joint disease affecting 16% of individuals aged 15+ years and 22.9% of those aged 40+ years [1]. As a leading musculoskeletal disorder [2], it poses a growing economic and health burden [3-5], necessitating effective management strategies to mitigate symptoms and improve patient outcomes.

Exercise, self-management, and patient education are essential for KOA management, as recommended by the Osteoarthritis Research Society International and the American College of Rheumatology [6-9]. However, barriers such as misinformation, low self-efficacy, limited physiotherapy access, and restrictive care pathways hinder their effectiveness [10-16]. In Slovenia, the shortage of physiotherapists (50‐70 per 100,000 inhabitants) leads to prolonged waiting times, a challenge also reported in Eastern and Southern Europe, as well as in the United Kingdom, Canada, and Australia, where delayed access to physiotherapy negatively impacts treatment outcomes [17,18]. Given KOA's significant health care, economic, and social challenges, efforts are focused on developing effective, accessible treatments. As defined by the World Health Organization, mobile health technology includes medical practices supported by mobile devices [19]. Mobile health apps offer scalable solutions by delivering behavioral interventions, facilitating remote monitoring, and providing access to educational resources and clinical guidelines. Health apps support patients in adhering to exercise regimens, managing symptoms, and making informed health decisions, effectively bridging the gap between patients and health care providers, thus improving KOA management and outcomes [10‐14].

The use of digital health technologies for managing KOA is gaining attention due to its cost-effectiveness and accessibility. Systematic reviews and meta-analyses have found that digital self-management interventions for managing KOA—delivered through mobile apps, internet platforms, telephone, audio, and video—lead to small to moderate improvements in pain and function, with effects lasting up to 1 year [20]. McHugh et al [21] found that remote exercise programs are more effective when they include study-initiated follow-up and behavior change counseling. Choi et al [22] emphasized the need for mobile health technologies to support self-management and collaborative decision-making. Shah et al [23] confirmed that digital interventions, including cognitive behavioral therapy and tools that facilitate patient-clinician communication, are as effective as traditional methods for managing KOA and highlighted the importance of integrating patient preferences and contextual factors, such as education level, into the design of digital health interventions, which are often overlooked in current research.

Previous qualitative studies have demonstrated that gender and age influence user engagement and preferences. Women often value comprehensive health information and interactive support features, while men prioritize ease of use and efficiency [24]. Younger users prefer advanced features and detailed tracking, whereas older users may face challenges with digital literacy, favoring simpler interfaces with larger text and intuitive navigation [25,26]. Past studies have also indicated that patients with higher levels of education are more willing to engage with advanced app features and provide detailed feedback, favoring functionalities such as data tracking and interactive educational resources [24,27]. Existing qualitative research has established motivation as a critical factor influencing app-based therapy adoption and sustained use. McHugh et al [21] demonstrated that follow-up and behavior change counseling interventions are more effective, emphasizing motivation's role in app engagement.

Although mobile apps hold promise for KOA management, their adoption remains low. Most users discontinue use within 90 days due to suboptimal development methods that fail to support regular communication and patient motivation [28]. Existing mobile apps for KOA management face limitations, including suboptimal user engagement, insufficient personalization, inadequate integration with health care providers, and poor long-term adherence. This highlights the need for personalized goal setting, real-time feedback, automated phone call reminders, and regular clinician-patient communication to enhance engagement, adherence, and clinical effectiveness. In this context, high-quality exercise videos play a crucial role by adhering to evidence-based physiotherapy principles, providing clear demonstrations, precise instructions, appropriate pacing, and modifications for different skill levels, and ensuring safety, accuracy, and effectiveness in guided exercises [28-31]. Studies advocate a co-design approach involving end users in developing, testing, and refining interventions to improve patient satisfaction and app effectiveness [28-31]. This study investigated the user-centered app design process with patients with KOA to develop a more effective app-based therapy.

This study addresses a critical gap in the co-design process for developing a KOA mobile app by using a mixed methods approach within the context of an underresourced health care system, such as Slovenia. While mixed methods research has been used in evaluating digital health interventions, previous studies have primarily focused on other rehabilitation and assistive technologies domains [32-34], with limited application to KOA management. This study aimed to examine the expectations of app-based therapy of patients with KOA, identify key functional requirements (eg, personalized goal setting, real-time feedback, and automated reminders), and assess barriers and benefits of mobile app use for KOA management. Furthermore, it analyzed these factors concerning demographic characteristics (gender, age, and education) and motivation levels. The study tested the hypothesis that perceptions of functional requirements, app usefulness, barriers, and benefits vary significantly based on demographic characteristics (age, gender, and education) and motivation levels.

Methods

Study Design

The study used a structured co-design approach based on participatory design principles [35], ensuring active stakeholder involvement. Using the Double Diamond framework, we conducted qualitative data collection to identify user needs

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(Discover), synthesized insights to define core functionalities (Define), iteratively developed prototypes with patients' feedback (Develop), and assessed usability and feasibility (Deliver) [35].

This study adopted a sequential explanatory mixed methods design, integrating quantitative and qualitative data to understand the research problem comprehensively. Integration occurred at multiple stages, including planning (study design), sampling (purposive selection based on survey results), data collection (qualitative interviews following quantitative analysis), data analysis (triangulation of qualitative themes with quantitative findings), and interpretation (integrated reporting for contextual depth). The quantitative analysis identified key trends and patterns, which then informed the development of qualitative interviews, allowing for an in-depth exploration of the emerging themes. A triangulation approach was applied to ensure systematic integration, mapping qualitative themes onto quantitative results to assess convergence, complementarity, and divergence. This method enabled a deeper contextualization of statistical findings, strengthening the study's validity, interpretability, and overall rigor [32-34].

Ethical Considerations

The National Committee on Medical Ethics of the Republic of Slovenia (no. 0120-471/2023-2711-4) granted ethical approval for this study. Informed consent was obtained from all participants before their inclusion in the study. Participants were thoroughly briefed on the research aims, their right to discontinue participation at any stage without penalty, and the voluntary nature of their involvement. To safeguard privacy and confidentiality, all data were anonymized before analysis, with no personally identifiable information being stored or disclosed. Data were securely stored on password-protected devices, accessible exclusively to research team members. No financial or material incentives were provided, as the study was designed to impose a minimal burden and relied solely on voluntary participation.

Quantitative Survey

A quantitative survey was conducted between March and June 2024 among patients with KOA recruited through purposive sampling to ensure a representative distribution of demographic characteristics and disease experiences. The sample size (n=82) was determined using power calculations, ensuring adequate statistical precision and validity. Participants were recruited after specialist examinations at Artros, Slovenia's leading orthopedic clinic. They met the inclusion criteria of having symptomatic KOA graded 1‐3 on the Kellgren-Lawrence Scale. Patients with cognitive impairment, wheelchair dependency, comorbidities, or limited language or digital skills were excluded. All participants provided informed consent and completed a 10-minute questionnaire, resulting in 82 completed surveys.

The instrument was developed based on measures or findings from previous studies [22-27] and refined for the Slovenian context through interviews with 5 experts, including academics and health professionals. It was piloted with 25 professionals (physiotherapists, rehabilitation specialists, and orthopedic experts) and patients to ensure clarity and relevance, incorporating various question types and scales for comprehensive data collection.

The survey tool was a structured questionnaire comprising 38 items designed to assess demographic characteristics, motivation, expectations, usability, barriers, and benefits related to a web-based application for KOA rehabilitation. It included multiple-choice questions, Likert scale ratings (1-10), and binary response options. The questionnaire consisted of 6 main sections: demographic data covering gender, age, education, and occupation; motivation to perform knee exercises, assessed using a 10-point Likert scale ranging from 1 (not motivated at all) to 10 (extremely motivated) and categorized as low (1-6) and high (7-10) based on established thresholds; expectations from the digital app (9 items), evaluating the importance of various app features such as educational content, goal setting, video demonstrations, reminders, and communication with physiotherapists; usability perception (6 items), measuring ease of use, navigation, and information clarity; potential barriers (10 items), identifying challenges such as technical difficulties, lack of web access, and low motivation; and perceived benefits (6 items), assessing factors such as time savings, improved motivation, and enhanced physiotherapist interaction (Multimedia Appendix 1). The questionnaire was self-administered in paper format within a health care setting, ensuring consistency in data collection while allowing respondents to complete it independently in a confidential environment. The questionnaire demonstrated high internal consistency, with a Cronbach alpha value of 0.85, indicating robust reliability.

Qualitative Study

In-depth interviews were conducted to understand the patient's needs, functional requirements, and esthetic preferences for a mobile KOA management app and identify barriers and facilitators to its use. After completing the quantitative survey administered by questionnaire (n=82 patients; Table 1), qualitative interviews were conducted with all selected participants, ensuring a comprehensive exploration of their experiences and perspectives.

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Table . Demographic characteristics (n=82).

Attribute	Share of total respondents, n (%)
Sex	
Male	27 (32.9)
Female	55 (67.1)
Age (years)	
31 - 40	2 (2.4)
41 - 50	15 (18.3)
51 - 60	25 (30.5)
61 - 70	23 (28.0)
71 - 80	17 (20.7)
Highest education level	
Secondary school or less	54 (65.9)
Bachelor's degree	24 (29.3)
Master's degree/specialization	3 (4.9)
Doctoral degree	N/A[a]

[a]N/A: not applicable.

A semistructured interview guide, developed by reviewing existing literature [24-31] and expert consultation, provided a structured yet flexible framework for in-depth discussions. Following the initial interviews, the guide was carefully reviewed and refined, with minor adjustments made to improve clarity and relevance in response to emerging themes. Patients were asked to provide detailed insights into their expectations, needs, functional requirements, and esthetic preferences for a mobile KOA management app. In addition, they shared their views on barriers to app usage and potential facilitators. Trained researchers with expertise in qualitative health research conducted interviews. These interviews took place face-to-face in confidential and comfortable settings, such as quiet rooms in health care facilities or other mutually agreed locations, ensuring participant comfort and open communication. Each interview lasts between 45 and 90 minutes. All interviews were audio-recorded with the participant's informed consent and transcribed verbatim.

Data Management and Analysis

The quantitative analysis was conducted using descriptive statistics to analyze mean (μ) values and the normality of data distribution was assessed using the Shapiro-Wilk test, which confirmed a normal distribution (P>.05). Consequently, parametric tests were used for further analysis. Differences between groups were evaluated using the independent samples t test and ANOVA, with statistical significance set at P<.05. All data analyses were performed using SPSS (version 25.0; IBM Corp).

For the qualitative component, we conducted the thematic analysis using NVivo (version 12; QSR International) software to facilitate systematic coding and organization of data. Two researchers (KE and PK) independently coded the transcripts, ensuring intercoder reliability and reducing potential bias. We applied an inductive coding approach, where codes were derived directly from the data and categorized into broader themes. We used an iterative coding process to address overrepresentation and potential errors, cross-checked themes against the dataset, and resolved discrepancies through researcher discussions and consensus-building. Themes were identified through pattern recognition, with recurrent concepts reviewed for coherence and alignment with the research objectives. Differences in interpretation were resolved through researcher consensus, with a third researcher consulted when necessary to ensure analytical rigor and objectivity.

Results

Overview

The results will be presented in thematic sections, explaining the quantitative findings with qualitative data. The study included 82 participants, with 67.1% (55) female and 32.9% (27) male respondents. The majority were aged 51 - 70 years (70, 58.5%), while smaller proportions were aged 31 - 40 years (2, 2.4%) and 71 - 80 years (17, 20.7%). Regarding education, 65.9% (54) had secondary school or less, 29.3% (24) held a bachelor's degree, and 4.9% (4) had a master's degree or specialization, with no participants holding a doctoral degree (Table 1).

Preferred Device for Remote KOA Management

Most respondents preferred performing KOA management via smartphone (44, 53.7%) or PC (33, 40.2%) due to their accessibility, convenience, and technical possibilities, as the in-depth interviews revealed. Smartphones offer quick and easy access to apps anywhere and anytime, increasing the likelihood of regular exercise. With their larger screens, PCs offer a better overview of exercise videos and instructions. Both devices support high-quality video content and easy web connectivity, which is essential for monitoring progress and communicating

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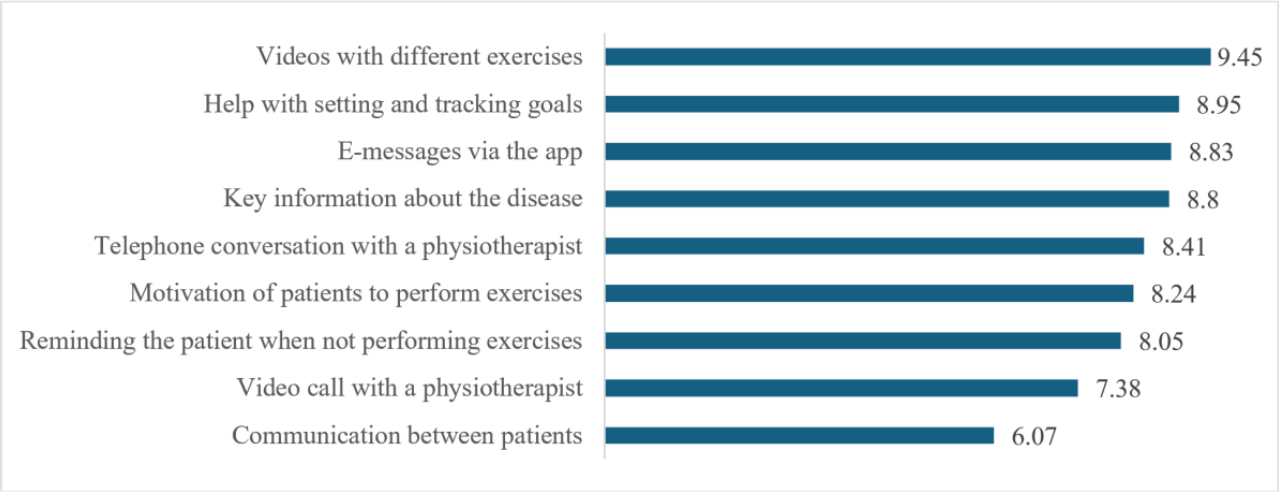
with physiotherapists. According to patient 1, "With the phone, I could exercise anywhere, while with the computer, I could have a better overview of the instructions and exercises.… So, I could combine them depending on the situation."

Importance of the Functional Requirements of Mobile Apps for KOA Management

The results showed that the importance of functional requirements for mobile apps managing KOA did not significantly vary between genders, age groups, or educational levels. Table 2 demonstrates that differences in the importance of functional requirements for KOA management mobile apps are significant among various motivation levels for only 2 features: "key information about the disease" and "videos with different exercises." Patients with higher motivation levels expressed a greater desire for comprehensive information about their condition, including disease details, treatment strategies, and healthy lifestyle tips. Specifically, those who reported higher motivation also placed greater value on having key information about the disease included in the app, as indicated by the significant differences in mean motivation levels (F_9=2.077; P=.04). Qualitative analysis also confirmed that highly motivated patients seek detailed information to support their KOA management. A typical statement was from patient 3: "Having detailed information about my condition and access to exercise videos could motivate me to stay on track with my therapy." Similarly, the data indicated that highly motivated patients emphasized the availability of videos with different exercises for knee strengthening. These patients rated the importance of exercise videos significantly higher than those with lower motivation levels (F_9=2.788; P=.01). This suggests that motivated patients are more likely to engage with an app that provides clear, visual guidance through exercise videos, enhancing their ability to perform exercises correctly and consistently. Patient 4 stated: "The exercise videos in the app will help me to understand how to do the exercises correctly and motivate me to keep going."

Figure 1 illustrates the importance ratings of various functional requirements of mobile apps for KOA management, measured on a Likert scale from 1 (not important) to 10 (extremely important), reflecting participant preferences. Analysis of the in-depth interviews showed that patients rated the importance of these features based on their practical needs and preferences in managing their condition. The highest-rated function, videos with different exercises (μ=9.45), reflected the patients' need for clear, visual guidance to ensure that the exercises were performed correctly, as the analysis of patient statements revealed. Setting and tracking goals (μ=8.95) was also rated highly, as patients considered it essential for monitoring their progress and staying motivated. Regular e-messages via the app (mean rating: 8.83) and essential information about the disease (μ=8.80) were identified as crucial for keeping patients informed and involved in their treatment plans. Direct communication with health care providers was deemed important, as evidenced by the high rating of phone calls with a physiotherapist (μ=8.41), which suggests that patients value personalized advice and reassurance from professionals. Features that support treatment adherence, such as motivation to perform exercises (μ=8.24) and reminders when exercises are not performed (μ=8.05), were considered critical for maintaining a consistent exercise program. Although video calls with a physiotherapist (μ=7.38) and communication between patients (μ=6.07) were rated lower, they were still important for some patients, especially those seeking more direct interaction or peer support.

Figure 1. Importance of the functional requirements of mobile apps for knee osteoarthritis management.



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Table . Differences in the importance of the functional requirements of mobile apps for knee osteoarthritis management regarding the level of motivation (ANOVA)[a].

Level of motivation	Sample size, n	μ[b]	σ[c]	*F* test (*df*)[d]	*P* value
Key information about the disease				2.07 (9)	.04
1	1	5.00	0.000		
2	2	6.50	4.950		
3	4	10.00	0.000		
4	2	8.00	2.828		
5	9	8.67	2.646		
6	8	8.00	3.071		
7	9	9.33	1.414		
8	22	8.05	2.420		
9	9	9.67	0.500		
10	16	9.88	0.500		
Videos with different exercises				2.788 (9)	.007
1	1	7.00	0.000		
2	2	6.50	4.950		
3	4	10.00	0.000		
4	2	9.00	1.414		
5	9	9.00	2.000		
6	8	9.63	1.061		
7	9	9.67	0.707		
8	22	9.32	1.041		
9	9	9.67	0.500		
10	16	10.00	0.000		

[a]All motivation measures in this and subsequent tables use a scale from 1 (lowest) to 10 (highest).

[b]Mean score of importance ratings for each functional requirement.

[c]SD values.

[d]ANOVA test statistic.

Appropriate Amount of Time to Exercise

Table 3 shows participants' preferences regarding the reasonable duration for app-based exercises, with response options of up to 15 minutes, 16 - 30 minutes, and 31 - 45 minutes. The results indicate that opinions on the appropriate exercise duration did not significantly differ based on gender, age, or educational level. This suggests a consensus among participants on the time they are willing to dedicate to physical activity within the mobile app. The analysis of the in-depth interviews revealed that a consensus between different demographic groups regarding the recommended duration of physical activity can be attributed to shared experience. Patients with KOA often experience similar symptoms, such as pain and stiffness, leading to a shared understanding of the benefits of exercise. Patient 5 said, "I know many people with this condition and can say that we all feel the same relief from exercise, regardless of our positions, so the recommended duration works for everyone."

As shown in Table 3, there was a statistically significant difference in opinion regarding the level of motivation based on the appropriate amount of time to exercise (F_9=2.490; P=.0.15). Patients with higher motivation levels (ratings of 7 - 10) favored longer exercise durations (mean ratings from 2.18 to 2.31) than those with lower motivation levels (ratings of 1 - 6, mean ratings from 1.00 to 2.00). A typical patient statement in this regard was from patient 6: "I find that longer exercise sessions could help me feel more accomplished and keep me motivated to stay consistent with my routine."

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Table . Differences in opinions of the appropriate amount of time to exercise regarding the level of motivation (ANOVA).

Category	Sample size, n	μ[a]	σ[b]	*F* test (*df*)[c]	*P* value
Depending on the level of motivation				2.490 (9)	.02
1	1	2.00	0.000		
2	2	2.00	1.000		
3	4	2.50	0.289		
4	2	1.00	0.000		
5	9	1.33	0.167		
6	8	1.88	0.295		
7	9	2.22	0.278		
8	22	2.18	0.125		
9	9	2.22	0.222		
10	16	2.31	0.151		

[a]Mean score of importance ratings for each functional requirement.

[b]SD values.

[c]ANOVA test statistic.

Usefulness of Mobile Exercise Apps for KOA Management

Table 4 indicates statistically significant differences in the assessment of the usefulness of mobile apps based on gender, measured on a 1 - 5 Likert scale (1=I do not agree at all, 5=I totally agree). According to the data, men generally rated KOA apps better than women in terms of overall ease of use, clarity of system information, and general friendliness. They also had significantly higher ratings than women for ease of use (μ=4.93 vs μ=4.71; F_1=3.961; *P*=.05), clarity of the exercise process display higher (μ=4.93 vs μ=4.71; F_1=3.961; *P*=.05), and ease of navigation on the tab (μ=4.89 vs μ=4.64; F_1=3.961; *P*=.04). In addition, men rated instructions on performing exercises higher (μ=4.93, σ=0.267) than women (μ=4.69; F_1=4.318; *P*=.04). Their ratings were also higher than women's ratings regarding providing help on how to perform exercises correctly (μ=4.93 vs μ=4.67; F_1=4.653; *P*=.03) and ease of communication with the physiotherapist (μ=4.78 vs μ=4.49; F_1=4.196; *P*=.04). These results show that, on average, men have higher expectations of user-friendliness, clarity of system information, and ease of app use than women.

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Table . Differences in opinions of the usefulness of mobile exercise apps based on gender (*t* test).

	Sample size, n	μ[a]	Σ[b]	*F* test (*df*)[c]	*P* value
Ease of use				3.961 (1)	.05
Male	27	4.93	0.267		
Female	55	4.71	0.533		
A clear display of the training process				3.961 (1)	.05
Male	27	4.93	0.267		
Female	55	4.71	0.533		
Easy tab navigation				3.961 (1)	.04
Male	27	4.89	0.320		
Female	55	4.64	0.589		
Instructions for carrying out the exercises				4.318 (1)	.04
Male	27	4.93	0.267		
Female	55	4.69	0.540		
Help with the correct execution of exercises				4.653 (1)	.03
Male	27	4.93	0.267		
Female	55	4.67	0.579		
Facilitated communication with the physiotherapist				4.196 (1)	.04
Male	27	4.78	0.424		
Female	55	4.49	0.663		

[a]Mean score of importance ratings for each functional requirement..

[b]SD values.

[c]ANOVA test statistic.

The analysis of in-depth interviews revealed that gender differences in the perceived usefulness of mobile apps were attributable to distinct priorities and user experiences between men and women. Men rated ease of use, clarity of system information, and overall usability higher than women, indicating a preference for simple, efficient interfaces and clear, structured data. For example, patient 9, a male, stated, “I find it very important that the app is easy to use so that I can get to my exercises quickly and without problems,” making it clear that he valued functionality and efficiency. Similarly, the qualitative analysis showed that men placed more value on a clear display of exercise progress and easy navigation of the tabs, as indicated by the feedback: “A clear display of my progress will help me stay motivated and keep track of my workouts” (Patient 11). This suggests that men prefer features that improve their ability to independently track and manage their workout routines. Furthermore, the importance placed on detailed instructions and help in performing exercises correctly, with statements such as “Exact instructions and assist could help with exercises ensure that I perform them correctly and safely” (Patient 12), indicates a preference for precision and correctness in their exercise plans. Finally, the higher rating of facilitated communication with physiotherapists, supported by statements such as “Being able to communicate with the physiotherapist via the app is very helpful to get quick feedback and advice” (Patient 13), underscores the importance of direct and immediate support.

Table 5 shows an ANOVA analysis examining differences in perceptions of mobile app usefulness based on motivation levels (ranging from 1 to 10). The analysis revealed statistically significant differences for only 2 specific functionalities, with “Ease of Use” being the only factor reaching statistical significance: ease of use (F_9=2.397; P=.02) and good organization of information (F_9=2.358; P=.02). Highly motivated patients (rating 10) rated user-friendliness the highest (μ=5.00), while those with lower motivation (rating 1) rated it lower (μ=4.00). Good organization of information was particularly important for those with very high or low motivation, with ratings of 3, 4, and 10 yielding a mean score of 5.00, while those with medium motivation (rated 7) assigned a lower score of 4.11. The in-depth interviews revealed that the differences in opinions about the ease of use and organization of the information in the mobile app were due to users’ different needs and expectations based on their motivation levels. Highly motivated individuals desired efficient and straightforward tools to maintain their exercise routine, as in patient 14’s statement: “The app needs to be very user-friendly because, as it now says, it should make me engage with my exercises and stay

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consistent." They would like an intuitive user interface to maximize their productivity and stick to their programs. Conversely, both less motivated and highly motivated users placed a high value on well-organized information, as clarity would help them focus and reduce cognitive load, improving comprehension and engagement. Patient 8 illustrated this statement: "When all the information is clear, I can focus better and know what I need to do next."

Table . Differences in opinions of the usefulness of mobile apps based on the level of motivation (ANOVA).

Level of motivation	Sample size, n	μ[a]	Σ[b]	*F* test (*df*)[c]	*P* value
Ease of use				2.397 (9)	.02
1	1	4.00	0.000		
2	2	4.00	1.414		
3	4	4.75	0.500		
4	2	5.00	0.000		
5	9	4.56	0.726		
6	8	4.88	0.354		
7	9	4.67	0.500		
8	22	4.91	0.294		
9	9	4.56	0.527		
10	16	5.00	0.000		
Good organization of information in the app				2.358 (9)	.02
1	1	4.00	0.000		
2	2	4.00	1.414		
3	4	5.00	0.000		
4	2	5.00	0.000		
5	9	4.67	0.707		
6	8	4.88	0.354		
7	9	4.11	1.364		
8	22	4.91	0.294		
9	9	4.67	0.500		
10	16	5.00	0.000		

[a]Mean score of importance ratings for each functional requirement.

[b]SD values.

[c]ANOVA test statistic.

Barriers to Using a Mobile App for KOA Management

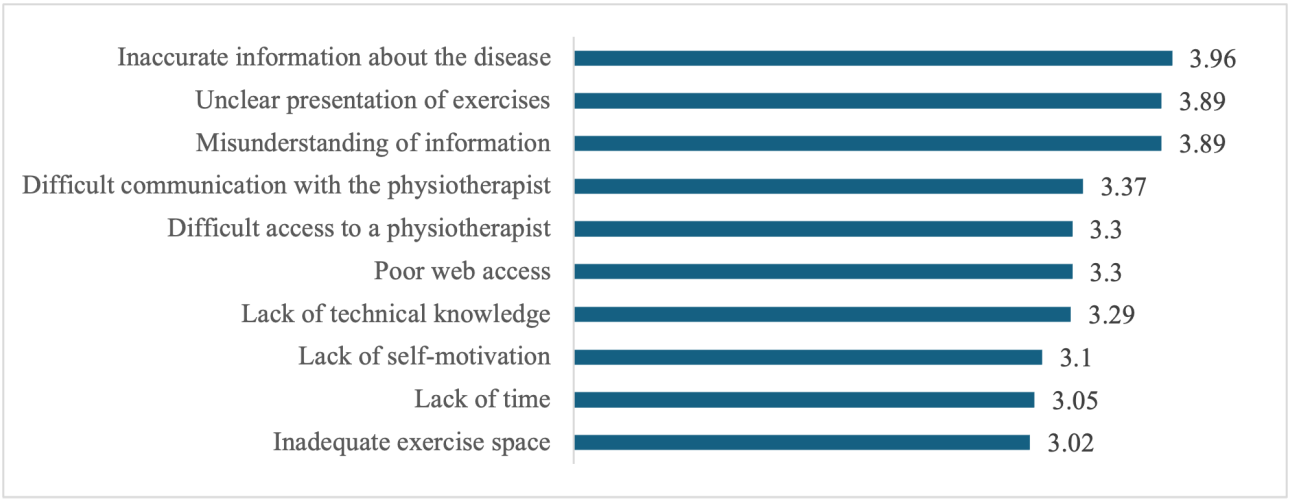
Figure 2 illustrates the barriers to using a mobile app to manage KOA, measured on a 1 - 5 Likert scale (1=I do not agree at all, 5=I totally agree). The highest-rated barrier was inaccurate information about the disease (3.96), closely followed by unclear presentation of exercises (3.89) and misunderstanding of information (3.89). Difficult communication with the physiotherapist (3.37) and access to a physiotherapist (3.3) were also important barriers. Poor web access (3.3) and lack of technical knowledge (3.29) reflected technology-related challenges. In addition, lack of self-motivation (3.1), lack of time (3.05), and inadequate training space (3.02) were moderate barriers.

Table 6 shows the results of an ANOVA analysis examining differences in the perceived barriers to using a mobile app for KOA management across different age groups. Participants aged 51 - 60 years reported the highest barrier scores for inaccurate information about the disease (μ=4.40), with younger participants younger than 40 years also expressing significant concern (μ=4.00). Similarly, lack of time was identified as an important barrier by participants younger than 40 years (μ=4.50) and those aged 51 - 60 years (μ=3.72). Motivation-related challenges were most pronounced among the youngest age group (μ=4.50, σ=0.707), while the unclear presentation of exercises was a key barrier for those younger than 40 years (μ=4.50, σ=0.707) and those aged 51 - 60 years (μ=4.36, σ=0.810). Participants aged 51 - 60 years exhibited a relatively low SD, suggesting greater consensus in their perceptions. In contrast, younger participants demonstrated higher SD values, indicating greater response variability, particularly regarding motivation and clarity of exercise instructions.

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The in-depth interviews revealed that the barriers to KOA management via mobile apps stem from individual needs, lifestyle restrictions, and expectations of the app. Patients emphasized the need for reliable information: “You know, accurate information is the most important thing for me to trust the app” (Patient 4). Time constraints were important, especially for younger patients, as patient 22 explained: “I find it difficult to fit exercise into my busy schedule.” Motivation was also an important issue, requiring clear goals and support, as noted by patient 23: “Without clear goals and support, it’s difficult to stay motivated. And without motivation, you can’t do it, so it’s a big problem.” In addition, the need for clear exercise instructions was crucial, as patient 24 emphasized: “I need clear instructions to make sure I’m doing the exercises correctly.”

Figure 2. Barriers to using a mobile app for knee osteoarthritis management (n=82).



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Table . Differences in barriers to using apps based on age (ANOVA).

Age (years)	Sample size, n	μ[a]	σ[b]	*F* test[c]	*P* value
Inaccurate information about the disease				2.774 (4)	.03
<40	2	4.00	1.414		
41 - 50	15	3.67	1.397		
51 - 60	25	4.40	0.707		
61 - 70	23	4.17	1.072		
71 - 80	17	3.29	1.490		
Lack of time				4.107 (4)	.005
<40	2	4.50	0.707		
41 - 50	15	2.93	1.486		
51 - 60	25	3.72	0.891		
61 - 70	23	2.65	1.335		
71 - 80	17	2.53	1.179		
Lack of motivation				2.661 (4)	.04
<40	2	4.50	0.707		
41 - 50	15	3.00	1.254		
51 - 60	25	3.56	1.215		
61 - 70	23	3.09	0.561		
71 - 80	17	2.35	1.272		
Unclear presentation of exercises				2.515 (4)	.048
<40	2	4.50	0.707		
41 - 50	15	3.47	1.246		
51 - 60	25	4.36	0.810		
61 - 70	23	3.96	1.147		
71 - 80	17	3.41	1.417		

[a]Mean score of importance ratings for each functional requirement.

[b]SD values.

[c]ANOVA test statistic.

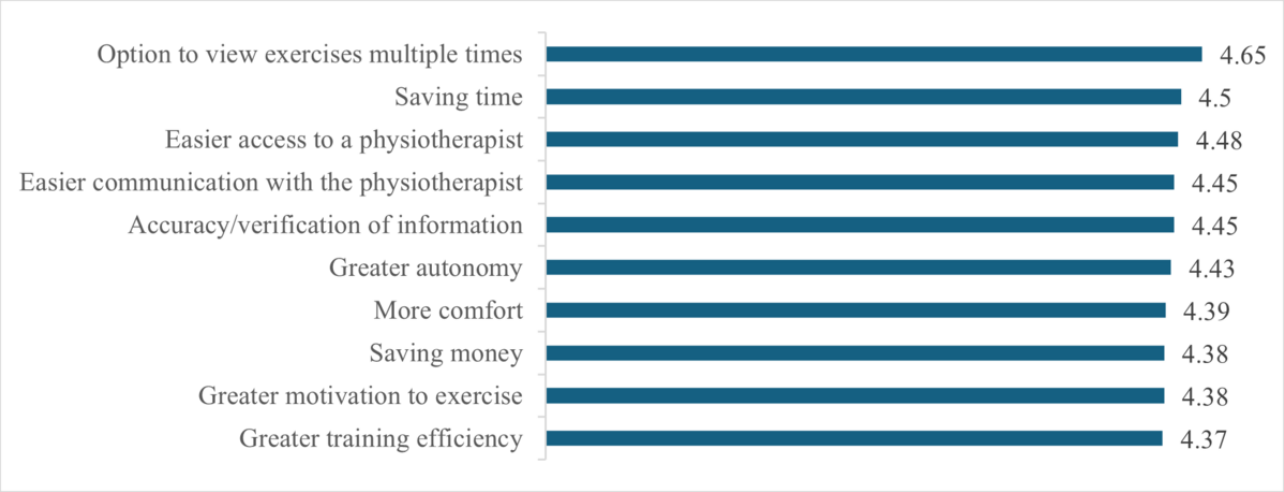
Benefits of Using a Mobile App for KOA Management to Manage KOA

Figure 3 illustrates the benefits of using a mobile app to manage KOA, measured on a 1 - 5 Likert scale (1=I do not agree at all, 5=I totally agree). The highest-rated benefit was the ability to view exercises multiple times (μ=4.65), which indicates how important clear, repeatable instructions are to users. Saving time (μ=4.50) and easier access to a physiotherapist (μ=4.48) were also rated highly, reflecting the importance of convenience and accessibility. Improved communication with the physiotherapist (μ=4.45) and the accuracy of information provided (μ=4.45) were critical to building trust and ensuring effective treatment. Greater autonomy (μ=4.43) and convenience (μ=4.39) underline that users appreciate being able to treat their condition independently and from home. Motivation to exercise (μ=4.38), cost savings (μ=4.38), and training efficiency (μ=4.37) highlight the comprehensive support offered by the app.

The analysis revealed no statistically significant differences between the perceived benefits of the app and demographic factors or motivation levels. Most respondents stated that they knew the potential benefits of using a mobile app for KOA management. For example, patient 26 said, “The benefits of the app are clear to me, and I think they’re also clear to the others waiting here, regardless of our age or situation. We all know that it can help us manage our condition effectively. That’s why it’s so important. I look forward to using it.”

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Figure 3. Benefits of using a mobile app to manage knee osteoarthritis (N=82).



Discussion

Principal Results

This study highlights the importance of motivation, usability, and content quality in adopting app-based therapy for KOA management. The findings indicate that exercise videos, goal setting, and clinician-patient communication are among the most valued app features, emphasizing the need for personalized digital interventions. While motivation levels significantly influenced the perceived usefulness of specific app functionalities, demographic factors such as age, gender, and education played a less prominent role in shaping user preferences.

Barriers to app adoption were primarily related to unclear exercise instructions, inaccurate health information, and limited communication with physiotherapists, suggesting that enhanced instructional clarity and interactive support are essential for improving user engagement. In addition, age-related differences in digital literacy and time constraints highlight the necessity of adaptable app designs that accommodate varying levels of technological proficiency.

The study also reinforces the value of on-demand access to exercise demonstrations, time efficiency, and improved clinician connectivity as key benefits of mobile health interventions. These insights emphasize the need for high-quality exercise content, real-time feedback, and user-friendly interfaces to optimize adherence and clinical effectiveness in digital rehabilitation for patients with KOA.

A correlation analysis between the 2 predominant patient-centric barriers (self-motivation and time) and the motivation measures revealed no significant associations, suggesting that, within our sample's limitations, these perceived barriers did not directly correspond to participants' self-reported motivation.

Comparison With Prior Work

The study revealed several significant findings about using mobile apps for KOA management, aligning with prior research that underscores the accessibility and convenience of app-based therapy for chronic disease management [27,36]. Consistent with previous studies on digital health interventions, our results confirmed that exercise videos were the most highly rated feature, supporting findings that visual demonstrations enhance patient comprehension and adherence to prescribed exercises [21,22,37]. Furthermore, goal setting, tracking, and regular electronic messages were rated highly, reinforcing evidence that structured feedback mechanisms contribute to sustained engagement in mobile health programs [21,27]. The high rating of telephone calls with physiotherapists further highlights the demand for personalized expert guidance, previously identified as a key factor in patient adherence and treatment satisfaction [22,36]. Features that enhance adherence, such as motivational support and automated reminders, were considered essential, echoing findings that digital health interventions incorporating behavioral reinforcement strategies are more effective in promoting long-term compliance [37]. While video calls with physiotherapists and peer communication were rated lower in this study than in some prior research [21,22,37], they remained valuable for individuals seeking real-time interaction or social support, consistent with the findings of Shewchuk et al [36]. This suggests that while many users prefer self-guided app-based therapy, integrating optional interactive elements may enhance engagement for specific subgroups. These results contribute to the growing literature on personalized mobile health interventions, emphasizing the need for flexible, user-centered digital therapy solutions tailored to patient preferences and engagement styles.

Significant differences in the perceived importance of functional requirements were observed based on motivation levels, with highly motivated patients placing greater value on detailed information and practical tools. This finding underscores the need for educational content and visual aids in mobile health apps, consistent with prior research indicating that higher motivation levels correlate with increased engagement in digital health interventions [21,37]. Studies have shown that interactive and visually enriched content enhances patient comprehension and promotes long-term adherence, particularly among those with high intrinsic motivation [22,38]. In addition, opinions on the appropriate duration of physical activity for KOA management also varied significantly by motivation level, reinforcing that individual motivation plays a critical role in adherence to prescribed exercise regimens [21,37]. Research

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on behavioral interventions for chronic disease management has demonstrated that customizing exercise programs based on motivation levels leads to better adherence and long-term health outcomes [27,39]. Our findings align with this evidence, suggesting that mobile health interventions for KOA should incorporate adaptive exercise planning and motivational support mechanisms to maximize patient engagement and compliance.

Statistically significant gender differences were observed in evaluating the mobile app's usefulness, with men rating ease of use, clarity of system information, and overall usability higher than women. These findings align with prior research indicating that men prioritize efficiency, simplicity, and functionality in digital health apps. In contrast, women may emphasize engagement, support features, and detail instructional content [24-27,37]. Similar patterns have been reported in health technology adoption studies, where men preferred streamlined, goal-oriented interfaces. At the same time, women were more likely to value interactive elements and comprehensive health-related information [24,25]. These findings underscore the need for gender-sensitive design considerations in mobile health apps, ensuring that user interfaces are adaptable to different preferences and digital literacy levels. Prior studies have emphasized that incorporating customizable settings, adaptive content presentation, and user-driven navigation options can enhance usability and satisfaction across diverse populations [26,27]. Our results contribute to this body of research by reinforcing the importance of personalized digital health solutions that accommodate gender-specific interaction styles, ultimately improving engagement and adherence in app-based therapy for KOA management.

The main barriers to using a mobile app for KOA management identified in this study—inaccurate disease information, unclear exercise presentations, and misunderstanding of information—are consistent with previous research highlighting the critical role of information clarity and accuracy in digital health interventions [25,26,37]. Similar concerns have been reported in telehealth and app-based rehabilitation studies, where patients expressed difficulties in interpreting digital exercise instructions without professional guidance, emphasizing the need for well-structured, evidence-based educational content [36,37]. In addition, difficulties with communication and access to physiotherapists were cited as major challenges, which aligns with prior findings that limited real-time professional interaction can hinder user confidence and adherence to app-based therapy [25,26]. Studies on chronic disease self-management apps have also pointed out that patients often require a balance between self-guided digital tools and clinician oversight. This suggests that incorporating structured communication channels, such as scheduled check-ins or chat-based physiotherapy support, could improve user experience [36]. Significant age-related differences in perceived barriers were observed, reflecting variations in lifestyle demands, digital literacy, and health priorities across different patient groups. Previous research has found that younger individuals prioritize flexibility and convenience, whereas older adults may face more difficulties with app navigation and digital engagement [37]. This underscores the importance of age-sensitive customization, particularly in enhancing information accuracy, integrating time management features, providing motivational support, and ensuring the clarity of exercise instructions. Such adaptations have improved adherence and overall user satisfaction in mobile health interventions for chronic musculoskeletal conditions [25,26,36,37].

Both statistical and qualitative analyses showed that most respondents recognized the potential benefits of using a mobile app for KOA management, regardless of demographic characteristics or motivation levels. This aligns with previous studies highlighting digital health tools' universal appeal and effectiveness across diverse patient populations [27,37]. Research has shown that mobile health interventions can enhance patient engagement and self-management in chronic conditions, including musculoskeletal disorders, by providing accessible, structured, and adaptable therapy solutions [21,22,36]. Furthermore, studies on app-based therapy for osteoarthritis indicate that perceived usefulness and usability are key determinants of patient adherence, often outweighing differences in age, gender, or baseline motivation [21,37]. Our findings reinforce this notion, suggesting that while individual preferences vary, well-designed digital interventions can effectively support self-management in a broad patient population. This is further supported by evidence indicating that even patients with lower baseline motivation can benefit from mobile health solutions when features such as reminders, structured guidance, and personalized feedback are incorporated into the design [22,27].

Implications

This study offers several unique contributions to the understanding and developing app-based therapy for KOA management, addressing the gaps not covered in previous research. First, it identifies motivation-specific functional requirements, revealing significant differences in the perceived importance of app features based on motivation levels. Highly motivated patients prioritized features such as detailed symptom tracking and exercise planning, highlighting the need for apps to cater to varying motivation levels to enhance engagement and adherence. Second, the study uncovers gender differences in usability, with men rating ease of use, clarity of system information, and overall usability higher than women, emphasizing the necessity of considering gender-specific preferences in app design. Third, it identifies age-related barriers, noting that younger participants reported time management issues, while older participants were concerned with the accuracy of health information and technical challenges. Tailoring app features to address these age-specific concerns can significantly improve user satisfaction and retention. Fourth, the study finds a universal consensus on exercise duration, with no significant differences in opinions about the appropriate duration of physical activity across gender, age, or education levels, suggesting that general exercise guidelines are broadly applicable. Fifth, it highlights the importance of repeatable instructions, with patients' highest-rated benefit being the ability to view exercises multiple times, providing a clear direction for developing user-friendly educational materials within the app. Finally, using a mixed methods co-design approach, integrating quantitative and qualitative data, provides a comprehensive understanding of patient needs and preferences, offering a

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nuanced view of the factors influencing app adherence and satisfaction that single-method studies may miss.

Limitations

Several limitations of this study should be acknowledged. First, the sample size of 82 patients, while sufficient for preliminary insights, may not represent the broader patient population with KOA. Recruitment from a single orthopedic clinic in Slovenia may limit the generalizability of the findings. Second, the mixed methods approach simultaneously captures patient preferences and barriers, which may not reflect changes over time. Third, reliance on self-reported data introduces potential biases, such as social desirability and recall bias. Although the mixed methods approach enriched the findings, future research could benefit from a longitudinal design to assess the long-term impact of mobile app usage on KOA management outcomes. Fourth, future research should investigate long-term adherence mechanisms and their effects on treatment outcomes to enhance the effectiveness and sustainability of mobile health interventions for KOA management. Fifth, because only 2 participants younger than 40 years were included, the SD in this subgroup was large, limiting the generalizability of our findings for this demographic. Finally, as observed in Slovenia, limited access to physiotherapy and rehabilitation services is a prevalent issue across Eastern and Southern Europe [38,39]. These health care constraints influence the expectations and priorities of patients with KOA for app-based management, highlighting the need for digital solutions tailored to regions with restricted physiotherapy availability. Therefore, addressing these limitations through innovative mobile health interventions is crucial for improving patient outcomes. Future research should validate these findings in diverse health care settings to assess the broader applicability of mobile health interventions.

Conclusions

This study demonstrates the usefulness of a mixed methods co-design approach for developing mobile apps for KOA management. The findings suggest that app-based therapy for KOA management should prioritize user-centered features such as accessibility, motivation, and clear communication. Smartphones and PCs should be optimized for ease of use with high-quality exercise videos. Integrating motivational features such as goal setting, symptom tracking, and regular e-messages can enhance patient engagement. Personalized communication strategies are crucial, with men preferring straightforward interfaces and all users benefiting from explicit educational content. Addressing barriers such as inaccurate information, unclear instructions, and access issues is essential. Age-specific features should provide flexible scheduling for younger users and detailed support for older users. Ensuring that exercises can be replayed emphasizes the need for clear, repeatable instructions. These considerations can help develop effective, user-friendly app-based therapy that improves KOA management and increases patients' quality of life, especially in countries with limited access to physiotherapy, such as Slovenia and comparable countries.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questionnaire.
[DOCX File, 37 KB - rehab_v12i1e64607_app1.docx]

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Abbreviations

KOA: knee osteoarthritis

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Virtual Reality Respiratory Biofeedback in an Outpatient Pediatric Pain Rehabilitation Program: Mixed Methods Pilot Study

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Abstract

Background: Chronic pain in adolescents is a significant and growing concern, as it can have negative implications on physical and psychosocial development. Management can be complicated by the increasing risks associated with opioid misuse, highlighting the need for effective nonpharmacological interventions. Biofeedback is an empirically supported behavioral intervention for chronic pain that targets the self-regulation of physiological responses. Virtual reality (VR) is a novel delivery method for biofeedback that could serve as an engaging and effective platform for adolescents.

Objective: The goal of this study was to assess the feasibility, acceptability, and preliminary effectiveness of integrating a VR-delivered respiratory biofeedback intervention into an outpatient pediatric pain rehabilitation program (PPRP) for adolescents with chronic pain.

Methods: In this pilot study, we recruited 9 participants from those enrolled in the PPRP at Nemours Children's Hospital. Participants underwent 2 VR respiratory biofeedback sessions per week over a 4-week period using AppliedVR's "RelieVRx" program. Feasibility was defined as >60% of eligible patients enrolling with at least 80% of VR sessions completed. Acceptability was assessed via validated acceptability questionnaires, with high acceptability defined as an average acceptability rating score >3 on a 5-point Likert scale. Open-ended responses were analyzed via qualitative analysis. Preliminary effectiveness was assessed with questionnaires measuring the quality of life (Pediatric Quality of Life Inventory [PedsQL]) and level of pain interference in daily activities (Functional Disability Inventory) before and after participation in the pain program. Finally, heart rate (HR) and blood pressure (BP) were measured before and after each VR session.

Results: Of 14 eligible PPRP patients, 9 (64%) enrolled in the VR respiratory biofeedback study, and 7 (77% of study participants) completed at least 80% of biofeedback sessions. Participants reported high acceptability with average session ratings ranging from 3.89 to 4.16 on post-VR program questionnaires. Of 224 open-ended responses, participants reported changes in stress and somatic symptoms (ie, pain distraction and breathing regulation). There was a statistically significant increase in the average physical functioning score of the PedsQL among participants (P=.01) from pre- to postparticipation in the overall pain program. The cohort's average emotional functioning score of the PedsQL also increased, though this change was not statistically significant (P=.17). Participants' Functional Disability Inventory scores significantly decreased from an average of 25.1 to 11 from before to after the pain program (P=.002). There were no significant differences between pre- versus post-BP or HR for any session. However, decreased BP and HR were observed across most sessions.

Conclusions: AppliedVR respiratory biofeedback demonstrated initial feasibility, acceptability, and preliminary effectiveness when implemented as part of a PRPP. This study underscores the need for future larger-scale studies analyzing the use of VR biofeedback in adolescent populations with chronic pain.

(JMIR Rehabil Assist Technol 2025;12:e66352) doi:10.2196/66352

KEYWORDS

chronic pain; adolescents; feasibility; respiratory biofeedback; virtual reality; VR; applied VR respiratory biofeedback; acceptability

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Introduction

Chronic pain affects upward of 38% of youths and negatively affects multiple aspects of development, including physical and psychological well-being [1-3]. Patients with chronic pain are often initially treated with pharmacotherapy and nonsteroidal medications including ibuprofen, acetaminophen, and in more severe cases, opioids [4]. Given the risks associated with these medications and the misuse of prescription opioids among children and adolescents in the United States, it is imperative to advance nonpharmacological interventions for pain [5,6]. Currently, nonpharmacological treatment for chronic pain in adolescents often involves a multidisciplinary approach encompassing pain education, psychological interventions, integrative medicine (mind-body techniques), and physical and occupational therapies [7,8]. However, these methods can be enhanced. While the etiology of chronic pain is not fully understood, dysregulation of the autonomic nervous system (ANS) is considered an important factor in maintaining many forms of chronic pain [9-12]. There is evidence that stress and anxiety, which trigger sympathetic nervous system responses, can increase pain perception [12]. For example, studies have shown that elevated sympathetic activity is implicated in altering pain perception and sensitivity [11,13]. Activation of the parasympathetic nervous system can help regulate the ANS, decrease pain perception, and increase overall functioning [14,15].

Biofeedback is among the most effective behavioral interventions for chronic pain; with biofeedback training, individuals learn how to control and self-regulate ANS responses such as respiratory rate or heart rate (HR) [16,17]. Visual or auditory cues are provided regarding physiological states, such as breathing rates or patterns [18]. This feedback increases patients' awareness of the physiological processes occurring in real time inside their bodies and allows them to adjust these processes in a desired direction [19,20]. There are many types of biofeedback modalities, including respiratory, HR variability, thermal, and neurofeedback. For example, during respiratory biofeedback, changes in breathing rate and pattern are monitored and displayed to the patient (eg, on a computer screen). The patient uses this feedback to match their breathing rate and pattern to a computer program that displays a "relaxed" breathing pattern. When the patient's breathing is smooth and steady (representing an increase in parasympathetic activation), visual feedback from the computer provides positive cues to reward the patient for establishing a relaxed breathing pattern. If the breathing rate becomes irregular at any point, this is indicated on the monitor, and the patient can try to correct their breathing pattern and return to a relaxed pattern.

Recent research demonstrates that biofeedback is effective for adolescents. They are able to significantly modify their respiration rates and reduce muscle tension through increased physiologic control from biofeedback training sessions [21]. While these results are promising, clinical experience suggests that adolescents may lose interest in traditional biofeedback, if it is not sufficiently engaging [22,23]. As a result, efforts are being made to increase pediatric or adolescent engagement in biofeedback therapies through creative platforms like computer games and virtual reality (VR). For example, one study using video game–based biofeedback in adolescent patients showed good retention across 8 sessions and improvement in anxiety and depressive symptoms [24]. VR has the potential to be even more engaging than a computer-delivered biofeedback program because VR limits outside distractions and can increase one's ability to focus on what is being presented in the VR headset. The use of VR alone, using only relaxing scenes without a biofeedback component, has demonstrated decreases in patients' perception of pain in both acute and chronic pain management [25,26]. Additionally, advancements in VR technology and increases in the affordability and portability of VR headsets allow for patients to use headsets in various settings and may reduce barriers to participation in biofeedback programs. A technology start-up company, AppliedVR, has developed a respiratory biofeedback intervention delivered with a VR headset that has demonstrated efficacy among adults with chronic lower back pain [27,28]. It is possible that this product could be engaging and effective for adolescents with chronic pain. However, the AppliedVR biofeedback intervention has not yet been studied in this population.

Thus, this pilot study used mixed methods to address this gap by assessing the feasibility, acceptability, and preliminary effectiveness of the AppliedVR, respiratory biofeedback intervention, delivered as part of an integrated pediatric pain rehabilitation program (PPRP) for adolescents with chronic pain. We hypothesized that the AppliedVR, respiratory biofeedback intervention, would be feasible to deliver as part of an existing PPRP. We also expected that the AppliedVR intervention would be rated, on average, as acceptable by adolescents with chronic pain through both quantitative and qualitative assessments. Additionally, we explored the preliminary effectiveness of the VR intervention, such that we anticipated the participants would show improvements in functioning and quality of life before and after the PPRP and decreases in blood pressure (BP) and HR before and after each VR session.

Methods

Participants and Recruitment

We aimed to integrate the VR biofeedback sessions into the PPRP at Nemours Children's Hospital, Florida. The Nemours PPRP is well-established at the hospital and includes 4 weeks of multidisciplinary chronic pain interventions. As a part of this program, patients typically spend 5 hours per day, 5 days per week, for 4 weeks undergoing physical therapy, occupational therapy, individual psychotherapy (including biofeedback), family therapy, adjustments to pain medicine, and weekly team care conferences. The individual psychotherapy sessions occurred once a week throughout the PPRP. While these sessions did not always focus on biofeedback, it was offered when clinically indicated and based on the patient's personal interest. The goal of including the VR biofeedback sessions was to offer an enhanced, immersive biofeedback relaxation training that could compliment the PPRP by increasing engagement in learning and allowing for the practice of relaxation skills (ie, diaphragmatic breathing) that are typically taught in the

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individual psychotherapy sessions. The VR intervention aligned with the goals of the overall PPRP, in that both aimed to reduce chronic pain among adolescents and help introduce coping mechanisms that may improve their overall quality of life.

Given that the primary goal of this pilot study was to assess the continuous outcomes of the feasibility and acceptability of the VR intervention, we aimed to recruit a sample size of 15 participants, which is considered adequate for these objectives [29,30]. Eligibility criteria for this pilot study included (1) age range between 13 and 18 years (lower limit of 13 years because the VR headset manufacturer, Oculus, does not recommend the use of the headset by persons 13 years or younger and upper limit of 18 years because only patients 18 years or younger participate in the PPRP), (2) English fluency in verbal and reading or writing (measures were not validated in other languages), (3) participating in the PPRP at Nemours Children's Hospital during the data collection time frame, and (4) no history of epilepsy or seizures (Oculus does not recommend persons with these conditions to use their VR headset).

As a part of routine clinical care, the PPRP coordinator sends each family a packet with information about the PPRP prior to their participation. While the study was actively recruiting, the families received a study flyer in their pre-PPRP information packet.

Ethical Considerations

A research team member met with each family in the first week of their participation in the PPRP. During this meeting, the research team member provided information about the research study, answered questions about the study, and obtained written adolescent assent and parental permission for the adolescent to participate. The data was deidentified. This study was approved by the Nemours Children's Health Institutional Review Board (1552864).

The VR Intervention

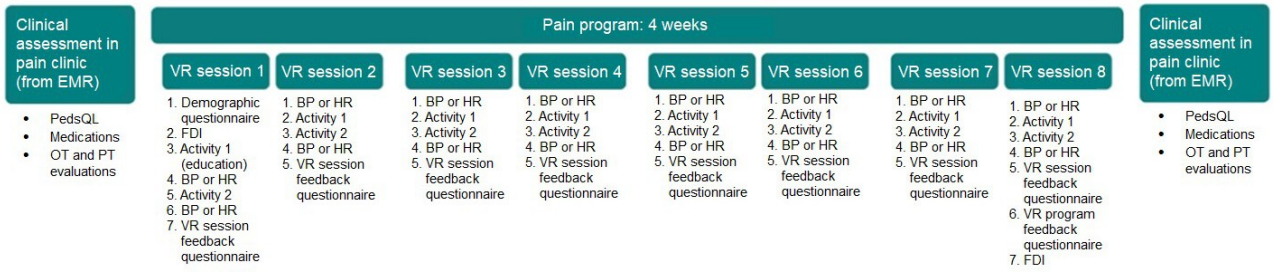
VR biofeedback sessions were conducted using AppliedVR's "RelieVRx" (formerly "EaseVRx") application on a portable Oculus Go VR headset [31]. The RelieVRx application included several activities that aim to improve cognitive behavioral and mindfulness-based pain management skills [31]. The software program includes an immersive VR system that incorporates biopsychosocial pain education, diaphragmatic breathing training, mindfulness exercises, and relaxation-response exercises [31]. A microphone on the bottom of the VR headset detects the user's breath, which is shown in the VR environment as bubbles or a stream of air. In this way, the user learns to regulate their breathing with cues in the VR environment, such as waves of light that move toward and then away from the viewer in a pattern that mimics a relaxed breathing rate.

Consented participants engaged in up to 8 VR biofeedback sessions that occurred each Tuesday and Friday over the course of the 4-week pain program. Each session included 2 activities from the AppliedVR "RelieVRx" application. For the first 2 weeks of the pain program (sessions 1 - 4), the research team members (PP, JS, and KR) instructed participants on the specific activities to complete. These specific RelieVRx sessions were selected by a licensed pain psychologist on the research team, as they provided an introduction to the program, built mastery in diaphragmatic breathing, and provided exposure to mindfulness-based attention training. During the final 2 weeks (sessions 5 - 8), participants were instructed to choose the RelieVRx content they engaged with, providing them the opportunity to explore other content or revisit prior activities. Activity 1 was divided into 8 sessions. Session 1 was pain care introduction of 3 minutes, session 2 was paced breathing of 6 minutes, session 3 was building breath of 6 minutes, session 4 was deep relaxation of 5 minutes, and sessions 5 to 8 were patient's choice. Activity 2 began with session 1 breath of hope of 7 minutes, session 2 focus game 1 of 2 minutes, session 3 focus game 2 of 3 minutes, session 4 focus game 3 of 3 minutes, and sessions 5 to 8 patient's choice.

Outcome Measures

Prior to the PPRP, all patients underwent a clinical assessment as a part of standard clinical practice, and results from the assessment are included in the patient's electronic medical record (EMR). Patients underwent the same assessment after completing the PPRP. For the purposes of this study, research team members extracted results from the pre- and post-PPRP clinical assessments from each participant's EMR. Additionally, as a part of the research study, participants were asked to complete questionnaires before the first VR session, after each VR session, and after the final VR session (Figure 1).

Figure 1. Schedule for outcome measures. BP: blood pressure; EMR: electronic medical record; FDI: Functional Disability Inventory; HR: heart rate; OT: occupational therapy; PedsQL: Pediatric Quality of Life Inventory; PT: physical therapy; VR: virtual reality.



Demographic information was assessed via a self-report questionnaire prior to the first VR session. Feasibility was assessed via recruitment and attendance records. We operationalized the feasibility of the VR intervention as >60% of eligible patients enrolling with at least 80% of VR biofeedback sessions completed.

Acceptability was assessed via an acceptability questionnaire designed for this study by a team of clinical psychologists with

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expertise in measure development. The items were adapted from a validated questionnaire (ie, Acceptability of Intervention Measure) that is commonly used to assess the acceptability of an intervention [32]. The session feedback questionnaire included 5 questions with Likert scale response options (modeled after the Acceptability of Intervention Measure questionnaire) and 3 open-ended questions (developed by the research team). Participants filled out this acceptability questionnaire after completing each VR session. An additional acceptability questionnaire was designed to assess patients' satisfaction with the VR biofeedback program as a whole. The overall program acceptability questionnaire included a similar structure (5-point Likert scale response items and 5 open-ended questions). We used the same 5-point Likert scale response (1=completely disagree to 5=completely agree) for both acceptability questionnaires. Negatively worded questions were reverse-coded, such that higher ratings indicated higher levels of acceptability. High acceptability was defined as an average acceptability rating score >3 (to capture more positive than "neutral" or negative responses). Open-ended responses were analyzed via qualitative analysis, as described below.

The preliminary effectiveness of the PPRP was assessed via 2 self-reported, validated questionnaires that were completed prior to and after the PPRP. Impairment in daily activities was assessed via the Functional Disability Inventory (FDI) [33,34]. The FDI is a self-report measure of how much pain interferes with day-to-day functioning for adolescents. Adolescents completed the self-report version of this measure prior to their first VR session and immediately after their last VR session. The FDI has excellent psychometric properties [33,34]. Quality of life was assessed with the Pediatric Quality of Life Inventory (PedsQL) Core Generic Scale [35]. The PedsQL is a well-validated and widely used 23-item measure of general quality of life, with separate forms for parental proxy report and a self-report form for youths in the 5 - 7, 8 - 12, and 13 - 18 year age ranges. The PedsQL yields a total score and reliable subscale scores for the child's physical, emotional, social, and school functioning. The PedsQL was delivered as a part of the standard pre- and postpain program clinical assessment. We obtained total PedsQL scores from the participant's EMR.

The preliminary effectiveness of the VR sessions was assessed via health outcomes. HR and BP were assessed via a Dinamap Carescape vital signs monitor. Research team members who were second-year medical students conducted each VR session. These team members were trained by a medical assistant on how to use the vitals machine and took noninvasive BP and HR readings using an upper arm cuff placement. These readings were assessed before and after each VR session.

Statistical Analysis

Demographic and clinical characteristics were summarized using descriptive statistics (mean, SD, and frequencies). Recruitment rate and acceptability questionnaires were analyzed using descriptive statistics. Preliminary effectiveness of VR biofeedback sessions was assessed using paired 2-tailed *t* tests evaluating changes in FDI and PedsQL scores from before and after the pain program as well as BP and HR change scores from each session. Given the main aims of the study were focused on acceptability and feasibility, we accepted any missing data as missing and analyzed means based on the data that were complete. Because surveys were completed with the research coordinator present and checked for completion, we only had 1 participant leave a single item blank on one of the postsession surveys. We dropped this missing item and averaged the remaining responses.

Qualitative Analysis

We conducted a thematic analysis to analyze open-ended responses on the acceptability questionnaire via the 6-phase approach to the thematic analysis described by Clarke and Braun [36]. First, we compiled all responses to each question into a Microsoft Excel sheet, collapsing across assessment time points. Second, 2 coders (JS and KR) reviewed all qualitative responses and coded each response to create initial codes. Coders were medical students who conducted the VR sessions with study participants. Because the qualitative data were limited due to the small sample size and open-ended questions on the questionnaire were typically short, 1-sentence responses, coding was not divided up but rather all of those involved reviewed all of the data. Although the Clarke and Braun [36] 6-phase approach does not require interrater reliability metrics, having all reviewers review all the data rather than dividing it enhanced the reliability of our coding procedure.

Third, themes were created by identifying broad areas of overlap among codes. Individual codes were collapsed into larger themes by identifying unifying features between them. For instance, codes associated with positive words and phrases about the VR sessions such as "relaxed or calming" were grouped into a larger theme of perceived effects on stress. Fourth, themes were quality-checked and reassessed again. Themes were checked against the extracted data to ensure that they worked in relation to the data. Occasionally, codes were relocated under a different theme, and some themes were collapsed into a broader, more coherent theme. Fifth, themes were named to encompass the overall essence of the individual codes that were grouped into them. Some themes were divided into subthemes. For example, our theme of perceived effects on stress was further split into subthemes of increased stress or decreased stress.

Finally, themes were organized into a flowchart to visualize subthemes with attached example excerpts from questionnaires. The themes and codes were reviewed and revised by the coding team and another research team member who has experience in thematic analysis (RW). Themes were summarized by one of the coders (JS) and distributed to coauthors for review.

Results

Feasibility

Over the course of a 12-month period (May 2021 to April 2022), 17 patients enrolled in PPRP at Nemours Children's Hospital. Of those, 3 were ineligible for the VR study due to age, and 5 declined due to scheduling conflicts or disinterest. Of the 14 eligible patients, 9 consented to the VR respiratory biofeedback study, resulting in a 64% recruitment rate. Participants were between the ages of 13 and 18 years, predominantly female (89%), and identified as Hispanic Latino (22%), non-Hispanic

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Black or African American (33%), and non-Hispanic White (33%).

In total, 2 participants withdrew from the study (1 after 3 sessions and 1 after 1 session) due to scheduling conflicts or disinterest. Thus, 77% (7/9) of the participants completed at least 80% (7/8) of the biofeedback sessions.

Acceptability—Quantitative Results

Average acceptability was examined for each session and for the overall VR program. Average session-specific ratings ranged from 3.89 to 4.16, indicating neutral to positive responses (Table 1). For the VR program as a whole, average acceptability ratings ranged from 4.14 to 4.43 (indicating positive to very positive responses).

Table . Average (mean) acceptability ratings for sessions 1 - 8[a].

Questions	Session 1, mean (SD)	Session 2, mean (SD)	Session 3, mean (SD)	Session 4, mean (SD)	Session 5, mean (SD)	Session 6, mean (SD)	Session 7, mean (SD)	Session 8, mean (SD)
1. The session was too long[b].	3.56 (1.24)	4.13 (0.83)	4.25 (0.71)	3.71 (1.11)	3.86 (0.90)	3.86 (0.90)	4.14 (0.69)	4.20 (0.45)
2. The session was too short[b].	3.67 (0.87)	3.75 (1.16)	3.75 (0.89)	3.86 (0.90)	3.86 (0.90)	3.86 (0.90)	4.00 (0.82)	4.00 (0.71)
3. The virtual reality made me feel dizzy or light-headed[b].	4.13 (1.46)	3.88 (1.13)	4.00 (1.07)	3.86 (1.07)	4.00 (0.82)	3.71 (1.25)	4.00 (1.00)	4.20 (0.45)
4. The session was easy to follow.	4.56 (0.53)	4.12 (0.64)	4.13 (0.83)	4.14 (0.69)	4.14 (0.38)	3.86 (1.07)	4.29 (0.49)	4.00 (0.71)
5. Overall, I liked this session.	4.33 (0.50)	4.38 (0.52)	4.25 (0.71)	4.14 (0.69)	4.57 (0.53)	4.14 (0.69)	4.29 (0.49)	4.40 (0.55)
Average (items 1-5) session acceptability	4.05 (0.43)	4.05 (0.24)	4.08 (0.21)	3.94 (0.19)	4.09 (0.30)	3.89 (0.16)	4.14 (0.14)	4.16 (0.17)

[a]This table includes responses to a 5-point Likert scale questionnaire (1=completely disagree, 2=somewhat disagree, 3=neither agree nor disagree, 4=somewhat agree, and 5=completely agree.

[b]The results of questions 1-3 were reverse-coded for consistency, in that higher scores indicate greater acceptability.

Acceptability—Qualitative Results

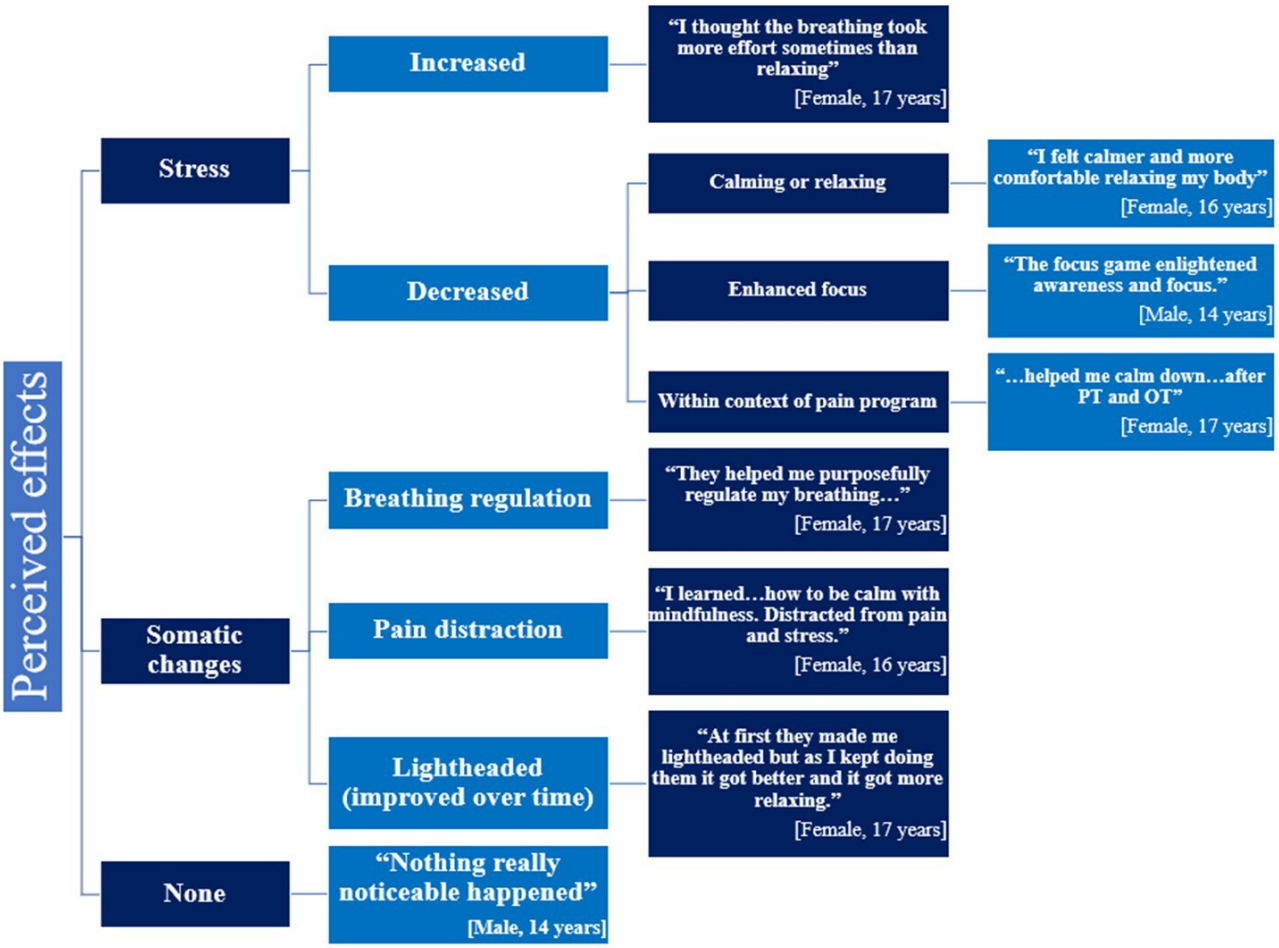
Of a total of 224 responses to open-ended questions (provided by 9 participants), themes included (1) perceived effects of VR (eg, stress, no perceived effect, and somatic changes) and (2) VR feedback (eg, general vs specific; Figure 2).

In general, most participants described the VR sessions favorably, reporting that it was calming and relaxing and distracted them from their pain. Additionally, participants endorsed that they had enhanced awareness and focus after the completion of each individual session, and they enjoyed being able to regulate their breathing in a way that interacted with the VR environment. One person reported feeling lightheaded or dizzy during the first couple of VR sessions, though, by the end of the program, she stated that she acclimated to the VR and ultimately enjoyed the VR sessions.

Participants also provided some specific feedback on the sessions (Textbox 1). Participants mainly enjoyed the digital nature of the VR sessions and how the surrounding environment could be changed in relation to their breathing patterns. Participants additionally expressed positive comments about the autonomy to choose their own games and breathing exercises in the last 4 individual sessions, and they liked that the sessions were typically at a relaxing pace (Textbox 1).

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Figure 2. Perceived effects of web-based subcategories. OT: occupational therapy; PT: physical therapy.



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Textbox 1. Sample responses across participants regarding specific feedback subthemes.

Length of session and breathing intervals

- "... make it just a little shorter" [Female, 17 years].
- "in paced breathing the gaps between inhaling seemed a little too long" [Male, 14 years].

Clarity of instructions

- "simple, easy to follow" [Male, 14 years].
- "I disliked that the first one did not say what to do, so I assumed to breathe with the tree" [Female, 16 years].

Amount of interaction

- "[I liked] the blowing in and out of your breath to move the circular stone" [Female, 13 years].
- "I liked how the breathing 'class' synced with the tree and how the greenery of the plants were all around me" [Female, 16 years].

Voiceover language

- "I didn't enjoy the words talking about my energy because I believe Jesus is how you grow and relax" [Female, 17 years].
- "Everything was nice except for the repetitive phrases in the first part" [Female, 16 years].

Virtual reality scenery and music

- "I like the scenery and calming music. I liked how it changed between day and night" [Female, 16 years].
- "[I liked] the music and graphics" [Female, 17 years].

Autonomy of choice and pace

- "I liked that the first one was kind of on your own and you could go at your own pace" [Female, 17 years].
- "[I liked] the choice of what I could do" [Female, 15 years].

Preliminary Effectiveness

Paired 2-tailed *t* tests were conducted to examine changes in quality of life (PedsQL) and pain interference (FDI) from baseline to postpain program. PedsQL scores were calculated in terms of both physical and emotional functioning. There was a statistically significant increase in the average physical functioning score among participants (t_6=−3.752; *P*=.01; 95% CI −37.585 to −7.915; effect size [Hedges correction]=17.139) from pre- to postparticipation in the overall program. The cohort's average emotional functioning score also increased, though this change was not statistically significant (t_6=−1.534; *P*=.18; 95% CI −35.214 to 8.071; effect size [Hedges correction]=25.003; Multimedia Appendix 1). Participant FDI scores significantly decreased from an average of 25.1 to 11 from before to after the pain program (t_6=5.394; *P*=.002; Multimedia Appendix 2).

Paired sample 2-tailed *t* tests assessed differences in systolic BP, diastolic BP, and HR before and after each VR session. We used the Bonferroni correction method to adjust the threshold for significance due to multiple tests (*P*≤.002) [37]. There were no significant differences between pre- versus postsystolic BP, diastolic BP, and HR for any session. However, a signal toward decreased BP was observed across most sessions (see Table 2 for general trends in pre- vs postsession BP and HR). All sessions also resulted in decreased HR, though these changes were not statistically significant.

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Table . Paired 2-tailed *t* test results of the average difference in systolic and diastolic blood pressures (in mm Hg) and heart rate (in bpm) before and after virtual reality (VR) session[a].

		Pre-VR	Post-VR	*t* test (*df*)	*P* value (2-tailed)
Session 1					
	Systolic	112.5	113.4	−0.214 (7)	.84
	Diastolic	65.4	66.1	−0.453 (7)	.66
	Heart rate	88	86	1.239 (7)	.25
Session 2					
	Systolic	120.0	114.1	2.056 (6)	.08
	Diastolic	64.7	62.4	2.359 (6)	.05
	Heart rate	90	87	1.094 (6)	.31
Session 3					
	Systolic	116.6	112.6	2.828 (7)	.02
	Diastolic	63.1	62.3	0.519 (7)	.62
	Heart rate	88	85	1.449 (7)	.19
Session 4					
	Systolic	114.0	113.4	0.272 (6)	.79
	Diastolic	64.6	62.7	0.692 (6)	.51
	Heart rate	88	86	0.721 (6)	.49
Session 5					
	Systolic	116.3	117.9	−0.675 (6)	.52
	Diastolic	64.7	63.6	0.481 (6)	.65
	Heart rate	92	88	1.391 (6)	.21
Session 6					
	Systolic	119.7	113.1	2.374 (6)	.05
	Diastolic	69.7	67.1	1.140 (6)	.29
	Heart rate	90	86	1.097 (6)	.32
Session 7					
	Systolic	119.4	115.4	1.362 (6)	.22
	Diastolic	65.9	64.9	0.544 (6)	.61
	Heart rate	90	90	0.137 (6)	.89
Session 8					
	Systolic	112.6	109.6	2.070 (4)	.11
	Diastolic	67.0	60.8	1.583 (4)	.19
	Heart rate	88	82	1.881 (4)	.13

[a]The threshold for significance was adjusted for multiple testing using the Bonferroni correction method.

Discussion

Principal Findings

AppliedVR respiratory biofeedback demonstrated initial feasibility, acceptability, and preliminary effectiveness when integrated into a PPRP. Additionally, open-ended, qualitative feedback on the overall VR program was positive. While not powered to detect changes over time, we did see changes in the expected direction in health outcomes (BP and HR) from pre- to post-VR sessions. The signal of generally decreased BP and HR after VR session is promising and should be further investigated in a large sample with greater power to detect changes.

The PPRP successfully improved reported functioning on 2 different self-report measures (the FDI and the PedsQL). This indicates that adding the VR sessions did not interfere with positive improvements, generally seen in the larger PPRP. Overall, this pilot study demonstrated that a larger implementation or effectiveness trial to assess the impact of integrating a VR-delivered relaxation and mindfulness training

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program into a PPRP is feasible and would likely be acceptable to adolescents. Our results further suggest that VR platforms may serve as an important tool in keeping adolescents engaged in biofeedback training; however, allowing for customization and personalization within these platforms among users may allow for even higher acceptability and user satisfaction.

Comparison With Prior Work

Since the completion of this study, 3 other published pilot studies of VR-delivered biofeedback programs have also demonstrated the feasibility and acceptability of using this technology with adolescents in the following settings: inpatient during the perioperative period [38], inpatient for those undergoing port catheter needle insertion [39], and outpatient or home setting for migraines [40]. Each of these 3 studies use slightly different technology and software for the VR and biofeedback components and did not use the same technology as was used in this study. Similar to our findings, the acceptability ratings in these 3 studies were high, with participants reporting that the VR environment was engaging and relaxing [38-40]. One study compared VR with biofeedback to a tablet (iPad)-delivered augmented reality with biofeedback intervention. Interestingly, adolescents reported that both interventions were acceptable but reported a preference for the VR and biofeedback intervention [40]. One unique aspect of this study is that we examined the feasibility of including the VR-delivered intervention as a part of an integrated PPRP. Prior work has examined using VR as an engaging tool in the pediatric rehabilitation setting, but the intervention was focused on increasing movement and range of motion rather than teaching biofeedback and relaxation techniques [41].

Limitations

The main limitation of this prospective pilot study is the small sample size, which limits generalizability and our ability to examine effectiveness. While our initial sample size goal was 15, reductions in clinical volume correlating to the COVID-19 pandemic restricted participation and recruitment. Given the small sample size, the results of this study may not be applicable to the broader adolescent population. Another limitation of our study is the lack of diversity among student participants with the sample being predominantly female. However, this demographic composition aligns with existing research, which indicates that chronic pain treatment is more prevalent among women and non-Hispanic White people in the adult population, suggesting that our participant demographics are representative of this group [42].

Additionally, because the VR biofeedback intervention in this study was integrated into a PPRP, we were unable to assess the independent effect of VR biofeedback on improvements in adolescent-reported physical or emotional functioning. Furthermore, this study did not include a control group, which will be important in future research to more clearly demonstrate efficacy. In addition, the VR sessions were conducted by medical students as a part of this research study. Thus, these methods may not transfer to a real-world setting, and to assess feasibility for use in an existing pain program, future studies likely will need pain program interventionists to be using the VR program in their sessions rather than having the study team conduct separate sessions. Finally, the AppliedVR program was initially developed for the adult population and has not yet been validated for use with adolescents; thus, while acceptable to adolescents, future research is needed to demonstrate efficacy and effectiveness in this population.

Conclusions

This prospective pilot study is novel in its use of VR in a PPRP for pediatric chronic pain management and provides a foundation for future larger-scale studies of VR biofeedback. Research into nonpharmacological adjuncts is essential to identify acceptable, feasible, and effective alternatives to chronic pain management. Innovative technologies such as video games, VR, and augmented reality may provide a more immersive experience for biofeedback sessions, but given their novelty, require testing to determine whether it is acceptable and feasible to patients and families. This study provides initial support for the acceptability and feasibility for a VR-based biofeedback in the management of pediatric chronic pain within the context of a multidisciplinary treatment program. More research is needed with larger, more diverse groups of adolescents to further determine the usefulness of such a program and perhaps identify any areas for adaptation and improvement.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PedsQL before and after the PPRP. PedsQL: Pediatric Quality of Life Inventory; PPRP: pediatric pain rehabilitation program.
[PNG File, 47 KB - rehab_v12i1e66352_app1.png]

Multimedia Appendix 2
Average FDI scores before and after the PPRP. FDI: Functional Disability Inventory; PPRP: pediatric pain rehabilitation program.
[PNG File, 24 KB - rehab_v12i1e66352_app2.png]

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Abbreviations

ANS: autonomic nervous system
BP: blood pressure
EMR: electronic medical record
FDI: Functional Disability Inventory
HR: heart rate
PedsQL: Pediatric Quality of Life Inventory
PPRP: pediatric pain rehabilitation program
VR: virtual reality

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Beneficial Effects of the Novel Digital Incentive Spirometer Device and Incentive Spirometer in Patients Undergoing Open-Heart Surgery: Randomized Controlled Trial

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Abstract

Background: The number of patients undergoing open-heart surgery (OHS) is persistently increasing. Additionally, postoperative pulmonary complications have been reported after OHS, and an incentive spirometer has been suggested to prevent postoperative pulmonary complications. However, no commercial incentive spirometer provides the precise inhalation volume. We developed a digital incentive spirometer (DIS) that displays the relevant data.

Objective: In this study, we aimed to explore the beneficial effects of a DIS on respiratory function in patients who underwent OHS.

Methods: A randomized controlled trial was designed with 32 patients scheduled for OHS: 16 individuals each were assigned to the DIS and the flow-oriented incentive spirometer (ie, Triflow incentive spirometer) groups, respectively. The patients were requested to use the DIS and Triflow incentive spirometer 15 times/set, two sets/day, from day 1 to 5 postextubation. All participants underwent lung function and respiratory muscle strength assessments prior to OHS and on day 5 postextubation postoperatively. For comparison between and within the groups, we performed an intention-to-treat analysis with a two-way mixed analysis of variance.

Results: In both the DIS and Triflow incentive spirometer groups, pulmonary function parameters and maximal respiratory pressure were markedly reduced on day 5 postextubation when compared with those prior to OHS (P<.05). There were no significant differences in pulmonary function or respiratory muscle strength between the two groups (P>.05).

Conclusions: Pulmonary function and respiratory muscle strength did not differ significantly between the DIS and Triflow incentive spirometer groups among patients who underwent OHS.

Trial Registration: The Thai Clinical Trails Registration TCTR20230922001; https://tinyurl.com/3mn7ck62

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KEYWORDS

digital incentive spirometer device; flow-oriented incentive spirometer; open-heart surgery; randomized controlled trial; respiratory function

Introduction

An incentive spirometer is typically used for patients with pulmonary issues and those at risk of postoperative pulmonary complications. This device exercises the lungs and necessitates deep breathing, requiring patients to inhale slowly and deeply to increase the volume of air entering the lungs [1,2].

A health professionals' survey on the perspective on the utility of an incentive spirometer among nursing and respiratory care staff reported that healthcare professionals agreed that an incentive spirometer is essential for patient care (92.7%) [3]. Furthermore, healthcare professionals believed that an incentive spirometer could improve pulmonary function (92.0%) and inspiratory capacity (93.0%). An incentive spirometer can also

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help prevent and reverse atelectasis (96.6% and 90.0%, respectively) and prevent and reverse pneumonia (92.5% and 68.4%, respectively) [3]. Among patients who underwent lung surgery, the incidence of postoperative pulmonary complications was lower in those who used an incentive spirometer preoperatively and postoperatively than in those who did not use an incentive spirometer [4]. Thus, the use of an incentive spirometer pre- and postheart surgery can reduce the risk of postoperative pulmonary complications or hospitalization [1,5,6].

A review of the literature published between 2010 and 2021 revealed that the average total cardiac surgical volume in high-income countries was 123.2 per 100,000 people annually, which included coronary artery bypass graft (CABG) and valvular heart disease (36.7 and 30.8 per 100,000 people per year, respectively). In high-middle-income countries including Thailand, the average total cardiac surgical volume was 86.1 per 100,000 people annually, with CABG and valvular heart disease reaching values of 35.4 and 13.3/per 100,000 people per year [7].

Among patients undergoing CABG, the use of incentive spirometer devices can reduce the duration of postoperative mechanical ventilation and shorten hospitalization [6]. Additionally, both flow- and volume-oriented incentive spirometer devices can improve pulmonary function (ie, the forced vital capacity [FVC], forced expiratory volume in the 1st second [FEV1], and the peak expiratory flow rate [PEFR]) in patients undergoing surgery [8].

Both volume- and flow-oriented incentive spirometer devices reflect respiratory performance and capacity and encourage improvements in deep inspiration. However, these devices fail to provide a specific volume or airflow of inspiration; for example, the flow-oriented incentive spirometer is designed to improve lung volumes and employs a flow-controlled mechanism using three floating balls. The device displays airflow at 600, 900, and 1200 ml/s as three different colored balls. Additionally, some patients may be unable to elevate their floating balls, which may lead to a lack of motivation.

Therefore, we developed a digital incentive spirometer (DIS) capable of displaying both the volume of airflow entering the lungs and the volume of air inhaled as numerical indicators, graphical representations, colors, and auditory signals. Furthermore, we explored the benefit of DIS on the respiratory performance of patients who underwent open-heart surgery (OHS).

Methods

Study Design

The study was twofold. The first part aimed to design and develop the DIS. The second part was designed as a randomized control trial to explore the benefits of DIS on pulmonary function and respiratory muscle strength.

Ethical Considerations

The protocol of the study was approved by the Ethics Human Committee of Thammasat University based on the Declaration of Helsinki, the Belmont report, CIOMS guidelines and the International practice (ICH-GCP) with COA No. 074/2566. The study followed the 2010 CONSORT Reporting guidelines (Checklist 1). Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the participants to publish this paper.

Design and Development

We designed and developed the DIS based on the principles of differential pressure flow meters. The MPX10DP (NXP Semiconductors, Thailand Co., Ltd) is a pressure sensor designed to measure pressures ranging between 0 and 10 kPa or 0 to 1.45 psi. It operates by comparing differential inputs to determine the pressure and provides an analog output signal. The circuit design utilizes the ESP32 microcontroller to read the analog signals from the MPX10DP sensor. In addition, an LM358N operational amplifier was employed to amplify the output signal and convert the analog signal into electrical voltage. Therefore, this voltage was used to calculate the pressure, which was then compared with measurements obtained from the AWM720P1 airflow sensor. Furthermore, the AWM720P1 airflow sensor is a standard device to measure airflow, expressed in units of standard liters per minute. The AWM720P1 airflow sensor has low hysteresis and repeatability errors (less than 0.35% of reading), providing better system accuracy. This sensor employs a microcontroller to read the sensor data, convert the analog signal into an electrical voltage, and compute the airflow rate, which is the output in L/s. The conversion of pressure to airflow is achieved by correlating the pressure readings obtained from the MPX10DP sensor with the airflow measurements from the AWM720P1 sensor. This is accomplished by integrating both sensors into a unified system and recording data concurrently to determine the linear relationship between pressure and airflow.

According to the concept of air passing through different cross-sectional areas and air pressures, the airflow from the prototype DIS device into the lungs passes through a tube with varying cross-sectional areas and air pressures. Therefore, the air volume was transmitted to the sensor and calculated using a microcontroller that has an analog-to-digital conversion module.

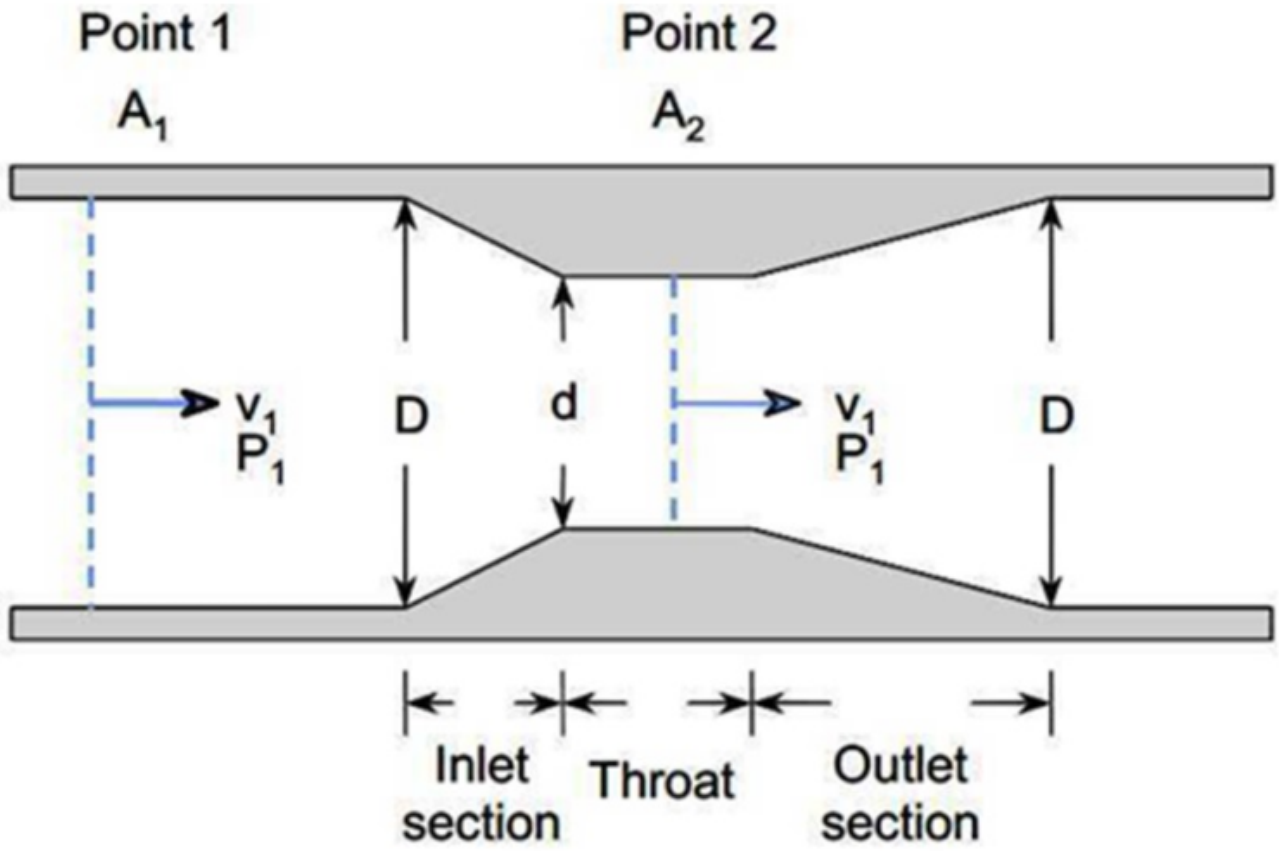
The principle of flow rate measurement involves generating a pressure drop within the tube through which the fluid flows using the principles of the continuity equation and the Bernoulli equation. The continuity equation can be summarized as the product of the cross-sectional area of the tube and the flow velocity of an ideal fluid, which remains constant at any position within the tube. This relationship ensures that the airflow is consistent according to the flow equation (Figure 1),

$$Q=v1\times A1=v2\times A2$$

where v denotes the mean velocity, A denotes the cross-section area normal to the direction of flow, and Q denotes the discharge or volume flow rate of water flowing at a given rate of time through any section of the area.

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Figure 1. Principles of the continuity equation and the Bernoulli equation.



The DIS was calibrated via the sensor, and the air pathways were connected in series between the prototype DIS and the industrial sensor. The readings acquired from the DIS prototype were in the form of pressure levels (analogs), which were compared with the known airflow rates from the industrial-grade sensor, referenced from the characteristic graph shown in Figure 2. Air was drawn at various levels during data collection to obtain sufficient data to create a regression equation model, which was used to determine the airflow rate from the electrical potential input obtained from the differential pressure sensor, as follows:

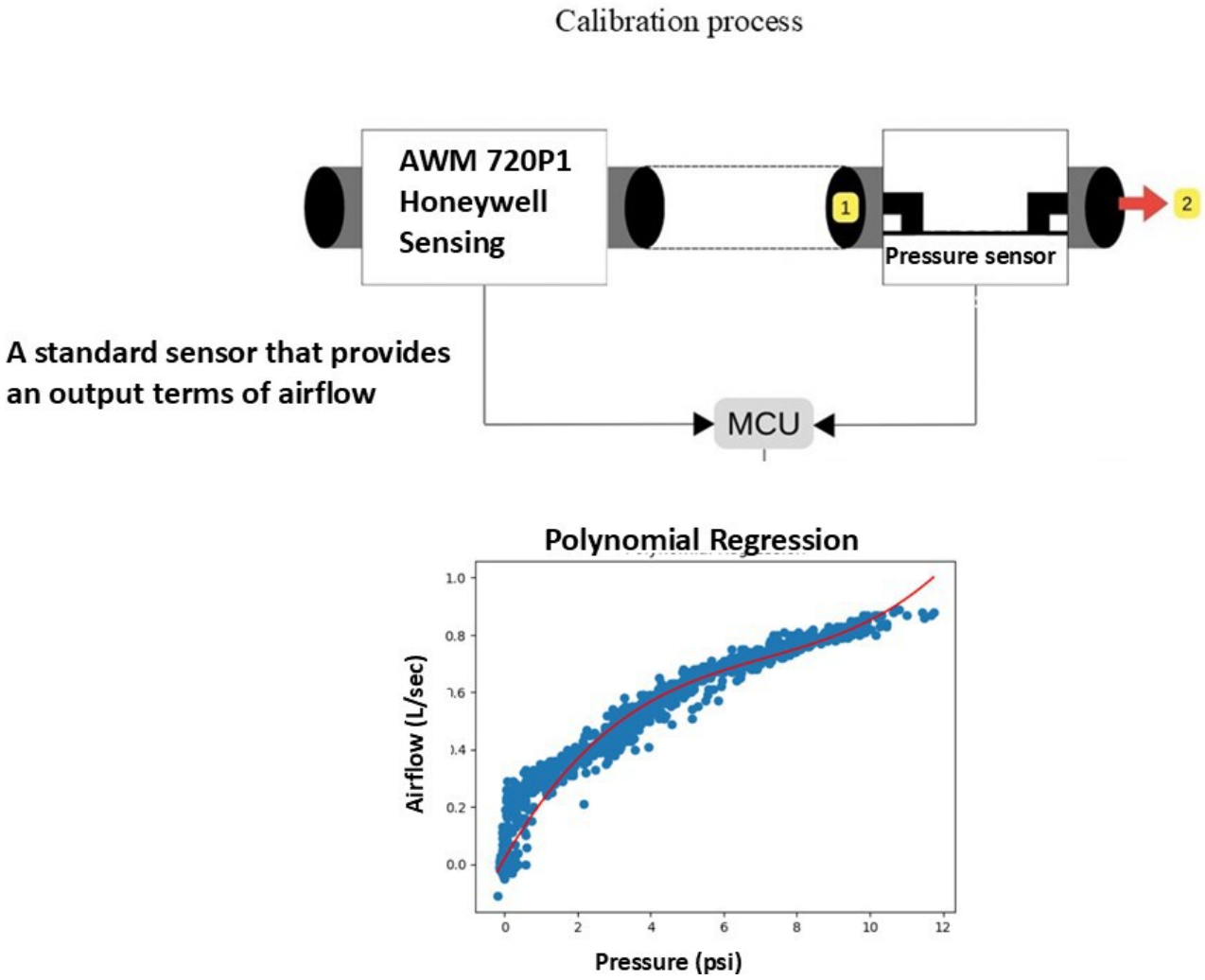
0.01967741+(0.22080302×pressure1)+(−0.0257367×pressure2)+(0.00119711×pressure3)

Therefore, a DIS device consists of the following three main components: (1) incentive spirometer device: This device includes a mouthpiece, tubing, and a main unit, and captures the inhaled air of the user. (2) Display screen: This includes a color bar, airflow volume levels, and a display of the air volume, and provides visual feedback to the volunteers undergoing the test. (3) Pressure sensor: The pressure sensor MPX10DP measures the inhalation pressure via the mouth, and it is highly accurate and reliable for a differential pressure flow meter type.

Volunteers can read the airflow volume readings while performing breathing exercises using the prototype DIS. The air volume display screen presents the volume of air inhaled and exhaled during each breathing cycle (Figure 3).

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Figure 2. Calibration of the digital incentive spirometer. MCU: microcontroller.



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Figure 3. Digital incentive spirometer device.



Experimental Design

We explored the benefits of using the DIS. In this study, we recruited patients who underwent OHS at Thammasat University Hospital. Patients who were scheduled to undergo CABG or valvular surgery, aged 35 - 80 years, both men and women, were enrolled. Patients with a history of heart surgery or arrhythmia 24 hours prior to the test and those with active respiratory infection (eg, tuberculosis, COVID-19, or multiple drug resistance) were excluded. In addition, the discontinuation criteria were patients who required reintubation, those with postsurgical infection, those with prolonged intubation exceeding 72 hours, and those who needed admission to the hospital less than 5 days after extubation.

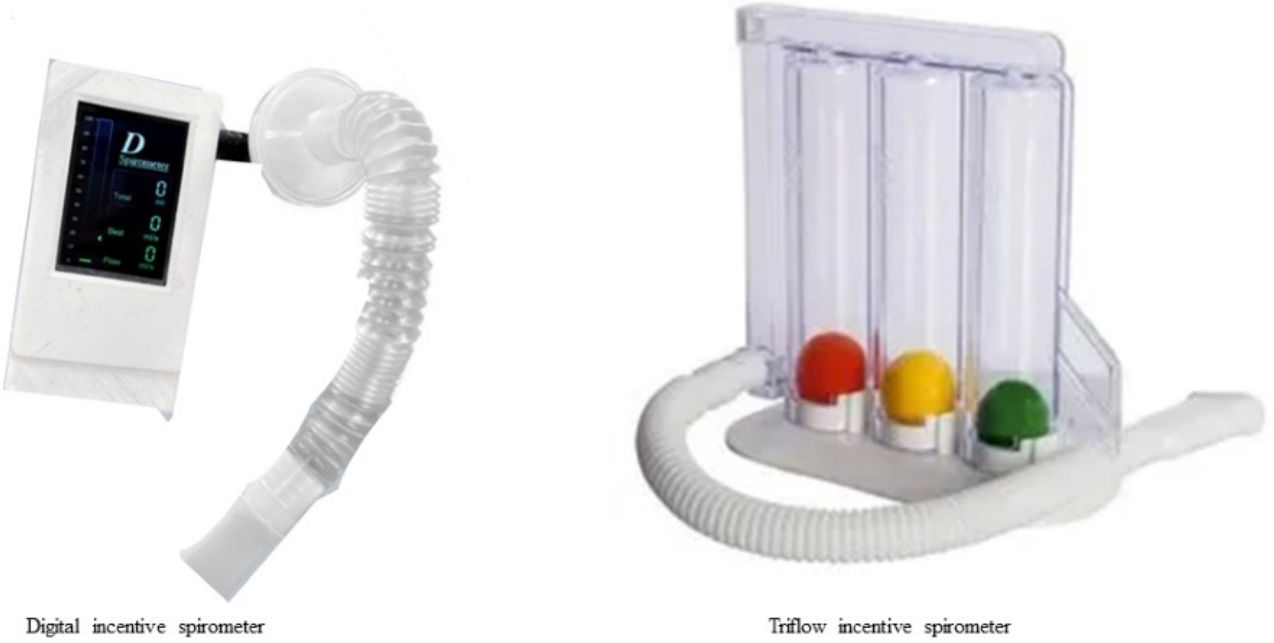
The sample size was calculated by using G-power 3.1.9.4, the effect size was set at 0.25, the statistical power was 0.80, and the alpha was .05; therefore, a total of 28 participants were examined initially. However, to avoid missing data or to adjust for potential dropouts, 32 randomly selected participants were finally enrolled. All participants were provided with an information sheet, and a consent form was signed before participation.

All participants were required to undergo pulmonary function evaluation (ie, the predicted %FVC and the predicted PEFR) by using CareFusion MicroLab (a Micro Direct company, United Kingdom) and respiratory muscle strength tests (maximal inspiratory pressure [MIP] and maximal expiratory pressure [MEP]) measured by a MicroRPM Respiratory Pressure Meter (Micro Medical Micro RPM., United Kingdom) prior to OHS and on day 5 postextubation postoperatively. A standard protocol for pulmonary function and respiratory muscle strength testing was followed according to the recommendations of the European Respiratory Society (ERS)/American Thoracic Society technical standard and ERS statement on respiratory muscle testing, respectively [9-11]. A single-blind randomized clinical trial was conducted with two assessors who were physical therapists.

The selected 32 participants were assigned to use the DIS or Triflow incentive spirometer (control group; Figure 4). The patients were required to use the DIS and Triflow incentive spirometer 15 times/set and perform two sets daily (ie, in the morning and evening), from day 1 to 5 postextubation. All participants were instructed on how to use the DIS or Triflow incentive spirometer via an in-person demonstration by a physical therapist who was not the assessor. The participant was required to sit on the bed or upright position and hold the device (ie, DIS or Triflow incentive spirometer). After that, they were asked to breathe out normally and then take a deep breath in via the mouthpiece and try to hold the breath for 3 - 5 seconds or as long as possible. During the intervention, all participants were supervised by two physical therapists, while other physical therapists were assigned to be assessors. In addition, those participants underwent physical therapy protocol, for example, breathing exercises, cough training with pillow support, calisthenics exercise, and ambulation (sitting, standing, and walking). The participants received physical therapy once a day until discharged from the hospital.

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Figure 4. Digital incentive spirometer and Triflow incentive spirometer.



Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 24.0. The Shapiro-Wilk test was used for assessing normal data distribution. An intention-to-treat analysis with a two-way mixed analysis of variance (time (2) × type (2)) was used to compare between and within groups for pulmonary function and respiratory muscle strength. Statistical significance was set at $P<.05$.

Results

Patient Classification

Sixty patients scheduled for OHS were included in the initial study. Unfortunately, 6 patients were excluded because they were <35 years of age, and 22 participants were included in the study during the initial session; however, due to the cancellation of their surgery, they were excluded from the study. Ultimately, 32 patients were enrolled in the study. A simple random sampling (ie, using a random lottery) was performed, and the patients were divided into two groups based on the device used: the DIS group (n=16) and Triflow incentive spirometer group (n=16). All participants underwent pulmonary function tests (ie, the predicted %FVC and the predicted %PEFR) and respiratory muscle strength (MIP and MEP) assessment prior to surgery. Twenty-two patients were reassessed on day 5 postextubation. Of the 10 patients who did not complete the test, 3 required prolonged intubation (ie, greater than 72 hours), 4 underwent reintubation, and 1 was discharged before the assessment; surgery was canceled in the final excluded patient (n=1; Figure 5).

Of the 36 patients who underwent OHS, 11 male and 21 female patients were included in the current study (Table 1). Considering patients assigned to the DIS and Triflow incentive spirometer groups, there were no significant differences in terms of age, comorbidities, type of operation, pulmonary function, and respiratory muscle strength (Table 2).

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Figure 5. Recruitment of participants.

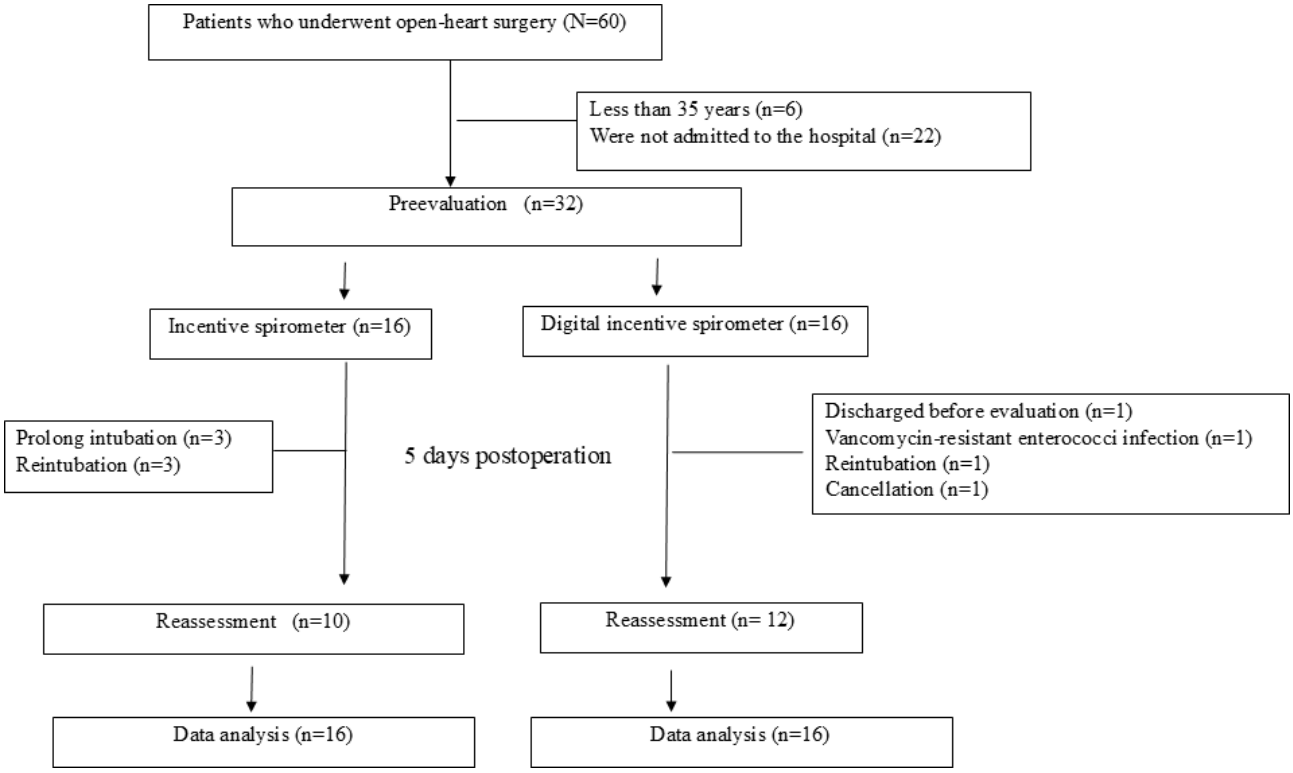


Table . Characteristics of patients who underwent open-heart surgery by group.

	Total (n=32), n (%)	DIS[a] (n=16), n (%)	Triflow IS[b] (n=16), n (%)	Chi-square *(df)*	*P* value
Sex, n (%)				0.139 (1)	.710
Male	11 (34.38)	5 (45.45)	6 (54.55)		
Female	21 (65.63)	11 (52.38)	10 (47.62)		
Diabetes mellitus, n (%)				3.137 (1)	.077
Yes	15 (46.88)	10 (66.67)	5 (33.33)		
No	17 (53.13)	6 (35.29)	11 (64.71)		
Hypertension, n (%)				0.183 (1)	.669
Yes	7 (21.88)	4 (57.14)	3 (42.86)		
No	25 (78.13)	12 (48.00)	13 (52.00)		
Dyslipidemia, n (%)				0.000 (0)	>.99
Yes	14 (43.75)	7 (50.00)	7 (50.00)		
No	18 (56.25)	9 (50.00)	9 (50.00)		
Surgery, n (%)				1.077 (1)	.584
CABG[c]	18 (56.25)	9 (50.00)	9 (50.00)		
Valvular surgery	13 (40.63)	6 (46.15)	7 (53.85)		
Combined	1 (3.13)	1 (100.00)	0 (0.00)		

[a]DIS: digital incentive spirometer.

[b]IS: incentive spirometer.

[c]CABG: coronary artery bypass graft.

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Table . Patient characteristics considering respiratory function.

Characteristic	Total (n=32)	DIS[a] (n=16)	Triflow IS[b] (n=16)	*t* test *(df)*	P value
Age (y), mean (SD)	62.25 (10.98)	63.75 (11.93)	66.75 (10.10)	−0.768 (30)	0.449
MIP[c] (cmH2O), mean (SD)	44.47 (26.99)	42.69 (31.06)	46.25 (23.11)	−0.368 (30)	0.715
MEP[d] (cmH2O), mean (SD)	38.81 (20.44)	33.69 (17.43)	43.94 (22.45)	−1.443 (30)	0.159
FVC[e] %, mean (SD)	69.63 (21.42)	68.25 (19.73)	62.50 (16.73)	0.889 (30)	0.381
PEFR[f] %, mean (SD)	46.09 (20.92)	47.56 (22.05)	44.63 (20.34)	0.392 (30)	0.698

[a]DIS: digital incentive spirometer.

[b]IS: incentive spirometer.

[c]MIP: maximal inspiratory pressure.

[d]MEP: maximal expiratory pressure.

[e]FVC: forced vital capacity.

[f]PEFR: peak expiratory flow rate.

Effect of the Intervention on Pulmonary Function and Respiratory Muscle Strength

Both groups exhibited markedly reduced pulmonary function and respiratory muscle strength on day 5 postextubation when compared with preoperative values (P<.05). However, patients who underwent DIS showed a slower decline in respiratory performance when compared with those who used the Triflow incentive spirometer device for MIP (mean difference [SE], −8.13 [3.86], P=.044 vs −9.94 [3.86], P=.015), MEP (mean difference [SE], −0.88 [3.99], P=.828 vs −6.38 [3.99], P=.121), %FVC (mean difference [SE], −19.63 [5.13], P=.001 vs −21.13 [5.13], P<.001) and %PEFR (mean difference [SE], −2.38 [6.76], P=.728 vs −11.81 [6.76], P=.091). In addition, there was no significant difference between DIS and the Triflow incentive spirometer after the intervention program (P>.05; Table 3).

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Table . Comparison in pulmonary function and respiratory muscle strength between a digital incentive spirometer and incentive spirometer among patients who underwent open-heart surgery.

Variable	Group		Mean difference (SE)	*P* value between groups
	DIS[a] (n=16)	Triflow IS[b] (n=16)	(DIS-Triflow IS)	
MIP[c] (cmH_2O)				
Preoperative, mean (SD)	42.69 (31.06)	46.25 (23.11)	−3.56 (9.68)	.715
Postoperative, mean (SD)	34.56 (24.92)	36.31 (20.33)	−1.75 (8.04)	.829
Mean difference (after-before) (SE)	−8.13 (3.86)	−9.94 (3.86)	N/A[d]	N/A
P value within the group	.044	.015	N/A	N/A
MEP[e] (cmH_2O)				
Preoperative, mean (SD)	33.69 (17.43)	43.94 (22.45)	−10.25 (7.11)	.159
Postoperative, mean (SD)	32.81 (15.08)	37.56 (15.52)	−4.75 (5.41)	.387
Mean difference (after-before) (SE)	−0.88 (3.99)	−6.38 (3.99)	N/A	N/A
P value within the group	.828	.121	N/A	N/A
FVC[f] (%)				
Preoperative, mean (SD)	68.25 (19.73)	62.50 (16.73)	5.75 (6.47)	.381
Postoperative, mean (SD)	48.63 (20.26)	41.38 (20.67)	7.25 (7.24)	.324
Mean difference (after-before) (SE)	−19.63 (5.13)	−21.13 (5.13)	N/A	N/A
P value within the group	.001	<.001	N/A	N/A
PEFR[g] (%)				
Preoperative, mean (SD)	47.56 (22.05)	44.63 (20.34)	2.94 (7.50)	.698
Postoperative, mean (SD)	45.19 (27.18)	32.81 (21.56)	12.38 (8.67)	.164
Mean difference (after-before) (SE)	−2.38 (6.76)	−11.81 (6.76)	N/A	N/A
P value within the group	.728	.091	N/A	N/A

[a]DIS: digital incentive spirometer.

[b]IS: incentive spirometer.

[c]MIP: maximal inspiratory pressure.

[d]N/A: not applicable.

[e]MEP: maximal expiratory pressure.

[f]FVC: forced vital capacity.

[g]PEFR: peak expiratory flow rate.

Discussion

Principal Findings

Herein, we aimed to explore the effects of using the DIS on the respiratory performance of patients who underwent OHS. Based on our findings, the pulmonary function (predicted %FVC and %PEFR) and respiratory muscle strength (MIP and MEP) values did not differ significantly between the DIS and Triflow incentive spirometer groups.

Pulmonary Function and Respiratory Muscle Strength

Reduced respiratory performance after heart surgery has been well documented [12-14]. The results of the study are in line with those of previous studies on pulmonary function after heart surgery. Narayanan and Hamid [12] reported that the inspiratory capacity dropped to 41% on day 1 post-OHS, gradually increasing to 106% on day 5 post-OHS. In patients who underwent valvular surgery, Alaparthi et al [13] found that pulmonary function (FEV1, FVC, and PEFR) values were reduced when compared with preoperative values and these values improved after day 7 postoperation.

Reportedly, patients who undergo OHS experience functional impairment including functional capacity, physical performance, and psychological health problems [14]. In the present study, pulmonary function (ie, predicted %FVC and %PEFR) and respiratory muscle strength values 5 days postextubation

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remained lower than the preoperative values. However, the benefit of a DIS gradually decreased when compared with that in the incentive spirometer group. The DIS device features specific attributes that enable the display of numerical values of visual and auditory elements as real-time feedback. Therefore, the use of this DIS device can enhance motivation while performing breathing exercises. Likewise, patients who underwent CABG and used an incentive spirometer experienced a markedly smaller reduction in pulmonary function values than those who performed only deep breathing therapy postoperatively [2,15]. Additionally, a systematic review and meta-analysis of postoperative cardiac surgery (n=1677 participants) revealed a small or no difference in incentive spirometer and standard respiratory care for postpulmonary complications (eg, atelectasis, pneumonia, and mortality) and lung function (eg, FVC, vital capacity, and FEV1), MIP, length of ICU stay or length of hospital stay after cardiac surgery [16]. In other words, the incentive spirometer is not superior to standard respiratory care in terms of clinical outcomes in postoperative cardiac surgery. However, another systematic review and meta-analysis in postoperative care in patients in the incentive spirometer group and without incentive spirometer group reported that patients undergoing incentive spirometryr had significantly shorter reduced risk of postpulmonary complications, and postoperative pneumonia compared with the control group without using IS [17]. Using incentive spirometers may be appropriate for lung re-expansion and oxygen uptake by taking long, slow deep breaths and a breath-hold of 3 - 5 seconds resulting in improved collateral ventilation and alveoli [18]. Therefore, a DIS, compared with incentive spirometers, may be an alternative tool for improving respiratory performance and preventing pulmonary complications.

Considering the limitations of this study, we could not compare participants who received the intervention (DIS or Triflow incentive spirometer) and those who did not receive any intervention. The severity of pulmonary function at baseline was not excluded from the study, which may have impacted the results. However, no significant differences were observed between the DIS and Triflow incentive spirometer at baseline. Additionally, the study had a short intervention period because it was conducted at a hospital. Finally, the medical reports and laboratory data were not recorded (eg, comorbidities, duration of operation, ejection fraction, or functional classification), which might affect the baseline characteristic data or initial health status.

Conclusion

There is a significant decrease in pulmonary function and respiratory muscle strength in the DIS and Triflow incentive spirometer on the 5th day postextubation when compared with preheart surgery values. Additionally, the effect of a DIS on pulmonary function and respiratory muscle strength was similar to a flow-oriented incentive spirometer. Therefore, the innovation of DIS motivates patients to increase their inspiratory effort, thereby encouraging deeper breathing.

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Data Availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Authors' Contributions

KY conceived and designed the experiments, analyzed the data, prepared figures and tables, authored or reviewed drafts of the paper, and approved the final draft. SH prepared figures and tables, received the grant, and approved the final draft. LM, NR, KJ, and CN, performed the experiments, analyzed the data, reviewed drafts of the paper, and approved the final draft. CK and OS provided the material, reviewed drafts of the paper, and approved the final draft

Conflicts of Interest

None declared.

Checklist 1
CONSORT E-Health Checklist
[PDF File, 1048 KB - rehab_v12i1e68158_app1.pdf]

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Abbreviations

CABG: coronary artery bypass graft
DIS: digital incentive spirometer
ERS: European Respiratory Society
FEV1: forced expiratory volume in the 1st second
FVC: forced vital capacity
IS: incentive spirometer
MEP: maximal expiratory pressure
MIP: maximal inspiratory pressure

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OHS: open-heart surgery
PEFR: peak expiratory flow rate

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Wearable-Enhanced mHealth Intervention to Promote Physical Activity in Manual Wheelchair Users: Single-Group Pre-Post Feasibility Study

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Abstract

Background: With the rapid advancement of technology, using wearable devices and mobile health (mHealth) apps to monitor and promote physical activity (PA) has become increasingly popular among individuals with various chronic conditions. However, such work remains limited among individuals with spinal cord injury (SCI), especially those who use a manual wheelchair for mobility.

Objectives: The study aims to describe the development of the WheelFit mHealth app for monitoring and promoting PA in manual wheelchair users (MWUs) with SCI and evaluate its feasibility and usability in free-living conditions.

Methods: The WheelFit app, based on the Fogg Behavioral Model with inputs from stakeholders, including MWUs, physical therapists, and personal trainers, was developed to promote PA in MWUs. It works with two commercial wearable devices, that is, an Android smartwatch and a wheel sensor, which stream users' upper extremity and wheelchair movement to the app to calculate PA variables using custom algorithms. Users can set personal goals, review daily progress and PA history, and access an adaptive workout library within the app. A 4-week single-group pre-post study, consisting of a 1-week baseline and 3-week intervention phase, was conducted to evaluate WheelFit's feasibility and usability. Feasibility was evaluated using the session attendance rate, device and app usage, and implementation of action plans. Usability was assessed using the system usability scale. The preliminary effectiveness was assessed by comparing preintervention and postintervention PA variables and scores from the SCI exercise self-efficacy scale.

Results: A total of 16 participants completed the study protocol with 100% session attendance and maintained 14.2 hours of daily device and app connection. Participants demonstrated varying levels of adherence to their action plans. The excellent usability of WheelFit was indicated by an average system usability scale score of 81.8 (SD 19.2) points. Statistically significant increases between pre-post daily exercise times (preintervention: mean 26.4, SD 16.9 minutes; postintervention: mean 33.3, SD 24.9 minutes; P=.049) and exercise self-efficacy scale scores (preintervention: mean 33.9, SD 4.5 points; postintervention: mean 35.9, SD 3.2 points; P=.043) were observed.

Conclusions: The WheelFit app demonstrated promising feasibility, usability, and a positive impact on promoting PA in MWUs with SCI. Future investigation exploring the potential integration of the WheelFit app into clinical practice is warranted.

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KEYWORDS

spinal cord injury; community-based research; exercise; workout; telemedicine; telerehabilitation; mHealth

Introduction

An estimated 302,000 people in the United States are living with spinal cord injury (SCI) as of 2023 [1]. On average, 39.3% of people in this population are manual wheelchair users (MWUs) [2]. In addition to direct changes in sensory and motor functions caused by the injury, 95% of people with SCI have at least one secondary complication [3]. Among these complications, obesity stands out with a prevalence of 66%

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[4,5]. A primary cause of obesity is the positive energy balance caused by decreased energy expenditure, often linked to reduced fat-free mass and physical activity (PA) in the SCI population [6]. Despite published PA guidelines, nearly half of this population remains sedentary and does not meet the minimum recommended guideline of 20 minutes of moderate to vigorous aerobic activity twice a week and 3 sets of 10 reps of strength training twice a week [7,8].

With the rapid development and cost reduction of commercial wearable devices, using such devices with mobile health (mHealth) apps to promote PA has become increasingly popular and shown promising benefits among the general population [9,10]. However, such success has yet to be fully realized among MWUs with SCI. One significant barrier is that the majority of commercial wearable devices are developed and optimized for ambulatory individuals, lacking validity for MWUs with SCI. As of November 2024, only the Apple Watch and certain Garmin smartwatches provide a wheelchair mode for push count assessment [11-13]. While the Apple Watch accurately tracks push counts for wheelchair users, it is costly and requires an iPhone, limiting its use among Android users and those with limited financial resources [14,15]. Validation studies on the Garmin smartwatch in the wheelchair mode are still lacking.

Currently, only a few studies have explored the use of commercial wearable devices in mHealth interventions aimed at promoting PA in MWUs with SCI. The majority of these studies mainly use wearable devices as outcome measurement tools. The Workout on Wheels internet intervention (WOWii) developed by Froehlich-Grobe et al [16] used a Polar A300 fitness tracker to manually log workout durations from 143 participants during workout sessions delivered through the WOWii web portal. The workout minutes were used for workout progress monitoring, which was displayed on the WOWii site to help participants track their progress toward established goals. The 24-week study comprised a 16-week intervention phase followed by an 8-week maintenance phase. During the intervention phase, 73% (123/168) of participants logged their workouts using the Polar fitness tracker, while approximately 29% (48/168) to 41% (69/168) continued to do so during the maintenance phase. Analysis of workout minutes revealed a significant increase in aerobic and strength workout time among participants during the intervention phase, a trend that was maintained through the maintenance phase [16].

Another mHealth intervention that used commercial wearable devices is the Scale-Up Project Evaluating Responsiveness to Home Exercise And Lifestyle Tele-Health (SUPER-HEALTH) developed by Rimmer et al [17]. The SUPER-HEALTH intervention is designed for individuals with physical disabilities, including those who can ambulate independently as well as those who use wheelchairs. Similar to the WOWii project, the SUPER-HEALTH delivered workout content through the website and used a Fitbit Charge fitness tracker to monitor participants' PA data. The PA was displayed to the participant in the activity dashboard of the SUPER-HEALTH site, and the study personnel also monitored the PA data and manually issued reminders to maintain intervention fidelity. The full quantitative results of the SUPER-HEALTH study are not available yet. It is worth noting that the Fitbit devices were designed to measure PA in the general population, and their validity in people with SCI remains unknown. Using such PA data may lead to biased outcome measurement [18,19].

On the other hand, the Personal Health Informatics and Rehabilitation Engineering (PHIRE) app developed by Hiremath et al [20] is a wearable device-oriented mHealth PA intervention for MWUs with SCI. It provides PA measures using data from a commercial LG Android smartwatch and a wheel sensor, processed by custom algorithms for MWUs with SCI [20]. The app quantifies participants' daily PA as energy expenditure, wheelchair travel distance, and PA minutes. The app was designed following the Just-in-time Adaptive Intervention (JITAI) framework, which aims to provide the right intervention at the right time [21]. Once the user completes a bout of PA, defined as a minimum of 3 continuous moderate to vigorous physical activity (MVPA) minutes, the app provides congratulations and issues JITAI messages based on various circumstances. If the user has not met their daily MVPA minutes goal, the app displays the current progress and the remaining minutes needed to reach the goal. Upon achieving the goal, the app congratulates the user. If the user exceeds the goal, the app shows the current accumulated MVPA minutes. Their pilot study results indicated that out of 16 participants, 38% (6/16) and 69% (9/16) of participants experienced a considerable increase (>10%) in light and moderate intensity PA, respectively [20]. While the PHIRE app integrates a wearable device with a validated algorithm for MWUs with SCI, it lacked the adaptive workout features found in the SUPER-HEALTH and WOWii studies.

Incorporating both wearable-based PA monitoring and mHealth-delivered adaptive workouts, we conducted this WheelFit study with 2 main aims. The first was to develop the WheelFit fitness app for MWUs with SCI. This app integrates daily PA monitoring and feedback using data from a commercial smartwatch and a wheelchair sensor, processed with custom algorithms for this population. Additionally, the app includes an adaptive workout library created by health care professionals. The second aim was to evaluate the feasibility and usability of WheelFit as an mHealth intervention for individuals with SCI.

Methods

WheelFit Devices

The WheelFit app is designed for Android and is deployed to pixel 3 phones (Google LLC), as shown in Figure 1A. The app communicates with two wearable devices to calculate PA variables: a TicWatch Pro smartwatch (Mobvoi Information Technology LLC), shown in Figure 1B, and a SensorTag wheelchair sensor (Texas Instruments), shown in Figure 1C.

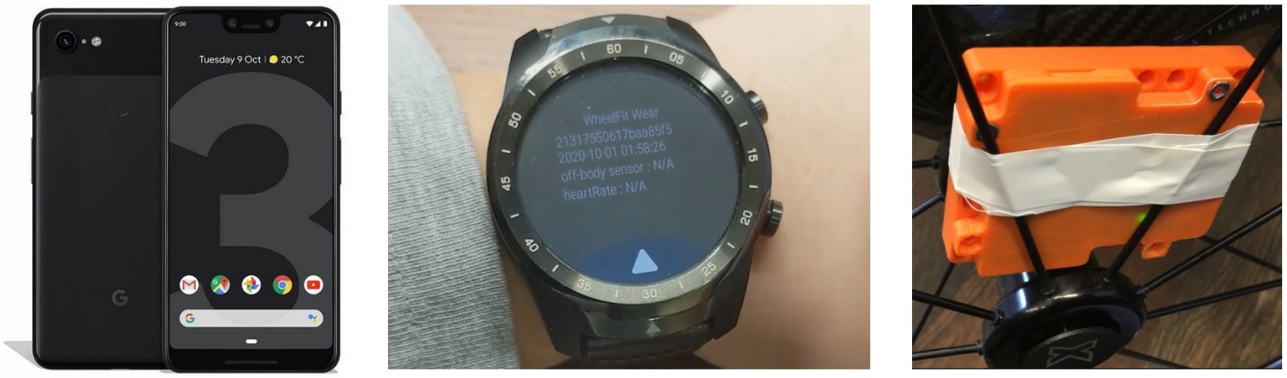
The TicWatch Pro is an Android WearOS-based smartwatch. We developed a WheelFit companion app for the smartwatch, which samples data from its accelerometer at 30 Hz and from the heart rate sensor at 1 Hz. Raw acceleration signal data are packed using the "batching" function of the WearOS and sent to the smartphone app each minute. The heart rate data are streamed to the smartphone app continuously. The companion app also shows the connection status and issues vibration

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notifications when the watch is disconnected from the phone or a sedentary behavior is detected. The battery of the smartwatch lasts about 10 - 11 hours.

The SensorTag is a multisensor Internet-of-Things device [22]. We developed custom firmware that samples only the accelerometer and gyroscope, deactivating other sensors to conserve battery life. The accelerometer is used to activate the gyroscope when wheelchair movement is detected. The gyroscope registers the wheel rotation at 5 Hz. The device then converts the number of rotations to the distance traveled according to the wheel diameter specified in the settings and continuously streams all data to the smartphone app through Bluetooth Low Energy protocol. The SensorTag is attached to the wheelchair spokes using a custom 3D-printed case. Powered by 2 AAA batteries, it has a battery life of 1.5 months.

Figure 1. WheelFit devices. (A) Google pixel 3 smartphone, (B) Ticwatch Pro Android smartwatch, and (C) SensorTag wheel sensor.



A. Google Pixel 3 Smartphone

B. Ticwatch Pro Android Smartwatch

C. SensorTag Wheel Sensor

WheelFit App Development

Conceptual Framework

We developed the WheelFit app based on the Fogg Behavioral Model (FBM) with inputs from stakeholders, including MWUs, physical therapists (PTs), and personal trainers, to promote PA in MWUs. The FBM includes three key factors: motivation, ability, and triggers [23]. It suggests that for a target behavior to occur, an individual must be sufficiently motivated, have the ability to perform the behavior, and be prompted by a trigger.

The WheelFit App

The WheelFit app adopted the multicomponent design (Figure 2), which has proven to be more effective than the single-component design, to address the three FBM key factors [24].

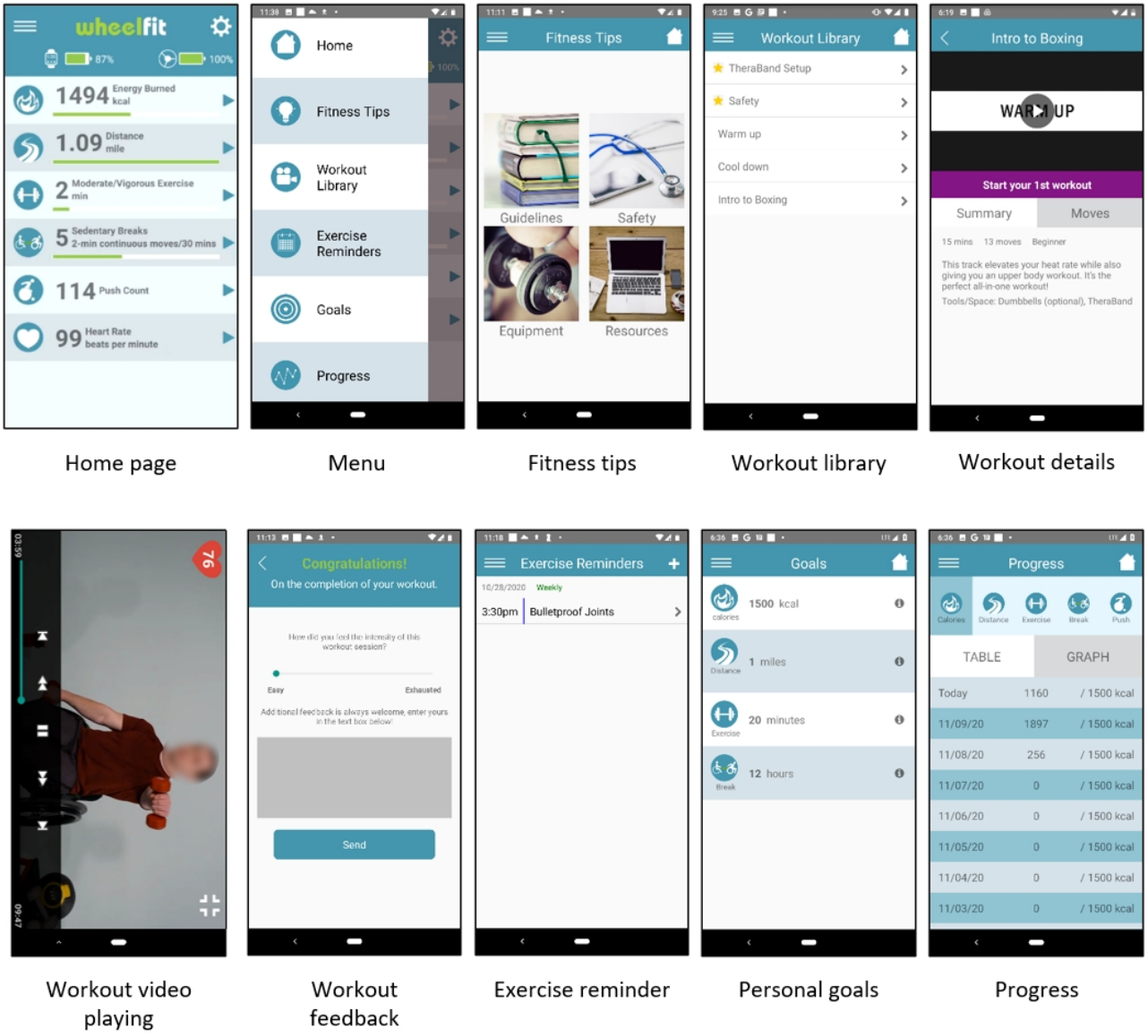
To address ability, the FBM suggests that making desired behavior easier to perform is simpler than training individuals to have new skills [23]. The WheelFit app meets this requirement by offering an adaptive workout library with short, accessible workout videos designed to lower the knowledge and time barriers to PA, as identified in previous research [25].

The app incorporates triggers to prompt actions [23], using smartwatch push notification reminders and vibration alerts for sedentary behavior. These triggers encourage users to engage in both structured and unstructured PA, ensuring consistent engagement and adherence to PA routines.

To enhance motivation, the app includes daily PA monitoring, fitness tips, goal setting, and progress-monitoring modules. The daily PA-monitoring module, featured on the app's home page, offers objective monitoring to support self-regulation, while the fitness tips module provides educational content on the benefits of PA. The goals and progress modules further motivate users by highlighting their achievements and monitoring their PA history [26,27].

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Figure 2. The WheelFit app.



Home Page (Daily PA Monitoring)

The home page layout includes a menu icon, a settings icon, device connection indicators for the watch and wheel sensor, and six daily PA measures. Users can navigate through the settings icon to the settings page to enter or update their demographic information and adjust the wheelchair wheel diameter for a more precise PA assessment. The device connection indicator shows the battery level of each connected sensor and displays the connection status. The six PA measures are (1) energy burned, (2) distance traveled, (3) moderate to vigorous exercise time, (4) sedentary breaks, (5) total push counts, and (6) real-time heart rate. The energy burned is estimated using a custom prediction model originally developed for ActiGraph devices in our previous studies and adapted to the Android platform [25,28]. The distance traveled is the cumulative distance calculated from the number of rotations by the wheelchair sensor. For the moderate to vigorous exercise time, the app first calculates the mean absolute deviation from the accelerometer data of the current minute and then applies the thresholds established by Shwetar et al [29] to classify the activity intensity into sedentary, light, or MVPA. The accumulated MVPA minutes are shown as moderate to vigorous exercise time. The sedentary break is defined as the total number of 30-minute periods where at least 2 consecutive minutes of activity above the light intensity are registered. For example, if a user is awake for 16 hours, the maximum possible number of sedentary breaks per day is 32. If the app detects that a sedentary break has not occurred within the initial 25 minutes of a 30-minute interval, it triggers a sedentary behavior alert through vibrations and texts on the smartwatch. The total push count shows the cumulative number of wheelchair pushes calculated through the application of algorithm by Veerubhotla [30] using the raw accelerometer data collected from the smartwatch. Finally, the real-time heart rate variable shows the most current measurement from the smartwatch's heart rate sensor.

Fitness Tips Page

The fitness tips page contains educational materials we have compiled regarding current PA guidelines, wheelchair exercise safety, exercise equipment and tools, and related resources, all formatted as web papers.

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Workout Library Page

We provide an adaptive workout library containing 11 workout tracks in three categories: (1) aerobic (3 tracks), (2) strengthening (5 tracks), and (3) flexibility exercises (3 tracks). Each track, lasting approximately 15 minutes, comprises a warm-up, several brief movements (around 1 - 2 minutes each), and a cooldown. These workouts are developed by clinicians and feature wheelchair users, drawing on research evidence and incorporating feedback from users. The description page of each workout track provides details such as workout duration, the number of movements, difficulty level, required equipment or space, and explanations. Given the diverse physical abilities and impairments of individuals with SCI, certain movements may be appropriate for some users but could present risks to others who have reduced range of motion or muscle strength. Therefore, we introduced the workout edit function, enabling health care providers or personal trainers to categorize each movement as "safe to perform," "adapt with modification," or "skip movement" while also offering the ability to highlight or hide each workout. When playing the workout videos, users can use the media control to start, pause, fast forward, and rewind the video. Users' real-time heart rate is displayed at the top left corner to provide an estimation of workout intensity. Upon completion of a workout, the app will prompt the user to rate their perceived exertion and share any feedback they may have.

Exercise Reminders Page

The exercise reminders page provides functions for users to create, edit, and delete exercise reminders. Users can designate the start time, workout type, recurrence, and alarm for the reminders. The app syncs the reminders with the Google Calendar app on the phone to use its built-in notification functions.

Goals Page

The goals page allows users to set their daily goals for energy burned, distance traveled, moderate to vigorous exercise minutes, and sedentary breaks. Goals are also reflected as progress bars on the home page. Users can view the progress bars to track daily progress toward goals.

Progress Page

The progress page presents historical daily PA variables except for the heart rate. Users can review their past data with either a table view that shows detailed numbers or a graph view that visualizes the trends of the past 30 days.

Feasibility and Usability Evaluation

Participants

Participants were included in the study if they were (1) aged between 18 and 65 years, (2) diagnosed with an SCI, (3) at least 1-year postinjury (if acquired) and medically stable, (4) not consistently engaging in regular PA for at least 6 months, (5) using a manual wheelchair as their primary means of mobility, (6) living in a community, and (7) experienced in using a smartphone. Potential participants were excluded if they had any active pelvic or thigh wounds or were pregnant (based on self-report). They were also screened for medical conditions (eg, cardiovascular diseases, stroke, pressure ulcers, fracture, musculoskeletal injuries, or COVID) that could limit PA participation. This screening involved a series of questions regarding hospitalizations and therapy received during the past year, physician clearance, and self-perceived limitations as related to each condition identified. If any potential conditions were identified, our PT reviewed the responses, conducted necessary follow-up, and determined whether the participant could safely participate, required further clearance from their primary care provider, or should be excluded. Participants were recruited by convenience sampling through study registries, flyer distribution, and direct outreach.

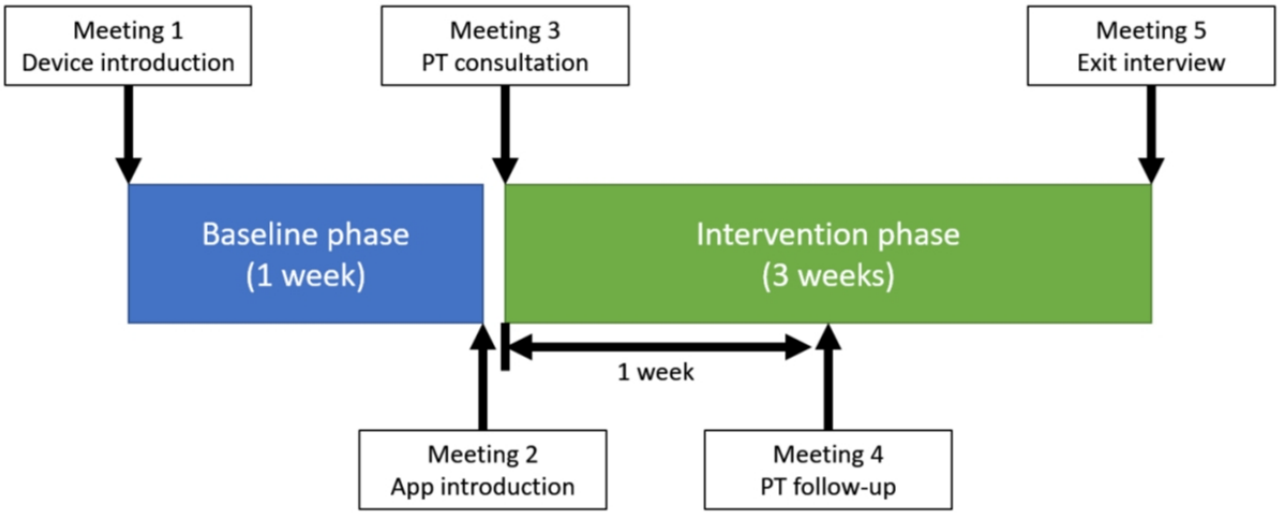
Power analysis was conducted based on PA effectiveness measurement (ie, daily moderate to vigorous exercise minutes) using data from a mHealth study on adults with diabetes aimed at improving daily light activities (Cohen d=0.93), as no relevant literature on mHealth interventions for individuals with SCI was available [31]. Assuming a power of 0.8 and an α level of .05, G*Power (Heinrich-Heine-Universität Düsseldorf) indicated a required sample size of 13 [32]. To account for a potential 20% attrition and compliance rate, we planned to recruit 16 participants.

Study Design

The 4-week full-remote study consisted of a 1-week baseline phase and a 3-week intervention phase, with 5 virtual meetings held via Zoom (Zoom Video Communications, Inc) (Figure 3). After informed consent, participants completed the demographics and SCI exercise self-efficacy scale (ESES) questionnaire via REDCap (REDCap Consortium) [33]. A study package was mailed to participants that contained a Google Pixel 3 smartphone, a TicWatch Pro smartwatch, a Samsung Galaxy tablet, a SensorTag wheel sensor, two sets of TheraBands, a wheelchair pouch, a tablet stand, a universal charger, and written instructions. Upon receiving the study package, the participant had the first meeting with the researchers. During this first virtual meeting, a researcher provided instructions on how to use the devices, with the participant following along using the study devices. The researcher also addressed any questions raised. Then, the participant was asked to independently complete a series of tasks to ensure their proficiency in using the devices. In case of any unsuccessful attempts, additional explanations and instructions were provided.

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Figure 3. Study procedure. PT: physical therapist.



Baseline Phase

The 7-day baseline phase began after the first meeting concluded. To maintain the integrity of participants' typical PA, most functions of the WheelFit app, including the home screen PA display and workout library, were deactivated. Participants were instructed to maintain the connection between all devices so that the app could record the PA silently. The participants were also asked to complete a daily log to record their bedtime and waketime and indicate whether each day was a typical day, defined as a day with routine activities without any unexpected events that affected their PA level (eg, illness). The daily log was sent to the participants' email every day throughout the study.

At the end of the baseline phase, participants were scheduled for a second meeting to introduce the WheelFit app. During this meeting, a researcher activated all functions of the WheelFit app and provided corresponding instructions. Participants were then asked to perform a series of tasks independently to demonstrate their understanding of the app. If participants were unable to complete a task, additional guidance was provided.

Intervention Phase

The day after the second meeting, participants had the third meeting with our licensed PT and personal trainer, both of whom had experience working with people with physical disabilities. Including both professionals ensured the safety of our study and provided flexibility in scheduling follow-up sessions. In the third meeting, our PT assessed the participant's knowledge of PA and gathered self-reported information, including wheelchair details, assistive technology use, medical and injury history, living situation, and transfer techniques. A functional assessment was conducted, covering the range of motion, muscle strength, and sensation. Due to the remote nature of the meeting, the PT visually assessed the range of motion via Zoom, guiding participants through various postures. Muscle strength and sensation information was collected based on participants' self-report. Traditional aerobic capacity assessments, which require emergency assistance personnel in laboratory settings, were not feasible in our remote format [34]. After the functional assessment, our personal trainer provided an educational session on PA, sedentary behavior, and the specific, measurable, achievable, relevant, and time-bound goal setting. The PT and personal trainer also assisted the participants in making an action plan for engaging in workouts according to the participant's functional assessments and personal goals. The PT and personal trainer directed the participants to perform all movements in each prescribed workout while observing their performance via Zoom. They provided feedback to correct improperly performed movements and suggested alternatives for movements that did not align with the participant's functional ability. If no alternative was available, the participant was instructed to skip the movement. All alternative or skipped recommendations were recorded in the WheelFit app. The completion of the third meeting marked the beginning of the 3-week intervention phase.

Participants followed their action plans using the WheelFit app for 1 week. Then, they had the fourth meeting held with the PT or personal trainer to address any questions and adjust the action plan as needed. Participants were instructed to adhere to their updated action plans for the remainder of the intervention phase. At the end of the intervention phase, participants had the fifth meeting with a researcher, where they completed the system usability scale (SUS) for WheelFit, the postintervention ESES, and a participant perception of use survey.

Outcome Measures

PA Measures

Since the goal of the WheelFit app is to promote PA and reduce sedentary behavior in MWUs with SCI, we consider "moderate to vigorous exercise time" and "sedentary breaks" as the primary outcomes for PA. The rest of the PA variables were not selected as they were not appropriate for goal setting and were only for participants' references. All calculated PA measures were stored on the study smartphone and retrieved after the participants mailed back the devices.

Exercise Self-Efficacy

Participants' exercise self-efficacy was assessed using the SCI ESES, a 10-item, 4-point Likert scale assessing an individual's confidence toward PA [33]. This scale has been validated in individuals with SCI [33]. The possible scores range from 10

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to 40, with a higher score indicating higher confidence toward PA. The ESES was assessed before and after the study using REDCap questionnaires.

Intervention Feasibility

The feasibility of the WheelFit intervention was evaluated in three areas: (1) session attendance, (2) device and app usage, and (3) action plan implementation. The session attendance was assessed as attendance of all study meetings except for the exit meeting, which is not considered part of the WheelFit intervention. If a participant missed a meeting but attended a rescheduled session, it was counted as valid attendance. Conversely, if a participant missed a meeting and was unwilling to attend any rescheduled sessions, it was marked as not attended. The device and app usage were assessed as the time participants maintained a connection between the smartwatch and the smartphone. The implementation of the action plan was assessed based on the completion rate of the prescribed workouts in each participant's action plan.

WheelFit App Usability

The usability of the WheelFit app was assessed through the SUS. The SUS is a 10-item, 5-point Likert scale that assesses users' perceived usability of the app. The possible scores range from 20 to 100. An SUS score larger than 80.3 indicates excellent app usability, while a score between 68 and 80.3 indicates that the app has acceptable usability but there is a need for improvement. A score below 68 indicates that the app has poor usability and needs to be revised [35-37]. The SUS has been validated and widely used to assess the usability of mHealth apps [35,38-41].

The participant feedback was evaluated through a participant perception of use survey. The survey included three questions: (1) a 4-point Likert scale question regarding the efficacy of WheelFit in facilitating an active lifestyle (ie, very helpful/somewhat helpful/not very helpful/not at all helpful), (2) a 4-point Likert scale regarding participants' perception of any health or functional improvements (ie, to a great extent/somewhat/very little/not at all), and (3) a question regarding participants' willingness to recommend WheelFit to other MWUs (ie, yes/no/cannot decide).

Data Preparation and Analysis

After retrieving PA data from the study phone, valid day data were extracted. A day is considered valid if it meets the following three criteria: (1) the daily data file must contain at least 30% of nonnull or nonzero smartwatch accelerometer data (approximately 8 hours, which is the minimum estimated smartwatch battery life after 1 full charge), (2) no abnormal data were observed (eg, zero wheelchair pushing distance), and (3) the participant confirmed in the daily log that the day was a typical day, with no events altering their daily routine. All other data were retrieved from REDCap.

The demographic data were analyzed at the group level. All valid day PA data were aggregated and averaged to the daily level for the baseline and intervention phase, respectively. Each participant's preintervention and postintervention PA data were presented in a table for a more detailed interpretation. The overall differences between PA variables (ie, moderate to vigorous exercise time, sedentary break, and travel distance) among all participants during the 2 phases and the ESES scores before and after the intervention were compared using a 2-tailed paired sample *t* test or its nonparametric equivalent if assumptions were not met. To further analyze individual PA change, we defined a ±10% change as the threshold for a "considerable" level of change for the "moderate to vigorous exercise time" based on prior studies [20]. Brief descriptions of participants' PA background, personal goals, and motivations were presented to aid in contextualizing the change in PA with the use of the app during post hoc analysis. The action plan workout prescription and execution were also presented. For feasibility and usability evaluation, the session attendance and device connection rate were reported. Descriptive analysis was used to summarize the SUS scores of WheelFit and participants' responses to the participant perception of use survey. Participants' digital literacy was assessed through observations of their interactions with the study devices and the WheelFit app, as well as relative information shared during all study meetings. This evaluation of their digital literacy level was used to enhance the comprehension of app usability during post hoc analysis. All statistical analyses were conducted using SPSS (version 28; IBM Corp), Microsoft Excel (Microsoft Corp), and Python (version 3.0; Python Software Foundation).

Ethical Considerations

This study was approved by the institutional review board at the University of Pittsburgh (STUDY19040049). Informed consent was obtained from all participants, who were also reminded of their right to withdraw from the study at any time. Identifiable data, such as meeting recordings, were securely stored on a university-approved drive with access restricted to the core research team. All data were deidentified prior to analysis to ensure participant confidentiality. Participants received a total compensation of US $225 for full participation in the study.

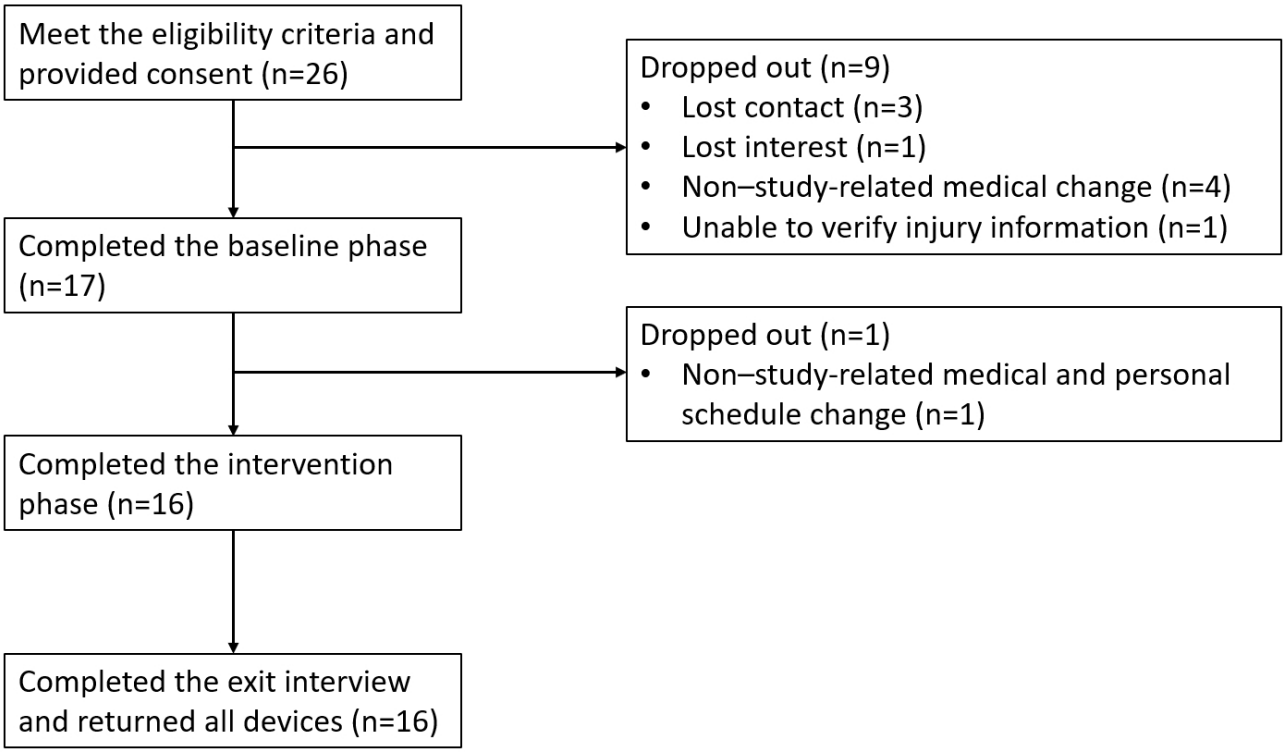
Results

The study commenced in November 2020 and ended in October 2022. A total of 26 participants enrolled in the study, with 16 participants completing the full study protocol. Of the 10 withdrawn participants, 9 dropped out before the study began (meeting 1) and 1 dropped out during the intervention phase. All dropouts are non–study-related. Figure 4 shows the participant diagram.

The demographics of the 16 participants who completed the study are provided in Table 1.

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Figure 4. Study participant diagram.



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Table . Demographics.

Demographics variable	Participants
Age (years), mean (SD)	48.0 (9.8)
Height (cm), mean (SD)	173.6 (10.2)
Weight (kg), mean (SD)	75.2 (18.6)
BMI, n (%)	
≤25	7 (43.8)
25 < BMI <30	5 (31.3)
≥30	4 (25.0)
Sex, n (%)	
Male	8 (50)
Female	8 (50)
Ethnic origin, n (%)	
Caucasian	13 (81.3)
African American	3 (18.8)
Injury type, n (%)	
SCI: complete[a]	5 (31.3)
SCI: incomplete	7 (43.8)
Spinal cord disease	1 (6.3)
Not reported	3 (18.8)
SCI level, n (%)	
C1-C8[b]	2 (12.5)
T1-T12[c]	9 (56.3)
L1-L5[d]	1 (6.25)
Not reported	4 (25.0)
Self-rate fitness level, n (%)	
Very good	4 (25.0)
Good	6 (37.5)
Fair	6 (37.5)
Self-rate nutritional habits, n (%)	
Excellent	1 (6.3)
Very good	4 (25.0)
Good	9 (56.3)
Fair	2 (12.5)
Employment status, n (%)	
Employed	6 (37.5)
Unemployed	10 (62.5)

[a]SCI: spinal cord injury.

[b]C: cervical.

[c]T: thoracic.

[d]L: lumbar.

Table 2 shows the average daily PA levels of the 16 participants during the baseline and intervention phases, along with the corresponding percentage change. The Wilcoxon signed rank tests indicated that there is a significant increase in moderate to vigorous exercise time during the intervention phase (median= 28.4) compared with the baseline phase (median=26.9, Z=1.97;

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P=.049; *r*=0.49), but no significant change in the sedentary break was found (*Z*=0.52; *P*=.605; *r*=0.13). Two-tailed paired sample *t* tests revealed that participants' ESES scores were significantly higher after the intervention (mean 35.9, SD 3.2) than before the study began (mean 33.9, SD 4.5; t_{15}=1.84; *P*=.043; *d*=4.35). A total of 9 participants (ie, participant numbers 2, 3, 4, 5, 8, 15, 16, 17, and 19) had a considerable increase in exercise time, 2 participants (ie, participant numbers 7 and 10) had a considerable decrease, while the remaining 5 participants (ie, participant numbers 11, 14, 21, 25, and 26) had no considerable change.

Table . Changes in physical activity outcomes.

ID	Moderate to vigorous exercise time (minutes)		Sedentary break (counts)		Travel distance (miles)		Exercise Self-Efficacy Scale (score)	
	Baseline	Intervention, change(%)	Baseline	Intervention, change(%)	Baseline	Intervention, change(%)	Baseline	Intervention, change(%)
02	2.8	4.4 (57)	14.8	13.5 (−9)	0.4	0.4 (0)	37.0	37.0 (0)
03	27.9	37.0 (33)	15.4	19.1 (24)	0.6	0.6 (0)	32.0	35.0 (9)
04	26.8	99.0 (269)	9.4	12.3 (31)	0.1	0.2 (100)	40.0	39.0 (−3)
05	42.9	73.3 (71)	19.4	20.1 (4)	0.7	1.3 (86)	34.0	38.0 (12)
07	47.0	17.1 (−64)	24.0	13.8 (−43)	1.7	0.8 (−53)	34.0	34.0 (0)
08	23.9	27.8 (16)	17.2	17.8 (3)	0.5	0.6 (20)	31.0	30.0 (−3)
10	57.8	44.1 (−24)	17.6	18.1 (3)	1.0	1.0 (0)	40.0	39.0 (−3)
11	45.0	48.5 (8)	22.0	21.7 (−1)	1.4	0.8 (−43)	37.0	40.0 (8)
14	11.8	11.1 (−6)	14.1	11.8 (−16)	1.0	0.7 (−30)	27.0	34.0 (26)
15	18.6	21.5 (16)	18.2	17.7 (−3)	2.1	1.8 (−14)	27.0	36.0 (33)
16	1.1	9.9 (800)	13.2	11.9 (−10)	0.2	0.4 (100)	33.0	34.0 (3)
17	32.9	39.6 (20)	20.4	20.9 (2)	0.6	0.8 (33)	30.0	37.0 (23)
19	5.9	18.1 (207)	13.0	17.9 (38)	0.4	0.8 (100)	38.0	37.0 (−3)
21	27.0	29.0 (7)	19.4	16.1 (−17)	0.8	0.7 (−13)	39.0	39.0 (0)
25	12.9	13.5 (5)	15.1	13.9 (−8)	0.1	0.3 (200)	36.0	29.0 (−19)
26	38.8	39.3 (1)	17.6	16.5 (−6)	1.1	0.8 (−27)	28.0	37.0 (32)
Mean (SD)	26.4 (16.9)	33.3 (24.9)	16.9 (3.7)	16.4 (3.2)	0.8 (0.6)	0.7 (0.4)	33.9 (4.5)	35.9 (3.2)

Most participants were prescribed 2-3 workouts per week based on their functional assessments and personal goals. Strength training workouts were prescribed to 14 participants, aerobic workouts to 9 participants, and flexibility workouts to 9 participants. Among the 16 participants, 4 participants consistently adhered to or exceeded their workout action plan for all 3 intervention weeks. Three participants followed their action plan for 2 weeks but missed some workouts during 1 week. Four participants adhered to their prescriptions for 1 week, while the remaining participants practiced the workout occasionally but did not consistently follow the action plan throughout the intervention phase.

In terms of feasibility, all 16 participants had 100% attendance at all study meetings. On average, they maintained the connection between the smartwatch and the WheelFit app for about 59% of the time (14.2 hours) every day. This wear time satisfies the daily valid wear threshold of 10 hours per day, which has been commonly adopted in wearable device–based PA studies [42].

An average SUS score of 81.8 (SD 19.2) was found. Four participants (ie, nos. 2, 4, 10, and 16) reported an SUS score under the "poor" usability threshold of 68. In terms of the participant perception of use survey, all participants reported that the intervention was helpful in facilitating an active lifestyle, with 11 participants rating it as "very helpful," 4 rating it as "somewhat helpful," and 1 rating it as "helpful." For the subjective perception of health and function improvement, a total of 8 participants reported a "to a great extent," 6 participants reported "somewhat," and 2 participants reported "not at all." All participants expressed that they would recommend WheelFit to others.

Discussion

Principal Findings

In this study, we developed the WheelFit mHealth app to promote PA in MWUs with SCI. Following the FBM, we integrated wearable device-based PA monitoring to increase users' motivation, an adaptive workout library to enhance their abilities, and wearable push notifications and vibration alerts to trigger users to engage in PA and break sedentary behavior. We further evaluated the feasibility and usability of a PA intervention facilitated by WheelFit in MWUs with SCI through a 4-week single-group pre-post study. A total of 16 participants

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completed the study protocol with a 100% session attendance rate. Significant improvements in PA outcomes and exercise self-efficacy were observed. The WheelFit app also received a high SUS score of 81.8, with all participants reporting favorable subjective perceptions regarding the intervention. The WheelFit appears to be a feasible and potentially effective mHealth intervention for promoting PA in MWUs with SCI.

Comparison With Prior Work

In terms of the WheelFit intervention's impact on participants' PA, our results showed a statistically significant increase in average MVPA (exercise time) minutes, indicating a positive effect on exercise time among participants.

These findings align with trends observed in other mHealth interventions for MWUs with SCI. Among these interventions, the PHIRE app study is most comparable with ours, as it also used wearable devices. However, it uses a different behavior intervention strategy based on the JITAI framework. Despite the difference in some behavioral components as well as the participants' age (WheelFit: mean 48.0, SD 9.8 years; PHIRE: mean 29.3, SD 28.1 minutes), the baseline MVPA (WheelFit: mean 26.4, SD 16.9 minutes; PHIRE: mean 29.3, SD 28.1 minutes) were similar [20]. Notably, in both studies, 56% (9/16) of participants experienced a considerable (>10%) increase in MVPA minutes [20]. The WOWii study involved participants of similar age (mean 48.0, SD 9.8 years). Its virtual workout intervention, accompanied by support linkage (eg, behavior skill promotion and peer support), focused on promoting structured exercises [16]. Over the 16-week intervention phase, participants successfully increased their aerobic exercise minutes from less than 100 minutes per week to more than 150 minutes per week and their strength training frequency from less than 3 days per week to more than 3.5 days per week. During the 8-week maintenance phase, participants maintained aerobic exercise levels above 150 minutes per week and achieved an average of 3.3 days per week of strength training [16].

After a closer look into participants who had a considerable increase in exercise time, we noticed that participant numbers 2, 16, and 19 had very low baseline PA, and all expressed a desire to use the WheelFit app to form a more physically active lifestyle. Participant numbers 4 and 17 in this group reported prior experience with wheelchair sports and tried to use the WheelFit app to enhance their PA training for the upcoming games. Participant numbers 5 and 8 reported that they were driven by a commitment to maintain good health and enhance body shape. Participant numbers 3 and 15 did not report any significant motivators and simply followed the recommendations of our PT and personal trainer. For the 2 participants who had a considerable decrease in exercise time, participant number 7 reported experiencing severe chronic neurological pain that prevented this participant from engaging in PA and any of the study workouts. Chronic pain has been identified as one of the barriers to daily PA by multiple studies, including the PHIRE study [20,43,44]. Therefore, pain management is an essential factor that should be considered in future mHealth studies. Participant number 10 reported recently starting a daily routine of visiting the local gym and opted not to engage in the prescribed workouts, deeming them too easy. The significant decrease in this participant's PA amount was presumably due to the high baseline PA status and normal fluctuation in the PA routine. Of the remaining 5 participants, 4 of whom experienced a slight increase in exercise time, and 1 experienced a minor decrease.

The participants in this study have varied preparticipation PA levels. Some participants had experience in wheelchair sports, while others were novices to structured training. Additionally, some participants had limited knowledge of PA and led a highly sedentary lifestyle. During the COVID-19 pandemic, MWUs with SCI had reduced access to health care providers and decreased PA amount due to the closure of facilities and concern about infection [45]. Under this circumstance, the WheelFit intervention may benefit people with SCI in 2 ways. For those who were actively seeking engagement in PA, the WheelFit app provided a new approach to increasing PA at home and potentially alleviating the pandemic's negative impact. Participant numbers 4 and 17 were the representative cases. Such benefit may also be generalized to potential users whose PA lifestyle is affected by factors such as cold weather and geographic location [46]. On the other hand, participants who lived a sedentary lifestyle experienced less impact from the pandemic as their baseline PA was already low. The WheelFit mHealth intervention assisted these participants in starting to engage in more PA by providing PA knowledge through consultation and PA monitoring through the app. Such a trend is further supported by participants' feedback, indicating that the WheelFit app facilitated them to adopt a physically healthier lifestyle.

Overall, the statistically significant increases in daily exercise time suggest that the use of WheelFit increased participants' PA levels. In addition, the statistically significant increase in ESES scores indicates that the participants became more confident in engaging in PA. As anticipated, there was no increase in wheelchair travel distance as our PT and personal trainer advised the participants not to use travel distance as an indicator of PA level and did not use this variable to compose their action plan. More specifically, excessive wheelchair pushing may increase the risk of shoulder injury instead of bringing health benefits [47]. Regarding the sedentary breaks, we noticed that many participants had a high number of breaks that were approaching the smartwatch's battery life, indicating a ceiling effect that highlights the limitation of our current definition of sedentary breaks—2 consecutive minutes of nonsedentary PA. Currently, in SCI research, there is no consensus on the definition of sedentary behavior or the ideal bout length [48]. It has been found that breaking up sedentary bouts to under 20 minutes with at least 1 minute of nonsedentary PA could yield health benefits [49]. Validating such effects could be valuable in the SCI population as it informs the development of future mHealth interventions. Strength training was the most commonly prescribed workout, with 14 out of 16 participants selecting it as a goal due to their limited knowledge and access to appropriate resources. Notably, flexibility training was prescribed to 9 out of 16 participants—the same as aerobic training—highlighting a strong interest in addressing joint tightness and muscle pain. Despite its importance, flexibility training is often overlooked in SCI exercise guidelines, which

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primarily emphasize aerobic and strength training [7,44]. Given its role in managing muscle stiffness and pain and preventing injury, future PA studies and mHealth interventions should integrate flexibility training as a key component for this population [50].

In terms of usability, the high SUS score of 81.8 suggests that the WheelFit app had excellent usability. This is further supported by the participants' overall positive feedback regarding the app. However, the large SD of 19.2 indicates that there is a large variance in participants' perceived usability. Upon reviewing the meeting recordings and tech support records, it was found that participant numbers 2, 4, and 10 exhibited low digital literacy, a factor that has been found to negatively affect the usability of mHealth apps [51]. All 3 individuals experienced challenges in using the study smartphone and needed more assistance than others. Participant number 16, despite having good digital literacy, expressed frustration with the requirement to launch the WheelFit companion app on the smartwatch to maintain the connection. The participant also found it difficult to understand and remember the meanings of the PA variables displayed on the home page. In future studies, the assessment of digital and health literacy could be integrated into the mHealth intervention to investigate their effect on the intervention and provide personalized assistance in the MWU with the SCI population.

Given the promising outcomes, PTs can integrate WheelFit into rehabilitation by introducing adaptive workouts during sessions and empowering clients to use the app to perform and track their at-home exercises. Personal trainers working with MWUs with SCI can also leverage WheelFit to guide clients in establishing and maintaining a structured exercise routine. Additionally, WheelFit serves as a valuable self-guided tool, enabling users to independently engage in PA and adopt a more active lifestyle.

Limitations

This study was conducted during the COVID-19 pandemic. Similar to other studies during this time period, factors such as the city lockdown and the limitation of health care resources caused the high non–study-related dropout rate of our study [52]. Given its pilot nature, this study used a single-group pre-post design. Without a control group, the study is unable to draw a definitive conclusion regarding the efficacy of the WheelFit intervention on PA. The intervention comprises multiple components, such as the wearable device, WheelFit app, and personal trainer, making it challenging to discern the essential and necessary elements. The 4-week duration is relatively short compared with other mHealth intervention studies, which can range from 6 to 48 weeks. For the ESES score improvement, as the minimal clinically important difference was not established for ESES, the clinical meaningfulness of such improvement remained unknown. It is worth noting that our participants exhibited a relatively high baseline ESES score (mean 33.9, SD 4.5 points), similar to the score for "exercisers" (mean 33.7, SD 5.3 points) reported in the original ESES manuscript [33]. This is probably due to our convenience sampling approach. As a result, the efficacy of the WheelFit mHealth intervention on MWUs with SCI who live a very sedentary lifestyle remained unknown. To ensure compatibility, we provided participants with a dedicated Android study smartphone, potentially affecting their interaction with the WheelFit app compared with using the app on their personal devices. With the WheelFit companion app running continuously, the smartwatch lasts only about 10 - 11 hours before needing to be charged in the middle of the day. This limitation increased participants' burden and was the main reason for daily PA data loss. Currently, the WheelFit app connects only with 1 wheel sensor, which lacks a quick attach and detach feature, potentially limiting its ability to track wheelchair movements for individuals using multiple wheelchairs, such as a sports or backup wheelchair. Future studies should contemplate a large-scale, multistage randomized design to delve deeper into the efficacy of the WheelFit intervention and the individual contributions of its components. Exploring the use of validated tools to assess participants' digital and health literacy could offer a more nuanced understanding of its impact on app usage. Addressing pain management is also critical when developing PA interventions. Additionally, investigating strategies to enhance participants' adherence to their action plans is also valuable.

Conclusions

In this study, we developed WheelFit, a fitness app accompanied by wearable devices tailored for MWUs with SCI. The app offers population-specific PA monitoring with custom algorithms for MWUs with SCI, allowing these individuals to track their daily PA progress toward self-designated personal goals and review their PA history. It also provides an adaptive workout library, facilitating easy access to exercise options. We designed a pilot 4-week intervention using the WheelFit app, led by a PT and a personal trainer. The WheelFit app and intervention have shown promising feasibility and usability, suggesting the potential to promote PA in this population. Improvements in the app and device usability are essential for future development iterations.

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Authors' Contributions

ZH participated in the conceptualization, data curation, formal analysis, investigation, methodology, project administration, writing—original draft, and writing—review and editing. DM participated in the conceptualization, methodology, investigation, writing—review and editing. RC participated in the investigation, methodology, and writing—review and editing. TC participated

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in the conceptualization, investigation, methodology, and writing—review and editing. YC contributed to data curation, formal analysis, writing—original draft, and writing—review and editing. DD participated in the conceptualization, formal analysis, funding acquisition, investigation, methodology, project administration, resources, writing—original draft, and writing—review and editing.

Conflicts of Interest

None declared

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Abbreviations

ESES: Exercise Self-Efficacy Scale
FBM: Fogg Behavioral Model
JITAI: Just-in-time Adaptive Intervention
mHealth: mobile health
MVPA: moderate to vigorous physical activity
MWUs: manual wheelchair users
PA: physical activity
PHIRE: Personal Health Informatics and Rehabilitation Engineering
PT: physical therapists
SCI: spinal cord injury
SUPER-HEALTH: Scale-Up Project Evaluating Responsiveness to Home Exercise And Lifestyle Tele-Health
SUS: System Usability Scale
WOWii: Workout on Wheels internet intervention

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Home-Based mHealth Platform (Active-Feet) for Children With Idiopathic Toe Walking: Design, Development, and Acceptability Study

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Abstract

Background: Physical exercise and stretching programs are the best initial options to treat idiopathic toe walking (ITW). These programs are designed to improve the flexibility and strength of lower limb muscles, enhancing the ankle's range of motion and allowing for a normal gait pattern. In the pediatric population, one of the major limitations reported by therapists is low adherence to rehabilitation treatments or a lack of follow-up. In this context, children using mobile health (mHealth) tools could play an active and central role in their treatment of ITW, while mobile apps could also allow for daily monitoring by health care professionals.

Objective: This study aims to design and develop a mHealth platform for individuals with ITW. In addition, a feasibility and acceptance test of a home-based exercise program was conducted using a comprehensive mobile app intended to improve walking in children with ITW.

Methods: This study describes the context, content preparation, and mHealth platform design, as well as subsequent evaluation using a self-administered satisfaction questionnaire. Initially, the main features of the Active-Feet platform were discussed, focusing on its primary goal of helping children with ITW adhere to the rehabilitation program. However, this study did not evaluate the platform's effectiveness in improving adherence or ankle range of motion. A set of 3D avatars consisting of animated characters was designed. Posterior muscle chain stretching exercises were selected following the main guidelines. The Active-Feet development process was carried out in 5 stages: requirements specification, platform design, platform implementation, platform deployment, and alpha testing of the app.

Results: The final version of the Active-Feet app was evaluated from both the parents' and children's perspectives. Twenty patients and 1 parent per child assessed the app over 2 weeks and answered specially designed questionnaires. Parents rated the app's impact on their child's motivation and its overall effectiveness highly, with median scores of 4 (IQR 4-4). Notably, the item related to reconciling family life with rehabilitation treatment received a median score of 5 (IQR 4-5). Children's responses also indicated positive ratings for motivation and user-friendliness, with a median score of 4 (very good; IQR 3.25-4). Questions about the app's impact, helpfulness in learning, and exercise mirroring received a median score of 3 (good; IQR 3-4).

Conclusion: This study describes the development process and testing of Active-Feet, an mHealth-based platform designed to offer treatment for children with ITW. After the long process, an attractive and easy-to-use platform for ITW was developed for the first time.

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KEYWORDS

digital health; mHealth; mobile health; avatar; platform; children and caregivers; paediatric, idiopathic toe walking; telerehabilitation; app

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Introduction

The normal gait pattern is acquired during growth. Toe-walking is generally regarded as the absence or limitation of heel strike during the initial contact phase of the gait cycle [1-3]. This condition is considered a common and normal deviation until the age of 3 years; however, to keep this gait pattern beyond that age could be pathological, and a specialist evaluation should be considered [4-7].

Toe-walking is a feature present in several neuromuscular conditions, such as cerebral palsy and muscular dystrophy, as well as behavioral disorders such as autism spectrum disorder [5]. However, it can be the result of a simple contraction or shortening of the lower limb muscles, specifically the hamstrings and triceps surae. Idiopathic toe walking (ITW) is a condition of unknown etiology. Currently, ITW is a diagnosis that can only be reached once other causes for a similar pattern of gait have been excluded, mainly cerebral palsy [8,9], muscular dystrophy [10], neuropathy [11], or foot malformation [12]. ITW represents a common referral to different specialists, and the prevalence was reported to be between 5% and 12% in the pediatric population, without gender differences [7].

A comprehensive assessment of children with ITW involves a detailed physical examination and observational gait analysis. This includes evaluating the range of motion (ROM) of lower limb joints, muscle strength, and performing muscle shortening tests, along with assessing the rotational profile of the lower limbs. This approach is essential to support a clinical diagnosis and to decide the proper and most effective individualized treatment for children with ITW. Electromyography, instrumented gait analysis [4,13], or the validated "Toe Walking Tool" can be used to support the presence of ITW [14,15].

The treatment options for ITW are based on age and the presence of limited ankle ROM due to muscle shortening. Nonsurgical treatments, stretching exercises, and orthotics are the main treatment options for children who have persistent toe walking with normal ankle ROM. However, if decreased ankle dorsiflexion flexibility exists, the treatment options are intended to improve the ankle ROM using serial casting, botulinum toxin, or surgery followed by orthosis to maintain the improvement and support gait training [16,17]. The 2019 Cochrane systematic review evaluated the effects of various interventions for ITW, including both conservative and surgical treatments. While the review aimed to assess improvements in ROM, it concluded that there were no significant differences in ROM between treatment groups due to the very low certainty of the evidence [18]. Physical exercise and stretching programs are designed to improve the flexibility and strength of lower limb muscles, improving the ankle ROM and reaching a normal gait pattern. Stretching exercises could contribute to maintaining the ROM obtained after surgical treatment [16]. Exercise and stretching programs can therefore be an effective and noninvasive option for the treatment of ITW.

In recent years, there has been a great expansion of health interventions mediated through new technologies. This has been called eHealth, and it includes the use of electronic technologies and digital communication to improve health care delivery. Mobile health (mHealth) interventions have emerged to facilitate and simplify access to medical care. They allow the collection of patient care–relevant data in real time and the use of this information to monitor, diagnose, and treat patients [19]. There are different mHealth interventions that contribute to the management of certain pathologies in pediatric rehabilitation programs, such as tools developed for parents and caregivers for children with cerebral palsy [17,20,21]. These apps should be developed under the participation, advice, and supervision of health care professionals to ensure the proper functioning for the benefit of both patients and health care systems [21].

In the pediatric population, loss to follow-up is common in children with ITW [22]. One of the primary challenges reported by therapists is low adherence to home exercise programs after the conclusion of physiotherapy sessions. This observation is supported by clinical practice experiences and discussions among specialists, underscoring the necessity for innovative tools such as the Active-Feet app to enhance adherence and support long-term therapeutic outcomes. There is a growing body of evidence supporting examples where physiotherapy has benefited from digital health technologies, primarily existing in the management of musculoskeletal [23] or neurological issues [24,25]. Specific exercise tools, virtual reality, and gaming have positively influenced rehabilitation [26]. Telerehabilitation focused on children with ITW is supported by the concept that this population has grown up in a technological environment and that mobile devices are a common way for them to interact with others.

A mHealth platform specially designed to meet the needs of children with ITW would be an innovative approach to improve both adherence and effectiveness of rehabilitation programs. Furthermore, children using mHealth tools could play an active and central role in treatment and, at the same time, the mobile app would allow daily monitoring of treatment by the health care professional.

This study aims to develop and evaluate an mHealth-based platform for children with ITW. In addition, it tested the feasibility and acceptance of a home-based exercise program using a comprehensive mHealth tool to improve walking in patients with ITW. This study describes the context study, content preparation, and mobile app design, with subsequent evaluation using a self-administered satisfaction questionnaire from the perspective of parents and children.

Methods

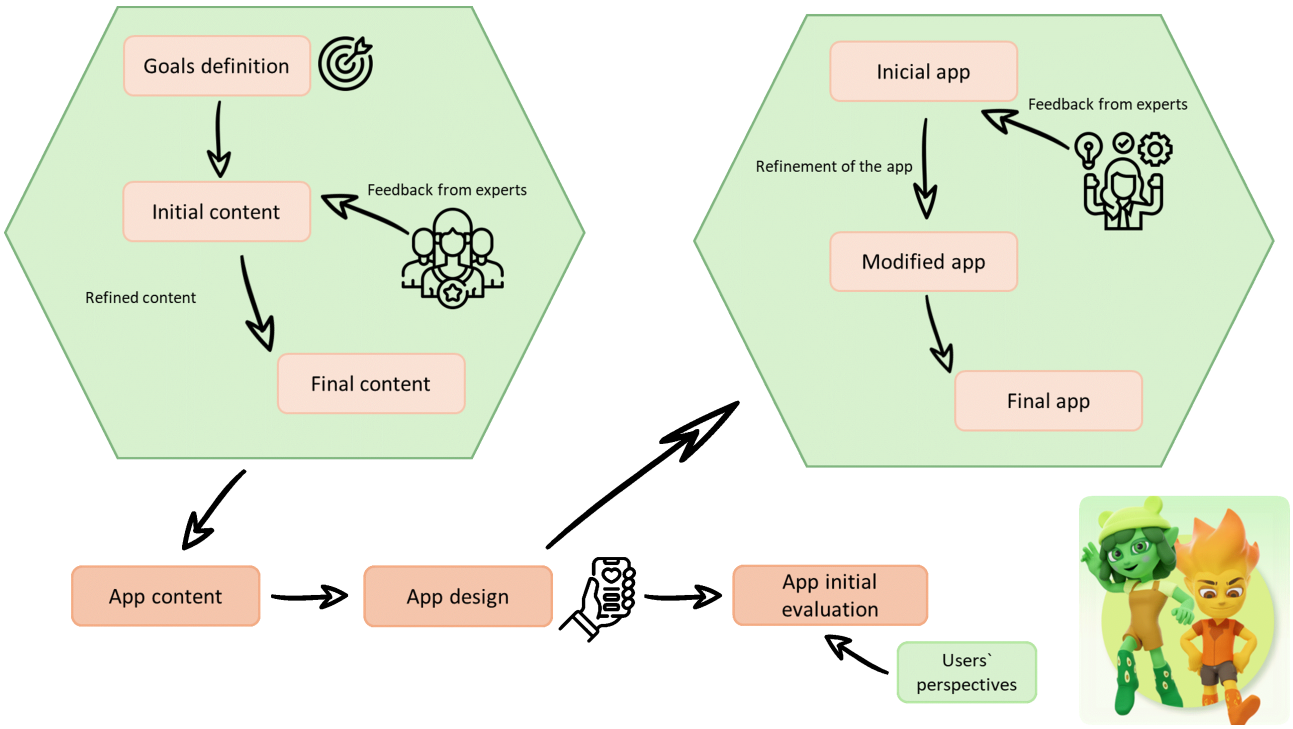
Study Design Overview

The reference population for the content development was children aged between 7 to 12 years with a diagnosis of idiopathic toe walking who attended a pediatric rehabilitation outpatient clinic. This study was conducted in three phases: (1) assessment of children with ITW needs for a home-based rehabilitation program (content preparation phase), (2) designing an attractive mobile app for children (app design phase), and (3) evaluating the app from the user's perspective (app evaluation phase).

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The development process, from conceptualization to pilot testing of the Active-Feet app, is outlined in Figure 1.

Figure 1. A schematic view of the main steps followed in the development of the Active-Feet app.



Content Preparation Phase

The original idea of developing a specific app for home-based exercise treatment in children with ITW arose from the monthly multidisciplinary meetings that take place in the pediatric outpatient rehabilitation clinic. A physiatrist, physiotherapist, and occupational therapist were involved in the initial content preparation. There were several reasons to consider a mHealth approach for rehabilitation in ITW, some of which are as follows: (1) an increasing number of referrals of children with ITW for physiotherapy treatment, (2) low post-treatment compliance with home-based exercise programs, despite written instructions on their execution. This observation is supported by clinical practice experiences and discussions among specialists, highlighting the need for tools such as an app to improve adherence, (3) the number of trips to the hospital for children and caregivers becomes disruptive for daily routines, so continuing physiotherapy sessions at the hospital was not an option for many families, and (4) performing repetitive exercises at home is not attractive for many children and could become a problem in the relationship between parents and children.

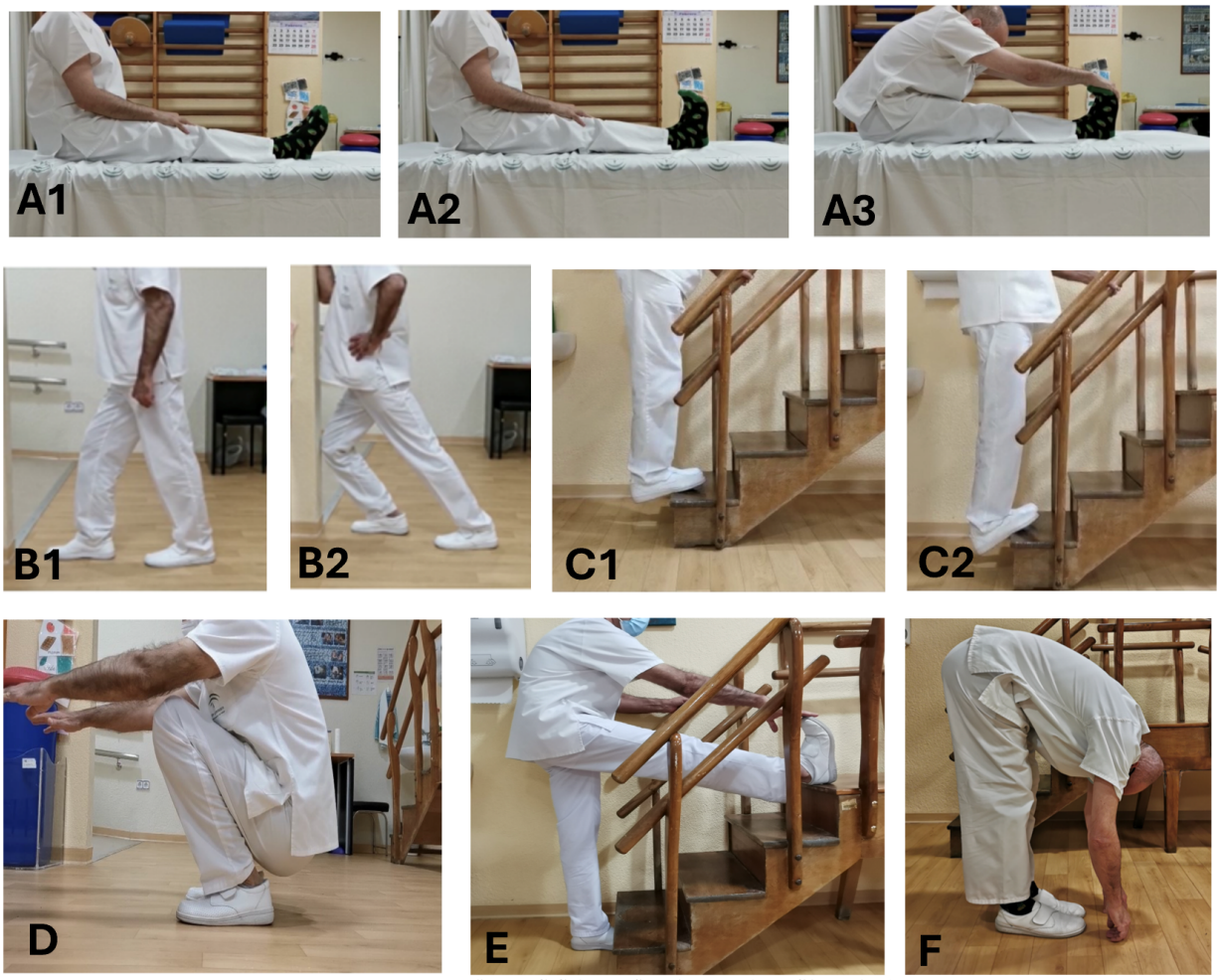
An exploratory search was carried out by researchers in PubMed, the Apple App Store, and Google Play Store, and no mobile app related to the treatment of children with ITW was found.

Initially, the main features of the Active-Feet platform were discussed, focusing on its primary goal of helping children with ITW adhere to the rehabilitation program. The app should allow health care professionals to view and to track children's compliance and execution of the exercises. At the same time, the patients could visualize themselves performing the exercises using the device's own camera. It was also considered important to develop a suitable and visually attractive app design for the pediatric population. The app should be intuitive, easy to use, and simple to access to avoid disuse. In addition, the app should be a communication channel between the physician or therapist and the patient.

In successive meetings of the multidisciplinary team, a consensus was reached regarding the type of exercises recommended for ITW. After reviewing different guidelines and considering that muscle shortening is a frequent finding, posterior muscle chain stretching exercises were chosen. The selected exercises are presented in Figure 2 and include posterior muscle chain stretches while sitting (A1-A3) and standing (F), triceps surae stretches standing (B1-B2) and using stairs (C1-C2), stretching the soleus (D), and one-leg hamstring stretch. Finally, the initial content was evaluated by senior specialists (1 physiatrist, 1 physiotherapist, and 1 occupational therapist) to get expert opinions. The initial content was finalized after applying the experts' recommendations.

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Figure 2. Main exercises: (A1-A3) posterior muscle chain sitting stretch, (B1-B2) triceps surae stretch, (C1-C2) stair (ladder) stretch, (D) soleus stretch, (E) one-leg hamstring stretch, and (F) posterior muscle chain standing stretch.



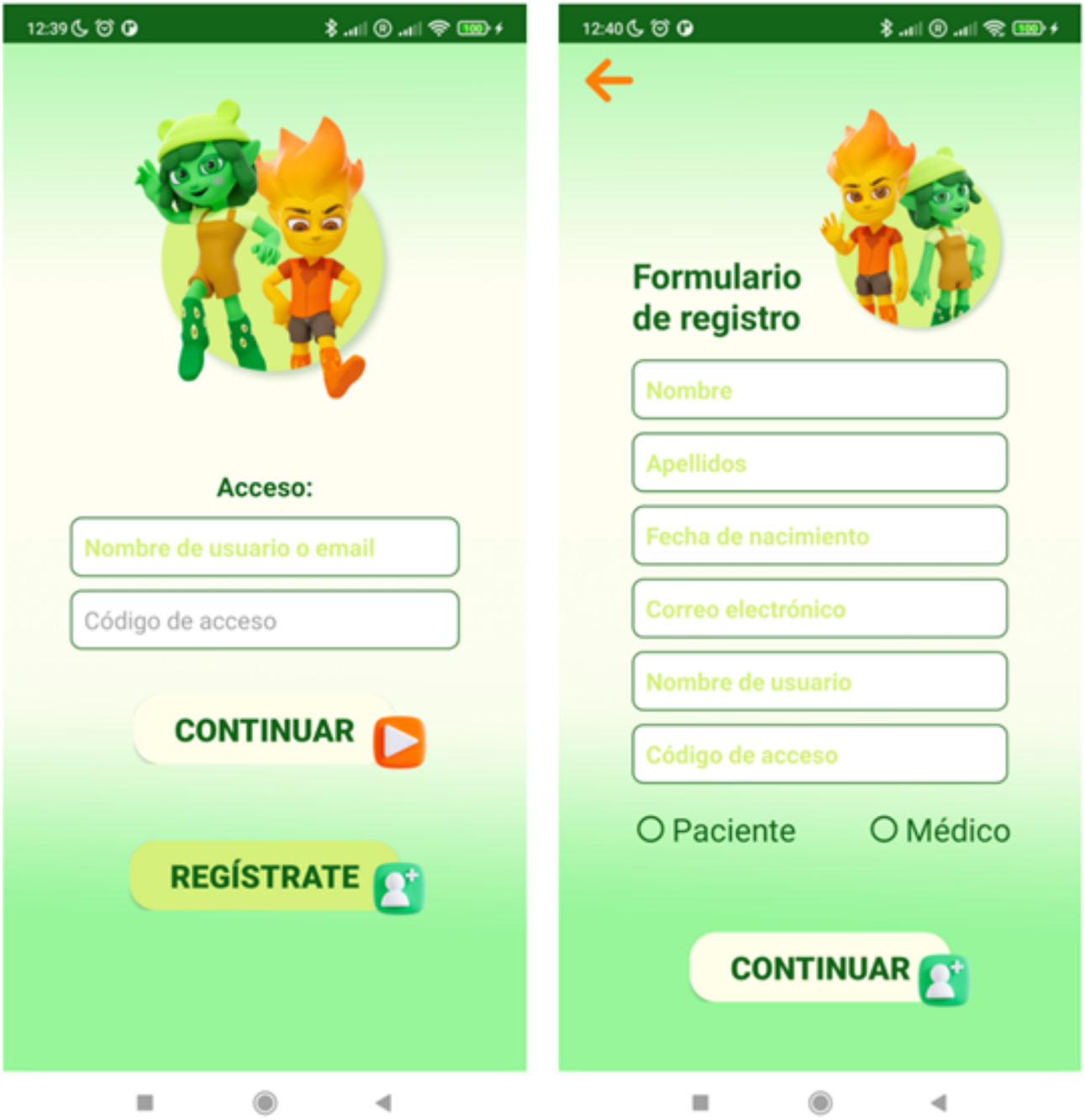
The first meeting with the computer scientists involved in the creation of the app was established. It was decided that the app should include three user profiles: administrator, patient, and health care professional. The health care professional profile (physician or therapist) should include functionality to design a customized exercise protocol for each patient. The health care professional could increase or decrease the number or intensity of sessions, eliminating or changing some of the proposed exercises and reviewing the sessions already carried out. In the same way, communications between children and therapists could be performed using the chat included in the app. The administrator role is fulfilled by both the physician, who registers the child in the app, and the therapist, who selects and adjusts the exercises weekly based on the patient's progress, including the number of sessions completed and the time dedicated to the rehabilitation program. This collaborative approach ensures both medical oversight and personalized therapeutic guidance.

Once the first design was reviewed, the researchers concluded that the appearance of the app was unattractive for children, so it was suggested to design 3D animated avatars to demonstrate the exercises as tutors. It was agreed that the avatars should meet certain requirements. The proposed characters should be visually attractive; they should bring the attention to the feet, the most important part of the body in this case. Therefore, the feet should be well-defined and subtly larger to highlight their relevance, barefoot to better visualize their movement, but they should wear striking socks to add extra visual appeal to the design.

From this entire process, TOBI and TOE characters emerged, 3D avatars enabling the guiding of the patient with ITW in performing the exercises were designed (Figure 3). At this point, the physiotherapists specialized in carrying out the chosen stretching exercises recorded themselves, and the recordings were used as templates for the avatars' motion. The exercises performed by the 3D avatars were designed to be simple and at the same time easy to mirror by children.

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Figure 3. Screenshots from the Active-Feet app showing the characters: TOBI and TOE. View to log in (left) and to request registration by a new user (right).



Platform Development Phase

The platform development process was carried out over five stages, executed sequentially: (1) requirements specification, (2) platform design, (3) platform implementation, (4) platform deployment and alpha testing of the mobile app, and (5) validation and performance testing of the mobile app (beta phase).

Stage 1: Requirements Specification

Tasks were conducted to gather both functional and nonfunctional requirements, aiming to specify the system's characteristics in terms of functionality (functional requirements): types of users, types of rehabilitation sessions, how interactions between patients and doctors would occur, and other details. In addition, nonfunctional requirements were addressed, primarily tackling three issues: (1) deployment architecture, (2) the need to enhance usability and ensure the accessibility of the app due to the needs of the end users (young patients), and (3) data protection.

Stage 2: Platform Design

In accordance with the requirements (functional and nonfunctional), a design phase was carried out. As a result of this phase, a list of use cases enumerating all the functionalities that should be present in the platform was obtained.

Furthermore, as a result of designing according to the nonfunctional requirements, it was agreed to use a client-server architecture with a single multiuser mobile app (for patients and doctors) that would display different views depending on

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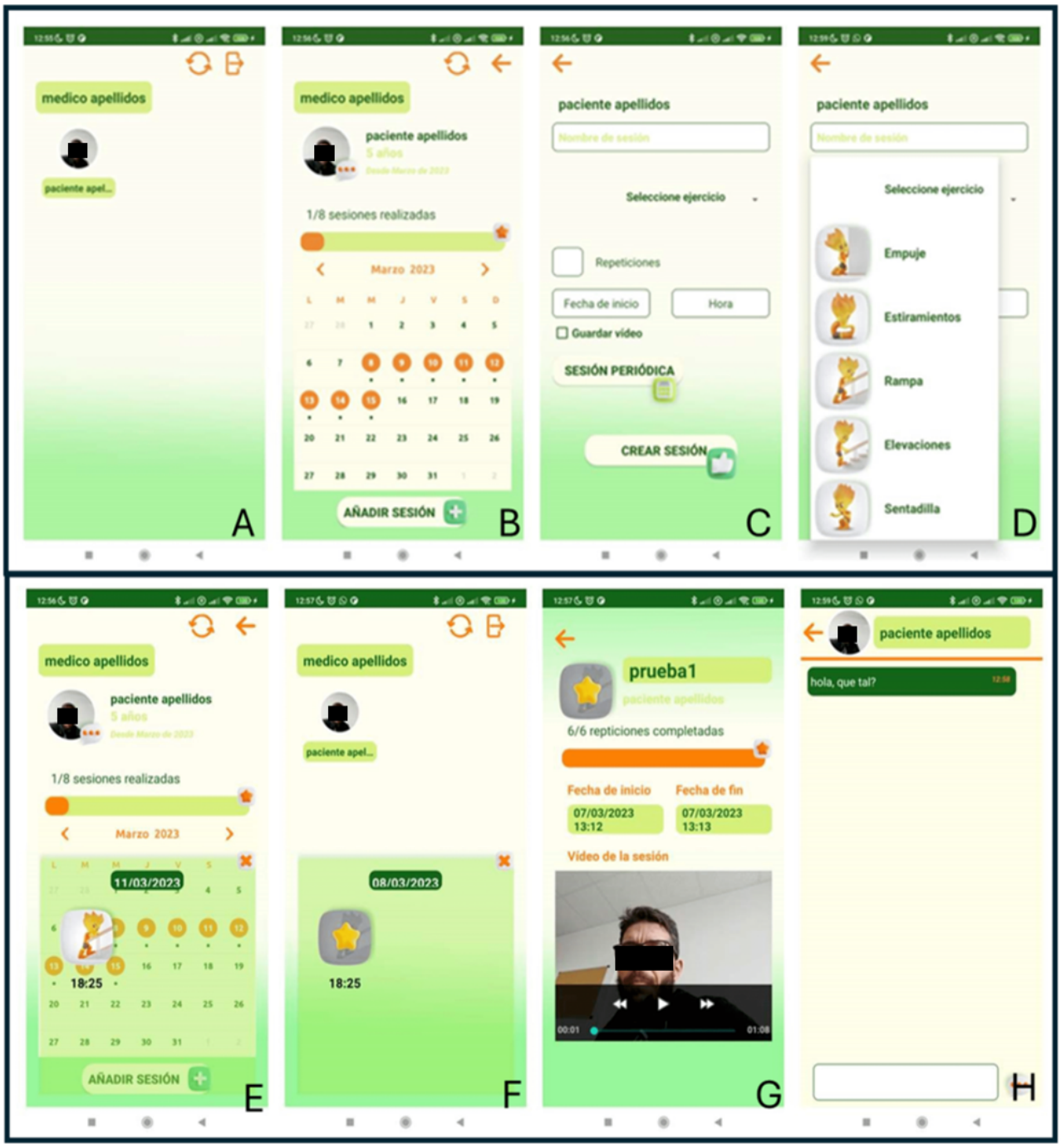
the role, as well as another view for the system administrator, which has typical administrative functions. (Figures 4 and 5 and Multimedia Appendix 1). The server is planned to serve as a provider of web services to implement part of the functionalities and as a database for information management and storage.

Figure 4. Sample of screenshots from the Active-Feet app patient profile.



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Figure 5. Sample of screenshots from Active-Feet app therapist or physician profile. (**A**) List of patients assigned, (**B**) summary of scheduled session from patient profile, (**C**) view to create a new session, (**D**) list of available exercises, (**E**) exercise scheduled to do, (**F**) exercise already done, (**G**) exercise review from record, (**H**) view from personal chat with the patient.



To ensure usability, the services of a company specializing in mobile app interface design were used. This company provided wireframes for the mobile app designed with a user-centered approach, aiming for maximum usability and accessibility.

The Active-Feet platform comprises two deployment environments: a secure backend hosted on a private server and a mobile app. The backend operates on a virtual machine with robust security and reliability measures. The mobile app was tested on 4 physical devices (2 smartphones and 2 tablets) and 2 virtual devices. Physical devices, such as the Xiaomi Redmi Note 12 and Samsung Galaxy Tab A8, demonstrated superior performance due to their advanced hardware. Conversely, the Samsung Galaxy Tab A7 Lite exhibited the lowest performance, likely due to its limited RAM and internal processes. Virtual devices also performed adequately, showcasing the platform's adaptability across varying specifications. (More detailed information is included in Multimedia Appendix 2). Overall, the platform proved compatible with low-to-mid-range devices, ensuring broad accessibility and delivering a satisfactory user experience, particularly on devices with greater processing power.

Finally, to ensure access to information, protocols were established so that only a patient and their associated doctor could access the patient's data. Similarly, doctors cannot view

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other doctors or patients for whom they are not responsible. Only the administrator can view all information. To achieve this, access control mechanisms were implemented. Furthermore, to ensure secure information exchange, all requests between the client (mobile app) and server are made securely using HTTPS and JSON Web Token.

Stage 3: Platform Implementation

The platform consists of blocks: the server-side (backend) and the mobile app (frontend). The server-side (backend) was developed using the Python programming language (Python Software Foundation) and the Flask framework (Pallet Projects) for web service creation. MongoDB (Mongo Inc.) has been used as the database management system. On the other hand, the mobile app (frontend) was implemented following the wireframes provided by the design company and implemented for the Android (Google LLC) operating system, compatible with versions 5.0 and later (since 2014).

Stage 4: Platform Deployment and Mobile App Alpha Testing

The backend (server) was deployed on a private server belonging to the University of Granada network, which was publicly accessible and equipped with security certificates. The mobile app was tested on three different devices: Xiaomi Redmi Note 8, Xiaomi Redmi Note 9, and Xiaomi Redmi Note 10. Validation tests were conducted to assess functionalities, and common errors derived from the implementation were corrected.

Stage 5: Validation and Mobile App Performance Testing (Beta Phase)

This stage is currently under development. The evaluation of the direct impact on clinical outcomes is being conducted as a second phase of the study by the research group. These follow-up investigations aim to evaluate the app's effectiveness in achieving functional improvements in children with ITW. The evaluation of exercise accuracy using the Active-Feet app will be carried out by the therapist through visual monitoring during each session. The therapist would observe the patient's posture to ensure proper alignment and movement, focusing on potential compensations at the pelvis, hips, or knees. In addition, the therapist will check whether the patient dedicates the correct amount of time to each stretch, typically 15 seconds, as specified in the treatment protocol. This process ensures that exercises are performed correctly and safely.

Exercise intensity will be monitored by progressively increasing the number of weekly repetitions for each exercise. Since patients may experience discomfort due to muscle shortening at the start of the intervention, the progression will be carefully adjusted to allow gradual adaptation and avoid excessive strain. Similarly, frequency measurements will include tracking the number of patient connections to the app, the number of days the patient engages in sessions, and the duration of each session. These combined metrics aim to provide a comprehensive understanding of patient adherence, engagement, and rehabilitation progress.

Evaluation of the App From the Users' Perspective (App Evaluation Phase)

The final version of Active-Feet app was assessed considering the perspectives of parents and children on the usefulness and attractiveness of the app, as well as the ability to encourage children to follow the home-based exercise program.

Participants for this feasibility and acceptance pilot study were required to meet the following inclusion criteria: diagnosis of ITW, aged between 7- 12 years, and ability to use an Android smartphone (with appropriate parental supervision and support). Twenty selected participants who were available and willing to cooperate assessed the app for 2 weeks. To facilitate the use of the app, a first guided use of the Active-Feet app was carried out face-to-face in the outpatient clinic by a therapist, with a detailed explanation provided to the children and parents.

Specific questionnaires were designed by the researchers (refer to Multimedia Appendix 3) and administered to both parents and children following the 2-week app testing period. The answers from adults were measured based on a 5-point Likert scale, while the questionnaire for the pediatric population was evaluated using a 4-point visual analog scale. To summarize data distributions, the median and IQR (25th-75th percentile) were calculated for all Likert scale responses. After collecting the questionnaires from parents and children, the data were analyzed using SPSS software (version 24; IBM Corp).

Ethical Considerations

Ethical approval for this study was obtained from the Granada Research Ethics Committee (CEI Granada; approval code: 95133). Written informed consent was obtained from all adult participants and from the parents or legal guardians of the children involved in the app evaluation. Children also provided assent prior to participation. All personal data collected during the study were anonymized to ensure participant privacy and confidentiality in accordance with applicable data protection regulations. No monetary compensation was provided to participants for their involvement in the study.

Results

Demographic and Physical Characteristics of the Participants

A total of 20 children participated in the study. The median age of the children was 10 (IQR 9-11) years, the median weight was 42.8 (IQR 35.6 - 55.7) kg, and the median height was 148 (IQR 138 - 160) cm.

Regarding ROM and flexibility measurements, the median plantar flexion was 70° for both the right and left sides, with IQRs of 60° - 75.5° for the right and 60° - 74° for the left. Median dorsiflexion with the knee extended was 0° on the right side (IQR −3.5° to 0°) and 1° on the left side (IQR −5° to 4°). With the knee flexed, median dorsiflexion was 10° bilaterally, with IQRs of 6° - 12° for the right and 8.5° - 13.5° for the left. The Silfverskiöld test was positive in all participants, confirming restricted dorsiflexion with the knee extended. Further details of the measurements conducted on the participants can be found in Multimedia Appendix 4.

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Characteristics of Parental and Children Questionnaires

Three main sections were considered in each questionnaire: (1) questions about the ease of use or user-friendliness, (2) questions about the impact of the app, and (3) attractiveness of the app and user feedback. All these aspects were addressed in both questionnaires using appropriate language for each group—parents and children.

A total of 20 parents, 1 per child in the study, completed the questionnaire. The ease of the registration process, learning to run the app, and access to different sections were the main questions assessed from parents (questions 1, 2, and 3). Regarding the impact of using the app, a question was addressed to the enhancement of their child's motivation with the app (question 4). Finally, acceptance and attractiveness were addressed by asking whether the content was appropriate for their children (question 5) and whether the app was helpful for the reconciliation of family life and the rehabilitation process (question 6).

In the questionnaire addressed to the children (n=20), questions were asked about how much fun they found (question 1) and their motivation to do the exercises daily (question 5). They were also asked whether they liked the avatars, as a measure of acceptance and attractiveness (question 2). Regarding the impact of using the app, questions addressed how the avatars helped them do the exercises (question 3) and whether the exercises shown by the avatars were easy to mirror (question 4).

Questionnaire Results From Parents and Children

The interaction between children and parents with the app technology was well received by all participants. In general, they were pleased with the quality of the graphical user interface, ease of navigation, and the overall impression of how patients interact with the mHealth system.

The parental question regarding the improvement of the child's motivation to perform the exercises (question 4) received one of the highest scores, followed by the section addressing the impact of using the app (question 5). Finally, the aspects related to the app's ease of use (questions 1 and 3) and learnability (question 2) were also rated highly by participants (Multimedia Appendix 5). The median score for the first 5 questions was 4 (IQR 4-4). The item referring to the reconciliation of family life with the rehabilitation treatment of their children (question 6) was highly appreciated by parents, showing a median of 5 (IQR 4-5). The overall mean percentage of parents responding "4" across all parental questions was 72.5%. Only 5% of the parents' responses scored 3 or lower on the Likert scale.

Children's responses to questions on user-friendliness and motivation demonstrated positive outcomes. For question 1, which assessed whether performing the exercises was an enjoyable experience, the median score was 4 (very good) with an IQR of 3.25-4. Similarly, for question 5, which evaluated whether children remembered to perform the exercises daily with TOBI and TOE, the median score was also 4, with an IQR of 4-4. Questions regarding the impact of use, the app's helpfulness in learning (question 3), and the ease of mirroring exercises (question 4) received a median score of 3 (good) with an IQR of 3-4. Regarding the acceptance and attractiveness of the app (question 2), children expressed positive feedback, with a median score of 3 (IQR 3-4). They found the avatars to be delightful and engaging. The overall mean percentage of participants responding with a score of 4 across all children's questions was 52%. No responses of "Bad" or "Very Bad" were recorded.

Discussion

Principal Findings

The aim of this study was to develop and implement an app for telerehabilitation in children with ITW. The findings of this research suggest that the Active-Feet mHealth-based platform is feasible for children. An attractive and easy-to-use app, designed to help patients perform exercises following the instructions of 3D avatars, was developed during the process. At the same time, the Active-Feet app allows for recording completed exercises, enabling the therapist to track the frequency, intensity, and accuracy of performance through their app profile. Corrections or recommendations via chat between the therapist and patient can improve interaction quality and provide guidance to users in the event of errors. Collecting real-time health care data from patients and using this information to monitor, diagnose, and treat them is one of the main advantages of mHealth tools [19].

The approach of ITW shows a lack of consensus regarding optimal conservative management. A wide variation in treatment across providers and institutions exists. However, stretching exercises are advocated as the core management for ITW [16,18]. Mobile apps can incorporate positive behavior change techniques to improve exercise adherence and thus optimize clinical benefits. In children with ITW, loss to follow-up is common [22], and long-term adherence remains challenging. Promoting the reconciliation of daily routines and rehabilitation treatment is important to avoid noncompliance to the treatment. Moreover, telerehabilitation improves patients' access to rehabilitation services and saves patient time traveling to the hospital or rehabilitation center. Evidence suggests that there are many potential applications to be explored to enhance connectivity of the interdisciplinary rehabilitation team in the pediatric population [27]. All these elements were considered in developing the Active-Feet platform.

Although the evaluation of the Active-Feet app did not use the Mobile App Rating Scale (MARS) used in previous studies, the questionnaires administered to assess the app revealed higher user engagement and satisfaction scores compared to similar mHealth apps. For example, pain-related apps evaluated with MARS achieved an average overall score of 3.17 out of 5, with functionality rated the highest and engagement often scoring lower [28]. In contrast, the Active-Feet app demonstrated strong user satisfaction and engagement among parents and children, highlighting its ability to effectively meet the needs of its target population. These findings emphasize the potential of the Active-Feet app to serve as a valuable tool for enhancing adherence and motivation in rehabilitation contexts.

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App Usability and Acceptability

This study describes the entire process of developing a specific app to perform the rehabilitation treatment for ITW in a complex population. The Active-Feet app showed to be attractive and easy enough to use for children and parents. Currently, there is no other app that has been developed for this condition, so no comparison can be made. The reference for this research was supported and guided by previous home rehabilitation interventions administered from our group of researchers in developing mHealth systems [29,30]. This paper assembles the preliminary qualitative and quantitative data on usability and acceptability of the Active-Feet app for conducting the home-based exercise program and to explore potential outcomes of the intervention. The direct impact on clinical outcomes such as adherence to rehabilitation protocols or improvements in ROM was not assessed in this study. Future research should focus on overcoming these limitations by using longitudinal studies with objective measures to assess how effective the app is in improving adherence and functional outcomes in children with ITW.

Potential Broader Applications

It is important to consider the impact on special groups of children using digital characters or avatars during rehabilitation treatment and the advantages of these kinds of mHealth systems. It was reported that patients with autism have shown benefits, such as being able to resemble the movements of the avatar [31]; improved the ability to recognize and express basic emotions [32]; and increased the capability for social interactions by practicing verbal and nonverbal behavior in virtual reality environments [33]. Autistic children who exhibit toe walking are generally not classified as ITW, and additional considerations may be needed for their cognitive and behavioral differences. Consequently, while this app is primarily designed for idiopathic toe walkers, it could also serve as a valuable tool for children with toe-walking behaviors associated with conditions such as autism or other motor impairments, provided appropriate adaptations are made. In addition, a recent systematic review of mobile apps for patients with chronic conditions or multimorbidity has called for further research to develop and evaluate apps that are both high quality and have a high capacity to promote positive behavior change in patients [34].

Limitations

This study had additional limitations. Twenty participants collaborated with the researchers to assess the app. Although some studies suggest that this sample size in usability tests can identify over 80% of usability issues [35,36], it may not capture all potential problems. In future research, we should consider a larger sample size and a more extended period of follow-up. The missing information regarding the participants' previous knowledge of the exercises was another limitation of this study. In addition, the assessment of exercise accuracy relied on visual monitoring by the therapist; however, the lack of quantitative metrics such as joint movement tracking may limit the precision and consistency of exercise evaluation. Future research could benefit from incorporating motion tracking technologies to provide more objective and accurate assessments of exercise performance.

The use of a custom-designed satisfaction questionnaire instead of a standardized usability assessment tool, such as the System Usability Scale (SUS), was also a constraint in our research. While our questionnaire was specifically tailored to suit the linguistic and cognitive needs of a pediatric population, it limits the comparability of our findings with those of other studies. Future studies should consider incorporating validated and widely used scales to enhance the generalizability of results.

Strengths and Future Directions

Finally, the findings of this study reveal the structure and process aspects of developing and optimizing a mobile app aimed at the pediatric population. However, the implementation of the Active-Feet app is not recommended until feasibility and effectiveness have been demonstrated in appropriately designed randomized controlled trials. This study also has strengths. First, the acceptance and satisfaction of the intervention have been demonstrated by users and parents. Second, the Active-Feet app was developed for both mobile and tablet devices. Third, to our knowledge, this is the first study showing the entire process of a mHealth platform created to deliver telerehabilitation programs for children with ITW.

Conclusions

Exercise and stretching programs can be an effective, noninvasive option for the treatment of ITW in children, and the use of mobile apps is an alternative for home-based treatment programs. Although the Active-Feet app has been implemented in patients with ITW, its use could potentially be extended to children who exhibit toe walking as a frequent finding, such as those with autism spectrum disorders. This study describes the entire process of developing a mHealth system, and an attractive, easy-to-use mHealth platform for children with ITW was developed for the first time. Future studies should evaluate long-term effectiveness of the app and determine whether it should be recommended for patients, relatives, or health care professionals.

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promotion, Area of Advanced Therapies and Biomedical Technologies (IBS-TECE20). The research group is from the Physical Medicine and Rehabilitation Department at the University Hospital “Virgen de las Nieves,” Granada, Spain.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample of screenshots from Active-Feet app administrator profile.
[DOCX File, 370 KB - rehab_v12i1e60867_app1.docx]

Multimedia Appendix 2
Technical specifications physical devices.
[DOCX File, 25 KB - rehab_v12i1e60867_app2.docx]

Multimedia Appendix 3
Questionnaire for parents and children.
[DOCX File, 254 KB - rehab_v12i1e60867_app3.docx]

Multimedia Appendix 4
Demographic and physical characteristics of the participants.
[DOCX File, 25 KB - rehab_v12i1e60867_app4.docx]

Multimedia Appendix 5
Results from questionnaires with the Active-Feet app performed by parents and children. (A) Frequencies of parents’ responses and (B) frequencies of children’s responses.
[PNG File, 254 KB - rehab_v12i1e60867_app5.png]

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Abbreviations

ITW: idiopathic toe walking
MARS: Mobile App Rating Scale
mHealth: mobile health
ROM: range of motion
SUS: System Usability Scale

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Personalized Predictions for Changes in Knee Pain Among Patients With Osteoarthritis Participating in Supervised Exercise and Education: Prognostic Model Study

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Abstract

Background: Knee osteoarthritis (OA) is a common chronic condition that impairs mobility and diminishes quality of life. Despite the proven benefits of exercise therapy and patient education in managing OA pain and functional limitations, these strategies are often underused. To motivate and enhance patient engagement, personalized outcome prediction models can be used. However, the accuracy of existing models in predicting changes in knee pain outcomes remains insufficiently examined.

Objective: This study aims to validate existing models and introduce a concise personalized model predicting changes in knee pain from before to after participating in a supervised patient education and exercise therapy program (GLA:D) among patients with knee OA.

Methods: Our prediction models leverage self-reported patient information and functional measures. To refine the number of variables, we evaluated the variable importance and applied clinical reasoning. We trained random forest regression models and compared the rate of true predictions of our models with those using average values. In supplementary analyses, we additionally considered recently added variables to the GLA:D registry.

Results: We evaluated the performance of a full, continuous, and concise model including all 34 variables, all 11 continuous variables, and the 6 most predictive variables, respectively. All three models performed similarly and were comparable to the existing model, with R^2 values of 0.31 - 0.32 and root-mean-squared errors of 18.65 - 18.85—despite our increased sample size. Allowing a deviation of 15 (visual analog scale) points from the true change in pain, our concise model correctly estimated the change in pain in 58% of cases, while using average values that resulted in 51% accuracy. Our supplementary analysis led to similar outcomes.

Conclusions: Our concise personalized prediction model provides more often accurate predictions for changes in knee pain after the GLA:D program than using average pain improvement values. Neither the increase in sample size nor the inclusion of additional variables improved previous models. Based on current knowledge and available data, no better predictions are possible. Guidance is needed on when a model's performance is good enough for clinical practice use.

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KEYWORDS

osteoarthritis; prediction; pain intensity; exercise therapy; machine learning

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Introduction

Background

Osteoarthritis (OA) is a chronic disease characterized by persistent joint pain and limited mobility, especially for those who experience from OA of the knee [1]. In the United States alone, the overall economic burden of OA is estimated at almost US $140 billion annually, highlighting the substantial societal and personal costs associated with the condition [2]. Pain is the most important outcome for patients with OA, with moderate to severe pain associated with greater functional limitations, treatment dissatisfaction, and reduced quality of life [3]. In managing OA, patient education and exercise therapy, which are the recommended first-line treatments according to clinical guidelines, play a critical role [4-6]. Treatment programs that combine therapeutic exercise with other treatments such as weight loss [7], manual therapy, and pain education have shown promising results in managing mild to moderate OA symptoms and provide complementary options to improve patient's pain, function, and quality of life [8,9]. Patient education further empowers individuals by enhancing their understanding of the disease and emphasizing the importance of lifestyle adjustments such as a balanced diet and regular exercise [10].

Prior Work

However, the implementation of recommended treatments could be improved [11]. The discrepancy between recommended and provided treatments has been attributed to several factors, including health care providers offering no evidence-based care and patients' lack of motivation and awareness about the long-term benefits of the recommended therapies [12,13]. Furthermore, some patients are hesitant to participate in exercise therapy programs, either because they are uninterested or face logistical difficulties [14,15]. It is relevant to develop strategies that assist clinicians and patients in an engaging way in the treatment decision process such as offering personalized outcome predictions.

Digital technology presents a promising solution to address such challenges in health care. Prediction models, particularly, have emerged as powerful tools to support patients and health care professionals in the treatment decisions and management of chronic diseases like OA [16-18].

The Goal of This Work

The GLA:D (Good Life with osteoArthritis in Denmark) program has garnered significant attention as a pioneering initiative in OA management [19]. Comprising three components—training for physiotherapists, a patient education and neuromuscular exercise therapy program delivered to patients, and clinical data collection—the program stands out as an example of evidence-based care [19]. To support shared decision-making, the acceptance, and participation rate of programs like GLA:D, we aimed to validate an existing model and introduce an updated concise personalized prediction model that estimates changes in knee pain intensity for patients with OA considering participation in the GLA:D program [20].

Methods

Overview

This paper follows the guidelines of TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) [21].

In this paper, we reproduced and validated the results of previous work [20] with some methodological changes as described below.

Source of Data and Participants

We used data from the Danish GLA:D initiative for patients with knee and hip OA. The initiative consists of a 2-day course for physiotherapists, a patient treatment program delivered in clinical practice, and a registry of data reported by patients and clinicians. The patient program combines 2 patient education and 12 supervised exercise therapy sessions aiming at improving symptoms, physical function, and quality of life. Patients can join the GLA:D program through referrals from health care professionals (eg, general practitioners or orthopedic surgeons) or via self-referral, followed by an assessment by a certified GLA:D clinician to confirm the OA diagnosis [22-25]. By 2023, in total, 257 clinics were offering the GLA:D program for knee or hip OA [26]. Of these, most clinics were private practices, but 20 clinics were public municipalities, and 2 municipalities offered the treatment for employees.

The GLA:D registry collects data from participants, which includes demographic details, medical history, pain intensity, and physical function measures [27]. The data are collected at three time points: at baseline, immediately following the program, and at 12 months follow-up. GLA:D was established in 2013 and is regularly updated to include new evidence. Comprehensive details about GLA:D's education, neuromuscular exercise program, and general information are previously available [19]. For this paper, we followed the inclusion criteria of a previous publication [20] but with an extended inclusion period from October 9, 2014, to November 12, 2022, instead of ending on August 31, 2017. We included patients who indicated their knee as the primary joint of complaint and provided complete data. We excluded participants for specific time periods due to technical problems in the registry, meaning one of our variables of interest was not collected. This was the case between May 13, 2016, and November 12, 2016, and April 10, 2018, and August 05, 2019.

Variable Selection

Outcome

"Change in pain intensity" was our outcome of interest. This measure was calculated by determining the difference in pain scores on the visual analog scale (VAS) from baseline to immediately after the program (after about 3 mo). The question asked to the patients was "On a scale that goes from no pain (0 mm) to worst pain imaginable (100 mm), what score best represents your knee pain during the last week?" [28]. We examined various thresholds, ranging from 5 to 20 mm, to define a significant change in pain intensity.

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Predictor Variable Selection

Our analysis incorporated 34 potential predictor variables: 11 continuous, 22 binary, and 1 with three categories. These variables were chosen for their relevance to knee OA and health outcomes, encompassing factors like clinical symptoms, lifestyle influences, and demographic details, to provide a comprehensive understanding of the disease's impact and patient outcomes. In comparison to the earlier study, we included 17 fewer variables (diabetes, S12 physical component and mental score, American Shoulder and Elbow Surgeons Shoulder Score pain and other symptoms score, and some medical disease) since their collection stopped (for 4 variables in 2018, for 2 variables in 2020, and for 12 variables, their collection stopped in 2021).

Selection of Important Variables

We used random forest regressions during variable selection and model development. The random forest regressor is an ensemble model that efficiently reduces variables without overfitting and captures complex, nonlinear relationships between predictors and the outcome variable [29]. Random forest regression was previously used on the GLA:D dataset to predict changes in VAS pain considering 51 variables in the training process; its performance is similar to a linear regression [20]. The preprocessing of our dataset was performed according to the previous study results, which we aim to validate [20].

We applied a 2-step variable selection process to optimize our predictive model and attempt to achieve clinical acceptance. Initially, we started with 34 predictor variables. To reduce the number of variables, we first evaluated the variable importance using Gini impurity [30]. The Gini index or impurity measures the probability of a random instance being misclassified when chosen randomly. The Gini impurity method evaluates the importance of each variable by examining how much it contributes to reducing impurity when used as a split criterion in decision trees [31]. Variables with higher Gini importance scores are considered more important in making accurate predictions. In many implementations, like scikit-learn's random forest, the Gini importance scores are normalized such that they all sum up to 1. Therefore, each variable's importance score will range between 0 and 1, with higher values indicating greater importance. We built and trained random forest regressor models, incorporating the top k variables, with k determined using the elbow method. The elbow method is a straightforward technique for determining the optimal number of variables in a model. It involves identifying the point at which adding more variables leads to diminishing returns, meaning their contribution to overall model performance becomes negligible [32]. To enhance the robustness of our analysis, we used cross-validation during the variable importance assessment.

The Gini coefficient is mathematically represented as:

$$Gini=1-\sum i=1C(pi)2$$

In the second step, we respected the importance of the individual variables and the elbow technique, as well as applying clinical reasoning to reduce and find the ideal set of variables. While this reduction of variables could potentially reduce the model's performance, we limited the number of questions, such that it would be convenient for end users to use the model, thereby increasing the likelihood of its clinical value.

With this 2-step approach, incorporating both Gini impurity and clinical reasoning, we aimed to achieve a balanced model that is both predictive and user-friendly.

Model Development and Evaluation

To develop and evaluate our predictive model, we began by splitting our dataset into two subsets: a training set for model development and a test set for validation. The training process was consistently applied on all models, regardless of training on all variables, on the top k predictor variables, or on a concise set of variables. To enhance the robustness and generalizability of our models, we integrated 10-fold cross-validation with random forest regression. Using the test sets, we validated our findings, ensuring that our results were not biased or limited to specific data instances by averaging results across the cross-validation test sets.

To evaluate the performance of the models, we used the root-mean-squared error (RMSE) and R^2 metrics. RMSE measures the average deviation between the predicted and actual values, providing an assessment of the model's accuracy. The R^2 represents the proportion of variance the model explains and indicates how well the model fits the data. To compare our personalized outcome predictions with predictions of the average model, we evaluated the number of correct predictions, in contrast to the previous publication, which used the absolute mean differences in a test dataset [20].

The predicted changes in pain intensity by our random forest regression constitute the personalized predictions. The average model prediction was defined as a mean function of the VAS pain change score of the training samples, $\mu=\sum n=1NVASChangeScoreN$. The average model always provides μ, regardless of the features of the unseen samples, as the predicted change in pain intensity. In this paper, we are always focused on the VAS pain change score, rather than the pain score at a specific time point. Recognizing that predictions inherently have some margin of error, we incorporated in our evaluation a margin of error that corresponds to a clinically relevant threshold.

$$In=\{1:if\ Ln\leq Predn\leq Un0:otherwise$$

In is the indicator value that will be one for cases where their predicted change in pain value is inside the interval. For all other samples, it is zero. $Ln=VASChangeScore-R$ and $Un=VASChangeScore+R$ show the lower and upper bound based on the clinical relevance threshold R. Finally, we calculate the percentage of predictions inside the interval ρ to evaluate and compare our model against the average model:

$$\rho=\sum n=1NInN.$$

Since the value of a clinical relevance R is debatable and ranges up to 20 mm [33-35] points, we evaluated the number of correct predictions with different tolerable margins of error, ranging from 5 to 20 points. Thus, we calculated the number of correct predictions for several cases, the first allowing a deviation of 5 points and the last allowing a deviation of 20 points from the true change in pain.

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All data analyses were performed in Python (Python Software Foundation) using Scikit-learn, Pandas, and NumPy libraries [36]. We used Pandas and NumPy for data preprocessing tasks, such as cleaning and variable scaling. Scikit-learn was used for validation techniques, including train-test split, cross-validation, and stratified sampling. We used standard hyperparameters for the random forest regression: n_estimators set to 100, max_depth limited to 10, and random_state fixed at 42. We chose to use them to provide a baseline performance that can be compared with other standard implementations.

Supplementary Analyses

To evaluate if the inclusion of recently added variables to the GLA:D registry improved our outcome predictions, we additionally developed and evaluated models following the same process as described above, but including 12 additional variables (load-related pain, reduced functional capacity, morning stiffness, crepitus, reduced knee movement, bony enlargement, previous joint injury, occupational or recreational overuse, family members with OA, Knee Injury and Osteoarthritis Outcome Score-12 pain, functioning, and Knee Injury and Osteoarthritis Outcome Score-12 summary score, which were added to the registry in May 2018). A flowchart for this additional analysis is provided in Figure S2 in Multimedia Appendix 1 [37].

Ethical Considerations

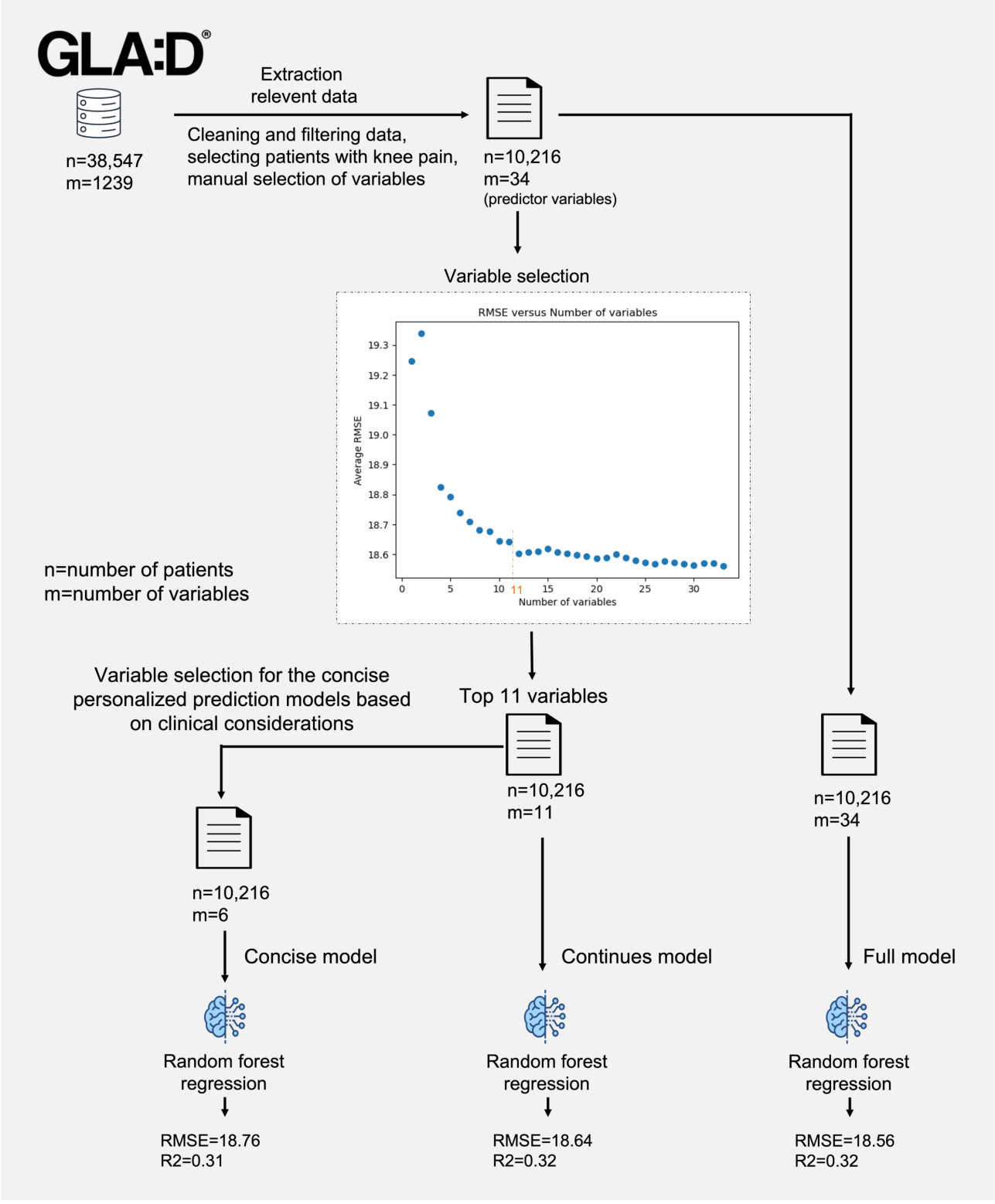
This study did not require ethics approval or clinical trial registration, as determined by the local ethics committee of the North Denmark Region, since it was a register-based study rather than a clinical trial. The GLA:D registry has been approved by the Danish Data Protection Agency, ensuring compliance with data protection regulations. In accordance with the Danish Data Protection Act, patient consent was not required, as personal data were processed solely for research and statistical purposes. To protect participant confidentiality, all data were anonymized before analysis, with no access to personally identifiable information. Data handling followed the regulations of the Danish Data Protection Agency. No compensation was provided to participants, as this study relied on secondary data analysis of the GLA:D registry.

Results

A brief overview of our results is displayed in Figure 1.

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Figure 1. A brief overview of the personalized prediction to predict changes in knee pain in patients with knee osteoarthritis. RMSE: root-mean-squared error.

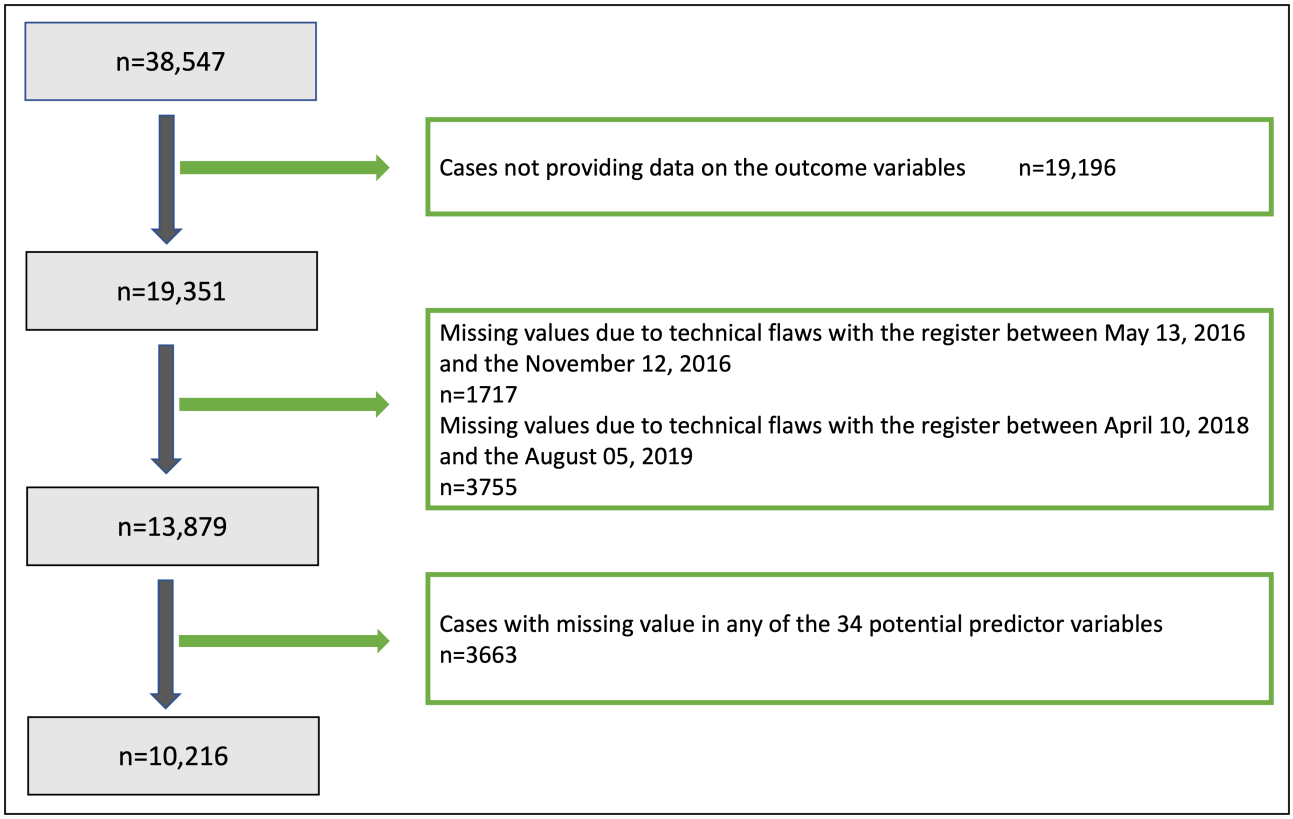


Source of Data and Participants

A total of 38,547 patients fulfilled our inclusion criteria for participating in the GLA:D program between October 9, 2014, and November 12, 2022. We considered patients with knee pain as the primary complaint and our analytical dataset was reduced to 10,216 patients. Details on the process of patient inclusion and exclusion are available in Figure 2.

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Figure 2. Flowchart of patient selection and data exclusion criteria for the study, showing initial cohort size and subsequent exclusions due to specific criteria and missing data.



Variable Selection

The Gini impurity scores for all variables are presented in Figure S2 in Multimedia Appendix 1 [37]. The characteristics of all included and excluded samples are provided in Table 1. Based on these findings, we applied the elbow method and included the top 11 variables (Figure 3).

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Table . Characteristics of all included and excluded participants.

Variable	Included cases (n=10,216)	Excluded cases (n=28,331)
Predictor variables		
Age		
Mean (SD)	65.01 (9.36)	65.08 (9.81)
Range (min-max)	23 - 94	18 - 100
Missing, n (%)	—[a]	0 (0)
BMI		
Mean (SD)	28.61 (5.28)	29.03 (5.53)
Range (min-max)	15.23 - 70.03	14.41 - 72.27
Missing, n (%)	—	218 (0.77)
Sex, n (%)		
Male	2892 (28.31)	8606 (30.38)
Female	7324 (71.69)	19,725 (69.62)
Missing	—	0 (0)
Duration of symptoms: how long has the patient had the symptom in the most painful joint? (months)		
Mean (SD)	43.05 (66.91)	34.34 (56.65)
Range (min-max)	0.0 - 756.0	0.0 - 840.0
Missing, n (%)	—	3170 (11.19)
Waitlisted for knee or hip surgery, n (%)		
Yes	174 (1.70)	353 (1.25)
No	10,042 (98.30)	19,365 (68.35)
Missing	—	8613 (30.40)
Radiographic signs of knee OA[b], n (%)		
Yes	8020 (78.50)	22,161 (78.22)
No	396 (3.88)	925 (3.26)
Unknown	1800 (17.62)	4947 (17.46)
Missing	—	298 (1.05)
Previous contact with physiotherapist because of the current joint problems, n (%)		
Yes	3437 (33.64)	9118 (32.18)
No	6779 (66.36)	19,212 (67.81)
Missing	—	1 (0.003)
Use of painkillers (paracetamol or NSAID[c] or opioids) in the last three months, n (%)		
Yes	6382 (62.47)	17,638 (62.26)
No	3834 (37.53)	10,693 (37.74)
Missing	—	0 (0)
Prior surgery in the index joint, n (%)		
Yes	2842 (27.82)	7390 (26.08)
No	7374 (72.18)	20,941 (73.92)
Missing	—	0 (0)
Time to complete 40-m walking test		
Mean (SD)	28.23 (7.98)	29.04 (8.80)
Range (min-max)	10.0 - 234.91	10.0 - 221.02

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Variable	Included cases (n=10,216)	Excluded cases (n=28,331)
Missing	—	2452 (8.65)
Use of walking aid during the 40-m walking test, n (%)		
Yes	177 (1.73)	534 (1.88)
No	10,039 (98.27)	26,009 (91.80)
Missing	—	1788 (6.31)
Number of chair stands during 30 seconds		
Mean (SD)	11.97 (3.70)	11.81 (3.95)
Range (min-max)	0.0 - 35.0	0.0 - 40.0
Missing	—	1794 (6.33)
Born in Denmark, n (%)		
Yes	9844 (96.36)	27,102 (95.66)
No	372 (3.64)	1221 (4.31)
Missing	—	8 (0.03)
Danish citizen, n (%)		
Yes	10,055 (98.42)	27,827 (98.22)
No	161 (1.58)	496 (1.75)
Missing	—	8 (0.03)
Living situation (are you living alone or with others?)[d], n (%)		
Yes	2461 (24.09)	7409 (26.15)
No	7755 (75.91)	20,914 (73.82)
Missing	—	8 (0.03)
Educational level: Do you have a higher education than secondary education? n (%)		
Yes	7266 (71.12)	13,907 (49.09)
No	2950 (28.88)	5802 (20.48)
Missing	—	8622 (30.43)
Smoking, n (%)		
Yes	787 (7.70)	2567 (9.06)
No	9429 (92.30)	25,757 (90.91)
Missing	—	7 (0.02)
Previous injury in the index joint that caused you to consult a medical doctor, n (%)		
Yes	5268 (51.57)	14,500 (51.18)
No	4948 (48.43)	13,818 (48.77)
Missing	—	13 (0.05)
Pain in hip or knee other than the index joint?, n (%)		
Yes	5906 (57.81)	16,478 (58.16)
No	4310 (42.19)	11,853 (41.84)
Missing	—	0 (0)
Walking problems due to the knee/hip problems, n (%)		
Yes	7811 (76.46)	22,098 (78)
No	2405 (23.54)	6222 (21.96)
Missing	—	11 (0.04)
Knee pain at least every day?, n (%)		

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Variable	Included cases (n=10,216)	Excluded cases (n=28,331)
Yes	8213 (80.39)	22,958 (81.03)
No	2003 (19.61)	5373 (18.97)
Missing	—	0 (0)
Afraid that your joints will be damaged from physical activity and exercise?, n (%)		
Yes	1528 (14.96)	4974 (17.56)
No	8688 (85.04)	23,351 (82.42)
Missing	—	6 (0.02)
Pain intensity in the index joint during the last month (VAS[e] scale 0 - 100, no pain to worst pain)		
Mean (SD)	47.19 (21.69)	47.75 (22.49)
Range (min-max)	0.0 - 100.0	0.0 - 100.0
Missing, n (%)	—	26 (0.09)
Number of painful body areas (collected via pain drawing)		
Mean (SD)	3.79 (3.25)	4.29 (3.83)
Range (min-max)	0.0 - 40.0	0.0 - 56.0
Missing, n (%)	—	7791 (27.50)
Pain in the lower back (collected via pain drawing), n (%)		
Yes	2686 (26.29)	6105 (21.55)
No	7530 (73.71)	14,435 (50.95)
Missing	—	7791 (27.50)
Are your hip or knee problems so severe that you would like an operation? n (%)		
Yes	1111 (10.88)	4210 (14.86)
No	9105 (89.12)	24,092 (85.04)
Missing	—	29 (0.10)
Working status: are you working or studying? n (%)		
Yes	3059 (29.94)	9387 (33.13)
No	7157 (70.06)	18,944 (66.87)
Missing	—	0 (0)
Sick leave during the last year because of knee or hip problems, n (%)		
Yes	147 (11.23)	3560 (12.57)
No	9069 (88.77)	24,734 (87.30)
Missing	—	37 (0.13)
Have you had a joint replacement in any hip or knee? n (%)		
Yes	939 (9.19)	2251 (7.95)
No	9277 (90.81)	23,768 (83.89)
Missing	—	2312 (8.16)
Frequency of exercise to the point of breathlessness or sweating at least 2 - 3 times a week? n (%)		
Yes	5188 (50.78)	14,226 (50.21)
No	5028 (49.22)	14,105 (49.79)
Missing	—	0 (0)
UCLA[f]-physical activity score (from 0 to 10, worst to best)		
Mean (SD)	5.77 (1.78)	5.48 (1.84)
Range (min-max)	1.0 - 10.0	1.0 - 10.0

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Variable	Included cases (n=10,216)	Excluded cases (n=28,331)
Missing, n (%)	—	21 (0.07)
KOOS-12[g] Quality of life subscale score		
Mean (SD)	46.06 (15.0418)	44.99 (15.5436)
Range (min-max)	0.0 - 100.0	0.0 - 100.0
Missing, n (%)	—	8 (0.02)
EQ-5D-5L score (–0.757 to 1, worst to best)		
Mean (SD)	0.78 (0.1816)	0.76 (0.2018)
Range (min-max)	–0.38 - 1.0	–0.63 - 1.0
Missing, n (%)	—	19 (0.06)
General health evaluated via EQ VAS (from 0 to 100, worst to best)		
Mean (SD)	70.37 (18.68)	68.53 (19.29)
Range (min-max)	0.0 - 100.0	0.0 - 100.0
Missing, n (%)	—	12 (0.04)
Outcome variable		
VAS pain change score from baseline to 3 month follow-up score 100 to 100 from pain got worse to pain got better, 0=no change in pain		
Mean (SD)	14.41 (22.6758)	11.67 (23.44)
Range (min-max)	–87.0 - 99.0	–98.0 - 100.0
Missing, n (%)	—	10,976 (38.74)

[a]Not applicable.

[b]OA: osteoarthritis.

[c]NSAID: nonsteroidal antiinflammatory drug.

[d]Yes: Living alone; No: Living with others (partner, family, friends, or others).

[e]VAS: visual analog scale.

[f]UCLA: University of California, Los Angeles.

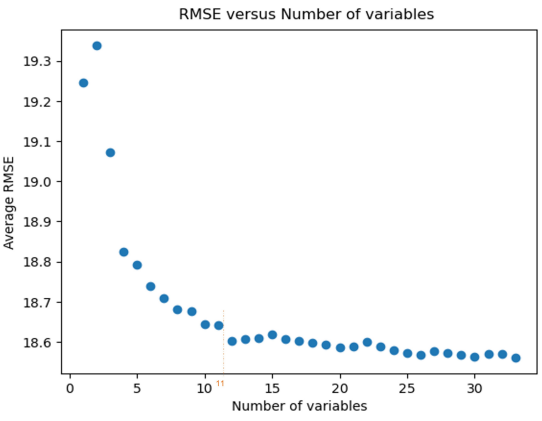
[g]KOOS-12: Knee Injury and Osteoarthritis Outcome Score.

Figure 3. Demonstrates the 2-fold analytical process where the left panel presents the ranking of variables by their relative importance using Gini impurity. Following this initial analysis, the elbow method, showcased in the right panel, was applied. KOOS: Knee Injury and Osteoarthritis Outcome Score; RMSE: root-mean-squared error; UCLA: University of California, Los Angeles; VAS: visual analog scale.

Gini Impurity to identify the most important variables:

	Variable	Importance
1	Pain intensity in the index joint during the last month/week (VAS scale 0-100, no pain to worst pain)	0.501185
2	EQ-5D-5L score (-0.757 - 1, worst to best)	0.061433
3	Duration of symptoms	0.055176
4	Time to complete 40 m walking test	0.053392
5	BMI	0.048837
6	Age	0.040594
7	EQ VAS general health (0-100, worst to best)	0.040419
8	Number of painful body areas	0.029249
9	KOOS-12 Quality of life subscale score	0.028501
10	Number of chair stands during 30sec	0.027997
11	UCLA - physical activity score (from 0-10, worst to best)	0.019213
12	Are your hip/knee problems so severe that you would like an operation?	0.009836
13	Pain in other hip or knee joints than the index joint?	0.006248
...	...	...
33	Use of walking aid during the 40 m walking test	0.001694
34	Danish citizen	0.001172

Elbow method to find top 11 variables:



Model Development and Model Evaluation

In total, we built 3 models each including a different set of variables (Table 2). The first includes all 34 variables (full model). The second one includes the 11 most important variables identified with the Gini impurity and elbow method (continuous model), highlighting the importance of these baseline variables in making predictions. The third includes the 6 predictive variables, which were chosen based on their importance and clinical reasoning—it is assumed that answering the underlying 11 questions would be applicable in routine clinical practice. These 6 variables are baseline pain, duration of symptoms, the EQ-5D score, time to complete a 40-meter walking test, age,

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and BMI. Each of those 6 variables contains 1 item but BMI and EQ-5D include 2 and 5 items, respectively.

The model performances are presented in Table 3 based on the average performance on the test sets in a 10-fold cross-validation process. Accordingly, the full model's average RMSE was 18.56 (SD 0.59), while the coefficient of determination (R^2) was 0.32. The continuous model displayed an RMSE of 18.64 (SD 0.58) and an R^2 of 0.32. Moreover, when considering variables in the concise model, the RMSE and R^2 were 18.76 (SD 0.64) and 0.31, respectively.

The comparison between true predictions based on our concise model including the top six most important variables and predictions using the average model is illustrated in Figure 4. It shows a small but distinct advantage of our personalized predictions over average-based predictions. Our personalized prediction method, based on random forest regression, performed better than the average prediction model by a margin of about 7% when allowing a difference of 15 points in each direction between the predicted and the true change on the test data [35]. Specifically, our results showed that the average model predicts 51.47% and our personalized model predicts about 57.82% of the cases correctly. We found that personalized predictions were slightly and consistently better than those based on the average improvement, regardless of the deviation allowed (5 points or 20 points). Table 3 shows correct personalized predictions and correct average predictions within the interval of ±15 points for all models. An illustration using these numerical values is as follows: if a patient, for instance, has a pain score of 45 before GLA:D and our personalized model estimates a change of 20 points, this means that it is estimated that the patient will have pain between 10 and 40 after the program with a 58% certainty.

Table . Overview of included variables per model.

Name of variable combination	Included variables
Full model	All variables
Continues model	The 11 most important variables were selected by Gini. Identified by variable selection
Concise model for clinical practice	Age, BMI, change in pain, duration of symptoms, time to complete 40 m walking test, EQ-5D score

Table . Overview of the performance of all random forest regression models.

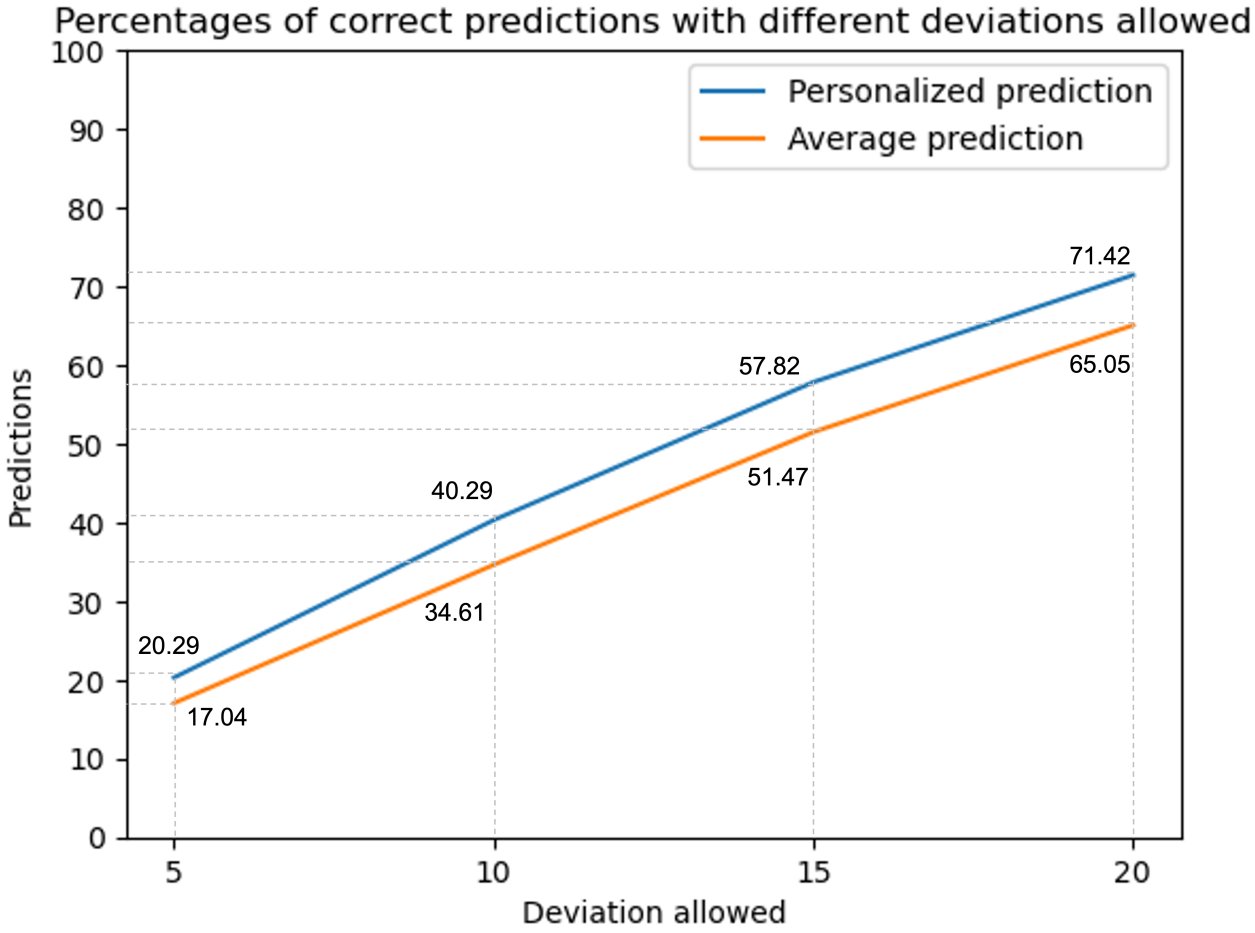
Variable combination	VAS[a] pain: GLA:D personalized prediction			
	RMSE[b]	R^2	Correct personalized predictions (within the interval of ±15 points)	Correct average predictions (within the interval of ±15 points)
Full model	18.56	0.32	58.17%	51.47%
Continues model	18.64	0.32	58.09%	51.47%
Concise model for clinical practice	18.76	0.31	57.82%	51.47%

[a]VAS: visual analog scale.

[b]RMSE: root-mean-squared error.

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Figure 4. Comparison of the percentage of correct predictions of our concise model and using the average model, allowing deviations between 5 and 20 points.



Supplementary Analyses

Including the 12 additional variables reduced our sample with complete cases to n=1458, since these variables were first added later. However, the evaluation of the variable importance followed a similar pattern highlighting that the now 14 continuous variables were the most important (Figure S2 in Multimedia Appendix 1 [37]). Similarly, the model performances and evaluations remained comparable among all three models (Table 4).

Table . Overview of performance summary of all random forest regression models of our supplementary analyses, incorporating 46 variables with 12 additional variables relative to the prior model[a].

Variable combination	VAS[b] pain: GLA:D personalized prediction			
	RMSE[c]	R^2	Correct personalized predictions (within the interval of ±15 points)	Correct average predictions (within the interval of ±15 points)
Full model	19.24	0.32	56.37%	49.45%
Continues model	19.25	0.32	56.64%	49.45%
Concise model for clinical practice	19.55	0.30	54.79%	49.45%

[a]This includes 30 binary variables, 2 categorical variables, and 13 continuous variables.

[b]VAS: visual analog scale.

[c]RMSE: root-mean-squared error.

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Discussion

Principal Findings

In this study, we developed personalized prediction models for changes in knee OA pain after supervised patient education and exercise therapy (GLA:D) and compared them to existing prediction and average-based models. Our findings validate the two previously developed models from Baumbach et al [20] and introduce a new concise personalized prediction model for estimating changes in knee pain intensity among patients with knee OA considering participating in the GLA:D program. Neither the increase in sample size nor the inclusion of additional variables improved the previous prediction model. Nonetheless, our concise model correctly predicted 58% of the cases and demonstrated a 7% improvement in the rate of correct predictions over the use of currently used average values for informing patients about their expected changes in knee pain.

In clinical decision-making, predictive models serve as pivotal tools across various disciplines. These models, akin to those used in cancer prognosis or the optimization of exercise regimens, underline the significance of personalized predictions in enhancing patient outcomes [38-42]. This study delves into this paradigm by comparing prediction models and validating the findings of an earlier study. As in the previous study [20], we used the GLA:D data and presented a full and continuous model to predict personalized outcomes. The latter was chosen based on the variable importance. While we used the Gini impurity and elbow method, the previous study determined the most important variables by the reduction in RMSE for out-of-bag cases and applying the elbow method [20]. Despite the difference in the used method, our findings that the continuous variables were most important align with the previous study. Our outcomes match those of the previous study, despite our model's sample size being doubled and the variables being reduced by 17 and 4 in the full and continuous model, respectively. For the full and continuous models, there was no difference, and a difference of 0.01 in the R^2 values, respectively. In addition, the RMSE aligned closely. In our supplementary analysis, we incorporated 12 new variables, included in the GLA:D registry between 2017 and 2018, which reduced our sample size to 1458 but maintained consistent variable importance and model performance. Thus, we found that neither an increase in sample size nor the added variables could improve the personalized outcome predictions compared to the earlier study [20].

Recent research [43,44] highlights that patients using analgesics, experiencing constant pain, or preferring the GLA:D program over saline injection demonstrated greater benefits from the program. Unfortunately, our data did not include "constant pain" or "preference for the GLA:D program." However, we considered "intake of analgesics," although it was not among the top predictive variables. The random forest method inherently models nonlinear relationships and interactions, enabling relevant subgroup distinctions within the data. This approach avoids reducing sample sizes and maintains robustness by incorporating all relevant variables in the model [45]. Including the variables "constant pain" and "preference for the GLA:D program" in future analyses could provide deeper insights into personalized outcomes and patient stratification. Additionally, it is important to note that our sample probably differs from the randomized controlled trial–based group in the study by Henriksen et al [43,44], as not all patients in our real-world cohort would have agreed to participate in a controlled trial.

To compare the personalized predictions with predictions based on average values, we again used a different approach than the previous prediction study. The previous study took the absolute mean difference and concluded that the difference between their model and the average improvements was not clinically relevant. In this study, we focused on the number of correct predictions, assessing a range of clinical relevance thresholds to determine whether our personalized model surpasses the average model's performance, despite changing the clinical relevance threshold. Here, we emphasize this incremental progress of increasing the clinical relevance threshold. As a result, allowing a higher deviation from the true change resulted in a higher number of correct predictions, for both our personalized predictions and the average prediction. Overall, we found that our personalized prediction model was able to predict about 7% more cases correctly compared to using average predictions, independent of the threshold allowed from the true change.

However, the question of whether these findings are sufficient for implementation into clinical practice remains open. Existing shared decision-making tools often concentrate on comparing different treatments and assisting patients in making informed choices [18]. Specifically, in the context of OA, where education and exercises are universally recommended and surgery is considered a last resort after the failure of previous treatments, the potential of improved prediction models to alter this recommendation landscape is significant [46]. If future models could reliably predict the likelihood of initial treatment failures for specific patient groups, clinical guidelines to treat OA could evolve. Future models could benefit from including more comprehensive patient characteristics, such as constant pain and treatment preferences [43,44], to further explore patient-specific responses to the GLA:D program. Yet, it is crucial to acknowledge that the current performance of our models is too preliminary for such decisive changes in clinical practice. This underscores the necessity for further research to enhance model accuracy and reliability, as well as to understand the needs and preferences of patients and clinicians, potentially reshaping treatment protocols for OA based on predictive insights.

Limitations

This study also has some limitations. Selection bias is possible in any registry-based study due to the cases lost to follow-up. However, we only excluded 28.44% due to missing information on the outcome at follow-up, suggesting no serious threats to its external validity [47]. Furthermore, from previous studies using the GLA:D data, we know that these patients do not differ to a clinically relevant level from the included patients [20]. Two periods of technical flaws in data collection were identified, and these missing values, unrelated to patient characteristics or variables, meet the criteria for missing completely at random.

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Participation in the GLA:D program may also be influenced by factors contributing to selection bias, such as limited accessibility, financial constraints, awareness and referral issues, perceived severity of OA, and language barriers [22,25,48-52]. Our sample's greater representation of female participants reflects known trends of greater knee OA prevalence and greater participation in exercise programs like GLA:D [53-55]. While this enhances relevance to real-world treatment populations, it should be considered when generalizing findings. This study suggests that the increased sample size does not significantly affect the predictive performance outcome [20]. However, it should be noted that we included fewer variables in comparison to the previous study [20]. These variables were deemed of less relevance and therefore excluded from the registry, nonetheless, they contributed to the predictions of the previous models. Therefore, to be precise, we can only conclude that the increased sample size was able to compensate for the reduced number of variables. Hence, to improve our models' predictability, new variables would probably need to be integrated. The newly integrated variables (12 additional variables) in our supplementary analyses, led to a reduction in the sample size (n=1458), however, the model performance remained similar. Consequently, we can (only) conclude that the newly added variables could compensate for the reduced sample size.

Based on these observations, we can point toward the limitation of available predictor variables. Implementing more detailed questionnaire-based measures for anxiety and depression might enhance pain predictions [56]. Weight loss is another recommended first-line treatment for individuals with overweight or obesity with knee OA [57] that is known to moderate systemic inflammation [58], extending the questionnaire to enquire about patients' dietary habits might thus be another possibility to increase the predictive value [59]. However, due to the clinical applicability, the extent of the GLA:D registry questionnaire needs to balance the collection of information against patient burden, adding additional variables with minor importance is not desired. In conclusion, we currently do not know which variables could have an additional major positive influence on the personalized outcome predictions over those already included [60].

Future Directions and Considerations

The precision of our model aligns with existing clinical studies, suggesting a need for future investigations into the practical value of such predictive accuracy within clinical settings [61]. Current initiatives like the A.S.K. report and Movement is Life have begun to explore the integration of predictive models and patient-reported outcomes to guide shared decision-making, demonstrating the utility of these tools in clinical practice [18,62]. However, there is a noticeable gap in the literature concerning the specific performance benchmarks required for predictive models in physiotherapy to be deemed clinically relevant, particularly in the management of OA. Therefore, before a decision on implementing our model as a web tool into clinical practice can be drawn, guidance on which metrics and predictive values need to be achieved in a model to be feasible for clinical practice needs to be investigated. Furthermore, it remains uncertain if the implementation of a model, like ours, which provides more correct predictions than what is currently used, but still several wrong predictions, is valuable enough for patients and clinicians to be implemented in clinical practice. Further, to the best of our knowledge, it is yet unknown if personalized outcome predictions regarding a treatment lead to different expectations than average outcome predictions in patients. Moreover, on ethical aspects, the consequences of wrong predictions in general on a patient's treatment, and mental and emotional well-being should be investigated. For patients with estimated worsening pain predicting other health outcomes additionally could be essential to motivate them to participate in the program. For example, prediction tools within GLA:D for secondary outcomes such as physical activity, which changes independently of changes in pain, could support participation rates, given the overarching health benefits associated with increased physical activity [27,60]. Similarly, patients might be more motivated if they knew about the expected changes in physical function and quality of life. Finally, any prediction tool needs to be comprehensively evaluated based on its role in treatment decisions, patient satisfaction, and overall treatment outcomes in clinical settings, before implementation.

Generalizability

The methodology used in this study, which leverages machine learning techniques to analyze questionnaire data and functional test data for predicting treatment outcomes has been used before and is a promising advancement in the field of personalized medicine [63,64]. This approach is characterized by the selection of predictive variables from data and can be used in similar questioning. Thus, our method extends beyond the specific context of the GLA:D program and could be applied to other exercise therapy programs targeting knee OA, and potentially, for a broader range of conditions [62,65-67].

Generalizing our findings, the model predictions of the GLA:D program for knee OA to other exercise and physiotherapy interventions are challenging. The unique combination of group-based exercises and education in GLA:D may be crucial and not present in all physiotherapeutic settings. Therefore, our outcome predictions specific to GLA:D cannot be expected universally. However, if the core principle of structured exercise therapy and education are incorporated into the treatment of a patient with OA, our model might be applicable. Nonetheless, the personalized predictions would likely deviate even further from the true changes than in patients participating at GLA:D, therefore, they should not be generalized.

Conclusions

We developed and validated a personalized prediction model for pain intensity changes in patients with knee OA participating in the GLA:D program. Our model's 58% accuracy is 7% better than using average pain improvement as a prediction. This likely represents the best possible prediction given current knowledge and available data. Although performance is improved, further guidance is needed to determine when such models are suitable for clinical implementation. This study highlights both the potential and current limitations of personalized prediction in knee OA management.

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Acknowledgments

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Data Availability

All the data for this study were acquired following a request to the GLA:D Denmark [22]. The codes for data preprocessing and prediction models analyzed during this study are available in the KneePainPrognosticModelGLA-D repository [68].

Conflicts of Interest

EMR is on the Editorial Board of Osteoarthritis and Cartilage, the developer of the Knee Injury and Osteoarthritis Outcome Score and several other freely available patient-reported outcome measures and cofounder of GLA:D, a not-for-profit initiative hosted at the University of Southern Denmark aimed at implementing clinical guidelines for osteoarthritis in clinical practice. STS has received personal fees from Munksgaard, TrustMe-Ed, and Nestlé Health Science, outside the submitted work, and is cofounder of GLA:D.

Multimedia Appendix 1
Additional figures.
[DOCX File, 1324 KB - rehab_v12i1e60162_app1.docx]

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Abbreviations

GLA:D: Good Life with osteoArthritis in Denmark
OA: osteoarthritis
RMSE: root-mean-squared error
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis
VAS: visual analog scale

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Machine Learning Clinical Decision Support for Interdisciplinary Multimodal Chronic Musculoskeletal Pain Treatment: Prospective Pilot Study of Patient Assessment and Prognostic Profile Validation

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Abstract

Background: Chronic musculoskeletal pain (CMP) impacts around 20% of people globally, resulting in patients living with pain, fatigue, restricted social and employment capacity, and reduced quality of life. Interdisciplinary multimodal pain treatment (IMPT) programs have been shown to provide positive and sustained outcomes where all other interventions have failed. IMPT programs combined with multidimensional machine learning predictive patient profiles aim to improve clinical decision support and personalized patient assessments, potentially leading to better treatment outcomes.

Objective: We aimed to investigate integrating machine learning with IMPT programs and its potential contribution to clinical decision support and treatment outcomes for patients with CMP.

Methods: This prospective pilot study used a machine learning prognostic patient profile of 7 outcome measures across 4 clinically relevant domains, including activity or disability, pain, fatigue, and quality of life. Prognostic profiles were created for new IMPT patients in the Netherlands in November 2023 (N=17). New summary indicators were developed, including defined categories for positive, negative, and mixed prognostic profiles; an accuracy indicator with high, medium, and low levels based on weighted true- or false-positive values; and an indicator for consistently positive or negative outcomes. The consolidated reporting guidelines checklist for prognostic machine learning modeling studies was completed to provide transparency of data quality, model development methodology, and validation.

Results: The machine learning IMPT prognostic patient profiles demonstrated high accuracy and consistency in predicting patient outcomes. The profile, combined with extended new prognostic summary indicators, provided improved identification of patients with predicted positive, negative, and mixed outcomes, supporting more comprehensive assessment. Overall, 82.4% (14/17) of prognostic patient profiles were consistent with clinician assessments. Notably, clinician case notes indicated the stratified prognostic profiles were directly discussed with around half (8/17, 47.1%) of patients. Clinicians found the prognostic patient profiles helpful in 88.2% (15/17) of initial IMPT assessments to support shared clinician and patient decision-making and discussion of individualized treatment planning.

Conclusions: Machine learning prognostic patient profiles showed promising contributions for IMPT clinical decision support and improving treatment outcomes for patients with CMP. Further research is needed to validate these findings in larger, more diverse populations.

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KEYWORDS

chronic pain; musculoskeletal pain; machine learning; interdisciplinary care; clinical decision support; musculoskeletal; prognostic

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Introduction

Chronic musculoskeletal pain (CMP) is a prevalent and debilitating condition that significantly impacts the quality of life for millions of individuals worldwide [1]. Patients with CMP often experience long-term pain, where all available treatments have been ineffective, resulting in debilitating pain; fatigue; limited mobility; and associated reduced social activity, employment, and quality of life. Interdisciplinary multimodal pain treatment (IMPT) has shown positive outcomes for CMP, with over 50% of patients reporting positive and sustained improvement [2-8]. CIR (Expertisecentrum chronische pijn), a multicenter pain rehabilitation clinic in the Netherlands, provides a 10-week IMPT program for patients with CMP, reporting consistent positive outcomes [8,9]. The IMPT program supports patients with CMP in modifying their behavior and assisting with pain management, focusing patient attention on specific value-based goals rather than fighting pain.

Recent advancements in machine learning have opened new avenues for enhancing clinical decision support and personalizing IMPT patient assessments. The promising potential of machine learning models to assist clinical decision support for IMPT patients has been previously reported [10-12]. Specifically, machine learning methods can assist with assessing multiple predictive outcomes to provide a stratified prognostic patient profile. This multidimensional approach is essential because, given the complexity of evaluating CMP, no single outcome measure is sufficiently reliable. Clinicians consider various dimensions when assessing patients for IMPT. Machine learning prognostic profiles have demonstrated potential in enhancing clinician assessments for IMPT and identifying individual patient objectives.

The primary objectives of this study were to (1) assess the effectiveness of machine learning predictive patient profiles in improving clinical decision support for IMPT programs; (2) evaluate the accuracy and consistency of prognostic assessments derived from multidimensional machine learning models; and (3) develop new summary indicators, including redefined prognostic categories and accuracy guides, to better assist clinicians and patients in interpreting the prognostic profiles and making informed treatment decisions.

Implementing machine learning prognostic profiles requires clinician collaboration and clear demonstration of their capabilities. Recent research has shown potential pathways to validate and build clinicians' confidence in using machine learning for IMPT decision support [13,14]. This pilot study aimed to investigate integrating machine learning with IMPT programs and its potential contribution to clinical decision support and treatment outcomes for patients with CMP.

Methods

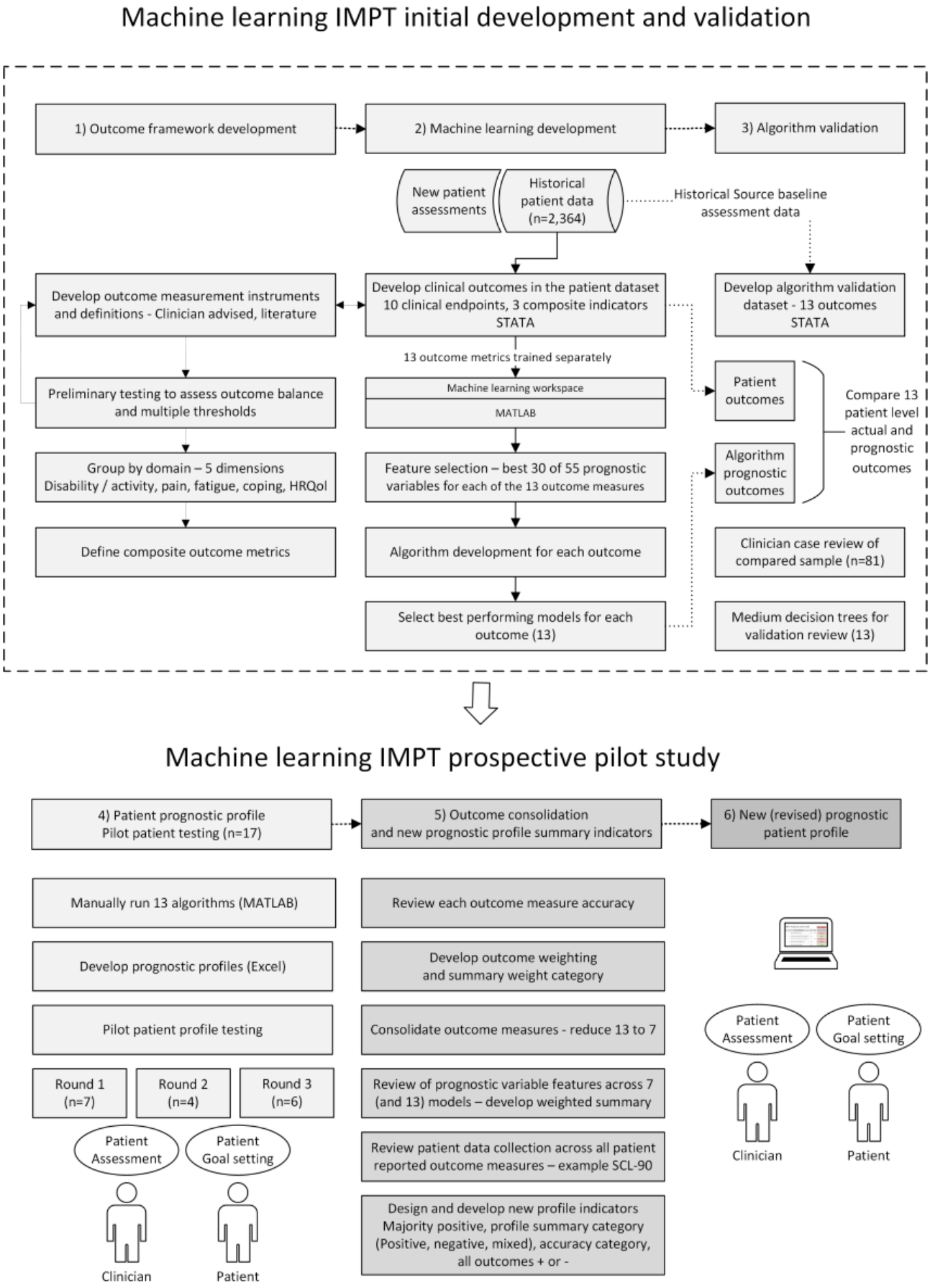
Study Design

This pilot study evaluated integrating machine learning predictive patient profiles with IMPT programs. Data included all patients with CMP referred for CIR program assessments in Eindhoven over 3 weeks in November 2023 (N=18). Eligible participants were adults 18 or older with CMP and at least 6 months of pain history, excluding those with severe psychiatric disorders, active substance abuse, or ongoing pain-related litigation [8,9]. One pilot study patient had experienced severe traumatic events and was clinician-assessed for referral to seek proper care in mental health and was not suitable for IMPT. For this patient, the IMPT prognostic profile was not relevant, as the IMPT outcome framework questionnaires do not include instruments to assess trauma. Due to the incorrect referral, this patient was excluded from the study, resulting in the final IMPT patient pilot study group (N=17).

The pilot study used multidimensional machine learning models that were previously developed to predict patient outcomes based on a comprehensive set of clinical, demographic, and psychosocial variables derived from historical data of previous IMPT patients (N=2364) [10]. The present pilot testing study applied these machine learning algorithms to generate prognostic profiles for new IMPT patients prior to their initial assessment. As illustrated in Figure 1, over the course of 3 weeks, each profile was prepared manually, involving finalization of patient data and multiple processing steps.

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Figure 1. Diagram of machine learning IMPT pilot study process. Algorithm development was previously undertaken for multiple classification models, selecting the best performing model for each of the final 7 outcome measures. Dashed section indicates previously reported IMPT model development [10]. HRQoL: health-related quality of life; IMPT: interdisciplinary multimodal pain treatment; SCL-90: Symptom Checklist-90.



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Data Sources and Preprocessing

Data collected from IMPT-referred patients in preparation for baseline assessments included demographics, clinical conditions, patient-reported outcomes, and a comprehensive evaluation of pain intensity, physical function, emotional well-being, social participation, and other relevant variables. The baseline data were used with previously trained algorithms to generate prognostic profiles for new patients using CIR data from the Asterisque system (electronic patient file). Clinicians assess some prognostic data items during initial patient examinations, such as indication for eye movement desensitization and reprocessing registration and pain diagnosis (level of complexity known as WPN classification). Other assessments, like the 6-minute walking test and 5 times sit-stand trials (performed at the actual start of the IMPT), were imputed based on age and gender averages from IMPT patient data, with supplementary checks to confirm consistency in prognostic profiles.

A machine learning development and validation checklist was used to ensure the quality and consistency of the models [15]. The checklist included steps for data preprocessing, model training, validation, and evaluation; details are provided in Multimedia Appendix 1.

Ethical Considerations

All records in the patient dataset were deidentified with a unique patient number, and clinician patient assessments of positive or negative IMPT referrals and case notes were reported for validation of each patient prognostic profile. The Medical Research Ethics Committee Isala Zwolle, the Netherlands, previously reviewed the initial study (case number assigned: 200510), and as all patients have consented to the use of their data for research, further ethics approval was not required. This satisfies that the study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

Revised and New Prognostic Profile Summary Indicators

The primary pilot validation outcome measure was the accuracy and consistency of prognostic assessments derived from the machine learning models in support of clinician and IMPT team-assessed prognosis. Secondary outcome measures included the effectiveness of the predictive patient profiles in improving clinical decision support, the development of new summary indicators, and the value of these indicators for clinician and patient shared decision-making. In this context, in line with the complexity of IMPT treatment and clinician assessment, a review of the multidimensional outcome framework was undertaken to consider how the results across the prognostic profile could best be summarized to assist clinician and patient interpretation.

Five new summary indicators were established (Table 1). The initial indicator shows positive or negative based on a majority count of positive outcomes (indicator 1), as well as the actual number of positive outcomes (indicator 2). A new prognostic profile summary indicator (indicator 3) was created to more clearly identify positive or negative profiles. The negative profile is defined as all 7 outcomes being consistently negative (zero positive), while the positive profile requires 3 or more positive outcomes. Profiles that do not fit either category are labeled as “mixed” and need further assessment. These summary categories supplement the complete set of stratified prognostic outcomes that are individually provided for clinician evaluation and optional patient discussion.

Additionally, each prognostic model was evaluated to create a weighted summary indicator of overall accuracy (summary indicator 4). This accuracy category was developed by summing true-positive rates (TPRs) and true-negative rates (TNRs) across each machine learning model for each outcome. This figure provides a weighted proxy indicator to adjust for outcome models with high TPRs or TNRs, derived by summing the opposite TPR or TNR for each predicted positive or negative outcome. For example, an outcome with an estimated TPR of 0.98 added the related TNR of 0.02 to the weighted accuracy score, reflecting a low contribution to the total profile. The resulting true-positive and true-negative weighted scores were then grouped into a prognostic profile accuracy category defined as low (<3), medium (≥3 and <4), and high (≥4). A supplementary indicator (indicator 5) was also developed to emphasize profiles where all 7 indicators were consistently positive or negative. While the full profile shows the number of positive or negative outcomes, this indicator clearly highlights these significant cases compared to mixed outcomes.

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Table . Revised and new interdisciplinary multimodal pain treatment (IMPT) prognostic patient profile summary indicators. Source: Machine learning IMPT prognostic patient profile pilot study (n=17).

IMPT prognostic patient profile indicator	Positive	Other	Negative
1. Positive majority (positive outcomes)	≥4 of 7	N/A[a]	<4 of 7
2. Number of positive outcomes (outcome count)	4, 5, 6, or 7	N/A	1, 2, or 3
3. Prognostic profile summary (positive outcomes)	≥3 of 7	Mixed=1 or 2	0
4. Profile accuracy category (weighted TPR[b] and TNR[c])	High	Medium	Low
5. All outcomes, positive or negative	All of 7	N/A	All of 7

[a]N/A: not applicable.

[b]TPR: true-positive rate.

[c]TNR: true-negative rate.

Statistical Analysis

Statistical analyses compared the accuracy and consistency of the IMPT machine learning prognostic profiles with clinician assessments in the context of IMPT clinical decision support; that is, how consistent are the machine learning profiles with clinician prognoses to start IMPT. Descriptive statistics summarized baseline characteristics and outcomes; categorical variables are presented as numbers and percentages, and continuous variables as mean and SD. Fisher exact test was used to measure associations due to the small pilot study sample (N=17) versus initial models (N=2364). Details on feature selection and individual machine learning model IMPT outcomes have been previously reported [10].

Data analysis and preprocessing were completed with Microsoft Excel 365 and STATA (version 16.1; StataCorp LP). Algorithm prediction was undertaken individually for each of the 7 outcome models using the MATLAB Statistics and Machine Learning Toolbox (Release 2023b). Prognostic patient profile results were transposed back to Microsoft Excel for clinician and patient review.

Results

In total, 17 patients with CMP participated in the study. The mean age of the participants was 45.3 (SD 12.4) years, with 10 females and 7 males. Most participants had a history of pain lasting more than 5 years. Baseline characteristics are detailed in Multimedia Appendix 1. As all patients have been referred for IMPT, patients in the pilot study group were diagnosed with CMP and classified through the Working Group on Pain Rehabilitation in the Netherlands (Werkgroep Pijnrevalidatie Nederland (WPN)). Based on this rating of the complexity of pain symptoms, the majority (64.7%) were assessed as WPN 3 chronic pain syndrome and 35.3% as WPN 4 (maximal score), consistently showing a clear indication of psychosocial factors underlying chronic pain and disability. Most participants lived with a partner, were employed, and used pain medication.

The machine learning IMPT prognostic patient profile with new summary indicators demonstrated high accuracy and consistency with clinician assessment in 82.4% (14/17) of cases (Figure 2). In 2 of the 3 mixed cases, the profiles were predominantly negative (patients 3 and 17 in Figure 2), and the clinician confirmed them as negative during assessment. The remaining mixed profile (patient 13) included 2 positive prognostic outcomes and was clinician-confirmed as positive. The prognostic profile was not used in 2 cases, one where the patient turned out to have no request for help with pain rehabilitation and another where the planned assessment was rescheduled beyond the pilot study period.

Notably, clinician assessment indicated the stratified prognostic profiles were directly discussed with around half (8/17, 47.1%) of patients and were reported as helpful for IMPT discussion, shared decision-making, and individualized planning. The patient review discussion was valuable for confirming profiles that were mostly positive, verifying the positive decision. The review discussions were also reported as helpful in 2 additional mixed profile cases, one where review of predicted negative outcomes helped the patient decide not to proceed with IMPT, even though one summary indicator was positive (patient 3), and another with mostly negative outcomes, which also helped confirm a decision not to proceed with IMPT (patient 17).

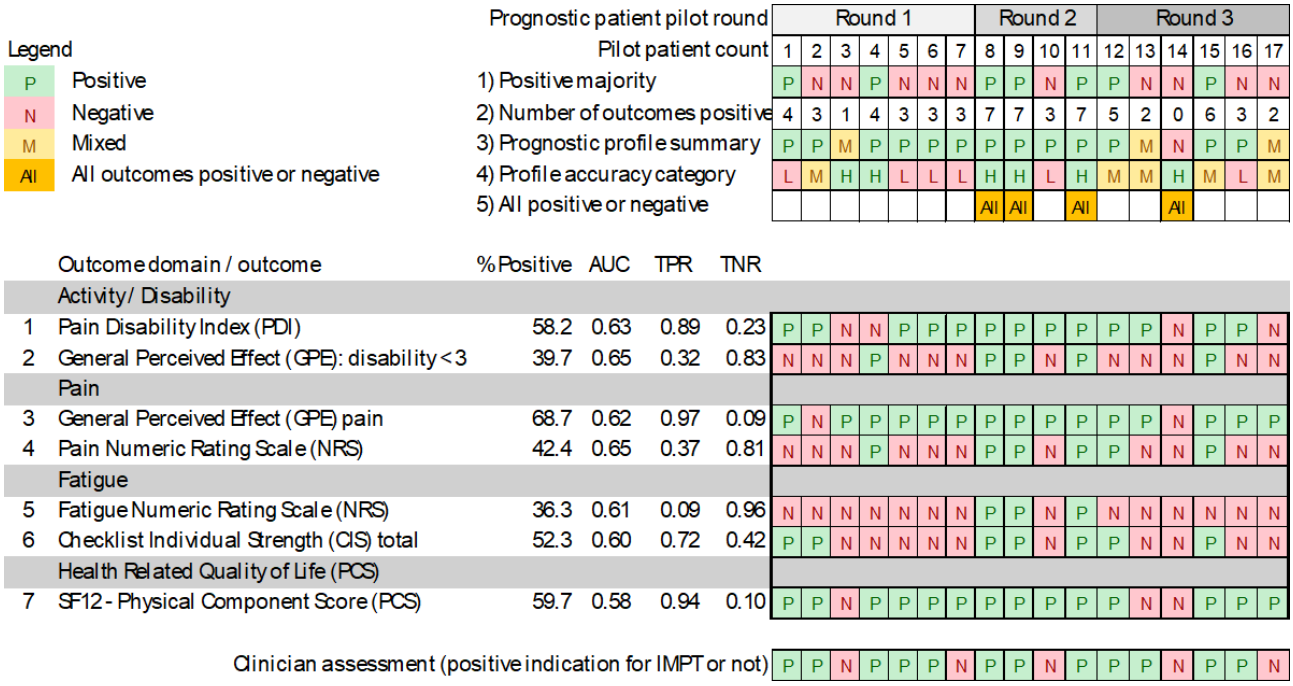
Collectively the prognostic patient profile indicators were clearly consistent with positive and the single negative clinician assessment in 12 cases and indirectly consistent through 2 mixed profiles (14/17), as above. A further example of machine learning prognostic profile value was a predicted positive profile (patient 10), even though the joint clinician and patient decision was not to proceed with treatment. In this case the profile showed the minimum of 3 positive outcomes out of 7, and the profile accuracy category was low. Combining this case with the previous 14 clinician-consistent results showed the prognostic patient profiles were helpful in 88.2% (15/17) of initial IMPT assessments. Clinician experience during the study indicated that the predictive profiles provided valuable insights into patient outcomes and facilitated more informed decision-making regarding individualized treatment plans.

The new prognostic profile summary indicators included a profile accuracy category (indicator 4). Although the pilot study

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is a small sample, the results consistently indicated that all 6 patients with a "high" accuracy category were confirmed to have a clinician-consistent prognostic profile. Many of this high-accuracy category group (4/6) had a clear positive or negative profile summary, highlighted by the final indicator where all 7 outcomes are consistently positive or negative.

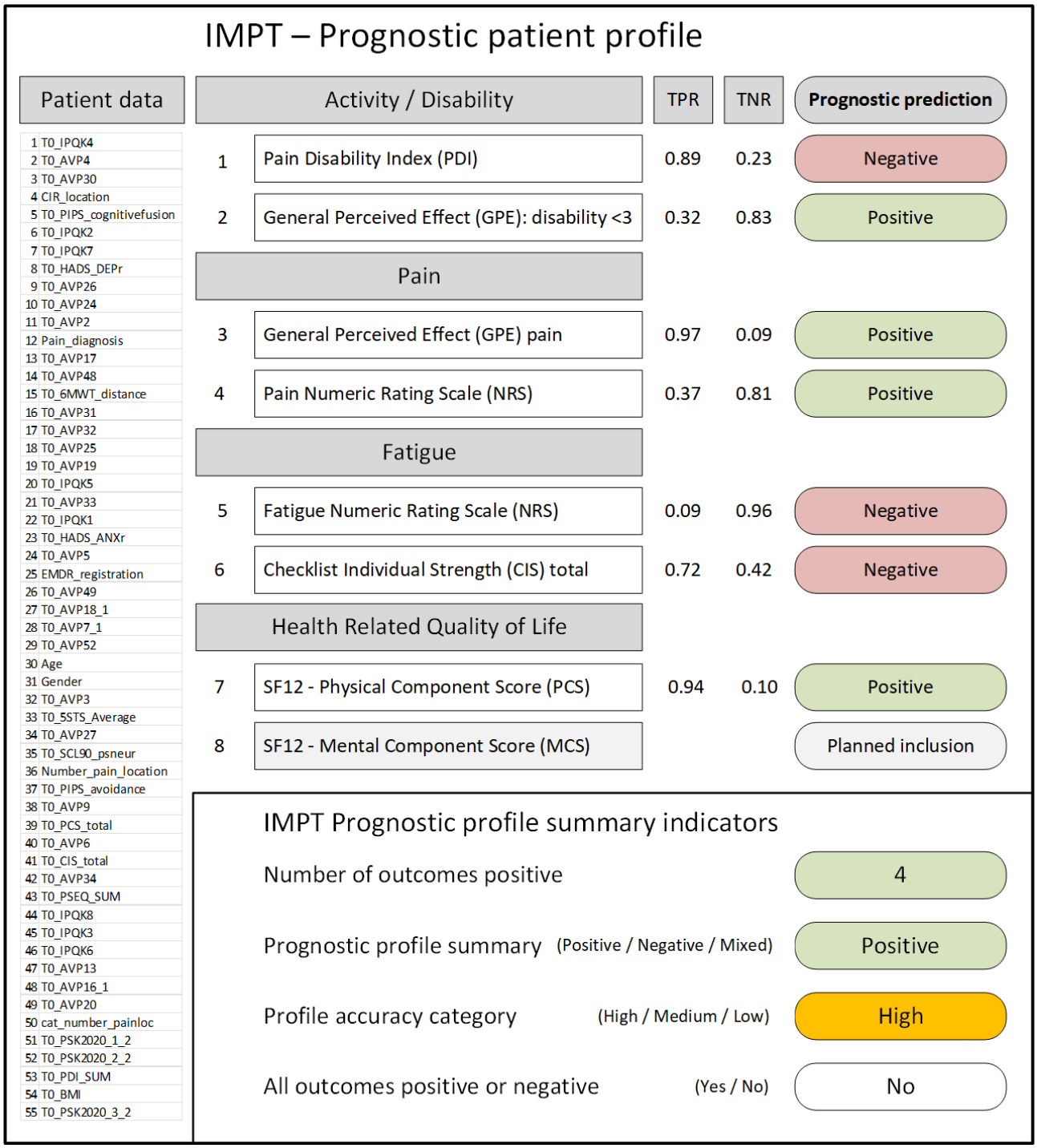
Figure 2. Pilot study prognostic patient profiles with 7 outcome measures and new summary indicators. Source: Machine learning interdisciplinary multimodal pain treatment (IMPT) prognostic patient profile pilot study (N=17). Profile accuracy: H=high, M=medium, L=low. AUC: area under the curve; M: mixed; N: negative; P: positive; TPR: true-positive rate; TNR: true-negative rate.



The above summary (Figure 2) presents results for all pilot study patients to show performance and overall results. However, the individual prognostic patient profile as used in IMPT clinical assessment provides clearly presented summary results for each patient. The IMPT prognostic patient profile included all patient baseline and demographic data for reference, the stratified outcomes by outcome dimension, and the prognostic prediction clearly displayed for each outcome. The example in Figure 3 shows indicative profile content, which would potentially be further designed and customized into a patient prognostic profile application. This illustration indicates the planned inclusion of an additional outcome measure for the Short-Form Quality of Life Survey (SF-12) Mental Component Score (MCS), as IMPT data for this scale is now available. The bottom section presents the prognostic profile summary indicators, in this case showing a positive summary with a high level of accuracy confidence.

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Figure 3. IMPT prognostic patient profile and summary indicators—pilot study example. Example patient number 4 prognostic profile with actual pilot testing study data results. Patient data section is shown for illustrative purposes, representing the 55 baseline prognostic variables and values that would appear on the patient profile. CIS: Checklist Individual Strength; GPE: Global Perceived Effect (disability); IMPT: interdisciplinary multimodal pain treatment; NRS: Numeric Rating Scale; PDI: Pain Disability Index; SF-12 MCS: Short-Form Quality of Life Survey Mental Component Score; SF-12 PCS: Short-Form Quality of Life Survey Physical Component Score; TNR: true-negative rate; TPR: true-positive rate.



Discussion

Overview

Chronic pain is a complex condition that needs assessment of multiple patient outcomes to create personalized treatments. Managing chronic pain is complicated due to its subjective nature and the variability in patient responses to treatments. In this context, the pilot study investigated the performance of a novel machine learning prognostic patient profile, which combined 7 separately trained outcome models across 4 clinically meaningful domains into a single prognostic patient profile [10]. The study investigated how this multidimensional approach assisted clinical decision support, shared clinician and patient decision-making, and individualized treatment planning.

IMPT Improved Program Outcomes and Efficiency

The pilot study externally validated the IMPT predictive patient profile, showing its potential to enhance chronic pain treatment and cost-effectiveness. By introducing new summary indicators

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and weighted accuracy measures, the study improved the tool's precision in predicting patient outcomes. It also identified key variables for better data utilization, suggesting that some, like the Symptom Checklist-90 (SCL-90) questionnaire, could be removed to reduce patient burden. The machine learning feature selection process can help minimize redundant information and optimize high-impact variables, leading to more effective chronic pain management. The IMPT prognostic variables weighted by minimum redundancy maximum relevance scores are provided in Multimedia Appendix 1.

Additionally, the overlap with current IMPT patient systems indicates potential for optimizing data usage. The pilot study revealed that clinicians spend approximately 15 minutes per patient collecting initial baseline data. Having the comprehensive prognostic profile available could save this time for more complex assessments. Separately, the prognostic patient profile might play a more nuanced role in patient assessment. These profiles could help identify a subgroup of patients who might benefit from an initial 4-week treatment period to further evaluate IMPT potential before proceeding to the full 10-week program. This approach could contribute to better assessment pathways and improved patient outcomes.

Furthermore, in a longer term perspective, the societal value of IMPT is linked to the positive patient pathways that emerge following participation in the program, which may persist for many years or even decades. Preliminary research indicates that the CIR program is likely to be cost-effective, with long-term results demonstrating significantly enhanced self-rated work capacity [2,8]. This offers a promising outlook for further efficiency gains and improved patient outcomes, where machine learning-driven predictive patient profiles may assist clinicians and patients in assessment and program engagement. Long-term outcomes could facilitate a return to working life, reduce the need for formal and informal care, and enhance quality of life.

Artificial Intelligence Advances in Chronic Pain Health Care

The use of artificial intelligence in health care, including chronic pain diagnosis and treatment, has become increasingly prominent [11,16-18]. However, most machine learning research has investigated pain diagnosis and progression to chronic pain, which had already been completed for the pilot study group, which consisted of patients with long-term CMP. All patients had previous consultations with at least 1, and up to 20, care providers for diagnostics and treatment, in addition to visiting a physical therapist in primary care. Patient pain complexity was reflected in WPN levels 3 or 4, indicating the presence of multiple biopsychosocial factors contributing to persistent pain, associated disability, and reduced quality of life. This suggested that monodisciplinary treatment would have been insufficient. This pilot study, however, went beyond diagnosing chronic pain and used machine learning to predict the success of IMPT for patients with CMP, especially when other treatments had failed.

Single Versus Multidimensional Outcomes

Many machine learning studies focus on predicting single outcomes for chronic pain treatment, such as whether a patient's pain will improve with specific therapy. These studies primarily address binary clinical decisions rather than developing multioutcome patient profiles. For example, one study used machine learning with features from dynamic surface electromyography readings to predict which patients with low back pain would respond to rehabilitation [19], showing high accuracy, possibly due to a specific signal in the data. Another study evaluated if patients with low back pain should seek professional care or self-manage, achieving around 70% accuracy [20].

A further single-outcome approach developed a neural network model to predict which patients with chronic pain and foraminal spinal stenosis would benefit from a transforaminal epidural steroid injection [11]. These single-outcome approaches focus on clinical procedures rather than personalized multimodal treatments. Overall, while high-resolution imaging may provide precise diagnoses, it cannot be compared directly to complex patient-reported chronic pain data.

Supervised and Unsupervised Learning

In addition to supervised machine learning investigated in the pilot study, unsupervised methods have been used to identify patient subgroups for better pain treatment selection [21]. For example, clustering has been applied to patients with fibromyalgia to find distinct subgroups based on symptom profiles like pain intensity, anxiety, and sleep quality [22]. Clustering helps understand mechanisms or prognoses for varied treatments. It aids in patient stratification and decision support but does not give direct recommendations. Clinicians can use clusters to guide treatment by matching new patients to typical outcomes. Clustering differs from supervised approaches as it explores and identifies patterns without assumptions. Furthermore, clusters require clinical interpretation and validation and do not have accuracy metrics like those found in predictive models. Recent research has also explored the mix of supervised and unsupervised methods to investigate underlying subgroups of patients with chronic pain [23]. Given the characteristic heterogeneity of patients with CMP, this research may help better identify prognostic subgroups, which could provide improved direction for ongoing supervised and reinforced IMPT machine learning development.

Prognostic Profile Implementation

An implicit machine learning research direction highlights the importance of carefully planned implementation to build confidence in these new methods and achieve acceptance from clinicians and patients. The challenges to successful implementation included training data quality, complexity of pain physiology, comprehensive validation of predictive models, privacy, biases, and ethical considerations [10-12,24]. Proactively anticipating and addressing each of these barriers from the outset is essential for the successful integration of machine learning into IMPT clinical decision support systems.

The machine learning pilot study involved continuous clinician collaboration in line with research indicating that clinician involvement during the design and validation phases is crucial for supporting potential implementation acceptance [25]. To further support design consistency and transparency, the pilot study built on a previously completed clinician checklist for

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algorithm assessment, which considered aspects like data quality, validation, and ethical concerns [10,26]. This checklist has now been extended with the Consolidated Reporting Guidelines for Prognostic and Diagnostic Machine Learning Modeling Studies, further enhancing standardization and building confidence for clinical integration [15].

External Validation

The pilot study has demonstrated initial external validation, as the prognostic profiles have been prospectively investigated with new patients who were not included in algorithm training data. A further interesting aspect has been the consistency with conventional logistic regression models as a form of cross-validation for the machine learning prognostic profiles. Separate research into IMPT logistic regression prediction models has investigated 3 of the 7 outcome dimensions used in the machine learning profiles and found consistent results for corresponding outcomes [27]. The logistic regression study examined the Pain Disability Index (outcome 1 in Figure 2), the General Perceived Effect (outcome 2), and the SF-12 Physical Component Score (outcome 7). These results reinforce the reliability and validity of the machine learning methods, and this cross-validation strengthens confidence in the prognostic tool's ability to provide accurate and useful predictions for IMPT patient outcomes. Importantly, the logistic regression results indicate that the SF-12 MCS was the highest performing model, and is a second outcome measure in the health-related quality of life dimension. This outcome was not trained during initial IMPT machine learning development as the data were not yet available. However, this measure is currently being integrated into the machine learning prognostic patient profile (shown as outcome 8 in Figure 2), suggesting further potential positive contribution beyond the pilot study results.

Limitations

Although the results are promising, this study has some limitations. As the IMPT patient data extraction and preparation were time-consuming and the machine learning models involved substantial manual effort to individually run across each outcome and collate into each patient profile, it was not feasible to run the pilot study for an extended period. This limited the pilot study group to a small sample of 17 patients over the 3-week project. For this reason, the results are presented as preliminary and have focused on individual profile analysis and clinician validation, rather than statistical significance.

Additionally, all pilot study patients were assessed at a single CIR location in Eindhoven, limiting the scope to examine other patient cohorts, clinicians, and potentially other IMPT program characteristics. The results are provided as indicative and descriptive, and the small sample and single-center study may affect the generalizability of the findings. Future research should aim to confirm these findings in larger, more diverse IMPT populations and investigate the long-term contribution of machine learning to clinical decision support and patient outcomes.

Conclusions

Integrating machine learning with IMPT programs can enhance clinical decision support and potentially improve treatment outcomes for patients with CMP. Machine learning predictive patient profiles can complement clinician assessments by providing insights into specific patient outcomes and facilitating informed clinician and patient shared decision-making. New summary indicators can further enhance predictive profile interpretation for consideration of whether IMPT is likely to provide a positive treatment pathway. Continued research and development in this area are necessary to fully realize the potential of machine learning in clinical practice and to ensure its successful implementation and acceptance by clinicians and patients.

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Data Availability

The study group patient dataset is confidential, managed by CIR (Expertisecentrum chronische pijn), and is not available for public access.

Authors' Contributions

FZ and RJEMS conceived the pilot machine learning patient validation project. The clinical patient dataset was developed and funded by CIR (Expertisecentrum chronische pijn). All clinical patient assessment of the machine learning prognostic patient profiles across outcome measures was provided by RJEMS. JSG provided clinical advice during the initial patient profile testing and assistance with initial patient data validation and clinical assessment of outcome measures, which are not routinely available at baseline. EVDG managed the patient data extraction and validation for each of the pilot study rounds as well as guidance on

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potential patient data enhancement and potential systems development. FZ developed the 3 rounds of machine learning patient test prognostic profiles from live data provided by CIR. The manuscript was prepared by FZ, with review and clinical advice from RJEMS and JSG, as well as data systems design and implementation perspectives from EVDG. All authors revised and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Machine learning development and validation checklist, participants' baseline characteristics, and data on prognostic patient profile.
[DOCX File, 172 KB - rehab_v12i1e65890_app1.docx]

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Abbreviations

CIR: Expertisecentrum chronische pijn
CMP: chronic musculoskeletal pain
IMPT: interdisciplinary multimodal pain treatment
MCS: Mental Component Score
SCL-90: Symptom Checklist-90
SF-12: Short-Form Quality of Life Survey
TNR: true-negative rate
TPR: true-positive rate
WPN: Werkgroep Pijnrevalidatie Nederland

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Exploring Compassionate Care in Virtual Rehabilitation: Qualitative Study

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Abstract

Background: Virtually delivered health care services can offer numerous benefits, and the demand for virtual care continues to grow among subgroups facing mobility challenges. The experience of compassion in health care is linked to patient satisfaction and clinical outcomes; however, this link in virtual rehabilitation settings is underexplored.

Objective: The objectives of this study were to explore what compassionate care means to rehabilitation patients in a virtual rehabilitation context and explore patients' experiences of how the technology associated with virtual rehabilitation impacted their experience of care.

Methods: We conducted one-on-one semistructured qualitative interviews with patients with limb loss and chronic obstructive pulmonary disease. A reflexive thematic analysis approach was used to generate domain summaries and initial themes across the sample. Themes were generated following analytic work over a series of discussions within the research team.

Results: Sixteen interviews were conducted. Four themes illustrating participants' perceptions of compassionate care were generated: (1) features of compassionate care include feeling valued, connected, and cared for by the health care provider; (2) threats to compassionate care in virtual rehabilitation; (3) facilitating compassion in virtual rehabilitation through preparation; and (4) benefits of virtual care.

Conclusions: Patient perceptions of compassionate care in a virtual rehabilitation setting may be impacted by the behaviors and communication of providers. Provider training and preparation and the personal connections formed with their patients may impact compassionate care experiences.

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KEYWORDS

compassion; rehabilitation; virtual care; virtual rehabilitation; limb loss; chronic obstructive pulmonary disease; qualitative interviews

Introduction

Virtual care refers to health care services that are delivered remotely through the use of communication and digital technologies in order to benefit patients and maximize the quality of patient care. The COVID-19 pandemic resulted in an increased use of virtual care in Canada, with broad adoption across provider groups and types of chronic disease [1]. The increased demand for virtual care during the COVID-19 pandemic is expected to continue post pandemic [2], especially for individuals and subgroups that experience challenges attending in-person, for example, due to mobility challenges [3,4].

A growing body of literature about virtual care has described its numerous benefits, including convenient access to quality care, reduced time and cost of traveling to appointments, and improved access for rural or isolated communities [5]. Virtual care is also particularly beneficial for patient populations with a high disease burden [5]. Some benefits for providers include improved care efficiency (eg, seeing more patients and fewer missed appointments) and more frequent contact between patients and providers [5,6].

There are also limitations to virtual care, such as difficulty establishing a therapeutic connection between providers and patients [7], the absence of physical examination [5,8], limited availability of physical equipment, absent or inadequate cellular

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services, and the costs associated with training personnel to implement virtual care [5,6,8].

Compassion is an important cornerstone of quality health care [9-11] and a critical element of person-centered care. Compassion has been defined in several ways, including recognizing suffering in others, understanding the humanity of this suffering, feeling emotionally connected with the suffering person, tolerating difficult feelings that arise, and acting or being motivated to act to help the person [12]. Compassion has been associated with improved patient satisfaction, compliance, and clinical outcomes [13-16]. According to Hodges et al [17], digital tools can shape individuals' expectations, actions, and behaviors; impact the patient-provider relationship; and shape the experience of compassion in health care. As we continue to use virtual care options, it is important to ensure that the care offered virtually is as compassionate and of high quality as the care offered in person.

In the rehabilitation setting, compassion is important for person-centered, empathetic care [18]. Although the importance of compassion in a rehabilitation setting is well recognized, there is very limited information on how compassion is communicated when the process is virtual. Individuals who experienced lower limb amputation (LLA) and individuals with chronic obstructive pulmonary disease (COPD) are examples of populations with chronic conditions who benefit from rehabilitation services to improve symptoms, function, mobility, and health-related quality of life. Exploring the experiences of individuals with LLA and COPD receiving virtual rehabilitation will provide valuable insights to inform the delivery of compassionate, person-centered care in practice. The 2-fold objectives of this study are (1) to explore what compassionate care means to patients living with limb loss and COPD who receive virtual rehabilitation consultations and (2) to explore patients' experiences of how the technology associated with virtual rehabilitation impacted their experience of care.

Method

Study Design

We adopted an interpretive descriptive approach [19]. Interpretive description is the investigation of a clinical phenomenon of interest for the purpose of capturing themes and patterns within subjective perceptions and generating an interpretive description to inform clinical understanding. We used the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines.

Ethical Considerations

This study received research ethics approval from the Joint Research Ethics Board at West Park Healthcare Centre (REB number: 22 - 005-WP). Informed consent was obtained from all participants prior to study participation and all data was de-identified. Participants received an honorarium of CAD $25 (US $19.59) for completing the interview. The conversion rate during the study period ranged between US $0.7203 and $0.7835.

Recruitment

Participants were recruited from a rehabilitation hospital in Ontario, Canada. Individuals who were over age 18 years and had participated in at least one virtual care appointment at the rehabilitation center were eligible to take part in the study. Participants were required to be able to communicate in English and tolerate participating in a 45- to 60-minute interview.

For feasibility reasons, a convenience sampling strategy was used. Participants with limb loss or COPD were recruited, as these clinical populations represented the majority of individuals who were offered virtual care in the rehabilitation setting. Sampling from 2 subgroups was appropriate for this study because the research focus was on the experience of compassion during the virtual care interaction, rather than on any condition-specific issues. Where experiences or perceptions vary between subgroups, this is described in the Results section.

Individuals who consented to be contacted for the study and had completed a virtual visit were approached to participate in the study. Informed consent was collected prior to an interview taking place.

Data Collection

One-on-one interviews using a semistructured interview guide were conducted remotely via telephone or Zoom. Interviews were conducted by one researcher (BL). The interview guide was developed by the research team based on previous literature (see Textbox 1).

Textbox 1. Interview guide.

1. Can you first briefly tell me about yourself and what led to your need for rehabilitation?
2. I understand you had a virtual or remote consultation with a health care provider related to your condition or disability. Tell me about that experience.
3. Tell me about what it was like having your consultation with the team virtually.
4. What worked well about the virtual consultation?
5. What did not work well about the virtual consultation?
6. We often talk about the importance of compassion in health care. What do you understand about the word compassion when you hear it?

Interview questions were open-ended, exploring virtual care experiences, including what worked well and what did not work well, the meaning of compassion, and the experience of compassionate care. Probes were used to elicit more in-depth information and clarify participant responses. After each interview, the interviewer wrote supplementary field notes to

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allow emerging insights to be incorporated in the ongoing data collection. Data collection and analysis were iterative. Demographic and clinical information was collected to describe the participants. Interviews ranged between 25 and 48 minutes.

Data were collected until researchers were satisfied that data were comprehensive enough with sufficient depth of data to identify recurrent thematic patterns in addition to having breadth of experiences in the context of the study setting. Interviews were recorded and transcribed verbatim. NVivo (Lumivero) qualitative software program was used to organize the data.

Analysis

A reflexive thematic analysis approach was used to generate domain summaries and initial themes, or patterns of shared meaning united by a core concept [20]. A coding framework was developed following data familiarization [20]. Two researchers familiarized themselves with the data by reading transcripts (BL and CM) before meeting to develop a preliminary codebook with codes and code descriptions. The codebook was used to code 2 additional transcripts, and revisions were made to the codebook. Subsequently, 2 researchers (BL and PF) coded each transcript. Incorporating 2 researchers allowed us to explore multiple assumptions or interpretations of the data. Memos were written as part of the analytic process to encourage reflexivity. Field notes were written after every interview, and notes were summarized and discussed.

Two reviewers (PF and AT) reviewed all codes and separately generated domain summaries before meeting approximately 5 times to discuss and record their interpretations of the data. Themes were generated inductively during this process. Following the generation of initial themes and domain summaries, 3 team meetings between researchers (PF, AT, and CM) were held to question one another, discuss and refine themes, clarify language, and interrogate the data to consider alternative interpretations.

Consistent with reflexive thematic analysis, the researchers played an active role in knowledge production and generation of themes [20] and considered the interpretation of the data. Themes were generated following analytic work over a series of discussions and were actively created through creative labor involving coding, discussion, questioning, and decision-making [20]. Memos and diagrams were generated to summarize and interpret the data. Demographic and clinical information was collected and summarized using descriptive statistics.

Results

Participants

Sixteen participants consented to take part in the study and completed the interview. The sample consisted of individuals with limb loss (n=7) and individuals with COPD (n=9). A description of the study sample is provided in Table 1.

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Table . Demographic data.

Characteristic	LLA[a] (n=7), n	COPD[b] (n=9), n	Total (n=16), N (%)
Gender			
Female	1	4	5 (31)
Male	5	4	9 (56)
Employment status			
Full time	0	1	1 (6)
Retired	5	5	10 (63)
Unable to work	1	2	3 (19)
Education (highest)			
High school completed	1	3	4 (25)
Some college or university	3	2	5 (31)
College or university completed	2	3	5 (31)
Living arrangement			
Alone	0	2	2 (12.5)
Spouse or partner	3	3	6 (37.5)
Children	1	1	2 (12.5)
Spouse and children	1	1	2 (12.5)
Parents	1	0	1 (6)
Sibling	0	1	1 (6)
Age (years), mean (SD)	61.33 (15.77)	70 (10.54)	66.29 (13.24)

[a]LLA: lower limb amputation.

[b]COPD: chronic obstructive pulmonary disease.

[c]Responses to demographic questions were provided by 14 of 16 study participants. Two participants could not be reached following the interview to complete the demographic questionnaire; therefore, data for those participants are missing.

Four themes were generated to illustrate participants' perceptions of compassionate care based on their experiences with virtual care in a rehabilitation setting.

Theme 1: Features of Compassionate Care: Feeling Valued, Connected, and Cared for by the Health Care Provider

Overview

This theme characterizes participants' perceptions of the key features of compassionate care. While the features may not be unique to virtual care, they were seen as important components of compassion in the context of virtual rehabilitation. Several participants described compassion as a feeling of being taken care of, being heard, and being validated. Compassion was equated to caring, kindness, understanding, and warmth. They described compassion as positive, personal, and individualized, not judgmental or offensive. One participant indicated compassion made them feel valuable, like their life is worth something. Reflecting on their experience of compassionate care, one participant stated:

> *I feel good. I mean it's very, you know, it's you feel safe. You feel looked after. You feel heard. It's very helpful and I think it can - overall contributes to the healing process if you've got someone who cares.* [Participant 2]

The following subthemes further describe the core components of compassionate care from the participants' perspectives.

The Caring Health Care Provider

A health care provider's (HCP's) ability to offer empathy, reassurance, caring, and attentiveness influenced participants' experience of compassion. Being caring was most often associated with compassion. For example, one participant stated having a caring and empathetic HCP was more important than other aspects of bedside manner. Caring was described as the effort that HCPs made to show patients they are valued. This included caring actions such as remembering specific details about the patient and asking questions. When participants reflected on instances of genuine caring, their accounts highlighted the importance of authenticity in caring and the importance of an HCP being curious, observant, and attentive and having genuine concern about how their patients are doing. One participant shared this perspective about caring for HCPs and compassion:

> *To me compassion is authentically, authentic concern and care for an individual. You can put it on and pretend it, you can fake it, you could, but compassion is when it's authentic genuine care and concern for*

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> *the wellbeing of someone else and you want the very best for them and the very best outcome for them.* [Participant 3]

Reassurance went hand in hand with caring and was also an important part of compassion. Many participants indicated they felt reassured when HCPs addressed their questions or concerns and went out of their way to be caring. Reassuring words and actions from the HCP helped establish comfort and trust, and made the patient feel like they could turn to and trust the HCP. Many participants shared stories about a difficult moment when an HCP was reassuring to them—participants valued this and interpreted that as compassion. One patient described that compassion involves the HCP understanding what is going on with the patient and advising and acting from that understanding.

Patient-Centered Behaviors: HCPs' Willingness to Help

Participants sensed compassion when HCPs seemed motivated to take action to care for them and were willing to help. Compassion was expressed as actions or words and involves "doing the little things" and "going the extra mile." Participants shared:

> *So, it can be actions. It can be words. It can be just making, you know, those, a lot of time it's words, just making sure like you know, if there's anything you need at all you just, please, please don't hesitate to call and let us know. We're here for you. That kind of extra bit.* [Participant 3]

> *I'm not very tech savvy, so yeah, the pictures I sent but I didn't send it to the right spot. So, then actually the doctor was on the phone with me and said, okay, this is how you do it and he started to help me, and we got it done…Yeah, so he was very, very…he's very helpful in all aspects…And anything that you need or anything – any concerns that you have, he addresses them…I mean usually they don't – doctors don't give you that kind of care, like, you know what, they brush you off and say okay, well you know what, you're gonna have to figure out – maybe get somebody to help you, no, he helped me…But yeah, step by step. Above and beyond.* [Participant 6]

> *And then with the virtual class now, one lady she does exercises with you and then there's another lady. I think she's just watching everyone to make sure everybody's okay. And if she sees that you look kind of distressed, she'll call you up and say…She'll say like I think you should just stop a minute, …they show compassion to everyone to make sure you're okay…You know, it's not just, okay, do this, do that and that, okay, next do this, do that. No. They make sure you're okay.* [Participant 14]

Willingness to help involved a genuine interest from an HCP for doing things to improve patients' well-being, including taking a step beyond traditional duties and building personal relationships. Many participants provided examples of HCPs exhibiting a willingness to help, which made participants feel cared for and motivated to get better. Participants consistently expressed that compassion felt like it was more than just doing a job and should not feel like it is a business. One participant stated:

> *To me, I never – I never really felt that, oh, you know, this is just – you're just a number and here we go. I find that they're very compassionate and they're very helpful to what you need. And I never felt brushed off, like, never rushed.* [Participant 6]

HCP Communication

Effective communication by the HCP helped participants feel compassion during virtual care appointments. Participants valued a HCP with good communication skills (eg, could "carry a conversation well"), who was personable, social, and attentive. Participants also felt better cared for when the HCP was organized, spoke clearly, and could be easily understood, and when the HCP made an effort to have a personal connection and to make patients feel comfortable (eg, by engaging in conversation outside of their medical condition). The attitudes, mannerisms, and tone of voice of the HCP conveyed compassion. Many participants interpreted clarity of information provided by the HCP as a component of compassion, as it enabled them to have a good understanding about their health condition. Several participants highlighted their preference that HCPs use language that could be easily understood and take the time to explain what is going to happen. One participant reported the following about HCP communication with patients and compassion even when they may not completely understand the experience:

> *…the doctors talk to you and explain things as if they were an amputee. Like they're not just saying do this, do that, you know, they kind of – I found it anyway that they really understood it and didn't make you feel like you were just some, you know, some guy with their leg cut off type thing. Like they understood, kind of understood what I was going through. And did their best to help me in that respect.* [Participant 5]

Participants indicated that not feeling rushed was an important part of making a connection with the HCP. In a virtual appointment, the conversation remained focused on the purpose of the appointment, and the duration of the appointment did not typically exceed what was scheduled. Compared to in-person care, where discussion could veer in many directions and many questions could be asked, some participants felt rushed during virtual appointments. One person shared their views on how feeling rushed may impact the experience of compassion:

> *That's just some of the things that was kind of like it just feels like the doctor doesn't really care or, you know, he's not compassionate about you. He's just more compassionate about getting his job done for the day type of thing.* [Participant 4]

Theme 2: Threats to Compassionate Care in Virtual Rehabilitation: Making a Connection

This theme illustrates the unique challenges of delivering compassionate care in a digital setting based on participants' experiences with virtual care. From the perspective of some participants, compassionate care was threatened when there was

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an inability to see the HCP in a virtual appointment. When individuals struggled with technology and required a phone consultation rather than video, some participants suggested this impacted their ability to connect with the provider, as they could not see visual information such as the HCP's face, facial expressions, and mannerisms. One participant stated:

> *Well, I think that's more difficult because it's just – it's not on the same level. You know. When you're standing next to a person or you're standing next to you, you do have that personal observation, that personal connection and on a screen you don't.* [Participant 15]

The lack of body language and expressions could make the visit feel impersonal. As such, one participant recommended the importance of an in-person meeting prior to virtual meetings so they could become familiar with the HCP.

> *Well, I think it would be important that there is a physical meeting before. So, you go in and you visit the physician face-to-face. So, when somebody is talking to you on the phone, it's not a disembodied voice, you can actually have a picture in your head, what this person looks like, some of their mannerisms so you start to feel more comfortable of what is going to happen. I think if you were to do a virtual – it gets very clinical. It gets very – well, I shouldn't use the word clinical. But it gets to be very sterile. Here is the question. Answer it. Move on. Next. You know, conclusion, we're out of here. See you.* [Participant 1]

As a result, most participants strongly preferred video over phone connections, stating the visual information made them feel more comfortable, and several participants linked this to the experience of compassion in virtual care.

> *Well, you know the whole compassionate aspect, it's only words really. You can't see the person. Well, I guess it would be a visual thing. I mean you can't really see their reaction or, you know. Talking to someone on the phone, you can't tell if they're, you know, what their feelings are or whatever.* [Participant 7]

Other participants identified the lack of touch to be a limit to connection in virtual care. This not only limited the HCP's ability to assess the patient fully but also could limit the connection for some participants as described by one participant:

> *Like just listen. Listen to their -- listen to their pain. Be sad if they're sad. Be happy if they're happy. I'm -- like, you know, I don't know. I mean you can't hold them. Like you can't reach out and touch them. And touch is being the greatest compassion at all that there is. And so, you can't do that. So, you got to try to do it with your eyes, with your expressions, with your facial expressions, etc.* [Participant 9]

One participant's account showcased the challenge of delivering compassionate care in a digital setting. The participant shared:

> *Well, all of the video calls that I had with my doctors, the only one doctor I didn't like how he handled his was that he used to go by a window frame. As soon as that window's over, your time's up type of thing. So, if he gives you a fifteen minute video call or a call or virtual call or whatever you want to call it, and then in that fifteen minutes your time's up and you didn't get to say what you wanted to say or the help that you needed wasn't provided at the time, that's the only downfall I see in the system…That's just some of the things that was kind of like it just feels like the doctor doesn't really care or, you know, he's not compassionate about you. He's just more compassionate about getting his job done for the day type of thing…So, that's the only downfall I had with my virtual appointments.* [Participant 4]

To mitigate some of the innate challenges to providing compassion in virtual care, some participants suggested that prior to delivering virtual care, HCPs should receive training on communication skills about etiquette such as making eye contact, using an interesting background, and not taking calls in non–health care settings. Some participants also discussed the benefits of forming a personal connection to establish rapport with the HCP prior to starting virtual care, for example, via a one-on-one call.

Theme 3: Facilitating Compassion in Virtual Rehabilitation Through Preparation

In this theme, participants highlighted the impact of adequate preparation by the HCP in advance of the appointment on their experience of compassion. Participant descriptions about preparation for the appointment revolved around 2 aspects of the appointment: the behaviors and actions of the HCP and the logistics surrounding the appointment.

Behaviors and Actions of the HCP

Many participants indicated that when HCPs exhibited confidence in the technical skills required to run a virtual appointment or familiarized themselves with patient files and patient history, these actions heightened participants' feelings of compassion in virtual rehabilitation. One participant illustrated how this was linked to compassionate care:

> *…But the doctor, you know, he remembered specifically what had happened at last year's visit…And he remembered the condition of the stump and he specifically asked, you know, did that, you know, has that stayed in that condition and yeah. He just – I think he cares I suppose. I think that's the overwhelming impression that I get left with… and if he doesn't remember, he's at least taken two minutes before getting on the horn and he's looked through my file and he's realized what he's done before, and he can make a comment on it. He familiarized himself with me that's all. And so, and that, you know, I mean whether or not that's his actual memory or not, it doesn't matter. It comes across to me as, you know, as make me feel cared for and important and all that.* [Participant 2]

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The experience was also described as more positive and pleasant when the HCP used a visually welcoming background during video calls.

HCP and Appointment Logistics

Participants indicated they perceived greater compassion in virtual care when they were clear in advance of their appointment on what to expect during their appointment. Participants felt better prepared when the purpose of the call was clarified, when they were informed about what would be happening during the appointment (eg, whether it will be telephone or video-based, which questions they might be asked, and which exercises they would be doing), and when they received instructions about how to join the call. When participants felt better prepared, they were more relaxed and confident about virtual care.

Some participants described the benefits of offering training to HCPs on the fundamentals of delivering virtual care, noting that such training could streamline HCP behaviors and appointment logistics. For example, one participant explained:

> *I mean take a Zoom 101 basics course or something like that (laughs) All those goofy mistakes that, you know, there's not a bright light behind him. All that sort of, you know, practical stuff. I think if you take all the technical stuff out of it and make it easy in that respect, you're just going to get better results trying to convey any kind of emotion through video.* [Participant 2]

Theme 4: Benefits of Virtual Care: Fitting Health Care Into Life

This theme describes how delivery of care virtually ensured that participants could fit their health care into their lives, enabling patient autonomy and control. The use of technology enabled participants to receive care while staying home, enabled them to be efficient with their time, and in some instances, offered additional autonomy and independence in their lives. Patients reported shorter wait times for virtual appointments; patients were seen sooner and had a greater number of touchpoints with the HCP, as it was much easier and faster to get to an appointment. Virtual appointments occurred on time as compared to in-person clinic visits, which often ran late. Through virtual care, patients avoided spending time on unnecessary tasks such as driving for long hours; finding parking; using a wheelchair, walker, or other assistive devices; and having someone else drive and attend the appointment, all of which were not required for virtual care. This was convenient for participants, and notably, it granted participants more autonomy and control in their lives since the call could be done independently and did not necessitate, for example, someone to drive them to the appointment. Participants shared the following views about attending appointments virtually:

> *And honestly, I think that that system is working much better, and it should be better for like I'm pretty sure any patient that's disabled. Like it would make your life so much easier and it's like you're in control. You don't have to go out of your house, get in a wheelchair or any assisted devices, get into a vehicle, have someone drive you or drive yourself, you know, it's more of a hassle, right, that you have to leave earlier. So, this is like more convenient for us I guess or not just us, but like for anybody, it's more convenient that you can do a virtual doctor's appointment and get the treatment that you need.* [Participant 4]

> *To me, that was great. I don't know about other people, but for me, it was great because I didn't have to try and get ready, try and get dressed. Put on the oxygen. Try and get in the car. Take the walker and trying, try and find where it is in the hospital. And then it's only like a half hour appointment, then you got to do all the things back home again. So, it was ten times easier for me.* [Participant 9]

While the option of virtual care often promoted autonomy, there were examples of participants still requiring assistance to partake in virtual care. A few participants noted they had the technology available but lacked the knowledge and confidence to use the technology to facilitate the call, especially to initiate the call. As such, they enlisted help from others, including family members and care staff, to facilitate the call or obtain the technology. One participant described:

> *Well, (laughs), if it wasn't for my grandchildren and my daughter, I wouldn't be able to do anything with technology because I'm one of them old farts that just – I can talk on the phone…* [Participant 5]

One participant suggested an approach by which the HCP and their team could assist patients with becoming oriented prior to the scheduled call, enable autonomy, and ensure a successful consultation:

> *So, it's just like there should be like an educational assistance, tutorial or a video of what apps or doctors if do use like virtual calls, have the person sit fifteen minutes earlier so they know how to flip the video over on the camera. So, there's a front camera and a back camera, right. So, like little things like that. I think that – if there was like a little tutorial on that just before your video call it would be fresh in your mind and I guess that'll help a lot of patients.* [Participant 4]

In most situations, virtual care enabled participants to fit their health care into their daily lives, allowing them to adjust to various circumstances (eg, patients' roles and responsibilities and weather conditions). For example, one participant highlighted that virtual appointments enabled them to sleep in, take calls in their pajamas, and even be home to receive packages and do other tasks. One participant reflected on the additional conveniences available to him; notably, attending virtually allowed him to continue being available to help his wife, who was also an amputee and to whom he was a caregiver.

In addition, the option of virtual care often enabled patient preferences to be incorporated into their health care. For example, HCPs often accommodated to the patient's schedule. Some participants noted scheduling an appointment seemed flexible and was not a hassle. One participant reflected on the flexibility:

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> *And they're always very convenient. That's the nice thing about the doctors are very flexible with their times. If I'm not available, I found that they're available at a different time. I think their time is a little bit different schedule for sure. So that is, that is an advantage. That okay, if you can't talk between 10:00 and 10:15, can we talk to you between 1:00 and 1:15 and that kind of thing. So that's nice because that makes it feel like it's not all on you to have everything figure out according to their schedule. It's still that your personal situation still matters.* [Participant 3]

The option of virtual care also provided safety and comfort to some participants by offering relief from concerns about the COVID-19 pandemic. A few participants described their concerns about being exposed to COVID-19 while attending appointments in person and while waiting for appointments. Participants expressed that virtual appointments offered a sense of relief and comfort and were a safer alternative that allowed them avoid going in to hospitals during the pandemic. For example, one participant noted:

> *…with the virtual visits I, of course, and being scared of Covid like everybody was, it puts your mind at ease that I didn't have to take a chance of going down and because it was actually a visit to the hospital.* [Participant 5]

Discussion

Principal Findings

This study provides an understanding of the perceptions and experiences of compassion in virtual rehabilitation from the perspective of individuals with ongoing functional disabilities as exemplified by LLA or COPD. These findings extend our understanding of the meaning of compassion from a patient's perspective and shed light on key elements of compassionate care. By highlighting how compassion can be enacted in clinical encounters and the unique facilitators and threats to compassionate care in digital environments, these findings can be used to inform strategies to support HCPs to optimize the delivery of compassionate virtual care for people in rehabilitation settings.

First, our research provided insight on how participants perceived compassionate care. Our study reported that a feeling of connectedness with the HCP, an HCP's genuine concern and willingness to help, and patient-centered communication by the HCP are paramount for compassionate care. This is consistent with prior research in which previous definitions of compassion in both face-to-face and virtual health care settings focused on connection and concern for patients. Baguley et al [21] highlighted the importance of connection in a health care setting. They reported that 71% of participants in their sample felt compassion when the practitioner displayed listening and paid attention. A recent qualitative study by Wu and colleagues [22] examined patient-provider communication and compassion in a virtual setting and highlighted the important role of the patient-provider connection. The authors noted that feelings of autonomy and being prioritized were foundational for experiencing compassionate care in a virtual care setting.

Participants identified unique threats to compassion in a digital environment, including lack of connection with the HCP. We also identified new insights about the ways in which HCP actions navigating virtual care during appointments; appointment logistics and HCP preparedness for consultations enhance patient comfort and feelings of compassion during a virtual visit. Study findings are consistent with recent work by Desveaux and colleagues [23] in a primary care setting, which illustrates that a provider's behaviors are linked to how compassionate care is perceived by patients.

Wu and colleagues [22] suggest the importance of virtual training in offering clinicians the requisite technical, examination, and communication skills for positively impacting their comfort and preparedness for virtual interactions with patients. Such strategies may help to address some of the threats to compassionate care imposed by virtual care by enabling people to have successful virtual visits. Delivering compassionate care may call for structured preparation and training of HCPs to deliver virtual rehabilitation (eg, digital skills and communication skills in a digital environment). Future work is needed to explore best practices to facilitate compassionate behaviors in virtual care and the optimal models for training HCPs for compassionate virtual care.

Interestingly, participant perspectives reported in our study suggest an interplay between compassion and autonomy and comfort experienced in virtual rehabilitation. Participants identified several benefits of virtual care, including that wait times were shorter, they expended less time and energy to attend virtual appointments as compared to in-person care, and appointment times were more flexible. This is consistent with literature highlighting the convenience of virtual care [5,6]. However, our findings suggest that the benefits go beyond convenience for populations with complex health needs by enhancing a sense of control, autonomy, and independence, with less disruption to other aspects of daily life.

Study Limitations

For pragmatic reasons, we recruited a convenience sample of individuals who attended a virtual appointment. This method may not have captured those who faced major barriers and were unable to access virtual care. There was variation in the mode of virtual care and types of virtual appointments that participants had attended (eg, phone and video) and the nature of the activities that were being completed during the virtual appointment (eg, physiotherapy and consultation with a nurse or doctor). While participants received at least one virtual rehabilitation consultation, some participants had additional virtual interactions, for example, as a result of participating in virtual exercise in a group setting. We did not ask study participants about the total number of virtual appointments they attended, and thus, could not consider how their level of experience and comfort with tools and technology may impact their perspective about their virtual care interaction. Findings may not be transferable to other settings or populations due to the unique needs and experiences of the participants in this study. Moreover, participants who opted for virtual care may

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have different characteristics than those individuals who did not or could not access virtual care.

Conclusion

Our study identified key aspects of the patients' perception of compassionate care in virtual rehabilitation settings. Ensuring that HCPs are prepared and adequately trained in forming personal connections with patients, communicating effectively in a virtual setting, and using the tools necessary to facilitate the connection prior to initiating a patient-provider relationship in a virtual setting will contribute to this being a positive patient experience. Future work could explore whether virtual care should be introduced only when extending an existing face-to-face patient-provider relationship and whether virtual care might be reserved to address only certain needs within the care journey. Potential changes to patients' attitudes and perceptions about virtual care as they progress through their care journey and develop rapport with their HCP could also be explored.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

COPD: chronic obstructive pulmonary disease
COREQ: Consolidated Criteria for Reporting Qualitative Research
HCP: health care provider
LLA: lower limb amputation

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Original Paper

The MyGuide Web-Based Self-Management Tool for Concussion Rehabilitation: Mixed Methods Cross-Sectional Study

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Abstract

Background: Web-based concussion self-management education programs for adolescents can improve functional outcomes, reduce concussion symptoms, and increase self-efficacy. However, there are a limited number of studies examining the perceptions and acceptance of these programs and the use of these tools in the adult concussion population.

Objective: This study aimed to investigate the perceptions and acceptance of clinicians and adults with concussions using MyGuide Concussion (Vancouver Coastal Health), a web-based concussion self-management tool.

Methods: Using a mixed methods sequential explanatory design, a convenience sample of 8 adults with concussions and 8 clinicians who used MyGuide Concussion over a 2-year period were interviewed, and their responses were analyzed.

Results: Participants reported two key benefits of using the web-based self-management tool: (1) the tool's emphasis on the interconnectedness of physical and psychological symptoms, and (2) the ability to provide reassurance that symptom being experienced were a normal part of the concussion experience. Clinicians described the tool as being useful as a supplementary source of information for clients in addition to clinical sessions and believed the content was useful for increasing clients' independence in managing their own recovery.

Conclusions: Overall, the evaluation of the MyGuide tool is an acceptable and well-perceived tool for adults with concussions who require a basic understanding of concussion recovery, particularly in the early stages of recovery. Future research may include optimizing MyGuide by targeting promotional strategies and addressing other barriers to use.

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KEYWORDS

concussion; self-management; health information technology; perceptions; concussion recovery; concussion management; concussion rehabilitation; rehabilitation; self-management tool; perception; digital health; e-health; mobile app; mhealth; web-based tool

Introduction

Lifetime concussion prevalence in adults has been estimated to be as high as 29% [1], with an annual incidence rate of approximately 1.2% in recent years being the highest it has ever been [2]. Concussion symptoms vary between people and across an individual's recovery process [3]. Symptoms can be experienced as physical (eg, nausea, headaches, and decreased

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balance), psychological (eg, worsened anxiety, depression), or cognitive (eg, changes in concentration and memory) [4-6]. While most people recover within 2 weeks without intervention, some people experience persistent symptoms [7].

Self-management is a type of educational intervention that provides an individual with strategies and lifestyle behavior changes to manage the injury and improve overall recovery [8]. Concussion self-management (eg, information about concussion symptoms, prognosis, self-management behaviors, and resuming preinjury roles) can improve a person's understanding of their injury and related symptoms such as sleep and anxiety, reduce postconcussion symptoms [9-11] and facilitate recovery and return to preinjury activities and roles [12-18]. Furthermore, the timely provision of concussion education in the early stages of recovery has been found to lower the risk of developing prolonged postconcussion symptoms, especially for those with more severe traumatic brain injury (TBI), and when implemented within 3 months of injury [13,19]. Though there is no consensus on the optimum time for the introduction of concussion education, studies reporting improvements mainly focused on participants who were between 1 week to 6 months post injury [13,17].

-Technology-based education programs for individuals experiencing concussion symptoms show promise for improving recovery outcomes and self-management self-efficacy, given their accessibility and convenience, particularly for those living in rural and remote areas or areas that do not offer specialized health services [20]. For clinicians, the web-based delivery of health services and education can enhance clinician-client engagement and improve client-driven active participation in their own health [21]. For adults, a self-paced, web-based educational intervention for civilian, military service members, and veterans with postconcussion symptoms was found to increase self-management self-efficacy and improve concussion symptoms for individuals that had longer periods since injury (ie, 1 year) [22]. Overall, the evidence, though limited in amount, supports technology-based concussion education programs as a far-reaching and accessible approach to enable behavioral change, improve recovery outcomes, and help individuals return to their occupations before their injury.

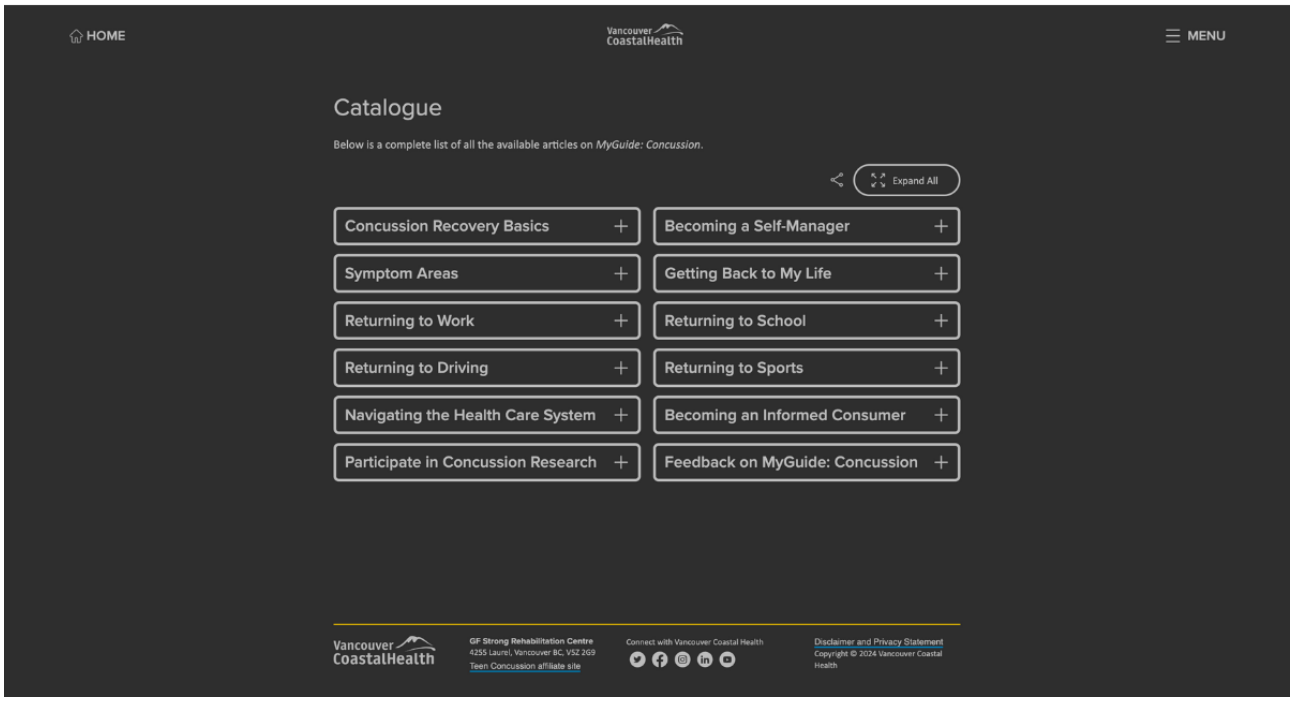
The MyGuide Concussion tool (Vancouver Coastal Health) aims to provide current best practice knowledge to help individuals with a concussion manage their symptoms and empower them with the skills and confidence to take action in their recovery journey. While there are a number of websites that provide evidence-based concussion education, the MyGuide Concussion tool was designed to fill a gap by providing customized material and actionable ways to implement evidence-based self-management strategies into daily life. It will thus be referred to as a self-management tool. The tool was developed in 2019 by experienced clinicians working in the field of concussion, content experts, and through consultation with community stakeholders. The clinical material provided in the MyGuide Concussion tool was based on the Guideline for Concussion/Mild Traumatic Brain Injury & Persistent Symptoms developed by the Ontario Neurotrauma Foundation [23], and information is updated every 6 months. The MyGuide Concussion tool creates a personalized guide for each user, specifically targeting adults (ages 18 years and older) at any stage of recovery. Content is based on modules that include information, tools, and worksheets on relevant topics for people with concussions, as shown in Figure 1. The tool provides reminders to facilitate positive health behaviors and promote self-management while engaging with the tool (eg, taking regular breaks). Though intended to be used on a desktop computer, the MyGuide Concussion tool can be used on any device that can access the internet site.

Much of the literature on technology-based interventions involves randomized controlled trials examining postconcussion symptom improvement after interventions; however, in addition to quantitative measures, understanding the perceptions and acceptance of self-management tools is essential to identify barriers and facilitators to adherence and effectiveness of these tools. In a study on digital health interventions for concussion in adults, the perceptions of the intervention were positive, with high overall usability [24]. Another study implemented a web-based concussion education program and indicated that the concussion education program was easy to use and helpful for participants' recovery [25]. Overall, the perceptions and acceptance of web-based concussion education programs for adults is a relatively underexplored area, and it is important to continue to explore the design considerations that may be unique to this particular population. Importantly, the perceptions of the MyGuide Concussion tool have not yet been investigated.

The main purpose of this study was to evaluate the perceptions and acceptance of the MyGuide web-based customizable concussion self-management tool in the adult population. Perceptions will be determined based on usability, accessibility, and suitability of the site, and acceptance will be evaluated based on adherence to and impact and relevance of the site.

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Figure 1. Modules from the MyGuide Concussion tool as they appear in the Catalogue view.



Methods

Study Design

This study used a mixed methods sequential explanatory design [26]. Integration of quantitative and qualitative data occurred at the level of sampling and analysis [27]. For sampling, we used a connecting approach in that participants who completed the quantitative surveys were invited to participate in the qualitative interviews. For the analysis, we used a merging approach, in that we compared responses from the surveys to comments from the interviews to identify any differences and gain a deeper understanding of the perceptions and acceptance of the MyGuide Concussion tool. Qualitative interview questions were developed based on responses provided in the quantitative surveys. The Design and Evaluation of Digital Health Interventions (DEDHI) framework was used to develop survey and interview questions in order to understand the perceptions and acceptance of using MyGuide. The DEDHI framework is a consolidation of various health promotion evaluation frameworks and life cycle models specific to digital health programs and can be used in all aspects of the technological life cycle, from early conceptual models to large-scale implementation in the health care sector [28].

Quantitative Recruitment

Recruitment occurred from December 11, 2020, to May 31, 2021, using convenience sampling. Recruitment for the survey was done through a pop-up window that appeared on the MyGuide Concussion tool. Individuals with concussion were included in the survey if they were 19 years or older, experienced a concussion within the last 2 years, and used the MyGuide tool. Individuals with any neurological health condition (eg, stroke, multiple sclerosis, Parkinson, and spinal cord injury) that may require services and resources beyond the scope of the tool were excluded from the study.

Quantitative Data Collection

A total of 8 participants with concussions completed a 10- to 15-minute survey conducted online or by telephone from January 24, 2021, to May 30, 2021. The survey included questions about general demographic information and an outcome measure of technology usability (Health Information Technology Usability Evaluation Scale (Health-ITUES)). This measure consists of 20 items with 4 subscales of impact, perceived usefulness, perceived ease of use, and user control, which have been used to assess the usability of web-based programs for adults living with a chronic health condition [29]. The measure has demonstrated high internal consistency reliability (Cronbach α=0.85-0.92).

Quantitative Data Analysis

The data are reported using the Good Reporting of a Mixed-Methods Study [30]. Quantitative data were analyzed using descriptive analysis to describe the demographics and Health-ITUES questionnaire.

Qualitative Recruitment

Recruitment occurred from February 7, 2021, to September 9, 2021. Participants with concussions were invited to participate in the qualitative interviews once they had reached the end of the quantitative survey. Recruitment for clinicians occurred through the use of the researchers' professional network. Clinicians were included if they were currently working in the concussion rehabilitation field for at least 2 years, had therapeutic roles (eg, occupational therapists, physiotherapists, doctors, and neurologists), were practicing in British Columbia, and were familiar with or used the content in the MyGuide tool.

Qualitative Data Collection

Participants (both clinicians and people with concussions) engaged in online semistructured interviews through Zoom [Zoom Video Communications] from February 7, 2021, to

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September 9, 2021. The interview guides for participants with concussions are provided in Multimedia Appendix 1. The interview guides for clinician participants are provided in Multimedia Appendix 2. Interview questions for participants with concussions were adapted from a previous study that examined the user experiences of a self-management tool for individuals with spinal cord injury and their caregivers [31]. Qualitative analysis occurred alongside data collection to ensure data saturation was obtained.

Qualitative Data Analysis

The qualitative data were analyzed using conventional content analysis. This involves an inductive process of reviewing the data as a whole, then deriving codes from the individual responses themselves and categorizing these to identify connections and relatedness [32]. Conventional data analysis allows researchers to avoid imposing preconceived ideas or categories on participants and, instead, to focus on getting information directly from participants [32].

The qualitative data followed a 2-step analysis process**.** First, qualitative interview data were recorded and transcribed verbatim using a transcription program. Once transcribed, 2 researchers reviewed the transcripts and audio recordings for accuracy and removed any potential identifiers to protect participant identity. Each performed conventional qualitative content analysis separately and then compared to ensure accuracy and resolve any interpretive discrepancies. Both researchers performing the analysis were female undergraduate students, one with a background in behavioral neuroscience and the other in biology and psychology.

The research team used two main trustworthiness strategies. First, the authors were mindful of their positioning throughout data collection and analysis. A diverse range of perspectives was included to establish consensus in data analysis, including the remaining authors following the first round of coding. Complementary perspectives on the data were thus acknowledged, which allowed the authors to reflect on their biases [33]. Second, rich verbatim quotations from the interviews were included in the results to fully capture the voices of participants and increase the credibility of the findings [33,34].

Ethical Considerations

Ethics approval was completed by the University of British Columbia’s Behavioural Research Ethics Board (H20-02982).

Results

Quantitative Results

A total of 8 participants with concussions completed the surveys. Participants with concussion included 4 female and 4 male participants with an average age of 33.8 years (SD 12.3; Table 1). Health-ITUES scores are included in Table 2.

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Table 1. Demographics of participants with concussions who participated in the interview.

Characteristics	Study participants (N=8)
Average age in years	
Mean (SD)	33.8 (12.3)
Median (range)	36.5 (21-54)
Gender, n (%)	
Female	4 (50)
Male	4 (50)
Race[a] , n (%)	
White	4 (57)
Black	1 (13)
South Asian	1 (13)
Middle Eastern	1 (13)
Highest education, n (%)	
High school	4 (50)
College or Bachelor's degree or higher	4 (50)
Residence , n (%)	
BC Greater Vancouver	5 (63)
Outside of BC Greater Vancouver	3 (37)
Time since concussion (months), n (%)	
<1	3 (37)
1-3	2 (24)
3-12	3 (38)
Mechanism of injury, n (%)	
Fall	4 (50)
Sports injury	2 (25)
Motor vehicle accident	1 (13)
Blow to the head	1 (13)
Currently experiencing symptoms, n (%)	8 (100)
Have had previous concussions, n (%)	4 (50)
Full recovery from previous concussions[b], n (%)	4 (100)
Decreased screen tolerance, n (%)	6 (75)
Receiving Occupational Therapy services, n (%)	1 (13)

[a]One participant preferred not to answer.

[b]Of the 4 participants who had a previous concussions.

Table 2. Health-ITUES (Health-Information Technology Usability Evaluation Scale) scores of participants with concussion.

Scale	Mean (SD)
Impact	4.41 (0.46)
Perceived usefulness	4.10 (0.57)
Perceived ease of use	4.42 (0.46)
User control	3.93 (0.45)

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Perceptions: Usability

The Health-ITUES subscales Perceived Ease of Use and User Control were used as indicators of ease of navigation of the tool, with higher ratings indicating higher perceived ease of use and user control domains. Results showed relatively high scores by participants with concussion, with the perceived ease of use being 4.42 (SD 0.46) and user control being 3.93 (SD 0.45) on a 5-point scale. Most participants were using the MyGuide tool on the desktop platform.

Acceptance: Adherence

Both quantitative and qualitative data were used to understand adherence to using the tool. Survey data suggested that most participants had 1 to 5 visits to the tool in total. Furthermore, the survey data indicated that almost half of users completed 5 or more of the 11 modules.

Impact

Based on the Health-ITUES measure, where a rating of 5 on a Likert scale indicates strongly agree, Perceived Usefulness was 4.10 (SD 0.57), Impact was 4.41 (SD 0.46), and Overall Usability was 4.27 (SD 0.35). These high scores indicate that the tool had a positive impact on self-management and quality of life. Participants with concussion reported that they were looking for strategies to manage their concussion symptoms (8/8, 100%), more information about concussion symptoms (7/8, 88%), specific strategies for returning to normal day-to-day activities (7/8, 88%), and information on how to navigate the health care system (5/8, 63%). Overall, survey data suggested that people with concussions were either satisfied (4/8, 50%) or very satisfied (3/8, 38%) with the tool and generally described that the tool had met their needs (6/8, 75%). Respondents indicated that the tool provided background information about concussion, provided ways to manage concussion symptoms, and motivated recovery. All survey respondents indicated they would recommend the tool to other people with concussions, as they noted it was informative and provided people with reassurance and normalization of symptoms being experienced.

Qualitative Results

A total of 8 participants with concussions and 8 clinicians were included in the study. Participants with concussion included 4 females and 4 males with an average age of 33.8 years (SD 12.3; Table 1). Clinician participants included 7 occupational therapists and 1 physiotherapist, averaging 13.1 (SD 10.8) years in clinical practice with 8.5 (SD 4.7) years in concussion rehabilitation specifically (more details in Table 3).

Table 3. Demographics of clinician participants.

Characteristics	Participants, n (%)
Profession	
Occupational therapist	7 (87.5)
Physiotherapist	1 (12.5)
Sector	
Private	7 (87.5)
Public	1 (12.5)
Average years in practice, mean (SD)	13.1 (10.8)
Average years in concussion rehabilitation, mean (SD)	8.5 (4.7)
Location	
BC Greater Vancouver	8 (100)

Perceptions

Usability

Interview data provided context to the quantitative data. The majority of participants with concussions reported that the tool was simple and straightforward to use. One participant said, “[the website is] very linear... It shows you what you’ve done and, what you haven’t, and what you need to do next… It’s very, very well structured.” Participants also indicated that the clearly labeled topics, easy-to-understand section titles, and simple layout of the tool made it easy to find information. However, some participants reported confusion around use and navigation when initially using the tool independently, without the facilitation of clinicians.

Interview data from clinician participants indicated that the tool provided useful, curated, easy-to-understand, and credible information. One clinician explained:

> *Having one sort of a one-stop shop of information that's easy to go through is useful… [people with concussions] get lots of different information from different providers, and if they're symptomatic at the time, it's hard to take it all in…having somewhere just one source to go to is helpful. [The tool is] in an easy-to-read format, so it's not a lot of medical speak.*

Some clinician participants mentioned that some sections had a lot of information, which may have made clients feel overwhelmed.

Accessibility

Participants seemed to show a preference for different visuals than others (eg, dark mode vs light mode, and font sizes), and many described the value of the individualization and customization of the tool. Participants also reported that the concussion-specific accessibility features inherent in the tool (eg, clear, short sections of information) were helpful in creating

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an accessible tool. One participant stated, "[The site] was very accessible…the sections were clear, they were short, you know, the content was good. You know, pretty hard to misunderstand." Furthermore, participants noted specific features that might enhance accessibility (eg, audio presentation of information and optimization of the tool on a mobile platform).

Suitability

Participants with a concussion indicated that the tool was suited for people who had had a recent concussion or were in the early stages of recovery and seeking basic information about their concussion. The suggested time for access to the tool was within the first 6 weeks of injury to receive the maximum benefit as knowledge and information were most needed at that point. As one participant described,

> *I think it would be used more as, like a stepping stone... I think it's something I'd go to for just the very basics, or I didn't know what was going on with my health or understand my situation, my condition.*

On the other hand, some clinician participants indicated that the MyGuide tool was appropriate for individuals with concussion at any stage of recovery. As one participant described their experience using the tool with different clients,

> *I've worked with people that are a week post-concussion to two years post-concussion, and I feel like it can work for everyone again, […] it's just kind of a foundation. I think I am comfortable referring every single one of my concussion clients.*

Clinician participants also noted that the tool could be suitable for individuals who were avoiding activities due to their concussion symptoms. These participants indicated that providing early education on topics like pacing was particularly important for these individuals, as the concept of pacing could be applied to various aspects of the person's recovery process or therapies (eg, physiotherapy). One clinician explained:

> *I would refer patients [to the site] who are probably struggling with pacing…I feel like getting their pacing under control is usually a higher priority than giving them, you know, some form of manual therapy, that's my perspective…because it's that art of figuring out what to address at what point in time, often when they are so significantly concussed.*

Clinician participants also indicated the different levels of suitability for some of their clients with chronic symptoms. As one clinician participant described:

> *Someone who's really chronic, let's say, post two years, oftentimes has built a pretty strong identity around their health... So I'm not sure that the impact would be the same per se, as someone earlier on in the experience. I think I'd still use it. It's really hard to know what somebody has been exposed to in terms of education and material… And maybe they haven't had any of that, or they have really low health literacy. So no, I still think it would be useful [but] in my experience, a lot of people have really built a disability identity by that point. And the concussion is something that has become part of who they are... if there's a tool like this might not be as impactful.*

Clinician participants indicated that the tool may not be appropriate for clients who are feeling overwhelmed and anxious, having difficulty processing information, and experiencing no screen tolerance, low computer literacy, and poor English comprehension.

Acceptance: Adherence

Based on the interview data, the primary reason people with concussions continued to actively engage in the tool was to seek out information to gain a better understanding of concussion recovery. Participants reported that they stopped using the tool when they acquired enough information or when they saw improvements in their recovery. One participant said of the tool, "It is sort of a learning tool, right?... But once I've learned how I can just focus on that myself, and I didn't really return to it, but I was using what it had taught me." Overall, the tool was often used over a short period of time and not used as a resource that participants with concussions were continuously referred to over a prolonged period.

Clinician participant perspectives gave further insight into other factors related to adherence. As most clinician participants noted they were actively referring their clients to the site, one factor that may have influenced their clients' adherence was based on how they were directing clients to the site. Participants mentioned they were either referring clients to the tool by working through the tool with their clients in sessions or by sending the link to their clients to have them go through the tool independently at home. For some participants, going through the tool was a good starting point for their clients, particularly when doing virtual sessions. One clinician said, "It's been really helpful for the clients when we do Zoom sessions... I can share my screen, and we can go through it together."

Clinician participants mentioned that most clients with concussions were only engaging with the MyGuide Concussion tool a few times independently but mostly accessed the tool when facilitated by the clinician. One participant stated,

> *I get the sense that, similar to most things I give them, [the client] needs to be directed and guided... I would say if I just gave the person that website, I would not anticipate that they're just going through it all themselves. If there are specific parts of it that I would want them to get out of it, I would definitely follow up and make sure that they really got what I wanted them to get out of it.*

As such, participants noted that the MyGuide Concussion tool was useful in therapy sessions but may not be as relevant if self-directed by participants.

Impact

Overview

During the interviews, participants reported value in the tool's information about various stages of concussion recovery. Participants with concussion noted that the tool was a trustworthy source of information, describing that affiliation with a predominant health care institute was helpful to increase

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the credibility of the tool. In addition, participants with concussions expressed that referral from clinicians or other people with concussions increased their acceptance of this tool as a credible source of information. Many clinician participants indicated that the tool reinforced the basic information about concussion recovery and concussion self-management that they were teaching their clients and helped the clients connect concepts important for their recovery.

Several participants with concussions reported that the self-assessment strategies in the tool helped them assess and become more aware of their triggers and were beneficial in helping alleviate symptoms. One participant expressed that the tool reminded them how everything is connected, referring to how their physical and psychological symptoms impact their ability to meet their life demands. The tool helped them manage their symptoms of low mood and find ways to meet their life demands while also balancing their other physical and psychological concussion symptoms. Clinician participants shared that the application of the tool decreased the risk of complications and potentially reduced the overall length of recovery. One participant said:

> *I generally see people that are at least six weeks, but generally more like three months post-concussion. And I would say the majority of them have gotten to that point because they've been avoiding all activity. And I think the tool does a really good job of letting people know that's not what to do to get back and gives people a bit of a guide. So, I think that's kind of the reason that it could decrease the complications that we know happen once somebody is avoiding things for too long.*

Many participants with concussions explained that while physical symptoms may be more clearly linked to concussion, the psychological impacts were not as recognized as symptoms of a concussion. As one participant described,

> *It help[ed] me to realize that a lot of the symptoms I'm experiencing weren't from some other thing. It was from my concussion, even though it had happened quite a while ago. … so just being able to appreciate that these things are normal, and that... there's not something else wrong.*

Another participant described their frustration of not knowing the cause of their symptoms to the point of questioning the validity of their symptoms. They reported that the information on the tool not only normalized their symptoms but also provided them with validation that their symptoms were indeed related to their concussion. Clinician participants similarly expressed that the tool helped their clients normalize the symptoms they were experiencing and provided reassurance to their clients.

Participants with concussion indicated various changes they made to managing their concussion symptoms or overall health based on what they learned from the tool, some of which included gradually returning to physical activity and improving their ability to manage stress. In contrast, other participants indicated that they had not made any changes to how they managed their symptoms because they had already made the necessary changes before finding the tool.

In the cases where clients were receiving services from multiple providers, some clinician participants noted that the MyGuide tool validated and reinforced the information provided to clients by different clinicians. For some other participants, the tool helped prime their client on a particular topic, which helped enhance the subsequent treatment session. In particular, one participant noted that not only did the tool provide opportunities to learn about concussion recovery outside of treatment time and enhance the client's understanding of their condition, but it also allowed for the client to elicit social support from friends and family. Therefore, the tool both empowered clients to self-manage their concussions and encouraged reengagement with their social network and daily life activities.

Table 4 summarizes participants with concussion and clinician's perspectives on the tool's impact. Overall, data collected from the clinician participant interviews supported the perspectives of participants recovering from a concussion.

Table 4. Summary of perspectives on the impact of MyGuide on concussion recovery.

Participants with concussion	Clinician participants
Improved understanding of concussion symptoms and recovery process (from acute symptoms to returning to life after concussion).	Reinforced basic information about concussion recovery and self-management.
Improved awareness of and ability to self-manage triggers.	Decreased potential complications associated with concussion.
Provided reassurance and normalized symptoms.	Provided reassurance and normalized symptoms.
Changed overall approach to recovery.	Increased client empowerment.
Improved stress-management.	Provided opportunity to elicit support from family or friends.
Facilitated gradual return to activity.	Supported occupational reengagement.

Relevance

From the interviews, participants with concussions indicated that the tool was useful for gaining basic knowledge about concussion recovery and self-management strategies. However, many reported that they found the information on the tool to be repetitive to other information they had already read; as one participant described, "it was a lot of reiterating stuff I kind of already knew... it wasn't really telling me anything new." Other participants expressed that the tool lacked specific and detailed content on various topics, such as nutrition and differentiating an acute concussion from persistent postconcussion symptoms.

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Another participant suggested that the tool would have been more useful if it included a self-monitoring tool, where individuals could track their symptoms and strategies used to manage their symptoms, which could be shared with their health care team.

Some participants with concussions expressed how they had only found out about the tool once they were further along in their concussion recovery and indicated that had they known about the tool earlier, it would have been much more useful to them then. One person highlighted this when describing their experiences after their injury, saying, "It took me months just to figure out what it was I was dealing with. So, if I had gotten [the tool] right away, it would have been extremely useful for me."

Another participant described why it would have been beneficial for them to have known about the tool earlier,

> *If I had had [the tool] immediately after having the concussion or shortly after [with]in the month... there would have been a lot less stress from having to deal with it, and not knowing what the cause of some symptoms were, and just being able to have a more well-developed understanding of what a concussion looks like.*

Participants with a concussion also indicated that the information on the tool may be outdated and perceived the tool to be less relevant as a result. Participants mentioned the importance of updating the tool regularly as new concussion research is published.

Clinician participants indicated that the tool supported and enhanced the services they provided to their clients. In particular, participants noted that the tool provided preliminary and important information for recovery in a timely manner, a mixture of information for different learning styles and needs, a reinforcement of information learned during in-person sessions, and an opportunity for remedial learning outside of treatment time. Learning outside of clinic time provided opportunities for clients to lead and participate more in their own recovery. One clinician said, "I tend not to refer, I tend to work through the concussion site with clients, I tend not to just […] sort of give it to them."

For some participants, it allowed them to focus on addressing more specific problems impacting recovery (eg, teaching the client about pacing). As one participant shared:

> *If it's a motivated person, and they are actually reading through [the tool]... I don't have to spend as much time necessarily providing some of that intro-level education. So, I think it can mean that we can move through treatment quicker. I like to give everyone the broad education, and then really more specific as we go to that person's individual barriers. But if a lot of the intro general stuff can be covered on that website, and the person's actually going through it… then I can get more specific quicker, which… for a clinician, that's great... it just means that I can do things faster.*

With the increase in demand for e-health services, many clinician participants expressed that the tool was compatible with this delivery method. In specific cases, the MyGuide tool could accommodate and provide access to important education on concussion recovery for individuals with limited or no insurance coverage. Other benefits of using the tool included improving overall workflow, providing consistent information across other clinicians or existing concussion rehabilitation programs, and enhancing other therapies (eg, physiotherapy).

Integration of Mixed Methods Results

Qualitative and quantitative results were integrated at the level of analysis. However, the accessibility, suitability, and relevance of the tool were only assessed using qualitative data. Multimedia Appendix 3 displays the integration of results using joint display.

Discussion

Principal Findings

Our study indicated that the MyGuide concussion self-management tool has good acceptance and perception by all participants (people with concussions and clinicians) using the tool.

Specific recommendations were provided by both participants with concussions and clinician participants to improve the ease of use of the MyGuide tool. Many clinicians requested that a downloadable PDF form be made for each module, as it would be beneficial to increase the accessibility of the tool for those with reduced screen tolerance. This format could also address the minor navigation issues that a handful of participants with concussions experienced when using the tool.

Participants also provided suggestions for increasing personalization and adherence to the tool. Participants with concussions reported that the use of the tool stopped when they acquired enough information or when they saw improvements in their recovery. Based on this, it would be beneficial to add more detail to modules, especially around nutrition, which one participant noted to be sparser. Clinician participants found that certain topics, such as return to sports, were irrelevant to the client's recovery, and some information was inaccessible to those with low or no screen tolerance or low computer proficiency. To address this, the tool should be recommended to clinicians as something that should be adopted into practice so they can support clients in refining the tool to be more relevant to their own recovery goals. Furthermore, adding audio or visual modes of delivery as opposed to text could increase accessibility for individuals with lower screen tolerance.

Comparison With Previous Work

Findings from our study indicated the benefits of the MyGuide Concussion tool; specifically, participants emphasized the importance of reassurance to people with concussions by normalizing their experiences. Previous research looking at brain injury found that reassurance was ranked as highly important when considering aspects of an intervention [35] and that normalization of emotions and behavior were important facilitators of self-acceptance and willingness to reach out for help when needed [36]. Furthermore, the MyGuide Concussion

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tool was seen as beneficial for identifying symptoms, which, in turn, helped with finding ways to manage triggers. A study exploring barriers and facilitators of reintegration after concussion found that lack of concussion education was a major barrier to returning to learning, suggesting that the information provided in the MyGuide tool may be a facilitator in returning to everyday life following concussion [37]. Furthermore, education on symptoms following a brain injury has been tied to higher self-awareness and positive experiences during interventions [36], as well as better outcomes [35].

Findings in our study indicated satisfaction and benefit with using a web-based tool for self-management of symptoms and overall recovery after concussion. Similar web-based interventions designed for facilitating recovery in adolescents with mild TBI have also found that web-based interventions were effective in improving executive functioning and functional disability, although this was identified by parents instead of the adolescents themselves [38]. Other studies on mTBI have identified the active coping style involved in self-management as being linked to improved recovery after concussion and improved pacing of return to activity [39]. Participants with concussion and clinicians in this study both agreed that the MyGuide tool was best for individuals in the early stages of recovery who require basic information about concussion and self-management. In particular, participants with concussions suggested that providing the tool within one month of injury would be most beneficial as this is when concussion education is essential to reduce stress related to understanding concussions and what they look like. In line with our findings, other web-based interventions for mild TBI have identified time as a key factor affecting the effectiveness of the intervention, as individuals do not have the same need for more information later in recovery [35,38,39]. One study described that receiving information during an optimal time of exposure was more crucial to maximizing symptom improvement as opposed to the frequency of use of the tool [38]. Several other studies have highlighted providing timely services after a concussion as being a key factor in the effectiveness of self-management websites [13,19].

The ease of use of the MyGuide tool was reported to be relatively high for participants, and aspects such as the linearity of the modules, simple layout, and easy-to-understand information were described as effective by participants. The use of desktop computers seemed to be the preferred medium for the use of the tool, and those using a mobile device voiced the need for improvement of the mobile platform. Usability studies on web-based tools for people with TBI have similarly found that simple interfaces are favored [40]. However, in contrast to our findings, several studies on digital health have found that participants prefer using mobile devices over desktop computers as more people have mobile devices, and most people keep their mobile phones with them at all times compared with their computers [40,41]. This contributes to quick access to the digital tool whenever they need it, rather than just at home. Although participants in the present study all resided in urban areas, the use of digital platforms for health-related self-management programs has been noted as beneficial for use by people remote from treatment centers [42] and especially in rural areas [43], suggesting that the MyGuide tool has the potential to have more far-reaching benefits than was discussed in this study.

Limitations

There are 3 main limitations to this evaluation. First, this study had a small sample size, which may limit the ability to generalize the findings to the broader clinical population of those with concussion. However, data saturation was met during qualitative interviews, and the findings show preliminary support for the use of the MyGuide tool. Second, there may have been selection bias with participants with concussions as they required the ability to participate in an online survey and, as such, a higher capacity to engage with screens than other people with concussions. To mitigate this effect, participants had the option of completing the survey by telephone, but no participants requested a telephone survey option despite 75% (6/8) of participants indicating decreased screen tolerance in the questionnaires. This suggests further research may be required to understand whether decreased screen tolerance impacted module completion and to assess the interpretability of the results to the questionnaires that reported having enough information as a reason to stop completing the modules. Finally, occupational therapists were overrepresented as clinician participants, with no physicians involved in the study and the findings not necessarily representing all clinicians. However, these findings provide crucial information for later studies that aim to specifically understand other clinicians' perspectives.

Future Research

Future research should be done to assess whether the tool can be used in practice by clinicians other than occupational therapists and if the earlier introduction of the tool can provide increased benefits to people with TBI. The use of the MyGuide Concussion tool should also be examined in the senior population, considering the frequency of concussions due to falls in this age category and because this study may have limited generalizability as it focused exclusively on young and middle-aged adults. In addition, it would be beneficial to gauge to what degree screen tolerance impacts the completion of modules and the need for clinician involvement. Finally, as this study revealed a lower rating for User Control relative to other features, it would be beneficial to explore what contributes to this lower rating and what improvements can be made to mitigate any difficulties.

The MyGuide tool is a web-based customizable concussion self-management tool with good acceptability and perceptions by people with concussions and clinicians in concussion rehabilitation. MyGuide provides foundational information on concussion and self-management strategies, normalizes symptoms, and provides reassurance and support for occupational reengagement.

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Authors' Contributions

AT and RK led the analysis and interpretation of qualitative data and coled the writing and critical appraisal of the manuscript. CY and COM designed and conceived the study, completed data collection, and participated in drafting the manuscript. PM and SB led the initial conception and design of the study and participated in data analysis and interpretations. JS facilitated the design and conception of the study, oversaw the data collection, analysis, and interpretation of the data, oversaw the writing of the manuscript, and led the review and revisions of the manuscript.
All authors reviewed and edited the manuscript and approved the submitted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview questions for client users.
[DOCX File , 16 KB - rehab_v12i1e59181_app1.docx]

Multimedia Appendix 2
Health care provider interview questions.
[DOCX File , 16 KB - rehab_v12i1e59181_app2.docx]

Multimedia Appendix 3
Integrated results matrix.
[DOCX File , 19 KB - rehab_v12i1e59181_app3.docx]

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Abbreviations

DEDHI: Design and Evaluation of Digital Health Interventions
Health-ITUES: Health Information Technology Usability Evaluation Scale
TBI: traumatic brain injury

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Improved Speech Recognition in Adults With Conductive or Mixed Hearing Loss Using a Direct-to-Consumer Bone-Conduction Device: A Multiple Methods Intervention Study

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Abstract

Background: Hearing loss affects 20% of the global population, including 250 million experiencing chronic suppurative otitis media, which can present challenges for conventional hearing aids due to ear discharge. Although assistive technology for hearing is available in high-income settings, provision is poor in low-income settings due to high costs and low availability of audiology services, reaching approximately 3% of those who could benefit from it.

Objective: This study aimed to evaluate the performance of a low-cost self-fitted direct-to-consumer bone-conduction headset for individuals with conductive or mixed hearing loss.

Methods: We conducted a multiple methods study to test the efficacy and acceptability of this device using a purposive sample. Participants with a range of conductive and mixed hearing loss underwent speech-in-quiet speech audiometry with and without the device and took part in feedback interviews exploring their subjective impressions of the device.

Results: In 33 participants, the device improved speech recognition in those with bone conduction thresholds <50 dB by a median of 11%, with larger air-bone gap associated with larger improvement. Participants rated the device positively on weight, style, and ease of use.

Conclusions: This multiple methods study assessed the acceptability and efficacy of a low cost self-fitted bone-conduction device in adults. We found the device provides hearing benefit for those with conductive or mixed hearing loss (with bone conduction thresholds <50dB HL). Those with significant conductive hearing loss were measured to have their speech perception significantly improved. Participants had a mixed response to device aesthetics. Further studies should seek to establish if this type of device has effectiveness in real-world trials and which individuals are most likely to benefit. This low cost device could provide hearing benefits to millions of people without access to other devices. Product designers and clinical researchers should explore device optimization. Given the economic impacts of hearing loss across the globe, this style of self-fitted device could represent a paradigm shift in future assistive technology for hearing loss, in both high and low resource settings.

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KEYWORDS

hearing loss; auditory perception; wearable electronic devices; medical device; health resources; rehabilitation; cost efficient; mixed-methods study; speech recognition; hearing aids; rehabilitation technology; rehabilitation device; assistive technology; otitis media; health intervention

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Introduction

Hearing loss affects 1.5 billion people globally with an estimated 250 million people with chronic suppurative otitis media (CSOM) [1-3], which carries the additional stigmatizing burden of a discharging ear (otorrhea) and associated difficulty using conventional in-ear air conduction hearing aids [4]. In children, hearing loss impairs cognitive development, language, social-emotional skills [5] and other milestones [6]. In low-resource settings, the burden of hearing loss is further compounded by poor health provision and infrastructure to address the needs of its hearing-impaired population [7]. One estimate found >400 million people are “in need” of hearing aids and called for the development of innovative low-cost technologies and effective service delivery models [8].

In UK primary schools in 2019, only 43% of children with any level of hearing loss reached expected numeracy and literacy (vs 65% of typically hearing pupils), and by age 16 years, children are on average 17.5 months behind the attainment of their typically hearing peers [9]. This impacts throughout the life course, as adult employment rates for those with hearing loss are 65%, compared to 79% in people with no long-term health issue or disability [10]. In England, 48% of people aged 50 years and older have some degree of hearing loss [11], and this costs the United Kingdom £25 billion (US $33 billion) a year in lost productivity and unemployment [12]. Efforts to address hearing loss are necessary: medically, socially, and economically, across the world.

Hearing loss can be conductive, sensorineural, or mixed, and many mild, moderate, and severe types of hearing loss of all causes can be rehabilitated with conventional air conduction hearing aids (which transmit sound via the air to the tympanic membrane). However, for patients with conductive or mixed hearing loss (eg, due to CSOM), surgical intervention or bone conduction devices (BCDs), which transmit sound via the skull to the cochlea, are an alternative for rehabilitation [3]. In cases where the conductive component of hearing is large (air-bone gap>25 - 35 dB), some users demonstrate better [13,14] or comparable [15] word identification using a BCD compared to air conduction hearing aids. At present, bone conduction is used in only a minority of cases of hearing loss. For example, in the National Health Service (NHS) in England, around 350,000 new air-conduction hearing aids are provided each year (Prof K Munro, personal communication), in comparison to 1292 BCDs surgically implanted between 2022 and 2023 [16].

Clinically fitted BCDs may be external (nonimplanted, eg, attached via headbands) or implanted into the skull. If not implanted, their audiological function is suboptimal as the headband pressure and depth of skin overlying the skull will attenuate their performance [17]. Hence, the normal clinical pathway is that after successful trial of an external device, a BCD is surgically implanted into the skull and is usually highly effective [18,19]. Such devices are classed and regulated as a medical device and are costly, with recent low estimates of £3150 (US $10,000 to US $17,000; excluding costs of the surgical procedure) [20].

The high cost of implanted devices and the need for surgery means that BCDs are likely underused [21]. External BCDs could allow this technology to be expanded, for example, to treat the most common cause of pediatric hearing loss, glue ear (chronic otitis media with effusion), as this causes a conductive hearing loss that is temporary [22], where implantation would not be appropriate. It could also be used to aurally rehabilitate adults and children with CSOM, a disease most prevalent in low- and middle-income countries [2], where access to traditional in-ear air conduction aids is sparse and often inappropriate, as they are less effective in the presence of otorrhea and may exacerbate it [23]. However, medically certified external BCDs (typically fitted attached to a soft headband) are of comparable cost to implanted devices.

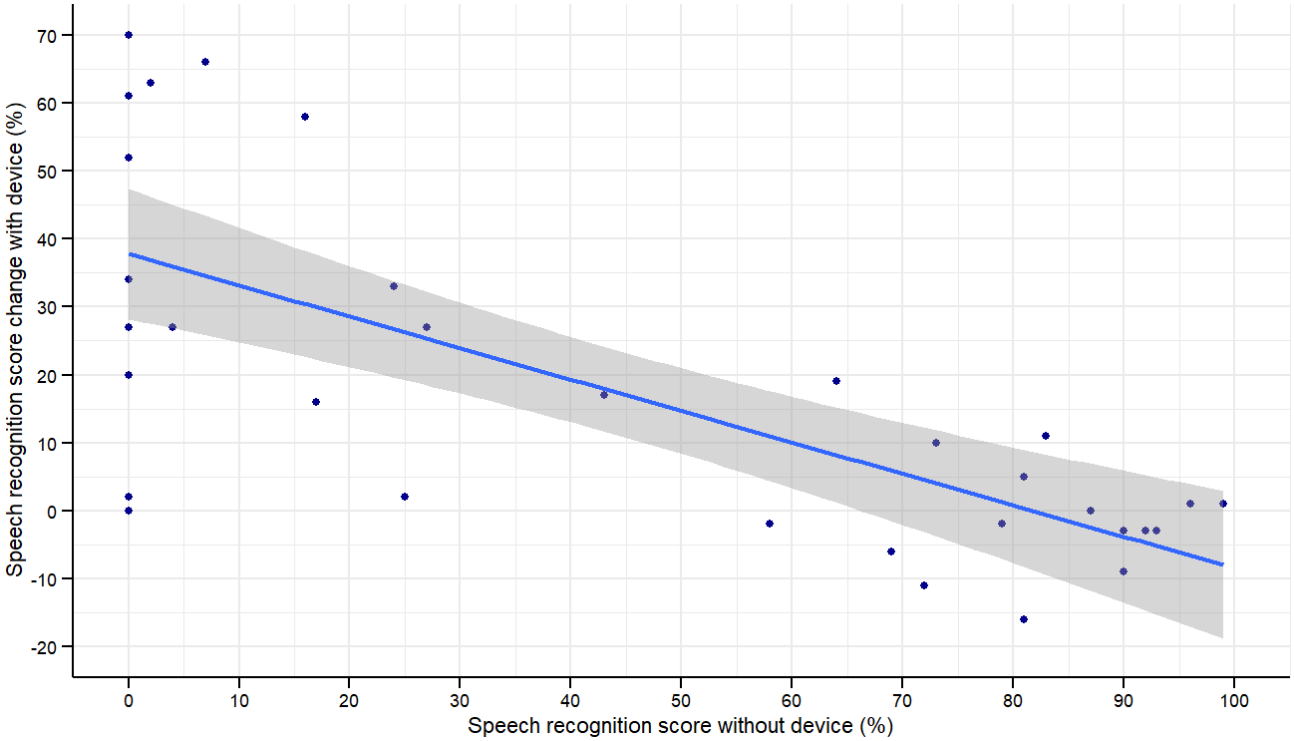
Previous pilot studies have shown benefit from a low-cost direct-to-consumer external bone conduction headset supplied by "Raspberry Pi Foundation” (Cambridge, United Kingdom) for rehabilitation of children with glue ear [24]. In 2 small trials, this device paired with a Bluetooth microphone (see Figure 1) improved word identification score by 23% in 20 children with hearing within normal limits [25] and reduced word discrimination threshold of distant speech in both quiet and in noise for 19 children with otitis media with effusion [26]. The majority of parents (22/26) opined that this device consistently helped their child to hear [24].

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Figure 1. (A) Raspberry Pi Hear Glue Ear Headset (SKU: 105890) [24]. (B) Alead Nolan LiveMIC2 Bluetooth Wireless Microphone [27].



Figure 2. Plot of percentage (%) speech recognition score change with device and baseline percentage (%) score without device.



In this multiple methods study, we tested the efficacy of this device for speech recognition in quiet listening conditions in adults and to assess participant acceptance of the device. We purposively recruited adult patients with conductive and mixed hearing loss. The inclusion of mixed hearing loss allowed us to measure the effect of raised bone conduction hearing threshold on word identification, which is important for describing the fitting range of the device for future applications. We hypothesized that the device would markedly improve speech performance on average across participants. We further hypothesized that unaided speech performance (without the device) would predict the amount of benefit, with people who are high baseline performance benefiting less than those who are low baseline performance. We expected this effect to be most pronounced where the bone conduction thresholds tended towards normal limits and were combined with a large air-bone gap.

Methods

Ethical Considerations

Ethical approval and sponsorship for the study was obtained from the Liverpool School of Tropical Medicine (21-079) and the national NHS Health Research Authority Research Ethics Committee (IRAS 304976). The study was registered with the University Hospitals Sussex Clinical Research Department. All participants gave informed consent to participate.

Although patients and the public were not directly involved in the development of the research question, design and conduct

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of this study, results will be disseminated to study participants either by post or email as per their expressed preference.

Participants

Purposive sampling sought eligible adults aged ≥18 years with documented conductive or mixed hearing loss regardless of etiology (unless otherwise indicated in exclusion criteria), including those previously fitted with hearing aids or BCDs (externally worn or surgically implanted). We excluded participants unable to converse in English (English did not need to be first language, but participant-determined fluency was the criterion), children, those with cognitive impairment that would limit word identification or device engagement, and those with medical conditions that would preclude wearing the device (such as severe eczema).

To recruit our sample, we interrogated our database of individuals who have previously attended outpatient ear, nose, and throat surgery or audiology clinic at University Hospitals Sussex NHS Foundation Trust, and recruited participants with a range of average bone conduction hearing levels. Details regarding previous aiding and rehabilitation are provided in Multimedia Appendix 1. We created *a* priori subgroups based on the World Health Organization (WHO) hearing-impairment grading system [7], but adapted to bone conduction thresholds only, to define mild (21 - 34 dB HL [decibels Hearing Level] mean bone conduction threshold), moderate (35 - 49 dB HL), and severe to profound (>50 dB HL) hearing loss [28,29].

Hearing threshold levels (HTLs) were measured using pure tone audiometry according to ISO [International Organization for Standardization]:8253 - 1 following the British Society of Audiology (BSA) recommended procedures (2018) in a soundproof booth (Eckel Audiology Suites, acoustic compliance HTM [UK Health Technical Memorandum] 2045/ISO 8253). Air conduction hearing thresholds were measured at 250, 500, 1000, 2000, 4000, and 8000 Hz for each ear independently. Bone conduction hearing thresholds were measured at 500, 1000, and 2000 Hz. Masking was applied where indicated, again as per BSA recommended procedures (2018). Hearing thresholds were measured using an audiometer (MedRx Avant A2D+ Audiometer, MedRx Inc) fitted with Telephonics TDH-39 supra-aural air-conduction transducers, 3M E-A-RTONE 5A insert earphone transducers, and Radioear B-81 bone-conduction transducer.

Measuring Speech Recognition Score

The BCD was a prototype (model G18) produced in collaboration by Hear Glue Ear and Raspberry Pi [24], paired via Bluetooth with an Alead LiveMIC2 Bluetooth Wireless Microphone (model A2DP; Alead Inc).

The efficacy of the BCD was measured by comparing word identification as a surrogate for speech recognition scores (SRS) from unaided (BCD inactive) and aided (BCD active) conditions. We used Arthur Boothroyd AB word lists comprising 15 lists of 10 monosyllabic, isophonemic consonant–vowel–consonant words [30]. We used AB testing because it is considered reliable (using phonemic rather than whole-word scoring), because normative data exist for adults and children [31], and because it is potentially superior in the assessment of speech audibility compared to Bamford, Kowal, Bench testing because context cues are not available and responses are less predictable [32].

The prerecorded English accent AB word lists were administered via a MOTU M4 Audio interface (MOTU, Inc) running a bespoke MATLAB program (MATLAB version R2022a) to present AB word lists in English (once with BCD active, once with BCD inactive). The air conduction dial level was set to give speech output level of 70 dBA root mean square through Etymotic ER3 insert earphones (Etymotic Research). Speech material presentation was diotic in all conditions (with both ears receiving the same signal). Insert earphones were calibrated using a Bruel and Kjaer ear simulator (Artificial Mastoid Type 4930 and Bruel & Kjaer Type 2250 sound level meter ISO 389 - 2). The bone conduction headset output level was set to give speech output level of 70 dB re 1 µN (with no frequency weighting), calibrated using a Bruel and Kjaer Type 4930 artificial mastoid. The air conduction speech stimulus was presented diotically at 70 dBA root-mean-square in both aided and unaided conditions.

For each condition, participants underwent a practice 10-word list followed by 5 test lists each formed of 10 consonant-vowel-consonant words presented in random order (uniform distribution). Responses were scored as the proportion of phonemes repeated correctly in each list of words (3 phonemes per word) [33].

We compared phoneme SRS from unaided and aided conditions. We recorded the number of participants in each hearing severity subgroup who attained a 50% aided word identification score (our definition of functional hearing) [34]. Statistical analysis was conducted in RStudio (Posit, 2020).

Questionnaire and Feedback on Device Performance and Acceptability

In total, 32 participants took part in semistructured feedback, of mean duration 8 (range 3 - 16) minutes. The feedback reported here focused on perceptions and impressions of the new device.

Each participant was invited to provide their opinion on device acceptability and performance using a 5-point Likert scale questionnaire. Extreme score anchors of heavy-light, ugly-stylish, and difficult-simple were used in the weight, style, and ease-of-use questions respectively.

Participants were then invited to provide verbal feedback to record more detail of their opinion. A pilot interview was used to adjust schedule prompts before finalizing, with an aim to interview for approximately 10 minutes. Interviews were undertaken in an audiology clinic room at the study site on the same day as the main experiment. An information sheet on the verbal feedback was provided via email before and offered again on the day. An audio recording of the interview was made (Philips 3200 SpeechMike Pro USB Microphone LFH3200) and anonymously mapped to study ID using Zoom software (Zoom Video Communications). Anonymized handwritten field notes were also taken.

Audio recordings were transcribed [35], coded using NVivo V.12 Pro software (Lumivero), and content analyzed for

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associations with audiometric and Likert scoring as well as for additional insights about design and acceptability. An inductive reflexive thematic analysis approach [36] was used to develop broader themes to illustrate participant experiences and selected excerpts used to summarize results. Due to the first author's epistemological standpoint about interview data, no frequentist attempts at triangulation, reproducibility, or mitigation of bias were made for the qualitative elements of this study.

Results

Participants

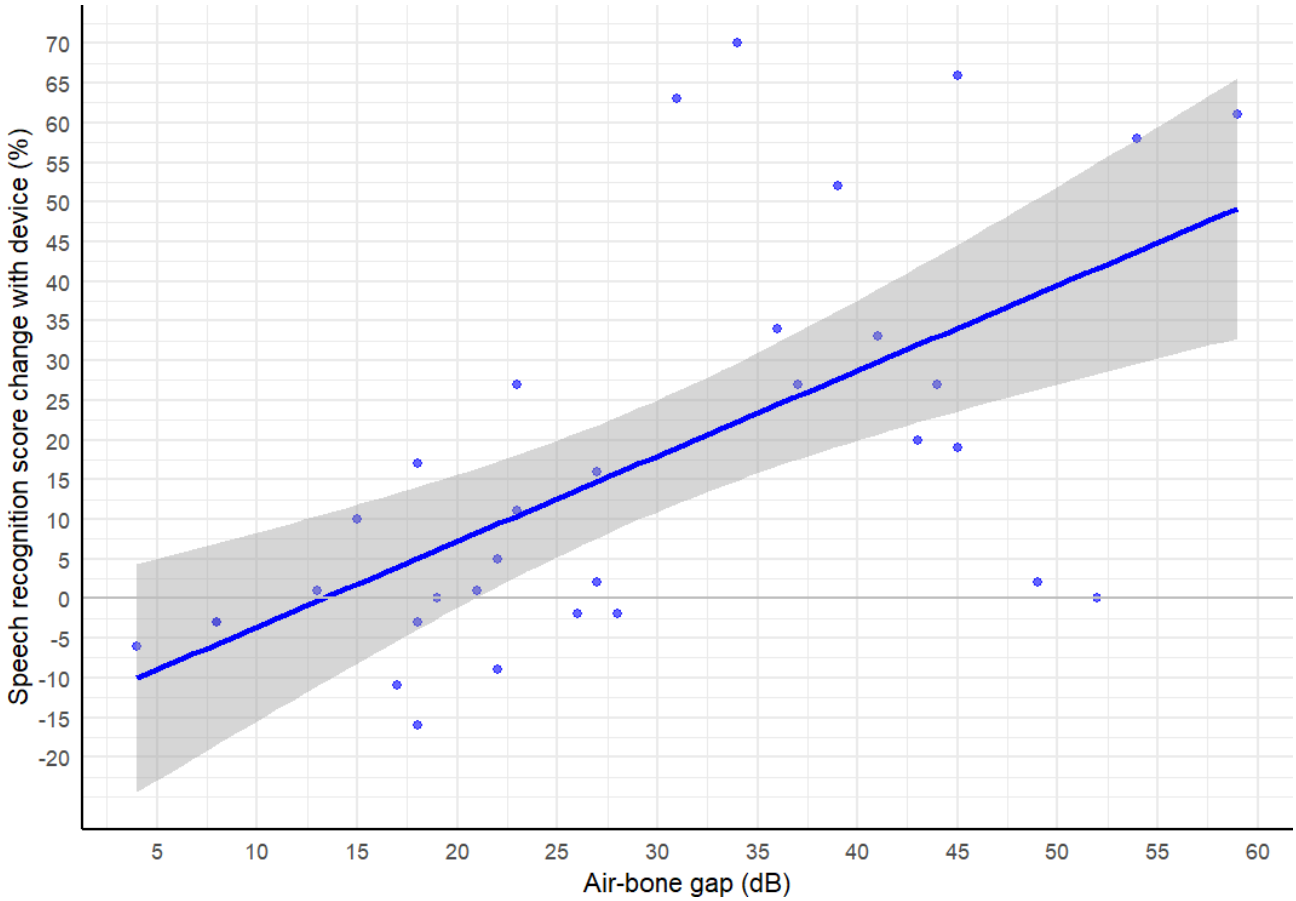
A total of 167 participants were contacted by letter, 36 expressed interest, and 33 attended and completed the study. Ages of participants ranged from 21 to 82 with a median of 70 (mean 66) years. Self-reported genders were male (n=15), female (n=16), and bigender or "any" (n=2). Participants were categorized according to average bone conduction HTL: 19 in mild (>20 - 34 dB HL), 10 in moderate (35 - 49 dB HL) and 4 in severe (>50 dB HL). The conductive element of hearing loss, the "air-bone gap," ranged from 4 dB to 59 dB (median 27 dB).

Audiometric Outcomes

Median speech recognition score change with the device across all 33 participants was 10 (IQR 29). Figure 3 shows the relationship between unaided SRS, which represents baseline performance with no BCD benefit, nor lip reading, and SRS change between unaided and aided conditions. Participants in this cohort with lower unaided SRSs exhibit a positive trend toward greater aided score changes. The R^2 of the regression model is 0.52 (P<.01), regression coefficient (β) was −0.463 (SE 0.08), and t-statistic −5.74.

We next investigated possible mechanisms to explain the relationship between unaided and aided SRS. We used a hypothesis-driven approach with forward selection of variables in linear regression models for change in score, optimizing Akaike Information Criterion with each iteration [37]. In total, 9 regression models were fitted, and we found the model with the best Akaike Information Criterion (291) included only the variables of air-bone gap (Figure 4) and category of bone conduction HTL (Figure 5).

Figure 3. Improvement in % speech recognition score with device, depending on participant air bone gap in decibels (dB).



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Figure 4. Scatterplot of speech recognition scores with (aided) and without device (unaided) for each participant. Solid line indicates an increase in score with device, and dashed line indicates no change or worse. The asterisk indicates statistically significant (P<.01) improvement with device for that group.

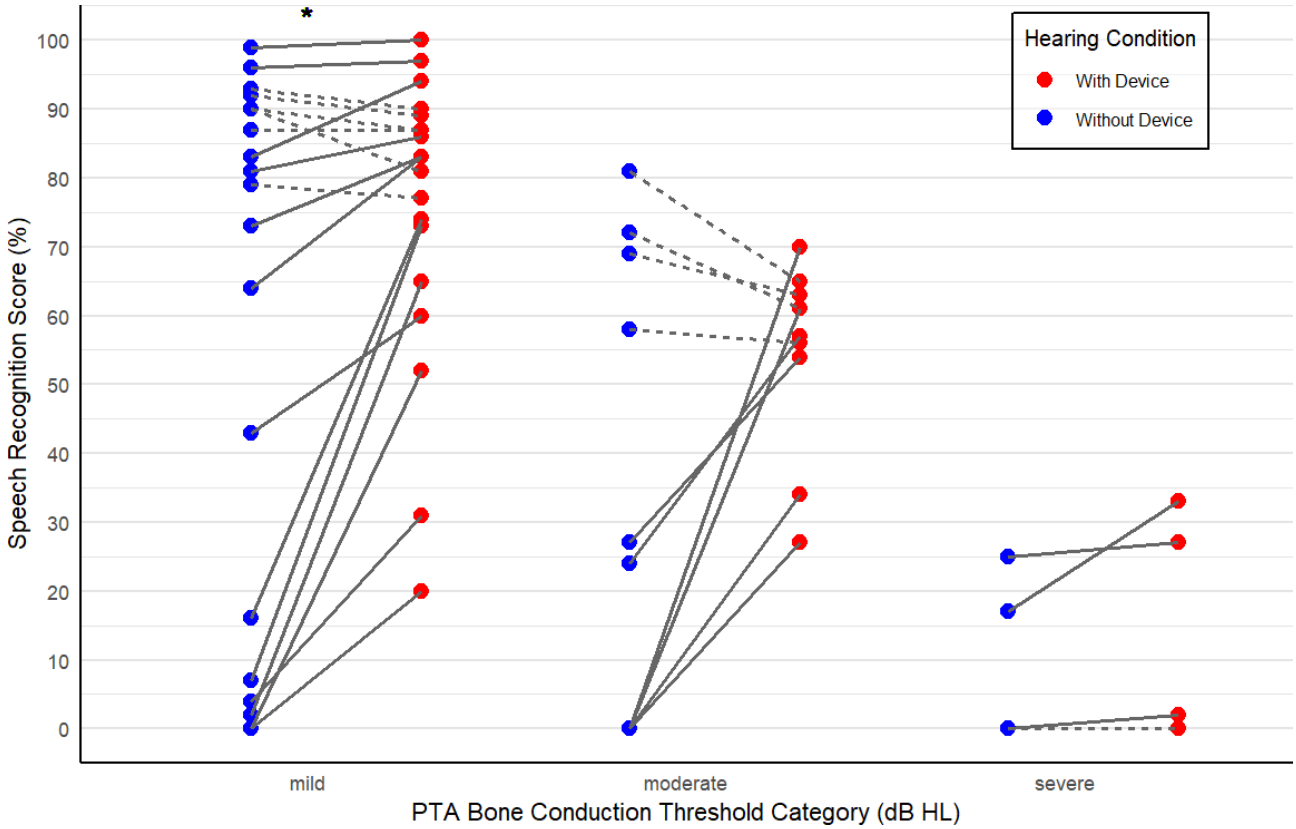
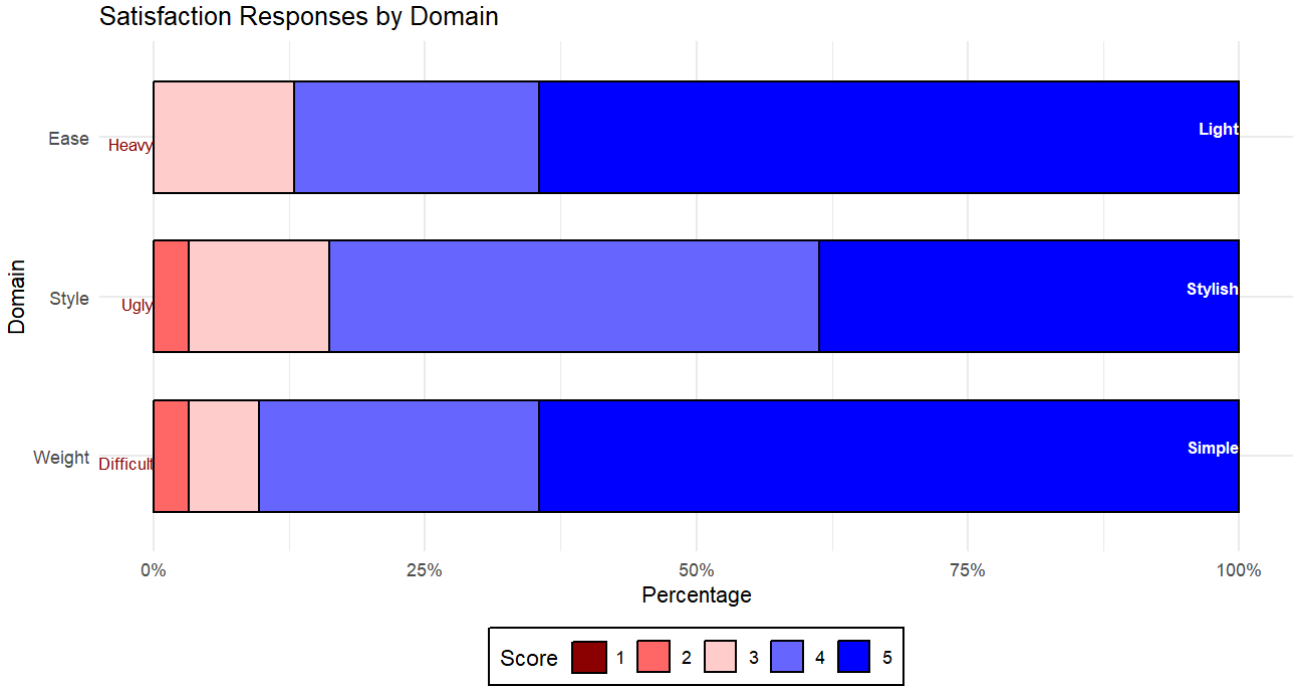


Figure 4 shows the relationship between air-bone gap, which represents the magnitude of hearing loss that is conductive, and the SRS change. Because the device provides sound transmission via bone conduction, we expected that greater magnitude of conductive hearing loss (air-bone gap) would be associated with greater aided SRS change. Regression analysis confirmed this prediction, with an adjusted R^2=0.459 (suggesting approximately 46% of variance in score could be explained by the model), and a coefficient of 1.2 (suggesting that for every 1 dB increased air bone gap, the AB score increased by >1 when using the device, P<.001).

Next, we investigated the effect of bone conduction HTL, which represents the magnitude of underlying sensorineural hearing loss (SNHL). Participants were categorized using the WHO hearing-impairment grading system according to their average bone conduction HTL. Figure 5 shows unaided (blue points) to aided (red points) SRS change for participants in the mild, moderate, and severe categories of bone conduction thresholds. Comparison of means between unaided and aided conditions across all conditions found a significant improvement in SRS (pooled Wilcoxon signed-rank test, V=409, Z=2.30, P<.01). Subgroup analysis showed a difference in SRS between unaided and aided conditions in the mild category (Figure 3, Wilcoxon signed-rank test, V=145, Z=2.01 P=.01, or P=.03 with Bonferroni correction for 3 comparisons), but differences in the other groups did not reach significance (z=1.78, uncorrected P=.08 for moderate and z=0.37, uncorrected P=.17 for severe).

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Figure 5. Histogram of device satisfaction score responses from 31 participants. Higher scores were taken to be "positive" impressions of the device, based on discussion with participants to clarify directionality even with anchors.



The median change in SRS for each bone conduction hearing threshold category is presented in Table 1. Using pooled data, participants with hearing thresholds <50 dB (mild and moderate categories) showed median gain in SRS of 11%. Of 33 participants, 17 had worse than 50% unaided SRS, of which 9 participants improved to >50% (in these 9, median SRS went from 7 unaided to 61 with device).

Table . Change in AB speech recognition score (%) by pure-tone audiometry bone conduction threshold category.

Bone conduction threshold category	Median change in aided versus unaided SRS[a]	IQR of change
Mild	+10	−1.0 to 23.5
Moderate	+27	−5.0 to 33.8
Severe	+2	1.5 to 5.5

[a]SRS: speech recognition scores.

Feedback on Device Performance and Acceptability

Two participants did not fully complete the questionnaire, and for analysis, their scores were excluded. For the remaining 31 participants, mean scores (from 1 to 5) for weight, style, and ease of use were 4.5 (SD 0.74), 4.1 (SD 0.80), and 4.6 (SD 0.69), respectively. No individuals gave a score of 1 (worst score), and the ease of use and appearance was scored 2 for one participant respectively (refer to Figure 6). We found no clear relationship between SRS and verbal reported perceptions of the device. Although there was some negative feedback from participants with poor SRS about how well the device performed (particularly among the severe hearing loss group), some of the lowest (even negative scoring) SRS participants felt the device "worked," "worked well," or was "better than… (their current) device."

We also found no clear relationship between normalized Likert scale satisfaction scores and verbal reported perceptions of the device. Participants with maximum satisfaction scores still had recommendations for improvements or preferred a discrete device, and one said outright "I didn't like the look of it." Conversely, where participants gave poor satisfaction scores, occasionally weight, style, and ease of use were still described favorably, with one low-scoring participant reporting "a good design and a nice weight… you can't feel that you've got it on, really."

We asked participants if they would recommend the device to friends and family if they had a similar hearing impairment. In total, 79% (26/33) of participants said they would recommend.

Themes Developed From Verbal Feedback

Many participants described their adoption of new hearing technology or devices as "transforming their life" and their quality of life without the aids as significantly impaired.

> *If I didn't have my hearing aids then I'd be lost completely.* [Participant 12]

Regarding the new device specifically, participants were divided about aesthetics. There were no obvious respondent characteristics to identify who liked or did not like the appearance, but a larger sample size could reveal trends. Responses largely correlated to personal preference about the appearance of the device (namely whether aids should be obvious and celebrated or unobtrusive and remain discrete).

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Some participants approved of the fact that the device (given its original purpose) looked like a music player or headphones.

> *People would wear them because they look like normal headphones… My cousin has some of these that he just uses for music!* [Participant 2]
>
> *They looked cool, and you wouldn't be embarrassed using them, because a lot of people go around with earphones anyway.* [Participant 4]

Several participants alluded to appearance, and perceptions of disability and attitudes in society. Some participants were happy the new device masked their disability, as it looked like a music device, but others liked that it proudly drew attention to their condition:

> *I mean if you're going to be deaf you're going to be deaf, so you might just as well flag it up.* [Participant 3]
>
> *If it was smaller, I could hide it under my hair…Because I'm quite vain. (Laughter).* [Participant 6]

For many participants, there were reflections on normality and disability, the hidden nature of deafness, and the difficulty experienced by participants coping with a hidden disability in an intolerant and ableist society. Many reflected on personal shame or stigma.

For some participants, having an obvious hearing aid of any description was something they found troubling given previous experiences. Many participants said they were more comfortable with devices as they grew older, reflecting perhaps that changes from their initial objections (which at the time, most put down to aesthetics) might represent growing personal acceptance of their hearing disability.

Discussion

Principal Findings

We investigated the efficacy of a low-cost direct-to-consumer BCD to improve SRS in participants with conductive and mixed hearing loss. The main findings were that (as would be anticipated) participants in this study with lower unaided SRS showed a trend toward the greatest improvement in aided SRS. Participants with larger air-bone gaps also showed a greater improvement in SRS (approximately 1% per dB of gap). The mean change in SRS for each category of bone conduction threshold severity was 17.4 for mild (SD 10), 21.7 for moderate (SD 27), and 5 for severe (SD 2), which was statistically significant only for the mild category group.

Our findings suggest that this low-cost device is likely to benefit individuals with a conductive hearing loss where underlying sensorineural thresholds are largely preserved, and, consistent with previous research [13,14], that benefit is more likely where air-bone gap is large.

Although statistical significance was not reached for the moderate bone conduction threshold group, 4 of 10 participants showed SRS change greater than 20%. This variability in outcome has several possible explanations. To categorize participants, we used average bone conduction HTLs, so it is possible that different shapes of bone conduction audiograms are better suited to the frequency response characteristics of the device. Interindividual variability in the moderate group could also be affected by characteristics other than bone conduction HTL, such as cognition [38,39] or capacity for speech recognition using additional information from lip cues and context [40]. In the severe bone conduction threshold group, there was no evidence of benefit (although this contained only four participants), which may be due to the reasons above, but more likely reflects the fact that this BCD is unable to rehabilitate when there is underlying severe SNHL.

Of 33 participants, 22 had an improved score, and nine had a worse score with the device. Of these, 5 participants with worse scores and 5 with better scores had scores equal to or within 5% of their original score. Concerns about test-retest within participant speech score variability are well documented [41]. Reassuringly, if all 10 participants with these small, potentially nonsignificant score changes were excluded from analysis, then the median score change remains significant to $P<.05$ for the mild but not the moderate threshold group, leaving our overall conclusions unchanged. Future studies should seek to predetermine minimally significant change levels. A score of 50% or greater on the Arthur Boothroyd word test has previously been defined as a marker of satisfactory rehabilitation with cochlear implants [42]. In our cohort, amongst the 16 participants where SRS was worse than 50% without the device, 9 achieved greater than 50% with the device, and mean SRS improvement in this group was 34 (SD 24).

Our qualitative investigation showed favorable opinions towards the size, weight, and ease of use of the BCD, with normalized mean satisfaction from these three variables of 0.8. Our interview data found that both word identification and questionnaire scores are imperfect surrogates of participant satisfaction. In the future, the satisfaction scores used for this questionnaire may benefit from correlation with an overarching construct of device satisfaction or a hearing-specific questionnaire.

Our findings suggest potential for the use of this kind of device. First, and perhaps foremost, the device could provide options for low-cost rehabilitation for those with conductive or mixed hearing loss in low-resource settings. In particular, many cases of hearing loss due to CSOM could be rehabilitated with a BCD [3]. A low-cost direct-to-consumer approach circumvents issues of conventional approaches to hearing aid provision in low-resource settings, including the need to travel to and attend a health facility, a lack of audiologists in such facilities (for example found to be 0.8 audiologists per million population in sub-Saharan Africa [43]), and the costs of a hearing device (an air conduction hearing aid can cost up to US $6000 in high-income settings [44], but commercially available BCDs for sports and recreation are available for £160 (US $149) [45], and the device used in this study was purchased for £18 (US $24.59) [24] (with the Bluetooth microphone an additional £79 [US $107.92]) [27]. These factors contribute to the fact that as few as 3% of people in low-income settings who would benefit from a conventional hearing aid currently have access [44], even though this is where an estimated 90% of people with

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disabling hearing loss live [46]. A bone conduction externally worn device could be reused or redistributed as it would not need a personalized mold or programming and might have less likelihood of being a vector for microbial transmission compared to in ear air conduction hearing aids [47]. A low-cost device could be made available through conventional retail outlets or schools, demedicalizing hearing rehabilitation and aligning with the WHO promotion of community ear and hearing care [48].

Other causes of conductive or mixed hearing loss could also be rehabilitated by this device, both in low- and high-resource settings. Glue ear (otitis media with effusion) is the most common cause of childhood hearing loss, but usually resolves, making it highly appropriate for rehabilitation with a nonimplanted BCD, and potentially avoiding the need for surgery (with preliminary evidence to support use for this purpose from the studies by Holland Brown [24,25,49]). However, this needs further investigation as a previous datalogging study from the United States [50] found that as many as 73% of children using an external BCD had low use (mean of 1.25 h a day).

Research exploring the pathways for bone conduction sound transmission has been conducted by the Stenfelt laboratory, showing that cochlear excitation is produced through 5 different routes. This evidence shows the profile of transmission for mastoid transducer placement includes all 5 but is dominated by cochlear fluid inertia [51,52]. In contrast, a recently published study from the same group shows the route of transmission for the headset investigated here is dominated by ear canal sound pressure because of the preauricular transducer position [53]. This transmission route depends on the oscillation of the soft tissue of the external ear canal, which by being coupled to the air in the canal produces transmission like air conduction. Therefore, conductive hearing losses caused by outer- and/or middle-ear abnormality will reduce both air and bone conduction transmission from this headset. An extreme example such as aural atresia may significantly reduce the effectiveness of headsets with preauricular positioned transducers. The investigation presented here included a range of types and severity of conductive hearing loss. Although none had atresia or microtia, it is possible the anatomical variations could have different effects on the ear canal sound pressure route of transmission. This may have contributed to the heterogeneity observed in the word recognition scores.

Study Limitations

The aim of our study was to measure the effect of the BCD with a controlled input level speech stimulus via air conduction and bone conduction (aided) and air conduction only (unaided). This was a repeated measures within-subject design with randomized order of (aided or unaided) conditions, but it is possible that participants could feel the difference between conditions because of the vibrotactile sensation associated with bone conduction.

The device was evaluated in a quiet listening environment with microphone input speech clear and stable, which may not translate to less favorable listening environments.

Some of the variability in outcomes within bone conduction threshold groups may relate to asymmetry in hearing threshold between ears, which can decrease binaural summation [54], although SRS is usually best predicted by “better” ear performance on bone conduction thresholds [55]. Outcomes of cochlear implantation have been shown to better map to total auditory receptivity of the brain (what signal, if any, was received) as opposed to ear-specific events [56]. Future work and larger sample sizes may allow us to investigate at what threshold of bone conduction of the worse ear this device may improve SRS and whether this correlates to the worse ear gaining audibility, the effects of binaural summation, or (as it seems) predominantly air-bone gap.

The median age in our cohort was 70, and so a large proportion of our cohort will have presbycusis [57], with associated limitations to speech recognition performance [58]; a younger cohort may achieve greater benefit, and it may be that device performance would differ in those with SNHL versus from other etiology.

We did not assess previous rehabilitation (namely previous experience, duration, and quality with other assistive devices), which may correlate with capacity to benefit and word identification ability. Future studies could seek to record the duration of previous auditory deprivation in addition to prior device use, as this could impact participants’ baseline auditory processing, and cognitive ability may impact the capacity to benefit from the device.

We used bespoke approaches to qualitative assessment and are aware that other questionnaires to evaluate assistive hearing technology have been validated [59,60]. Participants did not adjust settings or handle the device during the word identification task, and so our qualitative findings are based on the participant having only a brief interaction with the device.

Future Work and Wider Applications

This multiple methods study demonstrates efficacy for a low-cost self-fitted, commercially available BCD to improve SRS in individuals with conductive or mixed hearing loss.

Objective measures of device output in laboratory conditions and normative head tension and performance of individuals with typical hearing would help interpret existing and future investigations of speech performance using the device. This could guide engineering optimizations of the device such as headband tension, signal processing, and transducer characteristics. Exploring opportunities to optimize costs versus performance could include potentially differentiated offerings for use in low and high-resource settings. Future studies should also explore the benefit of this BCD in different clinical scenarios, for example, for CSOM or glue ear.

In summary, this study shows that a low-cost direct-to-consumer BCD effectively improved word identification, had high user acceptability, and could support a shift toward self-fitted (nonmedical) rehabilitation for conductive or mixed hearing loss, in both high- and low-resource settings.

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Data Availability

Anonymized data from this study will be made available on request to the lead author.

Authors' Contributions

TH was responsible for conceptualisation, methodology, funding acquisition, data acquisition and curation, analysis and interpretation, visualisation, project administration, writing of original draft, review & editing; MF was responsible for conceptualisation, methodology, software, supervision, data interpretation and curation, visualisation, review and editing; AS was responsible for methodology, data acquisition, interpretation, and curation, supervision, visualisation, review and editing; ML was responsible for methodology, data acquisition, project administration and review & editing; KM was responsible for methodology, funding acquisition, supervision, review & editing; MB was responsible for conceptualisation, methodology, data interpretation, visualisation, supervision, review & editing.

Conflicts of Interest

TH is supported by a Wellcome Trust Fellowship (203919/Z/16/Z) and a TWJ Thesis grant but no authors have any other competing interests. Neither Raspberry Pi (device manufacturers) or Wellcome Trust (the funders) had any role in study design, data collection and analysis, or preparation of the manuscript. Positionality Statement, statistical and exploratory analysis and interview schedule available on reasonable request.

Multimedia Appendix 1
Table of prior hearing rehabilitation details (ACHA: air conduction hearing aid).
[DOCX File, 5 KB - rehab_v12i1e66013_app1.docx]

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Abbreviations

BCD: bone conduction devices
BSA: British Society of Audiology
CSOM: chronic suppurative otitis media
dB HL: decibels Hearing Level
HTL: hearing threshold level
HTM: UK Health Technical Memorandum
ISO: International Organization for Standardization
NHS: National Health Service
SNHL: sensorineural hearing loss

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SRS: speech recognition scores
WHO: World Health Organization

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A Method for Custom-Contoured Cushion Fabrication Based on Pressure Mapping for Wheelchair Users to Prevent Pressure Ulcers: Feasibility Quasi-Experimental Study

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Abstract

Background: Pressure ulcers constitute a major health care burden, characterized by significant morbidity, diminished quality of life, and elevated treatment costs. Wheelchair users are predisposed to pressure ulcers due to sustained ischial and sacral interface pressures resulting from prolonged periods of sitting. Implementation of pressure-relieving interventions, including specialized seating systems engineered to redistribute load and augment the weight-bearing surface area, is critical for mitigating the risk of pressure ulcers.

Objective: This study aimed to evaluate a methodology for the custom fabrication of pressure relief cushions, through the user-cushion interface pressure mapping to reduce high-pressure areas and increase contact area in wheelchair users.

Methods: First, a validation study was carried out with 7 healthy volunteers. The pressure was determined with an FSA sensor (BodiTrak BT1510, Vista Medical Manufactures), and the cushion profile was obtained through a linear relation with pressure values. In the second phase, 10 cushions for wheelchair users were manufactured and tested. The resulting data from buttock pressure using a flat foam, Jay X2 (gel-foam), ROHO high profile (air), and customed-contoured cushions were analyzed and compared using the following 4 variables: peak pressure, peak pressure index, mean pressure, and contact area.

Results: In the validation study, the statistically significant difference between the flat and the custom-contoured cushion showed a better performance in pressure relief for the custom cushion (mean pressure 27.3, SD 4.5 mm Hg and 34.6, SD 3.5 mm Hg; $P<.001$). Regarding the study with wheelchair users, custom-contoured cushions had lower peak pressure (mean 91.3, SD 36 mm Hg), peak pressure index (mean 69.5, SD 33.7 mm Hg), and mean pressure (34.2, SD 17.4 mm Hg) against flat, Jay X2, and ROHO high profile cushions ($P<.005$). The contact area (mean 1457.6, SD 254.1 cm^2) was greater for the contoured cushion ($P<.001$) than for flat and ROHO high profile (Permobile) cushions; nevertheless, it was not significantly different from Jay X2 ($P=.59$).

Conclusions: The main finding is that the buttock pressure mapping method produces custom-contoured cushions that, compared with commercial cushions, have good pressure distribution and increased contact area. These results suggest that pressure mapping is a good alternative for manufacturing affordable custom-contoured cushions that can prevent the development of pressure ulcers.

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KEYWORDS

pressure ulcers; pressure map; custom-contoured cushion; wheelchair; wheelchair user

Introduction

Wheelchairs are a critical assistive technology, enabling mobility and participation for individuals with physical disabilities worldwide. The World Health Organization (WHO) has estimated that 90 million people require a wheelchair to assist their mobility. Yet, only 18 million people can access an appropriate wheelchair [1]. Official statistics for Mexico in 2024 indicate that 8.3 million individuals live with a disability, with

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3.3 million experiencing difficulty walking or rising from a seated position using their legs [2]. Furthermore, 4.1 million of this population lives in poverty [3]. The established correlation between poverty and disability in developing countries underscores the necessity for accessible, low-cost assistive technologies that are easily maintained and replaced.

Wheelchair users, who remain seated for prolonged periods, are considered a high-risk population for developing pressure injuries [4]. Pressure injuries, also known as pressure ulcers (term used in this work), decubitus ulcers, or bedsores, are localized lesions affecting the skin and soft tissues, resulting from sustained pressure and mechanical stress, typically over bony prominences or due to medical devices or personal items such as mobile phones [5]. These ulcers occur in 70% of cases at the sacrum, ischial tuberosity, and greater trochanter (pressure sites associated with the seated position). However, they may also develop on the occiput, scapula, elbow, heel, lateral malleolus, shoulder, and ear [6]. The etiology of pressure ulcers is multifactorial, involving a complex interplay of sensory deficits, alterations in skin moisture balance, and shear forces. The prevalence of pressure ulcers varies depending on underlying pathology, age, and comorbidities among wheelchair users. Notably, a systematic review and meta-analysis found that approximately one in 3 individuals with spinal cord injury develops pressure ulcers, highlighting the significant burden of this condition in this population [7].

One of the most widely used therapeutic strategies to mitigate the development of pressure ulcers is the use of pressure-relieving cushions for wheelchairs. These cushions are specifically designed to reduce focal pressure over bony prominences while increasing the contact area [8]. Various materials have been tested for fabrication, including foam, gel, air, and combinations [9-11]. In addition, dynamic cushions, which modify their shape through actuators such as pumps, have been developed to further alleviate pressure in high-risk areas [12,13].

While air and gel cushions have demonstrated efficacy in load distribution, they can be susceptible to damage, compromising their performance [14,15]. Consequently, the costs associated with repair and replacement can be prohibitive, limiting accessibility for many wheelchair users [9]. Custom foam cushions present a viable alternative for mitigating high-pressure areas [16]. However, inconsistencies in manufacturing processes and the complexity of mold generation can impede their widespread production. Furthermore, conventional fabrication techniques may pose risks to wheelchair users due to potential exposure to high-temperature chemicals that come into direct contact with the individual during the molding process. In addition, traditional molding is often time-consuming, and retaining information about the seat shape can be challenging due to the storage requirements for the molds [17].

The implementation of digital methodologies for shape capture and model generation in cushion fabrication facilitates the automation, acquisition, and storage of critical data, including cushion contour, pressure distribution profiles, and dimensional characteristics, streamlining and optimizing the manufacturing process. The pressure mapping of the user-cushion interface is a digital method for capturing the body shape, in which pressures are transformed into depth. The contoured cushion is produced through computer numerical control (CNC) foam carving. The main differences reported in the literature are the filters and smoothing of the pressure signals, as well as the relationship between the cutting depth and the interface pressure values, generally based on the deformation of the foam as a function of pressure [18]. Results have shown better pressure distribution performance in custom cushions than in flat cushions [19,20]. However, a comprehensive study has not been reported covering the design of the custom-contoured cushion through interface pressure, CNC manufacturing, and performance evaluation compared with the flat cushion and other cushions of different materials with the same pressure relief goal.

The objective of this study was to evaluate a methodology for the custom fabrication of pressure relief cushions, through the user-cushion interface pressure mapping to reduce high-pressure areas and increase contact area in wheelchair users.

Methods

Methodology

This work aimed to develop and validate a methodology for fabricating relief pressure custom cushions based on pressure maps of the user-cushion interface. Hence, the methodology is divided as follows: (1) pressure data collection, (2) surface model, (3) cushion fabrication, (4) validation study, and (5) cushion performance analysis and user satisfaction.

Pressure Data Collection

The pressure maps of the user-cushion interface were obtained using the commercial mat BodiTrak BT1510 with a 16x16 matrix of pressure sensors. The calibration kit of the mat (ACC16-Standard Small Calibration Jig) was used to calibrate regularly to ensure the accuracy of the measures. Before measuring a subject, initial tests with a constant known weight were performed; if the pressure data had atypical values, the calibration process was conducted.

The participants were asked to sit on the testing cushion: a commercial high-density polyurethane foam block (R-90) of 35 mm, covered with the pressure-mapping mat. Seat depth and footrest height were adjusted according to the anthropometrical dimensions of the subject to ensure a neutral seating position (hips, knees, and ankles at 90°). Pressure at the buttocks was recorded every minute for 10 minutes. If a located point reached the maximum value (200 mm Hg) during the test, the data set was discarded, and the mat and subject were repositioned, to conduct a new test.

The procedure explained above was used to generate the contoured profile of the manufactured cushions. However, the pressure maps obtained with the flat foam block and 2 commercial pressure relief cushions were also used to evaluate the performance of the manufactured cushion. For every participant, pressure maps were obtained with a flat R-90 foam block, a ROHO High Profile cushion (air), and a Jay X2 cushion (foam-gel). Finally, the same procedure was conducted with the custom-contoured cushion fabricated using the proposed methodology to compare the performance.

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Surface Model

The pressure values obtained from the user-cushion interface with the testing cushion (pressure data collection section) were processed to generate the surface model of the contoured cushion. A linear relationship converts pressure values into cushion thickness values, establishing that the highest pressure, regardless of magnitude, corresponds to the lowest cushion thickness (40 mm). The areas where no pressure was recorded correspond to the points of the greatest foam thickness (75 mm). The surface was determined as follows:

(A) Pressure measurements taken every minute for 10 minutes are averaged.

$$(1) P=(\sum i=110pi)/10$$

where *i* is the number of the map taken every minute for ten minutes and pi are the pressure matrix

$$(2) Pi=(P1,1\ldots P1,16 \quad P16,1\ldots P16,16),$$

- (B) The average pressure (P) is converted to a grayscale image (Pg).
- (C) The contour of the seated person is defined through a threshold value to remove the pressure points out of the user-cushion contact area; then, a Gaussian filter is applied to obtain an offset (Of) to soften the final profile of the cushion
- (D) Two smoothing filters are applied to Pg to increase the user-cushion contact area. First, a Gaussian filter, then the values are normalized. Finally, an averaging filter is applied to the normalized data (PgN).
- (E) The cushion profile is obtained according to the following relationship:

$$(3) Z=(ZM-ZmPgm-PgM)PgN+zM,$$

where  is the cushion thickness for each value in the 16×16 matrix in millimeters. ZM and Zm are the maximum and minimum cushion thicknesses, set to 75 mm and 40 mm, respectively. PgM and Pgm are the maximum and minimum smoothed and normalized grayscale pressure.

The offset Of is applied to the obtained surface *Z* according to:

$$(4) S=Z-Of,$$

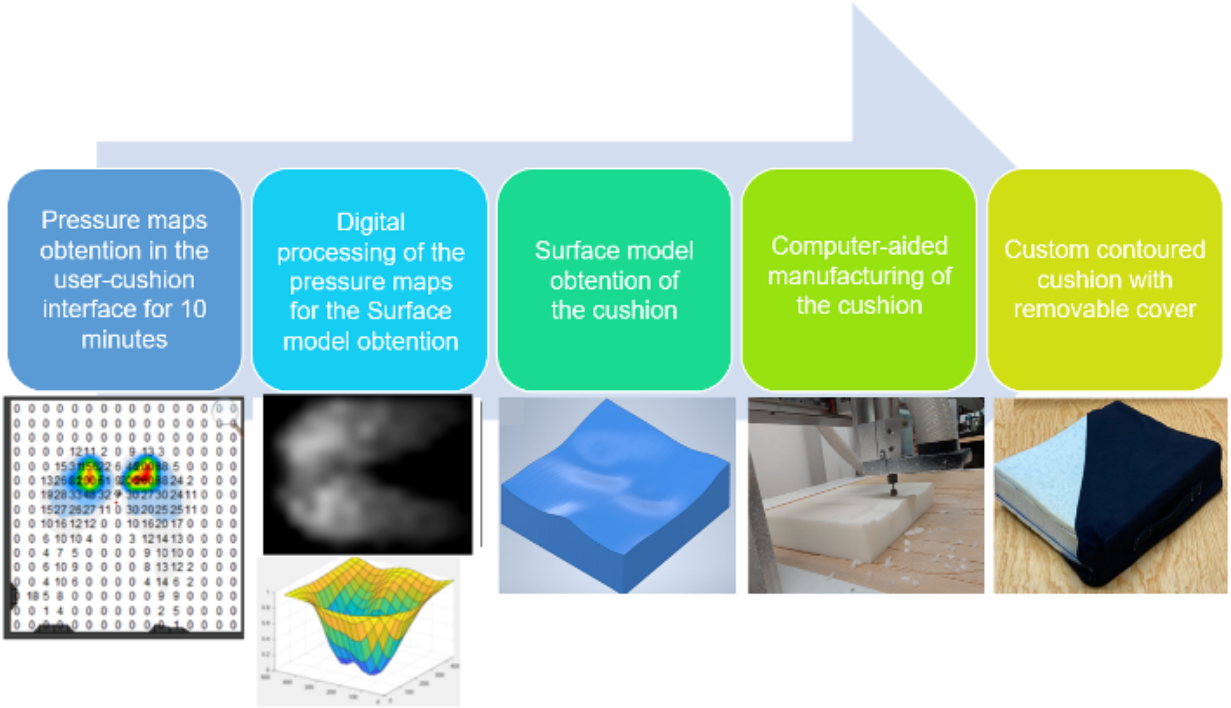
where *S* is the final profile of the cushion.

Cushion Fabrication

Once the surface model of the cushion was obtained ("Surface Model" section), the custom-contoured cushion was manufactured according to the following steps:

1. The values obtained with the procedure described in the section "Surface Model" were introduced into a computer-aided design (CAD) algorithm created in Inventor (Autodesk) to get the 3D model of the cushion.
2. The CAD model of the cushion was passed to a CNC milling machine (Shapeoko, Carbide 3D) to carve a commercial high-density polyurethane foam block (R-90) with dimensions of 45×45×7.5 cm to obtain the custom shape.
3. Once the foam has the desired shape, a sheet of 6.35 mm thick memory foam is added to each face of the foam.
4. A waterproof cover of a 1 mm layer of soft silicone (Smooth-On, Ecoflex 00 - 30) is cured onto the memory foam.
5. Finally, a custom removable cover was manufactured using a cloth of 94% cotton and 6% elastomer. The full procedure is represented in the schematic of Figure 1.

Figure 1. The schematic of the methodology developed to manufacture the custom-contoured cushion from the user-cushion interface pressure maps.



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Validation Study

The present study consists of two clinical phases.

Performance Validation of the Manufactured Cushion Using the Pressure Mapping Methodology

Seven nonwheelchair-using volunteers were included, with the following inclusion criteria: age between 18 and 60 years, absence of pain that would prevent them from remaining seated during pressure mapping data acquisition (10 min), and full range of motion in pelvic limbs, allowing for proper positioning (hip, knee, and ankle at 90°).

Assessment of the Performance of Custom-Contoured Cushions with Wheelchair Users

In addition, 10 wheelchair users were included, meeting the following inclusion criteria: age between 18 and 60 years, absence of pressure ulcers within the past year, absence of pain that would prevent them from remaining seated during pressure mapping data acquisition (10min), absence of joint limitations or postural abnormalities that would impede proper positioning during pressure mapping data acquisition, and absence of communication impairments or intellectual disability that would hinder informed consent.

For both groups of participants, anthropometric measurements and wheelchair dimensions were collected to evaluate their suitability. Then, the procedure explained in the "Pressure data collection" section was conducted: First, the pressure maps of the user-cushion interface with a polyurethane foam (R-90) of 35 mm thickness were recorded for 10 minutes. Then, the same procedure was repeated with the Jay X2 (gel-foam) and ROHO high profile (air) cushions. Finally, once the custom cushion was fabricated with the flat foam maps, 10 pressure maps were recorded using the custom-contoured cushion for performance evaluation.

Cushion Performance Analysis and User Satisfaction

The resulting data from buttock pressure using each cushion (flat foam, air, foam-gel, and contoured) was analyzed and compared using IBM SPSS software. The variables used to evaluate cushion performance were peak pressure (PP), peak pressure index (PPI), mean pressure (MP), and contact area. The pressure variables are reported in mm Hg and the contact area in cm^2.

Peak pressure is the highest-pressure value obtained in each measurement. Peak pressure index is the mean of the peak pressure with the pressures surrounding it; the PPI indicates the pressure under the ischial tuberosity area [21]. Mean pressure is the average value of the pressures distinct from zero. Contact area is the total area of the cells with a pressure value different from zero, reported in cm^2.

User satisfaction was evaluated using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0), which includes 12 items to assess satisfaction with a specific assistive device.

- Eight items assess the characteristics of the assistive device, including dimensions (size), weight, adjustments, safety, durability, simplicity of use, comfort, and effectiveness.
- Four items assess service aspects, including service delivery, repairs and maintenance of the device, professionalism of service, and follow-up service.

Participants were asked to rate their satisfaction with the device and service on a 5-point scale ranging from 1 ("not satisfied at all") to 5 ("very satisfied") [22].

Statistical Analysis

Descriptive statistics were performed for all variables, calculating means and SDs for quantitative variables, and frequencies and proportions for qualitative variables. Pearson correlation test was performed between anthropometric measurements and wheelchair dimensions of the users. Furthermore, medians were compared using Mann-Whitney *U* test to analyze pressure values and contact areas between the different cushions for all participants.

Ethical Considerations

This project was approved by the Institutional Review Board at Iberoamerican University (project number. 174/2022), and all participants signed the informed consent. The data of the participating subjects are found only in their clinical records and are protected by the current personal data protection laws in Mexico, to which the Universidad Iberoamericana adheres. For this study, the data of the subjects were anonymized, and their only compensation was their custom-contoured cushions.

Results

Performance Validation of the Manufactured Cushion Using the Pressure Mapping Methodology

A total of 7 nonwheelchair-using volunteers were included in the validation of the manufacturing process and performance of the custom-contoured cushions. Pressure measurements were initially taken on a flat foam surface, then cushions were manufactured according to these measurements. Pressures (PP, PPI, and MP) and contact area were compared. Statistically significant differences were found in all measurements, with lower pressures and larger contact areas observed in the cushions manufactured using the developed methodology (Table 1).

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Table . Comparison of pressure and contact area variables between flat foam and the manufactured custom-contoured cushion in nonwheelchair-using volunteers. Data are presented as mean (SD).

Variable	Custom-contoured cushion, mean (SD)	Flat cushion, mean (SD)	*P* value
Peak pressure (mm Hg)	75.5 (12.3)	101.0 (13.4)	<.001
Peak pressure index (mm Hg)	53.9 (12.4)	73.6 (14.8)	.005
Mean pressure (mm Hg)	27.3 (4.5)	34.6 (3.5)	<.001
Contact area (cm^2)	1716.4 (128.8)	1509.5 (137.4)	<.001

Assessment of the Performance of Custom-Contoured Cushions With Wheelchair Users

Wheelchair Users

A total number of 10 wheelchair users were included in the study, with a mean age of 47 (SD 12) years, of whom 6 (60%) were female. The most common diagnosis was spinal cord injury (3/10, 30%), followed by poliomyelitis (2/10, 20%), cerebral palsy (2/10, 20%), amputation (2/10, 20%) and cerebrovascular disease (1/10, 10%). The mean wheelchair usage time was 10 (SD 5) hours per day. None of the participants used pressure-relief cushions. Only 2 had a history of pressure ulcers and the most common comorbidity was hypertension (2/10, 20%) and diabetes (2/10, 20%).

To explore the correlation between a proper wheelchair prescription and the user's wheelchair characteristics, the relationship between anthropometric measurements and chair dimensions was evaluated. This analysis revealed a statistically significant correlation only between pelvic width (mean 41.7, SD 6.5 cm) and chair seat width (mean 41.1, SD 4.7 cm*; r*=0.83; *P*=.005). Conversely, no correlation was found between seat height (mean 45.8, SD 7 cm) with leg length (mean 42.3, SD 4.4 cm*; r*=0.19; *P*=.67) or seat depth (mean 83.6, SD 9.6 cm) with buttock-popliteal fossa length (mean 43.1, SD 4.8 cm; *r*=0.42; *P*=.29).

Cushion Performance Analysis

The performance of the custom-contoured cushion was evaluated by comparing pressure distribution variables derived from pressure mapping data, including PP (mm Hg), PPI (mm Hg), MP (mm Hg), and contact area (cm^2). These variables were compared between the custom-contoured cushion and 3 commercial cushions: flat foam, Jay X2 (gel-foam), and ROHO high profile (air). Statistically significant differences were found in all variables when comparing the custom-contoured cushion to each commercial cushion; the custom-contoured cushion exhibited lower pressure values and a greater contact area. The only exception was contact area when comparing the custom-contoured cushion to the Jay X2 gel-foam cushion, where no statistically significant difference was observed (mean 1457.6, SD 254.1 cm^2 vs mean 1442.4, SD 187.7 cm^2; *P*=.595) (Table 2).

Table . Comparison of the custom-contoured cushion manufactured with the proposed methodology with a flat foam cushion and 2 commercial cushions, through the 4 evaluated metrics: peak pressure, peak pressure index, mean pressure, and contact area. Data are presented as mean (SD).

Variable	Manufactured cushion	Commercial cushion					
	Custom contoured	Flat foam		Jay X2		ROHO high profile	
	Mean (SD)	Mean (SD)	*P* value	Mean (SD)	*P* value	Mean (SD)	*P* value
Peak pressure, mm Hg	91.3 (36)	119.9 (37.5)	<.001	100.7 (42.6)	<.001	106.5 (51.8)	;<.001
Peak pressure index, mm Hg	69.5 (33.7)	96.3 (39.6)	<.001	79.5 (37.8)	<.005	83.9 (45.8)	<.001
Mean pressure, mmHg	34.2 (17.4)	41.2 (23)	<.001	40.7 (19.8)	<.001	41.2 (21.4)	<.001
Contact area, cm^2	1457.6 (254.1)	1250.2 (264.8)	<.001	1442.4 (187.7)	.59	1357.1 (221.7)	<.001

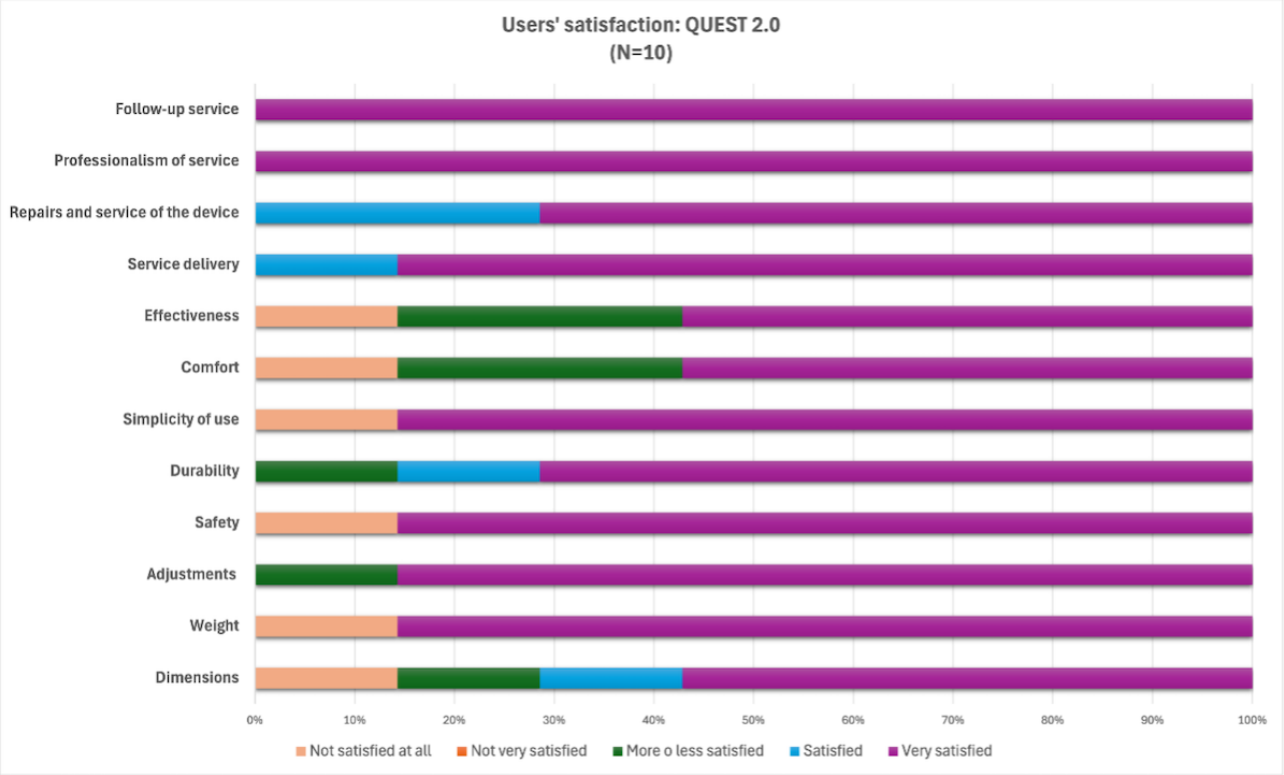
User Satisfaction With the Pressure Mapping–Based Custom-Contoured Cushion

User satisfaction was evaluated using the QUEST 2.0 questionnaire. The mean satisfaction rating for the assistive device was 4.2 (SD 1.07), while the service received a mean rating of 4.9 (SD 0.14). Among device aspects, adjustments and simplicity of use received the highest ratings (mean 4.7, SD 0.75). Furthermore, users reported a perfect score (very satisfied=5) for professionalism and follow-up service.

The distribution of user satisfaction related to the remaining eight items of the QUEST 2.0 questionnaire is presented in Figure 2.

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Figure 2. Users'satisfaction according to Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) questionnaire.



Discussion

Principal Findings and Comparison With Previous Works

This work aims to develop and validate a methodology for fabricating relief pressure custom cushions based on pressure maps of the user-cushion interface. Two validation phases were conducted; first, 7 nonwheelchair-using volunteers were included to evaluate the performance of the contoured cushion versus a flat foam cushion. Then, 10 wheelchair users were included in the study to assess the performance of the custom-contoured cushion versus 3 commercial cushions by comparing pressure distribution variables, including peak pressure (mm Hg), peak pressure index (mm Hg), mean pressure (mm Hg), and contact area (cm^2).

According to the results presented in Table 1, the performance of the manufactured custom-contoured cushion was better than that obtained with the flat foam, which was similar to that reported in the literature. Li et al [19] developed a custom-contoured cushion by converting the interface pressure under the buttocks into the carving depth, reporting a decrease in mean and PP under the buttocks against a flat cushion. Regarding the performance of the custom-contoured cushion against the Jay X2 and ROHO high profile, evaluated in the second phase of the validation study, the cushion manufactured with the proposed methodology presents lower PP, PPI, and MP. In the case of the variable of contact area, in our study, the best contact area is provided for the gel-foam cushion.

According to the literature, several studies have compared commercial cushions using the interface pressure. Sy and Tam [18] reported similar pressure relief characteristics between a custom-contoured cushion and ROHO and Jay 2 cushions; however, the recording time is not reported. As part of a rapid review, He and Shi [15] reported 3 articles using a Jay 2 and a ROHO high profile, reporting the pressure at ischial tuberosities between 94 to 160 mm Hg and 102 to 196 mm Hg, respectively, which is consistent with our results, the gel-foam cushion performs better than the air cushion. In the study by Gil-Agudo et al [11], a ROHO air cushion had lower pressure values than a gel-foam Jay cushion; the MP maps were obtained by averaging the data from 1.5 minutes of recording. Mendes et al [9] reported that in the static position, Jay Fusion Air showed the best rates for average pressure and contact area, while the Roho had the lowest average for the PP. The data were collected for 5 minutes, recording 10 frames per second.

However, user-cushion interface pressures captured using a pressure mat entails several challenges: the constant requirement to recalibrate the mat; its correct positioning under the user avoiding wrinkles or folds; high sensitivity to the user position and movement, which impacts the resulting contour; the user must wear smooth clothing, free of pockets, prominent seams, buttons, or any objects that generate high-pressure points; and finally, the time and frequency of pressure data capture, because they are important factors for the variables analyzed (MP, PP, PPI, and contact area). Regarding this last point, in the aforementioned studies, the time ranges from 1.5 minutes (without sampling frequency) to 5 minutes with 10 frames per second; in our case, the measurement duration was 10 minutes with one map per minute. The optimal duration of pressure measurements is still unclear and deserves further investigation.

On the other hand, this technique automates the user shape capture, avoiding manual, time-consuming methods and waste material. In the proposed methodology, the pressure values are

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converted into cushion thickness values by a linear relationship, in which it is established that the highest pressure, regardless of its magnitude, corresponds to the lowest thickness of the cushion (4 cm) and the lowest pressure corresponds to the highest thickness (7.5 cm), resulting in contours that have a thickness gradient that does not restrict the movement of the user.

Regarding to the relationship between anthropometric measurements and wheelchair dimensions, these parameters were intentionally examined, finding that only seat width and hip width had a statistically significant correlation. These results are unfortunate, as they reflect the limited access to custom-made wheelchairs in our country. These findings differ from the WHO's definition of an "appropriate wheelchair," which should meet the user's needs, offer a good fit, be safe and durable, be locally available, and include maintenance services [23].

At Iberoamerican University in Mexico, we aim to provide a personalized cushion designed for good pressure distribution at an affordable cost, as an alternative to commercial cushions. The university owns the necessary infrastructure for manufacturing the cushions, including the pressure mat, data processing software, and CNC equipment, and the institution covers its associated costs. The materials needed to manufacture the cushion are as follows: a block of polyurethane foam (R-90), a sheet of memory foam, a soft silicone layer (Smooth-On, Ecoflex 00 - 30), water-based contact adhesive (SILER), cotton cloth, and 2 zippers. The total cost for these materials amounts to US $50.

Conclusions

In this study, custom-contoured cushions were manufactured by mapping buttock pressure according to a linear relationship, establishing that the highest pressure, regardless of magnitude, corresponds to the lowest cushion thickness. Seven cushions were made for 7 healthy volunteers, showing better performance in pressure relief against flat foam. Ten contoured cushions were manufactured for wheelchair users, and the peak pressure, peak pressure index , mean pressure, and contact area were determined. The custom cushions showed better pressure relief characteristics than flat foam R90, Jay X2, and ROHO high profile cushions. This methodology presents an affordable option for wheelchair users to obtain a pressure relief cushion.

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Authors' Contributions

IBT, AMH, and COLL contributed conceptualization. IBT, AMH, COLL, and ABS handled methodology. ADLH, IBT, and AMH managed software. ADLH, IBT, AMH, ABS, MFCP, and COLL conducted validation. ADLH, AMH, and COLL handled formal analysis. ADLH, AMH, ABS, and COLL performed investigation. COLL conducted project administration, supervision, and resources. ADLH, AMH, and COLL handled data curation. ADLH and COLL performed writing—original draft preparation. ADLH, AMH, and COLL managed writing—review and editing. ADLH, AMH, and COLL performed visualization.

Conflicts of Interest

None declared.

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Abbreviations

CAD: computer-aided design
CNC: computer numerical control
MP: mean pressure
PP: peak pressure
PPI: peak pressure index
QUEST 2.0: Quebec User Evaluation of Satisfaction with Assistive Technology
WHO: World Health Organization

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Wheelchair Servicing for Older Adults: Cross-Sectional Study

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Abstract

Background: Wheelchairs are assistive mobility devices known to experience frequent part failures and breakdowns within 6 months of regular use. No tools or technologies exist to monitor the wheelchairs' condition or usage and inform stakeholders and users regarding when or how often they need to undergo servicing to avoid critical part failure.

Objective: We aimed to test the association between wheelchair usage and manual wheelchair damage, part failures, and consequences for older wheelchair users and evaluate their preferences for a new wheelchair servicing technology.

Methods: A cross-sectional study was performed with older manual wheelchair users atInstituto Nacional de Geriatría in Mexico. Demographic data, wheelchair information, failure counts, and preferences for new technology (sensor and smartphone app for servicing) were collected using surveys. Road shocks experienced by the wheelchair were collected for a week using a sensor.

Results: Ten participants (mean [SD] age, 78.8 [11.8] y; 8 female and 2 male) participated. Seven experienced an average (SD) of 2.86 (1.36) self-reported part failures. Road shocks correlated with self-reported loose brake failures ($r(8)$=0.58, P=.09), the damaged condition of tires ($r(8)$=0.61, P=.1), and the damaged condition of brakes ($r(8)$=0.58, P=.099). No consequences were reported. Part failures increased as self-maintenance occurrences increased ($r(9)$=0.67, P=.04). More than 8 participants responded that they would like to monitor the wheelchair's condition using the new technology and purchase it at an average (SD) price of US $28.95 (18.13).

Conclusions: In this study, the association between wheelchair usage and failures showed that data-driven wheelchair inspection schedules should be determined through a collaborative approach involving researchers and stakeholders in wheelchair repair provision and older adult users. Older adults are interested in using new technology to engage in wheelchair servicing.

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KEYWORDS

maintenance; mobile app; mobility; older adults; repair; seating; telemonitoring; wheelchair; wheelchair breakdown; wheelchair failure

Introduction

Mobility is an essential element of an older person's physical capacity. The loss of muscle mass and muscle strength, decreased flexibility, and problems with balance can all impair mobility [1]. Mobility impairment is found in 39% of people over 65 years of age, more than three times higher than that among the working population [2]. Wheelchairs enable mobility; however, these assistive mobility devices have a longstanding issue, that is, their parts break with little use.

Cross-sectional studies evaluating wheelchair durability in the community have reported manual wheelchair part failures within 2 - 3 months of use [3]. They lead to physical, social, psychological, and economic consequences for the user [4] as well as device abandonment [5]. This problem is particularly severe in older adults; a higher incidence of failures was observed with elderly wheelchair users in a study conducted in El Salvador [6]. About 57% of the elderly experienced breakdowns in the past 3 months of wheelchair use due to high-risk failures of critical wheelchair parts such as casters and wheels. Around 75 - 95% of the elderly participants rated their wheelchairs as unsatisfactory with unsafe working conditions, contributing to failure, breakdown, loss of mobility, and consequences.

In an effort to improve quality, the World Health Organization (WHO) Guidelines have recommended device quality testing using standards and routine follow-up with users, including the maintenance and repair of wheelchair parts [7]. However, this crucial area has been largely neglected. The maintenance checklists and programs developed by the WHO and research groups have enhanced users' knowledge, performance, and compliance but have yet to prevent community failures [8].

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Furthermore, a mixed-method study validating the user-led wheelchair servicing approach found that older adults using wheelchairs face numerous barriers to maintenance and repair, including health reasons, lack of tools, knowledge, and caregiver support [9]. This underscores the urgent need for novel strategies that can effectively prevent wheelchair failures and breakdowns in older adults.

For automobiles, advanced diagnostic technologies and odometer mileage direct maintenance and repair schemes. Similarly, low-cost sensors offer an opportunity. Using data loggers on community wheelchairs, studies have demonstrated a relationship between failure measures and wheelchair usage risk factors, such as wheelchair shocks and travel distance [10-12]. This study aims to validate this approach for older adult wheelchair users in Mexico. The study's primary objective was to evaluate the relationship between wheelchair shocks and failure measures and the secondary objective was to evaluate older adult's preferences for new servicing technology.

Methods

Study Location

The Ohio State University and Instituto Nacional de Geriatría (INGER) partnered to conduct a mixed-methods study with older adult wheelchair users in Mexico City.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and approved by the Research and Research Ethics Committees of theDirección de Investigación, Departamento de Investigación en Epidemiología Clínica at INGER, under the number DI-PI-009/2021 (date of approval August 11, 2021). Deidentified data transfer and use were permitted under a clinical study agreement between the two institutes. Written informed consent was obtained from all participants before beginning any test. The participants were reimbursed for their first visit travel to INGER.

Study Participation and Recruitment

Participants who were full-time wheelchair users with manual wheelchair models and ≥60 years of age were screened and recruited. Sixty years of age is considered old age in international settings [13]. Flyers and word of mouth were approaches used to recruit older wheelchair users.

Study Procedures

Between August and November 2021, participants underwent two study visits to the INGER facility in Mexico City to collect data. Survey administration, weight measurement, damage condition inspection using a validated Wheelchair Maintenance Assessment tool (W-MAT) [14], and sensor installation were conducted during the first visit. The W-MAT manual includes instructions for inspecting wheelchair parts and scores the damaged condition of parts on a Likert scale of 0 - 2 with 0 indicating poor or damaged condition, 2 indicating good working condition, and NA indicating part not installed. Surveys included demographic information about the participants, part failures, maintenance, and consequences observed over the last 12 months. Participant's preferences for smart wheelchair servicing technology, including interest in self-maintenance and receiving maintenance reminders and willingness to buy the technology, were gathered using Yes/No/Maybe responses through the survey.

During the study visit, the COVID pandemic was ongoing. The wheelchair-user population was considered vulnerable during the pandemic. Hence, disinfection and distancing guidelines were followed. The clinical visit room was cleaned prior to the visit. Only essential staff needed for data collection attended the participant and their accompanying caregiver, if present.

Sensor Description

An inertial measurement unit sensor powered by three D-size alkaline batteries was installed on the side frame of the wheelchairs (Figure 1). The sensor is an upgrade to the sensor used in a previous study [15]; a tube clamp was attached for securing the sensor tightly on manual wheelchair tubular frames. The sensor stored the data on a micro-SD card. Participants collected sensor data for a week and returned for a second visit for sensor removal.

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Figure 1. Wheelchair usage tracking sensor.



Data Analysis

Descriptive statistics (mean [SD]) were performed on survey data. The normality of the data was tested using the Shapiro-Wilk test. For normal data, counts, means, and SD were computed. For non-normal data, medians and IQRs were computed. Shocks greater than or equal to five times the root mean square of the resultant acceleration value [15] were computed from sensor data. Maintenance patterns were analyzed. The frequency of maintenance reported by participants was ordered with no/not possible=0, daily=5, weekly=4, monthly=3, quarterly=2, and yearly=1, and a cumulative total maintenance score for each participant was computed. Pearson correlation analysis was used to compare shocks, failures, part condition scores, and maintenance patterns. Since this was a pilot testing study with a smaller sample size, a less conservative α-level of 0.1 was selected.

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Results

Participant Characteristics

Ten attendant-propelled older adults using standard folding wheelchairs participated in the study. Their demographic characteristics are reported in Table 1. Seven participants experienced an average (SD) of 2.86 (1.36) self-reported part failures with tires, axles, wheels, casters, nuts or bolts, brakes, brakes, seat, and back supports. No consequences were reported.

Table . Demographic characteristics (N=10).

Characteristic	Value
Age, years, mean (SD)	78.8 (11.8)
Gender, n (%)	
Male	2 (20)
Female	8 (80)
Length of previous wheelchair usage, months, mean (SD)	36.8 (31.5)
Number of falls in the last year, median (IQR)	1 (0–2)[a]
Total weight (user and wheelchair), kg, median (IQR)	73.1 (66.3–105.05)
Weight on casters, kg, median (IQR)	23.2 (21.4–27.8)
Wheelchair weight, kg, median (IQR)	13.4 (13.2–16.4)
Maintenance score, mean (SD)	18.5 (17.25)[b]
Maintenance personnel, n (%)	
None	5 (50)
Caregiver	3 (30)
Technician	2 (20)
Days spent outside of the home environment, n (%)	
None	6 (60)
1–2	3 (30)
>5	1 (10)

[a]Only n=6 patients reported falls.

[b]The maintenance score was out of 125.

Usage-Failure Relationships

Participants collected data for an average (SD) of 5.74 (4.34) days. One participant collected data for an hour and was omitted from the shock data analysis. Wheelchair shocks were on 40.38 (48.31) times/day with an average (SD) value of 7.89 (0.83) g. Shocks were correlated with self-reported loose brake failures ($r(8)$=0.58, P=.09) and tire damage condition ($r(8)$=0.61, P=.1). Brake damage assessed using the W-MAT was associated with shocks ($r(8)$=0.58, P=.099). Caster damage assessed using the W-MAT was moderately correlated with shocks but was not statistically significant ($r(8)$=0.52, P=.15). The user's age was correlated with seat failures ($r(7)$=0.58, P=.08). Failures increased as maintenance occurrences increased ($r(9)$=0.67, P=.04).

Servicing Technology Preferences

Six participants noted interest in self-maintenance, and 2 in collaboration with the caregiver. Seven participants said that they would like to receive reminders about wheelchair service. Nine participants said that they would like to monitor the wheelchair's condition using the sensor and an app, and 8 participants said that they would like to buy the technology or use a mobile phone at an average (SD) price of US $28.95 (18.13).

Discussion

Principal Findings and Comparison With Previous Works

The findings from this study support the latest evidence on wheelchair usage-failure relationships and help drive the research efforts toward improving wheelchair reliability [11,12]. This study correlates road shocks with wheelchair part damage and failure measures experienced by older adults in less-resourced settings. Even though differences exist in wheelchair design, settings, materials, and demographic characteristics compared to previous studies with adults under 60 years old, usage dictates failure phenomena. The greater the usage, the more frequently servicing must happen. While the proportion of 70% experiencing at least one failure in 12 months is similar to the literature, a lower failure count among older adults is justified, an observation found with older power wheelchair users [10].

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Users whose chairs received maintenance more regularly witnessed more failures, similar to previous studies with adults [11,12]. Hence, it is essential to consider a collaborative approach to wheelchair servicing where users can take up simple maintenance tasks such as those listed in the WHO maintenance training, and clinicians and technicians can perform complex inspections since professional-led inspections reduce failures [16,17]. Collaborative approaches such as mobile clinics and the engagement of community-based rehabilitation workers in follow-up are promoted in the WHO Prosthetics and Orthotics Standards and can be applied to wheelchairs [18]. As several groups and stakeholders look forward to reforming wheelchair servicing, this research emphasizes considering performance data in decision-making and approach development.

Older adults' interest in using smart servicing technology coincides with a previous study in which 75% of participants upvoted new technology development, including smartphone apps [9]. This favorable outcome motivates the authors to continue developing new technologies while addressing barriers to wheelchair servicing reported by older adults. Following positive findings in this study, the authors aim to build a servicing intervention based on the usage-failure relationship and test its efficacy in preventing wheelchair failure.

Limitations

The small sample size and use of a significance level of 0.1 for this pilot study increases the chance of a type 1 error. Hence, the authors aim to validate the usage-failure correlations in a larger cohort in future studies.

Conflicts of Interest

None declared.

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Abbreviations

INGER: Instituto Nacional de Geriatría
WHO: World Health Organization

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Co-Designed Digital Device for Tracking Rehabilitation Dosage in a Clinical Environment After Stroke: Mixed Methods Validity and Feasibility Study

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Abstract

Background: In 2023, the National Clinical Guidelines for Stroke revised the recommended daily multidisciplinary therapy dose from 45 minutes per therapy to 3 hours of therapy overall. To monitor the achievement of these guidelines, there is a need for accurate measurement. This study introduces a novel co-designed digital dosage tracking system that uses Near Field Communication technology to log rehabilitation activities and demonstrates its feasibility and accuracy in a clinical setting through comparison with the current clinical method of manual recording.

Objective: This study aimed to assess the validity, feasibility, and usability of a novel co-designed digital tracker using Near Field Communication technology to automatically log rehabilitation dosage in people with stroke history, providing an objective and low-burden solution for clinical environments.

Methods: This pilot mixed methods study included 2 phases. Phase 1 involved a usability trial with 9 participants conducted at a university research center, assessing usability with the System Usability Scale (SUS) and Intrinsic Motivation Inventory (IMI). Phase 2 consisted of a clinical trial in a National Health Service stroke ward with 15 inpatients, comparing the digital tracker with manual therapist recordings for validity and feasibility using paired *t* tests, Cohen *d*, and Bland-Altman plots. An acceptable discrepancy range was set at ±5% - 10%.

Results: The digital tracker demonstrated high usability with a mean SUS score of 91.43 (SD 9.53) and strong user satisfaction (IMI score 6.29/7, SD 1.50). Clinical trial results showed a strong agreement between the digital and manual methods (t_{206}=−1.60; *P*=.11; Cohen *d*=−0.06), with a small mean time discrepancy of 1.23 (SD 11.01) minutes across 207 activities. The Bland-Altman plot indicated good accuracy and consistency between methods, with limits of agreement within the clinically acceptable range.

Conclusions: The co-designed digital tracker has been shown to agree with a manual method for recording rehabilitation dosage. This development presents the opportunity for objective, automated, and low-burden recording of rehabilitation dose to support prescription, monitoring, and research.

Trial Registration: ClinicalTrials.gov NCT05981729; https://clinicaltrials.gov/study/NCT05981729

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KEYWORDS

stroke; digital tracking; rehabilitation technology; design; user-centered; digital health; digital technology; digital interventions; assistive technology; wearable health; health care innovation; therapy adherence; therapeutic dosage tracking; rehabilitation tracking; usability

Introduction

Rehabilitation is crucial for regaining functions lost to stroke. The National Clinical Guidelines for Stroke in the United Kingdom and Ireland now recommend at least 3 hours of daily multidisciplinary therapy, a fourfold increase from the previous 45 minutes [1]. Yet, in practice, people often receive a total of 35.6 minutes per day of in patent stay therapy [2,3]. These shortfalls were attributed to highly varied nurse and therapy staffing levels exacerbated by understaffing issues, and

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organizational factors such as the timing of therapy assessments and the presence of weekend therapy services. In addition, less than half of stroke teams provided an extended weekend therapy service.

Stroke rehabilitation activity in the United Kingdom is measured through manual tracking, typically based on therapists' notes. The Sentinel Stroke National Audit Programme (SSNAP) database is a national stroke register that audits care from approximately 250 stroke teams in England, Wales, and Northern Ireland through a combination of electronic data entry by the stroke team and manual data inputting to the SSNAP's online clinical database. Whilst SSNAP captures daily therapy duration and other key metrics, it lacks data on the structure, content, and timing of therapy sessions, and inconsistencies in therapist-reported durations have been noted with a tendency to overestimate the duration of treatment sessions [4]. This absence of standardized, automated, and objective methods for monitoring rehabilitation dosage and intensity hinders adherence to guidelines, personalized care, and research into innovative interventions.

Rehabilitation dosage refers to the total amount of therapy delivered, encompassing the intensity, frequency, and duration of rehabilitation activities [5]. Intensity, as defined by the United Kingdom's National Institute for Health and Care Excellence (NICE) guidelines, involves tailoring the amount of therapy each day to meet the individual's needs across various domains, such as physiotherapy, occupational therapy, and speech and language therapy [6]. In the National Health Service (NHS), the dosage of stroke rehabilitation a participant receives is typically recorded manually by health care professionals, who document the time spent undertaking their rehabilitation during a therapy session, the specific activities performed, and the intensity of these activities in relation to the amount of therapy each day to meet the individual's needs [7]. This manual recording process is regulated for auditing and developing stroke care pathways [8].

The use of Internet of Things (IoT) and mHealth devices for self-rehabilitation shows promise in improving post-stroke recovery and quality of life [9]. Near-Field Communication (NFC) has been proposed as a means of recording patient information [10], yet there remains limited evidence of its use for clinically tracking acute or subacute stroke rehabilitation dosage or intensity. One study measured stroke dosage through electronic counters that required participants to press a button after each repetition [11]. While a promising approach, this places the burden of measurement on the participant. Home-based rehabilitation tracking using computers and tablets have also been investigated, particularly in post-stroke aphasia, and been suggested as a potential solution to standardizing dose measurement [12-14]. However, studies proposing electronic or digital methods for dosage tracking often do not adopt a co-design approach that would accommodate the full range of stroke severities, including cognitive and aphasic impairments. According to Medical Research Council recommendations [15], the usability of rehabilitation tracking technology should be driven by a collaborative process involving both users and health care professionals, ensuring that design and functionality are optimized to address diverse user needs.

This study introduces a novel, co-designed tracker that uses NFC technology to track the dosage of rehabilitation across multiple domains (physical, cognitive, and communication). The tracker was designed with users (stroke survivors and stroke rehab professionals) to be accessible, clinically appropriate, and easy to implement, providing a comprehensive and user-friendly solution for monitoring compliance with stroke rehabilitation guidelines.

Methods

Overview

This pilot study, conducted in 2 phases, evaluated the digital dose tracker, co-designed by users, by assessing its feasibility, validity, and usability. Phase 1 focused on a usability study (n=9) conducted in a research setting. Phase 2 involved a clinical trial to assess the trackers' feasibility and validity (n=15). The primary outcome for Phase 1 was usability, measured by the System Usability Scale (SUS) and Intrinsic Motivation Inventory (IMI). The primary outcomes for Phase 2 were dose validity (comparison with the current method) and tracker feasibility [16]. Feasibility was defined as the ability of the digital dose tracker to be effectively used by all participants, including those with cognitive or physical impairments, without requiring significant modifications or support. It was assessed by the absence of user errors in Phase 2, withdrawals, and the successful capture of accurate rehabilitation data across various activities [17].

Co-Design of Digital Dose Tracker

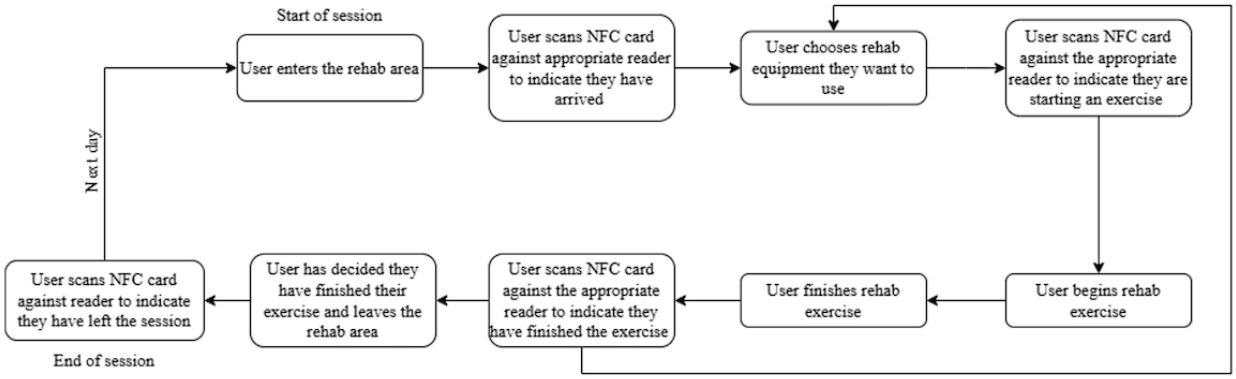
Two focus groups were conducted; first, to determine the need for a digital tracker and brainstorm ideas with the stroke rehabilitation community, second to create the product design criteria and user requirements for both hardware and software [16]. The same participants (6 stroke survivors and 1 physiotherapist) were involved in both focus groups. Design requirements were extracted through thematic analysis and ranked by priority which was determined by the frequency of mentions paired with the number of participants contributing. Once the design criteria were prioritized this was verified with the focus group participants. The key outcomes of these focus groups were the clear need to create a device that could track both dosage and intensity but was simple to use and could motivate engagement with rehabilitation [18].

Device Specifications

A recommendation from the cocreation process was to use a contactless ID card reader positioned at various rehabilitation workstations (Figure 1) [19,20], enabling users to tap their card and self-track their dosage in real time.

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Figure 1. The user journey of the digital dose tracker. NFC: Near-Field Communication; rehab: rehabilitation.

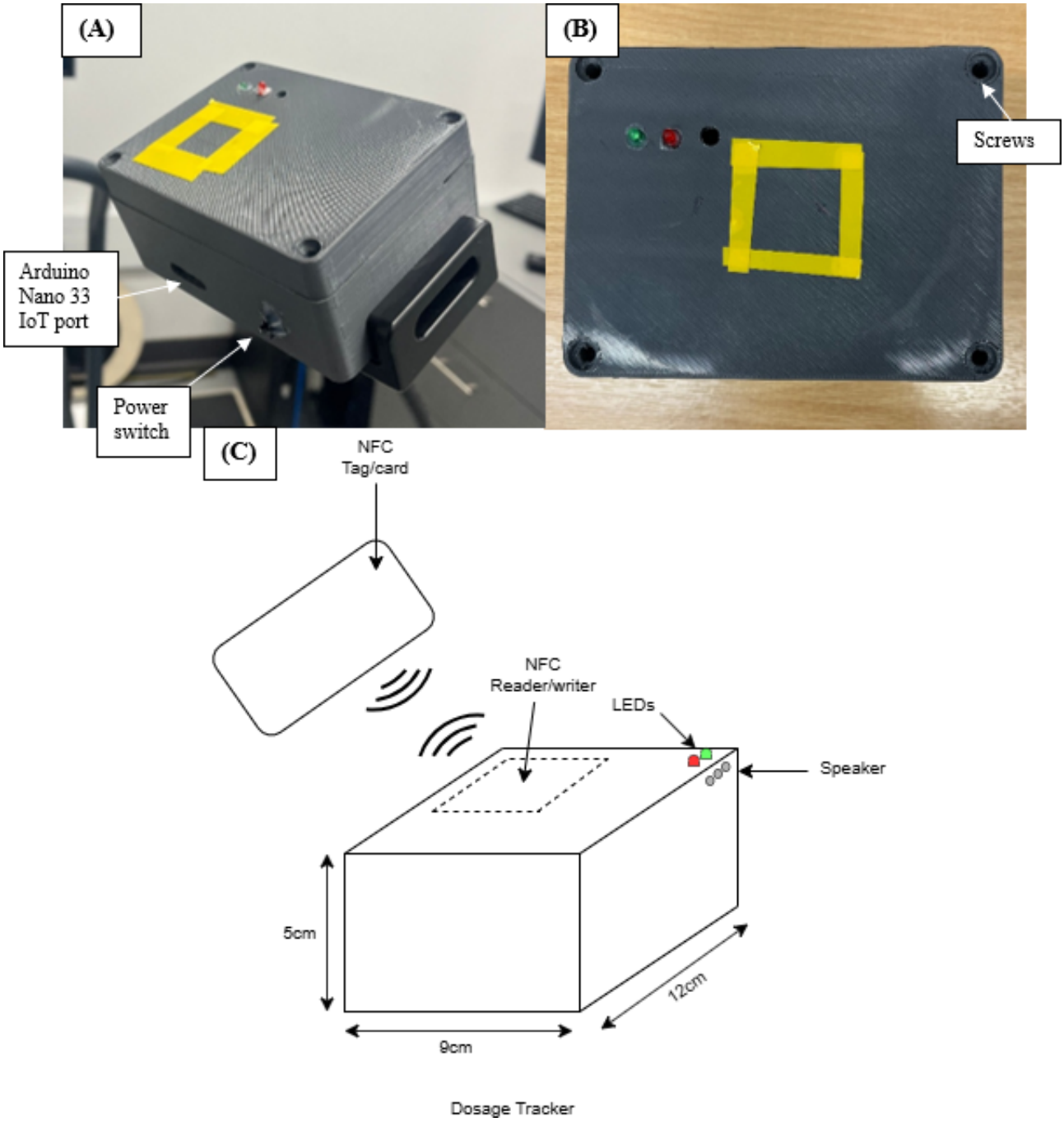


The dosage trackers (Figure 2) consisted of an Arduino Nano 33 IoT (SAMD21, Arduino, Italy), a PN532 NFC module (NXP Semiconductors, Netherlands), green and red LEDs and an Adafruit mini speaker (Adafruit Industries; Figure 3) to provide visual and audio feedback. A rechargeable battery (5 volts, 1 amp) provided the power. Each tracker was programmed (C++) to register a participant's unique identifying number when they scanned their NFC card, allowing each rehabilitation activity and the corresponding time spent at each workstation, to be attributed to the correct user. Figure 2 highlights the positions of the light-emitting diodes, speaker openings, and the Near-Field Communication reader and writer. In addition, it depicts a Near-Field Communication card being brought into proximity with the device to facilitate communication between the card and the reader for logging participant dosage. The yellow markings in Figure 2A and 2B serve as visual guides to indicate the precise location of the Near-Field Communication reader, minimizing scanning errors.

When a user places their unique NFC card near a tracker for the first time, the green LED flashed once, and the speaker emitted a tone indicating a successful "scan in" to the equipment or room. Holding the card near the tracker a second time caused the green LED to flash twice, accompanied by another tone, confirming a correct "scan out." If a user then presented the same card to the tracker again, the system recognized that the same piece of equipment was being reused, or the same room was being re-entered. The card not being placed close enough to the tracker or being moved away too quickly could create registration errors. In these instances, the red LED flashed 3 times, and the speaker played an error sound, prompting the user to re-scan the card.

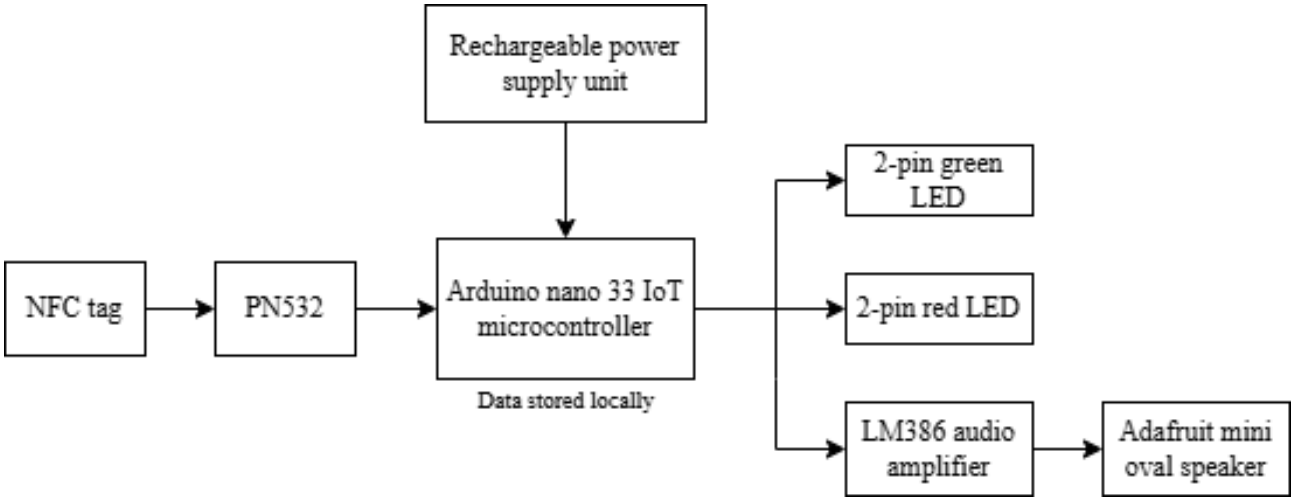
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Figure 2. Photographs and diagram of the near-field communication dosage tracker. (A) Overall view of the tracker, (B) top-down view, and (C) diagram illustrating key components and functionality. IoT: Internet of Things; NFC: Near-Field Communication.



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Figure 3. System block diagram. IoT: Internet of Things; NFC: Near-Field Communication.



Phase 1: Usability

Participants

The usability of the digital dosage tracking system was tested with 9 participants recruited from an ongoing trial (ClinicalTrials.gov; NCT06787768) at the Sir Jules Thorn Centre for Co-Creation of Rehabilitation Technology, University of Strathclyde [17,18]. That trial was investigating the feasibility of a technology-enriched rehabilitation gym for people living with stroke, delivered entirely through technology (eg, virtual reality, treadmills, weight suspension, and power assistance equipment) over an 8-week program. Individuals in the trial were required to have experienced a stroke at least 12 months before, be in stable health, and be able to attend at least 2 of the 2-hour sessions per week, follow instructions in English, and offer verbal or written feedback. Within the technology-enriched rehabilitation gym, a physiotherapist designed, supervised, and reviewed each participant's program using principles of intensity, feedback, cognitive engagement, and aerobic activity, aligning it with the participant's goals and baseline outcome measures. Since all 9 participants met these criteria, they were also eligible to join our 8-week usability study, providing a controlled environment to evaluate the digital dosage tracking system.

Testing

Participants attended rehabilitation sessions in the research facility, where they used the trackers to log their rehabilitation activities. The activities and workstations used during this usability trial were matched to those in the subsequent clinical trial, maintaining consistency across both study phases. After completing the 8-week usability trial, participants filled out the SUS and IMI surveys to assess their experience with the system.

Analysis

The data gathered from the SUS and IMI surveys were analyzed to determine the usability of the digital dosage tracking system. The SUS provided a quantitative measure of usability, whilst the IMI offered insights into the participants' motivation and engagement with the system. The results were used to evaluate the trackers potential for integration into clinical practice

Phase 2: Feasibility and Validity

Participants

In-patients at a local NHS hospital, with a diagnosis of stroke and referred for rehabilitation, were invited to participate in the study, provided they met the following inclusion criteria: diagnosis of a new stroke by an NHS Lanarkshire physician, more than 48 hours since the stroke event, medically fit for rehabilitation as determined by medical staff, deemed to require rehabilitation, and able to provide informed consent. Individuals were excluded if they were acutely medically unwell, had active cardiac disease (such as unstable angina), active delirium or significant levels of confusion, had a seizure within the past 7 days, were being managed under the Adults with Incapacity Act, or were known to be pregnant. Those with aphasia and other cognitive or communicative difficulties resulting from their strokes were not excluded from participating. Given the nature of the stroke population, a significant proportion of participants were likely to have these impairments. In the United Kingdom, it is estimated that 50% of stroke survivors experience cognitive impairment, and approximately one-third have aphasia or other communication difficulties, particularly in the acute and sub-acute phases of recovery [21].

Testing

Participants attended as many sessions at a rehabilitation gym located on the stroke ward as able, with sessions lasting up to 2 hours. The tracker recorded the start and stop times when a participant scans their card at each activity, providing a log of the total time spent at each activity, the person who used it and exactly what the activity was to a local database based within the ward. At the same time, 2 supervising clinical staff members observed all participants and manually recorded the rehabilitation activities and durations. This manual logging was intended to simulate typical clinical practice, based on the advice of the local rehabilitation team, where therapists record the time spent at each station or device without tracking finer details such as repetitions or specific exercises.

Analysis

To assess the equivalence of the digital dosage tracking system with manual recording methods, paired sample *t* tests were used

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to compare the mean times recorded by the 2 methods for each activity. Cohen *d* was calculated to quantify the effect sizes of any observed differences, with small effect sizes being indicative of negligible differences. Bland-Altman plots were used to visually explore the relationship between the 2 methods, and the limits of agreement (LOA) were calculated with a 95% CI to determine the range within which most differences would fall. Time recordings were standardized to minutes, and the average absolute time discrepancies and their variability are presented in the Results section. An acceptable range for discrepancies was decided to be within ±5%.

Ethical Considerations

This study received ethical approval from the Strathclyde University Ethics Committee under the protocol number UEC20/08: Kerr: Generic Framework Application: User experience of a technology-based rehabilitation program. All participants provided informed consent before their involvement in the study. Participants did not receive compensation, and all data were anonymized. The study was part of a clinical trial (ClinicalTrials.gov; NCT05981729) and received NHS Research & Development ethical approval from South East Scotland Research Ethics Committee 1 (IRAS ID No. 329156).

Results

Phase 1: Usability

A total of 9 people participated in phase 1 of this study (Table 1); however, 2 participants decided to withdraw from the trial in the final week, 1 due to other commitments and the second due to short-term illness. High usability was demonstrated with a mean IMI score of 6.29/7 (SD 1.5; Table 2), and a mean SUS score of 91.43/100 (SD 9.53); the total SUS score was calculated based on participants' responses to the 10-item questionnaire, with each item rated on a 5-point Likert scale. The scores were normalized and converted to a range of 0-100 (refer to Table 3 for further SUS results).

Table . Participant characteristics of usability trial.

Characteristics	All participants (n=9)
Age (years), mean (SD)	62.56 (10.32)
Sex, n	
Male	8
Female	1
Aphasia, n	
Aphasic	2
Non-aphasic	7
Living situation, n	
Live with family	4
Live alone	4
Hemiplegic side, n	
Left	7
Right	1
Both	1
Time since stroke (months) mean (SD)	50.9 (21.5)

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Table . Collective adaptive Intrinsic Motivation Inventory results with averages.

Question	P1	P2	P3	P4	P5	P6	P7	Mean (SD)
I enjoyed using this system very much.	7	7	7	6	7	6	6	6.57 (0.53)
I think I am pretty good at using this system.	6	7	7	1	6	5	6	5.43 (2.07)
I put a lot of effort into using this system.	6	6	7	3	7	6	6	5.86 (1.35)
I did not feel nervous at all whilst using it.	7	7	7	7	4	4	4	5.71 (1.60)
I thought using this system was a boring. (R)[a]	7	7	7	7	7	6	7	6.86 (0.38)
I believe this system could be of some value to me.	6	7	7	2	7	6	7	6 (1.83)
I believe I had some choice about using this system.	7	7	7	3	6	6	6	6 (1.41)
I didn’t try very hard to do well at using the system. (R)	7	7	7	7	6	5	2	5.86 (1.86)
I think that using this system is useful for tracking my rehabilitation exercises.	7	7	7	7	6	6	7	6.71 (0.49)
This system did not hold my attention at all. (R)	7	7	7	7	7	6	7	6.86 (0.38)
I felt very tense whilst using the system.	1	1	1	1	4	4	1	1.86 (1.46)
I felt like it was not my own choice to do this task. (R)	7	7	7	7	4	4	4	5.71 (1.60)
I thought this system was quite enjoyable	6	7	7	7	6	6	7	6.57 (0.53)

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Question	P1	P2	P3	P4	P5	P6	P7	Mean (SD)
I would be willing to use this again because it has some value to me.	7	7	7	7	6	6	7	6.71 (0.49)
I am satisfied with my performance at using the system.	6	7	7	7	5	5	6	6.14 (0.90)
It was important to me to do well at using the system.	6	6	7	6	5	5	6	5.86 (0.69)
I used this system because I wanted to.	6	7	7	6	6	6	7	6.43 (0.53)
Using the system was an activity that I couldn't do very well. (R)	7	7	7	7	7	6	7	6.86 (0.38)
I felt pressured while doing this.	1	1	1	1	1	2	1	1.14 (0.38)
I think doing this activity could help me to motivate myself in continuing my rehabilitation.	7	7	7	7	7	6	7	6.86 (0.38)

[a]R: reverse scored.

Table . System Usability Scale questions with average results; each item was rated on a 5-point Likert scale.

Question	Results, mean (SD)
I think I would like to use this system frequently in the cohort.	4 (0)
I found the system unnecessarily complex.	3.86 (0.35)
I thought the system was easy to use.	3.71 (0.45)
I think that I would need the support of a technical person to be able to use this system.	2.71 (1.75)
I found the various functions in this system were well integrated.	3.57 (0.49)
I thought there was too much inconsistency in this system.	3.57 (0.49)
I would imagine that most people would learn to use this system very quickly.	3.86 (0.35)
I found the tool very cumbersome to use.	3.57 (0.73)
I felt very confident using the system.	3.86 (0.35)
I needed to learn a lot of things before I could get going with this system.	3.86 (0.35)

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Phase 2: Feasibility and Validity

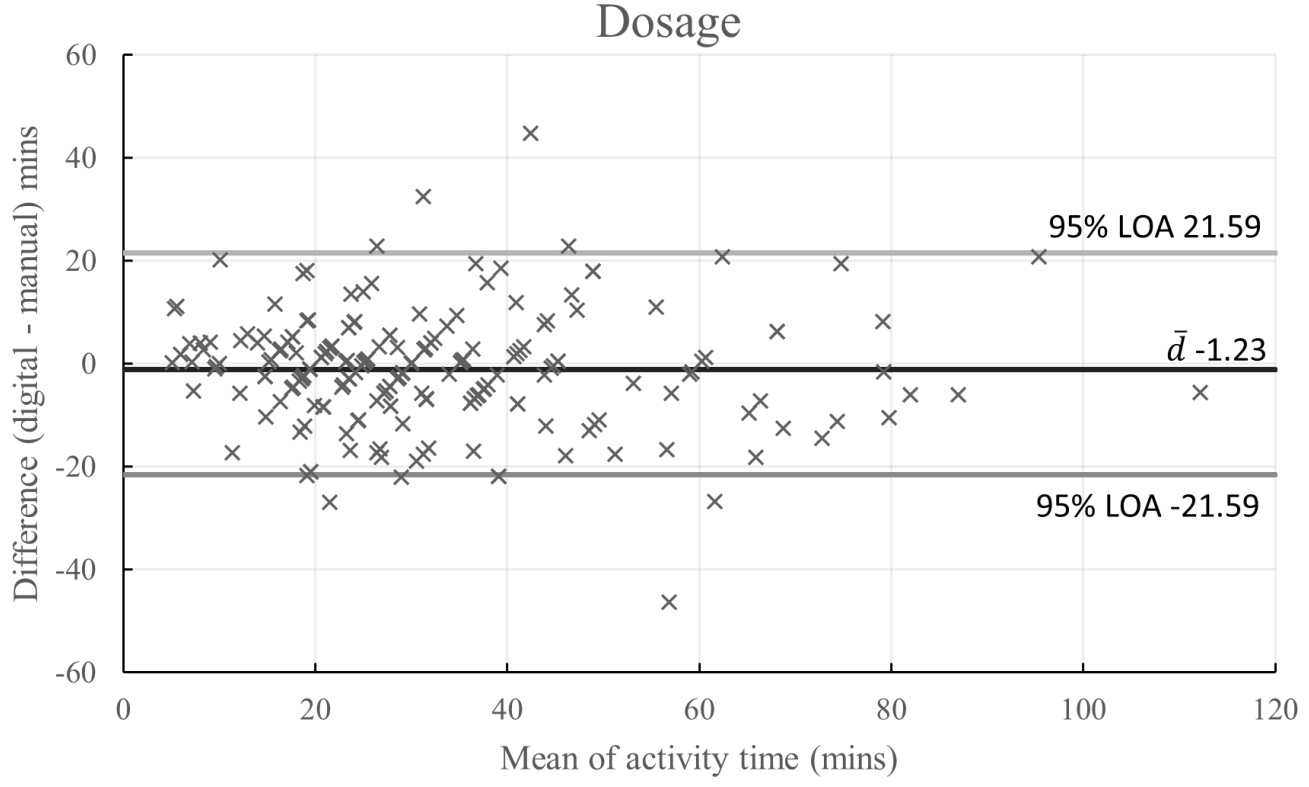
Throughout the 6-month duration, 15 participants were recruited and completed the study (Table 4). Across the 15 participants, 207 activities were recorded by both digital and manual methods with an average number of sessions during inpatient stay of 9.1 (SD 7.4). There was a generally high agreement between the methods (t_{206}=−1.6; *P*=.11; Cohen *d*=−0.06), confirming the equivalence of the 2 tracking methods. The overall analysis, encompassing all recorded data from the various rehabilitation stations and gym attendance, revealed an average absolute mean time difference of 1.23 (SD 11.01) minutes across 207 total uses. This absolute mean time difference reflects a small 1 - 2-minute discrepancy between the digital and manual recorded times, indicating that whilst minor differences existed, they were not systematic and likely stemmed from normal variations in manual documentation.

Table . Participant characteristics of feasibility and validity trial.

Characteristics	All participants (n=15)
Age (years), mean (SD)	70.93 (13.31)
Sex, n	
Male	7
Female	8
Stroke type, n	
Ischemic	13
Hemorrhagic	2
Time since stroke (days), mean (SD)	19.5 (14.99)

The Bland-Altman plot (Figure 4) shows an even spread across the range of activity durations, indicating consistent agreement between the digital tracker and manual recordings. The plot reveals a bias of −1.23 minutes, suggesting good accuracy of the digital tracker relative to the manual method, with only a small systematic bias. The LOA were calculated to be from −21.59 to 21.59 minutes, which encompasses most of the observed discrepancies. Despite this range, the review of activity-specific durations revealed only minor differences, no greater than 6 minutes on average (Table 5), further supporting the reliability of the digital tracking system.

Figure 4. Bland-Altman plot comparing digital and manual dosage tracking methods. This plot shows the difference between the digital and manual dosage tracking methods for all recorded activities (n=207) at the stroke ward, plotted against the mean activity time. The plot includes the mean difference (bias, d-) and the upper and lower limits of agreement at a 95% CI. The bias value, closely aligned with the x=0 axis, indicates a high degree of validity between the 2 methods. LOA: limit of agreement.



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Table . Summary of rehabilitation workstations and mean time discrepancies between digital and manual recordings. This table details the number of uses, the equipment involved, and the average time discrepancy (SD) in minutes between the digital tracker and manual recordings for each workstation. The "overall" row shows the combined data across all workstations and gym attendance.

Workstation category	Equipment	Number of uses, n	Time discrepancy (minutes), mean (SD)
Upper limb station	Graded Repetitive Arm Supplementary Programme (GRASP) kits, Gripable	24	5.23 12.8)
Cognitive applications	TinyTablet	24	2.73 (6.52)
Speech applications	TinyTablet	3	5.26 (21.08)
Power assist equipment	Three MOTOmed devices	67	3.23 (9.87)
All equipment uses	All above-listed equipment (excluding gym attendance)	118	0.27 (10.72)
Total time spent in rehabilitation gym	Attendance in gym	89	4.5 (14.55)
Overall	__[a]	207	1.23 (11.01)

[a] Not applicable.

Discussion

Principal Findings

The aim of this study was to evaluate a novel digital dose tracker against the standard manual recording method. Primary results showed a high level of agreement between the digital and manual methods, with Cohen *d* indicating a negligible effect size, which suggests that the differences between the 2 methods are minimal. This result confirms the digital tracker's consistent and complete data capture. Manual recording is currently the method used for auditing and developing stroke care pathways [8]. The digital tracker's ability to collect a broader range of activity data, as shown in Figure 4, highlights its potential to describe the intervention in greater detail, benefiting health care providers attempting to improve their services and researchers aiming to better understand response to rehabilitation interventions.

Phase 1 outcomes demonstrated the device's clear usability among users. The high scores for SUS and IMI were not surprising given the preceding co-creation process. Usability is a critical factor in health care and rehabilitation settings, as it directly influences the likelihood of a device being adopted in routine practice. The high usability demonstrated by this digital dose tracker ensures that both health care providers and people with stroke history can integrate the device into daily operations without significant disruptions or extensive training. This ease of use supports seamless implementation in clinical environments, enhancing the overall user experience and increasing the likelihood of widespread adoption [22]. In rehabilitation, where consistent and accurate use of technology can significantly impact patient outcomes and care efficiency, high usability is particularly important [23].

Whilst the mean time discrepancy between the digital and manual methods is relatively small (1.23 min), the larger SD 11.01 min indicates some variability in individual time recordings. This variability could be attributed to factors such as differences in manual recording practices among therapists, variations in task complexity, and individual participant behavior during rehabilitation sessions. Despite this variability, the overall agreement between the 2 methods remains strong, suggesting that the digital system is a valid tool for tracking rehabilitation dosage, especially when considering the average results across multiple sessions and participants.

The digital tracker accurately tracked rehabilitation activities by logging the unique identifiers of both participants and devices, ensuring precise data collection. Conducted under direct observation, therapists manually recorded the time spent at each station, reflecting standard clinical practice. Whilst a minor average discrepancy of about 1 minute was noted between the digital system and manual recordings, this difference was minimal and fell within an acceptable range.

In line with the definition of rehabilitation dosage, which includes the intensity, frequency, and duration of rehabilitation activities, the digital tracker successfully captures the essential elements of dosage as required by this definition. Although intensity refers to the individualized adjustment of daily therapy across various domains such as physiotherapy, occupational therapy, and speech therapy, this tracker is particularly adept at accurately recording the frequency and duration of therapy sessions. By logging the start and stop times of each session, the tracker provides a measure of the total duration of rehab, which is critical for ensuring that people with stroke history receive the appropriate amount of therapy prescribed to them and can be used to monitor achievement of guidelines.

The digital trackers approach to tracking rehabilitation dosage mirrors the standard clinical practice where therapists estimate the total time a patient spends at a therapy station. Therapists typically log this time without distinguishing between active therapy and brief pauses, which has been an accepted method in clinical practice for years. The 1-minute average discrepancy observed between the therapists' manual logs and the digital recordings reflects the minor variations inherent in manual estimation. Importantly, the fact that these times align so closely and fall within clinically acceptable margins of error

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demonstrates that this method does not negatively affect the results. This small difference is within the clinically acceptable range, reinforcing the digital trackers reliability as a tool for tracking rehabilitation dosage.

The distribution of attendance across the different rehabilitation workstations also provides insight into the priorities and preferences of people with stroke history during their rehabilitation. Users at the stroke ward's rehabilitation gym had the autonomy to select the rehabilitation they preferred, with guidance and supervision, during their sessions. The Power Assisted Equipment station had the highest number of uses (n=67) which may reflect a common patient priority of focusing on motor recovery [24]. This preference is often driven by the desire to regain physical independence, which has been previously recognized as a priority for individuals with stroke over cognitive or speech rehabilitation.

The Bland-Altman plot, Figure 4, showed that the device was accurate in depicting a user's rehabilitation journey and the LOA were calculated with a 95% CI. There is currently no clinical documentation which specifies an acceptable LOA, but a margin of error within ±5% - 10% was deemed acceptable, given that manual recording in rehabilitation contexts could vary widely, affecting the reliability of data [25]. The LOA determined in this study was within this range.

Table 3 shows that 3 rehabilitation workstations had an average time difference of just under 6 minutes. This discrepancy is attributed to the need for hoist or transfer assistance for users with low to no mobility, resulting in waiting periods. This also applies to the time taken for participants to transfer in and out of the rehabilitation gym. Overall, wide differences were rare, and outliers were attributed to instances of human error in the manual recordings when the therapist was observing and recording multiple participants at once.

The feasibility of the digital dose tracker was further demonstrated by the fact that all users of the rehabilitation gym, regardless of their varying levels of cognitive or physical impairment, were able to effectively use the system. There were no withdrawals in Phase 2 or errors recorded by the tracker during the study, nor were any observed by the 2 clinical staff, demonstrating the trackers accessibility and functionality across a diverse stroke population.

Whilst the dosage tracker can operate on its own, it is a subcomponent of a more complex device with the intended purpose to measure both dosage and intensity of a person's rehabilitation. This device is a prototype and proof of concept, throughout the phase 1 usability trial participants were allowed to give feedback about the device to allow for adjustment and modifications, this included adjusting the brightness of the LEDs and increasing the volume of the speaker to improve audio and visual feedback. The device is limited in the quality of its components due to funding however if additional funding were to be obtained this would contribute to the refinement of the trackers to reduce the size and thus improve portability.

The study faced challenges related to the rate of participant uptake. A significant number of potential participants could not be included because they were only in the hospital for a few days, which did not allow sufficient time for the consent process. In addition, the rate of uptake in the study and the number of viable participants varied depending on the number of people admitted to the stroke ward during the study period. This limitation reduced the overall sample size, impacting the generalizability of the findings. Future studies could consider running for a longer duration to accommodate the consent process and variations inpatient admissions, thereby ensuring a more comprehensive assessment of rehabilitation dosage.

Conclusion

This study has evaluated a novel, co-designed, digital system for monitoring rehabilitation dose finding it largely agreed with traditional manual methods. It is one of the first studies to implement such a method of rehabilitation dosage tracking in a clinical rehabilitation setting. This promising system has the capacity to provide an accurate and automated method for measuring achievement of the new National Clinical Guidelines for Stroke recommendations and providing practical support for therapists and researchers.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

IMI: Intrinsic Motivation Inventory
IoT: Internet of Things
LOA: limits of agreement
NFC: Near-Field Communication
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
SSNAP: Sentinel Stroke National Audit Programme
SUS: System Usability Scale

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Original Paper

A Technology System to Help People With Multiple Disabilities Increase Contact With Objects and Control Environmental Stimulation: Single-Case Research Design

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Abstract

Background: People with severe-to-profound intellectual disability and sensory-motor impairment tend to be passive and detached from their immediate context.

Objective: This study assessed a new technology system using a webcam to detect participants' responses (ie, hand contact with objects) and to trigger computer delivery of preferred environmental stimulation, such as music, contingent on (immediately after) the occurrence of those responses.

Methods: In total, 8 adults with severe to profound intellectual disability and extensive motor and visual impairments participated in the study. Each participant was exposed to an ABACB design. The technology system did not provide stimulation during the A (baseline) phases, provided stimulation contingent on the responses during the B (intervention) phases, and provided stimulation throughout the sessions during the C (control) phase. Sessions lasted 5 minutes.

Results: During the first baseline phase, the participants' mean frequency of responses per session was between about 3 and 6.5. During the first intervention phase, it increased to between about 10 and 18. It showed a clear decline during the second baseline phase, remained low during the control phase, and increased again during the second intervention phase. During this phase, it ranged from about 13 to 19.5.

Conclusions: The new technology system might be a useful tool to help people with intellectual and sensory-motor disabilities increase object contact and stimulation control.

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KEYWORDS

technology; sensor; webcam; blindness, intellectual disability; motor impairment; object contact; stimulation

Introduction

Background

People with severe-to-profound intellectual disability and sensory-motor impairment tend to be largely passive and detached from their immediate context [1-6]. Indeed, they may not have particular interest in the objects available to them, may lack speech and possess only minimal and inefficient forms of nonverbal communication, and may be unable to access environmental stimulation independently with the consequent risk of low and poor stimulation input [1-7].

This situation is largely unsatisfactory, and efforts have been reported to reduce its negative implications. Some of the efforts have been directed at increasing the level of interaction between

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these people and their staff and caregivers to increase their stimulation input and the opportunity of practicing basic forms of communication [2,6-12]. Other efforts have been more specifically focused on enriching these people's daily conditions with increased levels of environmental stimulation [13-19]. These latter efforts presented a clear differentiation based on whether their scope was to (1) provide people with a rich stimulation context [18,20-22] or (2) enable people to exercise self-determination, thus seeking and controlling environmental stimulation through their own responses rather than relying on staff mediation [16,23,24]. Promoting self-determination can be considered a critically important goal within the rehabilitation process, that is, a goal that is instrumental to counter passivity (isolation) and foster independent contact with the immediate context and objects [25,26].

Studies aimed at enabling people to seek and control environmental stimulation independently (through their self-determination) have often relied on technology systems, including sensors (microswitches) linked to a computer, smartphone, or tablet [16,27-34]. Sensor activations via specific responses triggered the computer, smartphone, or tablet to deliver brief periods of preferred stimulation. In essence, the technology was arranged to ensure that even people with a limited response repertoire would always have 1 or 2 responses that they could use as tools (instruments) to seek and control environmental stimulation.

The results of those studies were largely encouraging. First, people were typically successful in using the responses selected for them to perform and thus enriched their stimulation input based on their own initiative (self-determination) and independent choice. Second, people seemed to enjoy such a situation. In fact, studies reported that they tended to show indices of happiness during sessions in which they were able to control their stimulation input through their responses [16,33,35-38]. Third, comparative evaluations seemed to indicate that indices of happiness tended to be higher (more frequent) in situations in which people controlled the stimulation through their responses than in situations in which the stimulation was automatically delivered (ie, independent of people's responses) [16,36].

The results mentioned earlier constitute an important basis for supporting the use of technology-based interventions aimed at enabling people to independently seek and control their environmental stimulation. Extending the use of those interventions poses questions about the responses the participants should be required to produce and the sensors that could be used to detect those responses. As to the responses, it would seem advantageous to select those that involve people's physical contact with objects (ie, to curb their isolation and detachment). As to the sensors, the main question is to ensure that they are suitable and dependable in detecting responses involving touching or exploring objects. The answer to this question is not always obvious. For example, one may argue that optic sensors placed in the proximity of the objects to be touched or explored could easily detect the responses. Yet, response detection might become inaccurate if the sensors' focus is altered during the sessions by people's erratic response movements. Pressure sensors under or to the side of the objects to be touched and explored could be effective. Yet, that would require that people apply some pressure on the objects.

Objectives

The purpose of this study was to assess (1) the suitability (applicability) of a sensor that did not need to be displayed in the proximity of the objects to be touched or explored but would detect the responses from a distance, thus bypassing the difficulties mentioned regarding optic and pressure sensors, and (2) the effectiveness of the sensor and related technology system in helping the participants increase contact with objects and control environmental stimulation. A positive answer regarding each of these 2 assessment points was thought to have relevant practical (clinical) implications for future work with people with multiple disabilities. The sensor consisted of a webcam. The technology system of which the sensor was part involved a portable computer fitted with specific software, a mini speaker, and a smart Wi-Fi plug. In total, 8 people with severe to profound intellectual disability and sensory-motor impairments were involved in the study, which was carried out using single-case research methodology.

Methods

Participants

The 8 participants represented a convenience sample [39] in that they were selected from rehabilitation and care centers of a single organization. All of them, however, shared a complex condition in terms of disabilities and limited engagement with the immediate context and were adults. Table 1 lists the 8 participants via their pseudonyms and reports their chronological age and their Vineland age equivalents for Daily Living Skills, personal subdomain (only this subdomain of the Vineland Adaptive Behavior Scales was used as it seemed the most representative of their general functioning). Their chronological age ranged from 27 to 48 years. Their Vineland age equivalents (obtained via the second edition of the Vineland Scales [40,41]) ranged from below 1 year to 2 years and 2 months, underlining the seriousness of their situation and their dependence on external support. All participants had congenital encephalopathy and presented with intellectual disability, motor impairments (ie, lack of ambulation or ambulation with support and arm-movement restrictions), absence of speech or any formal communication means, and minimal residual vision (Logan and Harper) or blindness (all others). No IQ scores were available for them as no formal testing was possible given their situation. The psychological services of the rehabilitation and care centers that they attended estimated their level of intellectual disability to fall in the profound or severe-to-profound range.

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Table 1. Participants' chronological age and Vineland age equivalents for Daily Living Skills (personal subdomain).

Participants (pseudonyms)	Chronological age (years)	Vineland age equivalents[a] (years, months)
Liam	43	2, 2
Hallie	37	<1, 0
Logan	31	<1, 0
Kali	48	1, 3
Harper	43	2, 1
Jacob	33	1, 5
Millie	27	1, 1
Isabel	34	1, 2

[a]Age equivalents are based on the Italian standardization of the Vineland Scales [40].

The participants were included in the study based on a number of conditions, which had been verified through preliminary observations and staff interviews. First, they were generally passive with very limited contact with their immediate context but possessed the arm-hand motor schemes necessary to reach and touch objects on their desk. Second, they showed signs of interest in forms of environmental stimulation (eg, could display alerting and smiling in relation to music and songs). The assumption was that such stimulation could be used contingent on their object contact responses during the study. Third, they seemed to alert and sometimes to activate themselves (eg, producing a reaching response) in relation to the presentation of alerting stimuli such as verbal encouragements or noises. Fourth, rehabilitation personnel considered an increase in the participants' responses highly useful to break their withdrawal and to promote functional motor schemes. Fifth, the use of a technology system to help the participants acquire and consolidate their responses was viewed favorably within their daily contexts by regular staff and caregivers.

Setting, Sessions, Responses, Research Assistants, and Stimuli

Quiet rooms of the rehabilitation and care centers that the participants attended were used as the setting for the study sessions. In total, 3 types of sessions were available, that is, baseline, intervention, and control sessions. All sessions lasted 5 minutes. They were implemented on an individual basis, typically 2-3 times a day (nonconsecutively), 3-6 days a week. A response consisted of the participants making a new hand contact with (ie, touching or exploring) either one of the 2 objects available in front of them, that is, on the desk at which they sat. The objects included simple everyday materials such as sponges, small boxes, rings, and bottles, which were fixed on the desktop.

In total, 4 research assistants were responsible for implementing the sessions and checking their agreements and disagreements with the technology system regarding the responses it recorded and followed with stimulation delivery. They had university degrees in psychology and were familiar with the implementation of technology-aided programs with people with disabilities and with data recording procedures. Expert research assistants were involved in carrying out the study because they were expected to need only minimal practice (preparation) time and to be procedurally reliable given their experience. Moreover, contrary to staff personnel, they did not have care and rehabilitation duties that could interfere with the timing and implementation of the sessions.

The stimuli used during the intervention and control sessions included music, songs, noises, and voices or combinations of them with various types of lights (Logan) or mild airflows (Millie). The stimuli had been selected through a stimulus preference screening procedure carried out before the start of the study. The procedure consisted of presenting each of three 10-second segments of the songs and music pieces as well as clips of different lights, voices, and noises or brief airflows for at least 10 nonconsecutive times (ie, over different assessment periods). The stimuli were retained for the intervention and control sessions only when the research assistants and staff members involved in the screening agreed that at least 50% of their presentations were followed by positive reactions (eg, orienting and smiling) [26].

Technology System

The technology system was similar to that used by Lancioni et al [28] and included a webcam sensor linked to a portable computer, a Bluetooth mini speaker, and a smart Wi-Fi plug. The smart Wi-Fi plug was used only when the preferred stimuli following the responses included lights or airflows (see the *Setting, Sessions, Responses, Research Assistants, and Stimuli* section). The computer was fitted with Windows 11 and specific software. The webcam was mounted on a tripod to monitor the participants' responses from a distance. At the start of the study, the research assistants determined the best position of the webcam for each participant so that it could provide the computer and related software with a clear image of the participant's face and hands and of the objects to be touched. The software, which is freely available [42], was developed using the Python programming language and built on open-source libraries. These included OpenCV for image processing, MediaPipe Pose for detecting human body landmarks (specifically, hand landmarks) in 3D space, and python-kasa for controlling the smart Wi-Fi plug.

The software enabled the system to perform a number of essential functions. First, the system (1) monitored (via the webcam) the position of the participants' hands relative to the objects placed in fixed positions on the desk during all study

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sessions, and thus (2) could determine whether the participants performed object contact responses by comparing the hand landmarks with the object positions. Second, the system provided participants with a 10-second period of preferred stimulation, such as music, contingent on (immediately after) each response performed during the intervention sessions. During the 10-second stimulation periods (and, for consistency, the 10-second period following each response in all other study sessions), the system halted its hand position monitoring so that no new response was recorded during that time. Third, the system controlled the presentation of alerting events during the different phases of the study (see the *Baseline I* section). Fourth, the system memorized the session setup parameters recorded for each participant at the start of the study (following the positioning of the webcam) so that the same parameters could be applied across all sessions. Fifth, the system assisted in recording the frequency of responses that occurred in the sessions. Preferred stimulation and alerting events were presented via the Bluetooth mini speaker, which served to increase their volume.

Measures and Data Recording

The first measure concerned the frequency of responses the participants performed during the baseline, intervention, and control sessions and was recorded via the technology system. The second measure concerned the level of research assistants' agreement with the system on the responses the system recorded and followed with stimulation during about 50% of the sessions of Intervention II. In connection with each of those responses, the research assistants were to note whether they did or did not agree with the system's recording. The percentage of agreement between research assistants and the system (computed on single sessions by dividing the agreements by the agreements plus disagreements and multiplying by 100%) ranged between 88% and 100%, with means for the single participants exceeding 96%.

Experimental Conditions and Data Analysis

Overview

Each participant was exposed to an ABACB design, in which A represented the baseline condition, B represented the intervention condition (with the system delivering stimulation contingent on the participants' responses), and C was a control condition [43]. The first baseline (A) phase included different numbers of sessions for the different participants according to a nonconcurrent, multiple baseline design across participants [43]. This single-case research design format was considered adequate to determine the strength and internal validity of the data gathered in the study [43].

To ensure a high level of accuracy from the research assistants (ie, a high level of procedural fidelity [44]) during the implementation of the 3 types of sessions, 2 strategies were adopted. The first strategy consisted of the research assistants practicing the use of the technology system prior to the start of the study. This was to enable them to determine the best position of the webcam and setup of the system with the participants. The second strategy consisted of the availability of regular feedback for the research assistants. Specifically, they were informed as to whether or not they were accurate in their implementation of the procedural conditions by a research supervisor who had access to video recordings of the sessions. This feedback was viewed as a precautionary measure more than a necessity given the research assistants' initial practice with the system and the fact that the system memorized the participants' session parameters and followed (enacted) those parameters automatically.

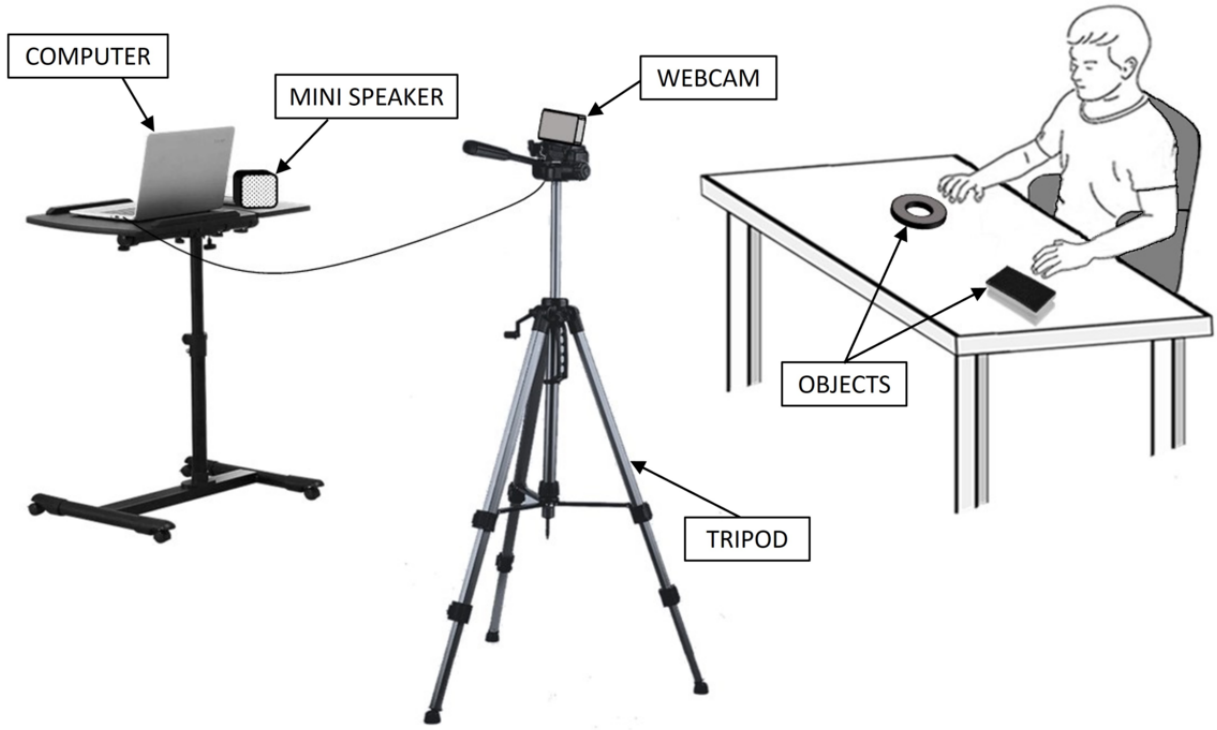
The participants' frequency of responses across the study phases was summarized in graphic form. The differences in response frequency between the (1) first baseline and first intervention phase, (2) second baseline and second intervention phase, and (3) control phase and second intervention phase were assessed using the percentage of data points exceeding the median (PEM) method [45,46]. This method, which is a basic and practical tool for the evaluation of within-subject research data, served to determine for each participant the percentage of intervention sessions with a frequency of responses higher than the median of the previous baseline or control phase.

Baseline I

Baseline I included 5-10 sessions. The participants sat at a desk that contained 2 easily reachable objects; that is, they were in a situation familiar to them (Figure 1). Before the start of a session, the research assistants guided the participants (through physical prompts, which could be accompanied by a verbal expression such as "Touch here") to touch the objects once or twice; that is, they provided 1 or 2 response practice trials. In an attempt to avoid the risk that the participants would remain passive throughout the sessions, alerting events were presented after periods of 30-40 seconds of no responding. These events (ie, 2-word verbal encouragements or brief sounds and noises triggered by the computer and delivered via the mini speaker) were to enhance the participants' vigilance and attention and eventually facilitate some responding (see the *Participants* section). The technology system was available (see Figure 1 for a schematic view of the webcam, computer, and mini speaker) but only served to present the alerting events and record the responses. In fact, no stimulation was scheduled for the responses.

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Figure 1. Schematic representation of a participant sitting at a desk with objects and of the webcam, computer, and mini speaker.



Intervention I

Intervention I included 15-31 sessions. Conditions were as in Baseline I with the difference that the system provided the participants with 10 seconds of preferred stimulation (eg, music and song clips) after each response. The first session was preceded by 5-7 response practice trials with stimulation following each response. Intervention I continued until the participants had shown a clear response increase.

Baseline II

Baseline II included 5-9 sessions. Conditions were as in Baseline I.

Control Phase

The control phase included 5-8 sessions. Conditions were as in Baseline II with regard to the availability of objects and alerting events. The difference was that the participants were provided with stimulation throughout the sessions. Stimulation changed several times during the session to minimize the risk of habituation effects [16]. The control phase was included to determine if stimulation availability per se was responsible for the participants' increased responding, that is, if responding was the result of general activation (excitation).

Intervention II

Intervention II included 43-74 sessions. Conditions were as in Intervention I. During about half of the sessions, research assistants were to note whether they did or did not agree with the system regarding each of the responses the system recorded and followed with stimulation delivery (see the *Measures and Data Recording* section).

Ethical Considerations

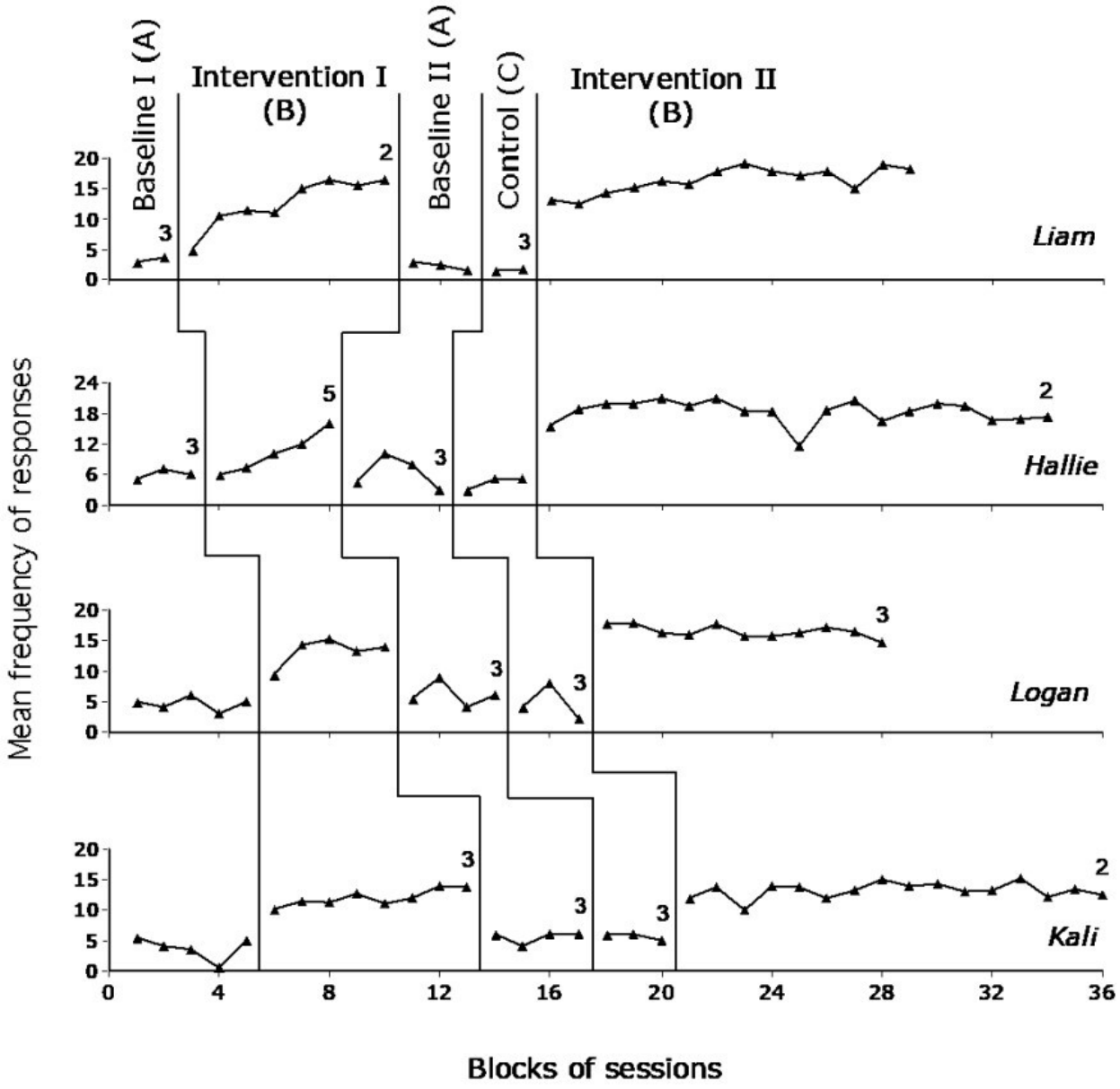
Staff and caregivers considered the study a positive opportunity for the participants. In fact, the study was intended to help them acquire and practice functional motor responses and access preferred stimulation within a comfortable session arrangement that was free from any specific risk. The participants' legal representatives (who were contacted given the participants' inability to give their consent to the study) fully agreed with the staff and caregivers' view. They signed a consent form authorizing the participants to be involved in the study with (1) the possibility of ending such involvement at any time and (2) the guarantee of data deidentification. No participant compensation was available. The study complied with the 1964 Helsinki Declaration and its later amendments and was approved by the Ethics Committee of the Lega F. D'Oro, Osimo (AN), Italy (P030820241).

Results

Figures 2 reports the data for Liam, Hallie, Logan, and Kali and Figure 3 reports the data for Harper, Jacob, Millie, and Isabel over the different phases of the study. Each data point represents the mean frequency of responses per session over a block (group) of sessions. The blocks, which are used to simplify the graphic presentation of the data, include 2 sessions during the baseline and control phases and 4 sessions during the intervention phases. Blocks with numbers of sessions differing from those mentioned earlier are marked with a numeral, which indicates how many sessions those blocks include.

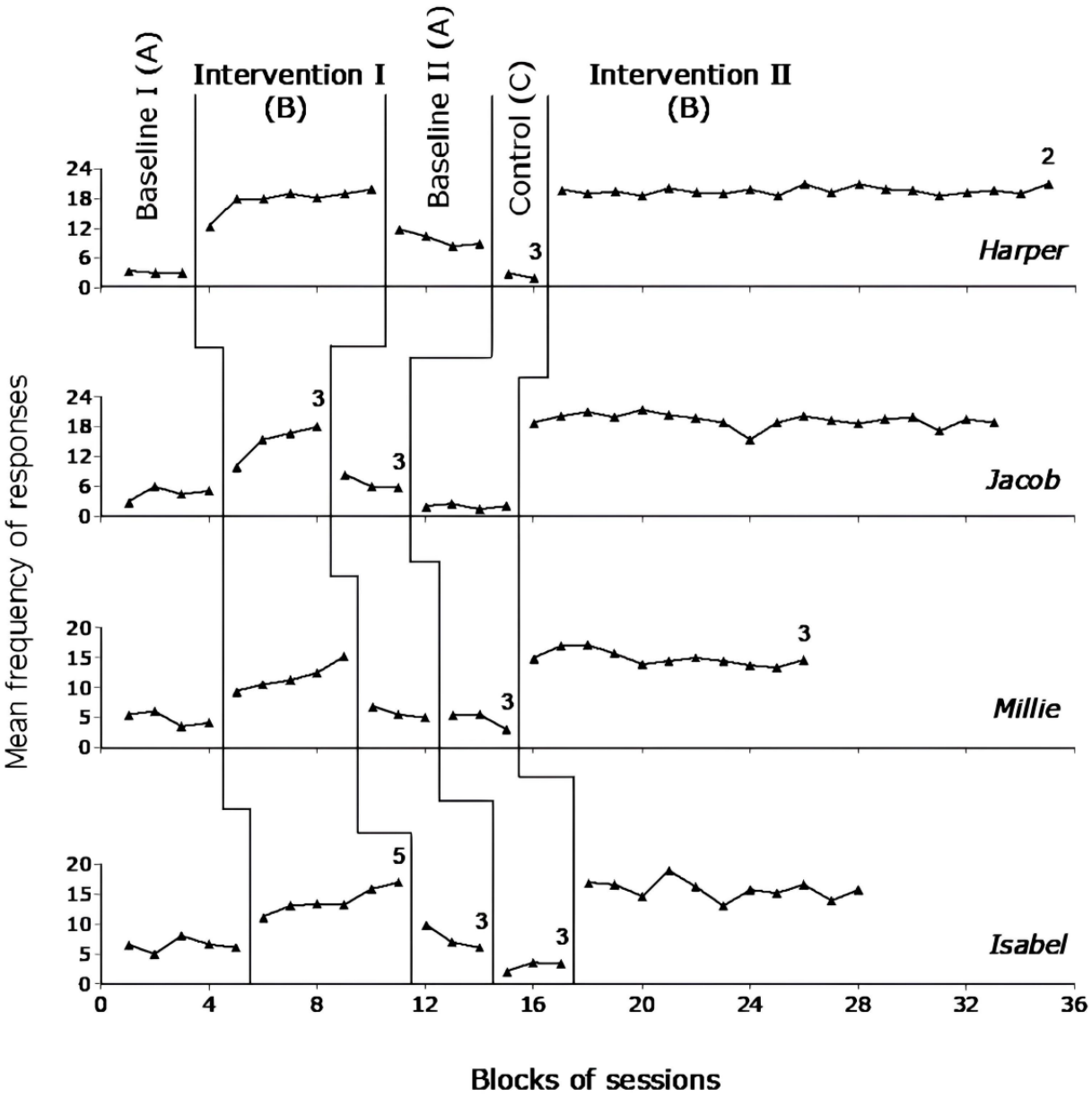
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Figure 2. Data points for Liam, Hallie, Logan, and Kali. Each data point represents the mean frequency of responses per session over a block of sessions. The blocks include 2 sessions during the baseline and control phases and 4 sessions during the intervention phases. Blocks with numbers of sessions differing from those mentioned earlier are marked with a numeral, which indicates how many sessions those blocks include.



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Figure 3. Data points for Harper, Jacob, Millie, and Isabel. Each data point represents the mean frequency of responses per session over a block of sessions. The blocks include 2 sessions during the baseline and control phases and 4 sessions during the intervention phases. Blocks with numbers of sessions differing from those mentioned earlier are marked with a numeral, which indicates how many sessions those blocks include.



During Baseline I, the participants' frequency of responses per session varied between 0 and 10, with means ranging from about 3 (Harper) to 6.5 (Isabel). During Intervention I, all participants showed a clear response increase. Their frequency of responses per session varied between 5 and 23, with means ranging from about 10 (Hallie) to 18 (Harper). The PEM method used to compare the data of Intervention I with those of Baseline I provided indices of 0.86 to 1. These indices pointed out that the response frequency of all or nearly all Intervention I sessions was above the median values of Baseline I, thus confirming the positive impact of the intervention conditions.

During Baseline II, the response frequency decreased for all participants. Their frequency per session varied between 1 and 14. Their means ranged from slightly above 2 (Liam) to about 10 (Harper). The response frequency did not seem to increase during the control phase. In fact, several participants tended to have a decline in responding. During Intervention II, the participants showed a response frequency similar to that observed toward the end of Intervention I. Their mean frequency ranged from about 13 (Kali) to 19.5 (Harper). The PEM method used to compare the data of Intervention II with the data of Baseline II and of the control phase provided indices of 0.98 to 1. These indices pointed out that the response frequency of all or nearly all Intervention II sessions was above the median values of Baseline II and of the control phase, thus confirming the strong impact of the intervention conditions. The difference between the intervention condition and the control phase indicates that the stimulation contingent on the participants' responses (and not the availability of stimulation per se) was responsible for the response increase.

The research assistants' level of agreement with the system on the responses that the system recorded and followed with

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stimulation delivery was high. Indeed, the percentages of agreement (already reported as part of the data recording process; see the *Measures and Data Recording* section) ranged between 88% and 100%, with means for the single participants exceeding 96%. It may also be added here that no specific system dysfunctions were reported during the study and that the research assistants were successful in using it. In fact, they quickly managed to (1) determine the best position of the webcam for each participant (ie, the position that provided the system with a clear image of the participant's face and hands and of the objects to be touched), (2) save the related parameters in the system, and (3) apply those parameters at the start of all study sessions to ensure reliability across them.

Discussion

Principal Findings

The results indicate that the webcam-based sensor was adequate to ensure monitoring of the participants' responses, and the technology system in its entirety was effective in helping the participants increase the frequency of those responses [16,27]. The dependability of the sensor was confirmed by the high percentages of agreement that research assistants had with the system regarding the responses it recorded and followed with stimulation delivery. The effectiveness of the system in its entirety was underlined by the differences in participants' response performance between the intervention phases and the baseline and control phases. The fact that the study sessions were implemented by expert research assistants (see the *Setting, Sessions, Responses, Research Assistants, and Stimuli* section) does not imply that regular staff would not be as successful following a brief practice period with the technology.

Using a sensor that is largely unobtrusive (ie, that does not need to be connected to the participants' body or to the objects that the participants are to touch and explore) can be considered an important practical advantage compared to using conventional sensors such as touch and optic sensors [47-50]. The latter sensors, in fact, although profitably used in the past [3,27,34], need to be arranged in contact with or proximity to the objects targeted for the participants' responses, with the risk that those responses may alter their position and make their functioning inaccurate. Accessibility to the sensor and technology system reported may be facilitated by the fact that (1) the webcam, portable computer, Bluetooth mini speaker, and smart Wi-Fi plug are commercial devices, and (2) the software is freely available. The cost of the system in its entirety is about US $850. This cost might be viewed as relevant for a single user and quite reasonable for a rehabilitation center in which several participants could benefit from the system. One might also expect that cheaper and simpler versions of the system will be developed in the near future, given the great demand for technology support in this area [29,30,51].

The existence of a reliable sensor, applicable in situations in which other (conventional) sensors such as touch, pressure, and optic sensors may be difficult to use, can be considered an important step forward in the development of technology-aided programs for people with extensive multiple disabilities (ie, people who tend to be passive and largely dependent on staff and caregivers for accessing environmental stimulation). Indeed, a reliable and suitable sensor can enable care and rehabilitation staff to help participants strengthen a developmentally relevant behavior, such as contact with the immediate environment, in a substantially independent (self-determined) manner [52-55].

Pursuing participants' independent contact with their immediate context and control of environmental stimulation may be viewed as a significant clinical and rehabilitation objective within any intervention program for people with extensive disabilities [27,56-58]. In fact, people who make contact with and explore objects in their immediate proximity (1) exercise useful motor responses that curb their tendency to be passive and detached, and (2) discover the power of their responses through the stimulation following those responses [54,59-61]. This discovery can then help them maintain their responses over time (strengthening their self-determination) and contribute to improving their appearance, mood, and quality of life [16,55,61-64].

While no direct data were collected regarding the participants' mood during the intervention sessions of this study, evidence from other studies in the area suggests that intervention conditions may have a positive impact on mood [16,33,37,38,65,66]. As to the discovery of the power of one's own responses, the data of this study add useful information. The participants' consistent responding during the intervention phases and the low responding during the control phase indicate that responding was not simply the consequence of stimulation availability. Rather, it appeared to be linked to the participants' discovery of the stimulation contingency value or, in other words, of their responses' power to control stimulation occurrence [60,61,63]. Such a discovery could be taken as a clear sign of clinical and rehabilitation progress [58,62].

Intervention approaches based on the use of a technology system like that used in this study or a new version of it may have relevant implications also for staff personnel. In fact, the system would allow them to offer participants extra opportunities for positive engagement with relatively limited time investment. This could be viewed as an extension and enrichment of the intervention protocol with affordable extra costs in contexts where staff resources are typically limited.

Limitations and Future Research

The study presents 2 main limitations, that is, the absence of maintenance and generalization data, and the lack of a social validation check. The first limitation prevents one from making statements as to whether the system can be effectively used over time and across different contexts. To amend this limitation, future studies will have to extend the data collection to longer periods of time using a variety of objects as well as different settings [60,61,67,68]. Positive maintenance and generalization data would provide a strong basis for considering the system a profitable tool within an intervention protocol designed for people with extensive disabilities. Support for the system might be further strengthened by the recognized need for technological assistance within programs directed at people with extensive and multiple disabilities [27,29,30,49,51].

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The second limitation prevents one from making statements as to how the system may be viewed by staff, caregivers, and other service providers working within daily contexts for people with extensive disabilities. One way to address this limitation is to arrange surveys with care and rehabilitation personnel about the system's effectiveness, acceptability, and applicability in daily contexts. Surveys could be carried out by having the personnel (1) view video clips of intervention sessions carried out with different participants, and (2) rate the content of those clips in terms of system effectiveness, acceptability, and applicability [66,69,70].

One might also find the relatively small number of participants and the use of short (5-min) sessions to be additional limitations of the study. As to the first of these 2 potential limitations, one may argue that the single-case experimental methodology used with the 8 participants to evaluate the impact of the system was adequate to confirm the internal validity of the data reported [42,71,72]. Single-case replication studies and studies using group designs could provide new important evidence to determine the external validity of the present findings [71-73].

Regarding the short sessions, 2 views may be expressed. On the one hand, it may be argued that the use of short sessions represents a limitation of the study that does not allow one to determine for how long people like our participants can remain positively engaged with objects. On the other hand, it can be stated that, given the typically limited attention of these people [74,75], using short sessions may be a largely justified choice.

Conclusions

The results indicate that the technology system used in the study was adequate to ensure monitoring of the participants' responses (ie, touching and exploring objects) and to control the automatic delivery of preferred environmental stimulation contingent on those responses. A sensor that is largely unobtrusive and does not need to be near or physically connected to the objects to be reached (1) can be considered advantageous compared to conventional sensors such as touch and optic sensors, and thus (2) can allow new intervention opportunities for people with extensive disabilities. While highly encouraging, these results are to be taken with caution until new research evidence is available, and the limitations of this study have been addressed.

Acknowledgments

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Data Availability

The datasets generated during this study are available from the corresponding author on reasonable request. The software the authors developed to control the experimental conditions is available at no cost [41].

Authors' Contributions

GL was responsible for setting up the study, acquiring and analyzing the data, and writing the manuscript. GA and CF collaborated in setting up the study and the technology system, in acquiring and analyzing the data, and in editing the manuscript. NS, MOR, JS, VC, and OT collaborated in setting up the study, analyzing the data, and writing or editing the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

PEM: percentage of data points exceeding the median

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Original Paper

Mainstream Smart Home Technology–Based Intervention to Enhance Functional Independence in Individuals With Complex Physical Disabilities: Single-Group Pre-Post Feasibility Study

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Abstract

Background: Mainstream smart home technologies (MSHTs), such as home automation devices and smart speakers, are becoming more powerful, affordable, and integrated into daily life. While not designed for individuals with disabilities, MSHT has the potential to serve as assistive technology to enhance their independence and participation.

Objective: The study aims to describe a comprehensive MSHT-based intervention named ASSIST (Autonomy, Safety, and Social Integration via Smart Technologies) and evaluate its feasibility in enhancing the functional independence of individuals with complex physical disabilities.

Methods: ASSIST is a time-limited intervention with a design based on the human activity assistive technology model, emphasizing client-centered goals and prioritizing individual needs. The intervention follows a structured assistive technology service delivery process that includes 2 assessment sessions to determine technology recommendations, installation and setup of the recommended technology, and up to 8 training sessions. An occupational therapist led the intervention, supported by a contractor and a technologist. Feasibility was evaluated through several measures: (1) the ASSIST Functional Performance Index, which quantifies the number of tasks transitioned from requiring assistance to independent completion and from higher levels of assistance or effort to lower levels; (2) pre- and postintervention measures of perceived task performance and satisfaction using a 10-point scale; (3) the number and types of tasks successfully addressed, along with the costs of devices and installation services; and (4) training effectiveness using the Goal Attainment Scale (GAS).

Results: In total, 17 powered wheelchair users with complex physical disabilities completed the study with 100% session attendance. Across participants, 127 tasks were addressed, with 2 to 10 tasks at an average cost of US $3308 (SD US $1192) per participant. Of these tasks, 95 (74.8%) transitioned from requiring partial or complete assistance to independent completion, while 24 (18.9%) either improved from requiring complete to partial assistance or, if originally performed independently, required reduced effort. Only 8 (6.3%) tasks showed no changes. All training goals, except for 2, were achieved at or above the expected level, with a baseline average GAS score of 22.6 (SD 3.5) and a posttraining average GAS score of 77.2 (SD 4.5). Perceived task performance and satisfaction showed significant improvement, with performance score increasing from a baseline mean of 2.6 (SD 1.2) to 8.8 (SD 1.0; $P<.001$) and satisfaction score rising from an average of 2.9 (SD 1.3) to 9.0 (SD 0.9; $P<.001$).

Conclusions: The ASSIST intervention demonstrated the immediate benefits of enhancing functional independence and satisfaction with MSHT among individuals with complex physical disabilities. While MSHT shows promise in addressing daily living needs at lower costs, barriers such as digital literacy, device setup, and caregiver involvement remain. Future work should focus on scalable models, caregiver engagement, and sustainable solutions for real-world implementation.

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KEYWORDS

physical disabilities; smart home technology; assistive technology; assistive technology service delivery; functional independence; participation; occupational therapy; artificial intelligence; AI

Introduction

Background

Assistive technology (AT) is federally defined as "any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities" [1]. Traditionally, AT refers to specialized devices designed for individuals with disabilities, such as wheelchairs, environmental control units (ECUs), and augmentative and alternative communication devices. Recent advancements in digital consumer electronics have expanded the scope of AT. Mainstream smart home technologies (MSHTs), such as home automation devices and smart speakers, have emerged as a viable alternative to traditional ECUs [2,3]. These technologies, while not explicitly designed for individuals with disabilities, can perform similar functions by promoting autonomy, reducing caregiver reliance, and enhancing quality of life [4-6]. Their affordability, accessibility, and integration of cutting-edge technologies, such as artificial intelligence (AI) and the Internet of Things (IoT), further underscore their potential. However, individuals with disabilities, particularly those who are not technology savvy, may struggle to envision how these technologies can meet their needs without proper guidance [2,4,5,7]. The wide variety of available options can also create confusion, especially when sales representatives lack training in addressing disability-specific needs or AT principles. Integration issues, such as ensuring MSHT devices work seamlessly with each other and existing AT while being compatible with the physical environment, further complicate their implementation. These challenges highlight the need for structured support to maximize the potential of MSHT as AT.

A scoping review by Cleland et al [8] identified 11 studies (up to July 2022) that examined the outcomes of home automation for individuals with disabilities. In total, 4 of these studies were noninterventional, focusing on exploring user experiences with their existing home automation technologies [4,9-11]. The remaining interventional studies primarily investigated specialized devices and applications or interventions using a room equipped with home automation technologies [12-17]. Notably, only 1 study specifically provided MSHT for individuals with amyotrophic lateral sclerosis, but it focused on a limited set of devices, including a smart speaker, light bulbs, and smart plugs [18]. Furthermore, only 4 studies were published after 2020 [4,13,14,18], emphasizing the need for updated research to reflect the rapid evolution of MSHT. A few recent studies after this scoping review have further explored the role of MSHT in supporting individuals with disabilities, highlighting both the potential and challenges associated with their implementation. Ripat et al [19] presented a case series of 3 individuals with high-level tetraplegia, emphasizing the benefits of low-cost, readily available technologies over stand-alone, dedicated devices. However, their effective use depends on appropriate access or interface methods, integration with current and future technologies, and the availability of training and maintenance support. Arthanat et al [7] developed an interventional protocol based on the human activity AT model for individuals with Alzheimer disease and their care partners, focusing on using MSHT to support personalized goals, such as safety, activity engagement, and caregiver connectivity [7]. While all 5 dyads reported positive goal attainment, challenges included unfamiliarity with MSHT, misconceptions about its use, and technological complexities that sometimes outweighed its benefits. These findings emphasize the need for comprehensive systems and support to optimize MSHT as AT solutions.

As MSHT continues to proliferate and integrate into everyday life, it is crucial to examine how these technologies can be effectively delivered to individuals with disabilities. While MSHT is readily available off the shelf, a structured AT service delivery process, commonly emphasized for traditional AT, may also be considered for MSHT [20]. AT services are defined as "any service that directly assists an individual with a disability in the selection, acquisition, or use of an assistive technology device" [1]. Research has shown that both the quality of AT and a robust service delivery process are vital to ensuring effective and tailored solutions for individuals with disabilities [21]. Our group conducted a qualitative interview study with 15 practitioners experienced in providing MSHT as AT. One of the key themes that emerged was the critical role of thorough needs and ability assessments before selecting devices. Practitioners noted that commercial technologies, despite their availability, still require specialized evaluation to ensure they meet the unique needs and abilities of clients with disabilities. Participants also highlighted the importance of demonstrating or trialing MSHT not only to aid in device selection but also to educate clients about its potential and secure their buy-in [3]. These insights align with the findings by Larsson Ranada and Lidström [22] that a structured service delivery process significantly contributes to the usability and satisfaction of AT devices.

Despite the growing availability of MSHT, limited research has systematically explored how these technologies can be effectively implemented as AT. Ripat et al [19] and Arthanat et al [7] briefly introduced their client-centered intervention protocols that addressed technology selection, customization, and training. The Delphi survey by Mun and Kim [23] identified 59 key features of a smart home modification program for individuals with physical disabilities, spanning 4 domains: user tasks, physical functions, environmental factors, and smart home characteristics. These features provide valuable guidance for implementing MSHT interventions, but further work is needed to explore how structured processes and individualized

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approaches can optimize MSHT's role in supporting individuals with disabilities.

Objectives

In this study, we developed and evaluated the feasibility of ASSIST (Autonomy, Safety, and Social Integration via Smart Technologies), a comprehensive MSHT-based intervention designed to enhance functional independence and participation among individuals with complex physical disabilities. Grounded in the principles of AT service delivery, ASSIST used a structured process to assess users' needs, abilities, and contexts; select and acquire suitable devices; assist with installation and setup; and deliver targeted training. The intervention used a range of commercially available MSHT devices and mobile apps to address critical areas, including environmental control, activities of daily living (ADL), instrumental activities of daily living (IADL), communication, leisure, and emergency management.

Methods

ASSIST Intervention

Conceptual Framework

ASSIST was designed to enhance independent living and participation for individuals with complex physical disabilities through the use of MSHT. The intervention is guided by the human activity AT model [24], which comprises 4 key components: human, activity, AT, and context.

The activity component focuses on key activities that can be supported by MSHT based on user needs and priorities. Due to the dynamic and rapidly evolving nature of MSHT, there is often limited awareness among people with disabilities about the available technologies and their potential applications to meet diverse needs [2,3,5,7,20]. To address this gap, we developed and validated an ASSIST Functional Performance Index (AFPI) [2]. The AFPI features an item bank comprising 46 everyday tasks that can be addressed using off-the-shelf MSHT. These tasks span several areas, including environmental control, ADL, IADL, communication, leisure, and emergency management. The AFPI serves 2 primary purposes: helping clients identify and prioritize tasks most relevant to their needs and assessing task performance both before and after the intervention to measure the impact of MSHT.

The human component is considered an intrinsic enabler, emphasizing the importance of aligning individual abilities with the functional requirements of MSHT [25]. For the ASSIST intervention, a comprehensive assessment of human abilities is conducted to ensure an appropriate match. This includes evaluating motor, cognitive, visual, hearing, speech, and tactile abilities, as well as activity tolerance. In addition, factors critical for effective MSHT use, such as proficiency with mobile devices, existing technology use, and comfort and attitude toward technology, are assessed.

The context component encompasses cultural, physical, institutional, and social dimensions, all of which play a critical role in the selection and effective use of MSHT. Facilitators and barriers within these contexts are key considerations. For the ASSIST intervention, contextual factors, such as the home environment, type of caregiver support, and personal beliefs and values, are assessed.

The AT component is considered an extrinsic enabler. For ASSIST, this includes not only the MSHT itself but also access methods (eg, voice control, switches, and accessibility features), the integration of various technologies, and customization tailored to the client's abilities and needs. In addition, "soft technologies," such as training clients in the use of MSHT, are incorporated to ensure successful adoption and use.

Intervention Protocol

Overview

ASSIST uses a structured AT service delivery process, consisting of up to 10 in-person sessions (each 60-90 min) conducted in clients' homes over a period of 3 to 6 months. A licensed occupational therapist (OT) leads the intervention and is supported by a technologist who assists in identifying and customizing technology solutions and a contractor who handles technology installation. The process includes 2 assessment sessions to identify technology solutions, followed by technology installation and up to 8 sessions for setup and training. The detailed components of ASSIST are outlined in the subsequent sections.

Intake

Before the assessment, clients were asked to provide background information on their health, functional status, insurance coverage, living conditions, caregiver support, and technology use, including their experience with traditional AT and MSHT, mobile device proficiency via the short-form Mobile Device Proficiency Questionnaire (MDPQ) [26], and their comfort and attitude toward technology.

Assessment 1

During this session, the OT introduced the ASSIST program and conducted a brief interview to clarify intake information as needed. The OT then worked with the client to sort and rank tasks using the AFPI, identifying the top 10 priorities. For each of these tasks, the OT collected self-reported baseline performance using the AFPI's independence scale and had the client rate their perceived performance and satisfaction on a 10-point scale. In addition, the OT conducted functional assessments relevant to the identified tasks in areas such as upper extremity motor function, cognitive function, visual function, auditory function, tactile function, speech and language function, and activity tolerance. A mobile device assessment was also conducted, where the OT observed the client perform 5 smartphone tasks: making a phone call; sending an SMS text message; checking the local temperature using a weather application; using the internet to find the best local pizza place (with a distracting phone call); and downloading, moving, and deleting an application. Performance was documented regarding phone stabilization and positioning, manual access and control, speech and voice access, and cognitive considerations.

Assessment 2

This session aimed to help the client select smart home ecosystems and input methods that matched their functional

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abilities, comfort level, and use context to support task performance. The OT guided the client in trialing devices, input methods, and ecosystems using a custom smart home demo station and conducted an environmental assessment to ensure compatibility with the home's physical characteristics and power sources. Others in the home were also consulted to understand their needs and preferences. The OT then collaborated with the technologist to identify technology solutions and shared the recommendations along with a training plan with the client.

Technology Installation

Once the client approved the technology selection and training plan, the OT coordinated the device acquisition and any necessary installation requiring hardwiring or significant physical labor by an affiliated contractor.

Training Sessions

Up to 8 training sessions were scheduled for each client. During each session, the OT began by assisting with pairing the devices and integrating them into the selected smart home ecosystems, if applicable. The OT then provided training on foundational digital skills, if needed, and familiarized clients with the MSHT devices designed to support the identified tasks. The Goal Attainment Scale (GAS) [27] was used to monitor progress throughout the training, which prioritized cognitive strategy training over traditional instruction-based methods. This approach taught clients to systematically plan, execute, and evaluate tasks, fostering critical thinking, adaptability, and self-reliance [28]. By emphasizing problem-solving, the training aimed to promote skill generalization and long-term use of MSHT, even in situations where devices malfunctioned, enhancing clients' confidence and independence. In addition, clients were provided with a device manual in their preferred format (digital, print, or both). The manual included comprehensive information about the products, such as maintenance requirements and manufacturer contact details for troubleshooting and support. At the conclusion of the final training session, the OT collected self-reported posttraining performance using the AFPI's independence scale and had the client rate their perceived performance and satisfaction on a 10-point scale.

Follow-Up

The OT conducted phone follow-ups at the end of the first and second months after the training to address any client questions, assist with troubleshooting, and provide additional training if needed. During the final in-person follow-up at 3 months, the OT collected self-reported performance using the AFPI's independence scale, gathered client ratings of perceived performance and satisfaction on a 10-point scale, and conducted an exit interview.

Feasibility Evaluation

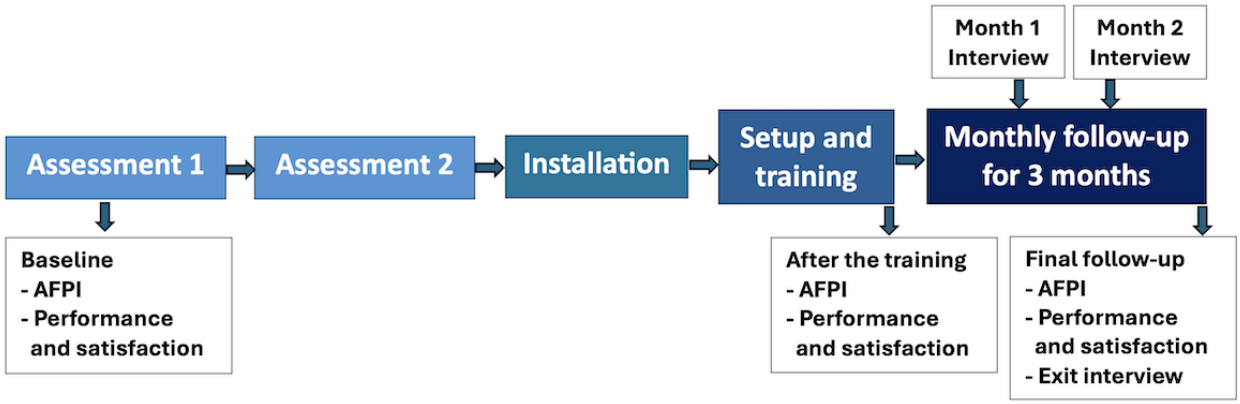
Participants

Participants were eligible for inclusion if they met the following criteria: (1) aged ≥21 years; (2) had a physical disability that prevented independent control or access to their environment; (3) used a powered wheelchair as their primary means of mobility for ≥40 hours per week; (4) had been living in their own residence for at least 6 months; (5) scored 12 or higher on the Mini Montreal Cognitive Assessment 5-Minute Brief Version or 18 or higher on the traditional Montreal Cognitive Assessment (using modified scoring for individuals with physical disabilities and omitting written tasks), indicating no more than mild cognitive impairment [29]; (6) used a smartphone, tablet, or augmentative and alternative communication device; (7) were receptive to using MSHT in their residence; and (8) had internet service in their residence. Exclusion criteria included (1) being medically unstable, defined as having been hospitalized >3 times in the previous 12 months and (2) planning to change residence within 1 year.

Study Design

The study used a mixed methods pre-post design, following the ASSIST protocol as previously described (Figure 1). After providing informed consent, participants completed demographic and intake questionnaires via REDCap (Research Electronic Data Capture; Vanderbilt University). Eligible participants collaborated with study OTs to identify up to 10 tasks to address. Each participant was allocated up to US $5000 to cover the costs of devices and installation services required for these tasks.

Figure 1. Study procedure. AFPI: Autonomy, Safety, and Social Integration via Smart Technologies Functional Performance Index.



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Data Collection

Technology Comfort and Attitude

Participants were asked to rate their technology comfort on a 4-point Likert scale with the following options: very comfortable, comfortable, uncomfortable, and very uncomfortable. They were also asked to select all descriptors they felt applied to their attitudes toward technology from a list, including satisfied, dissatisfied, enjoyment, frustration, confident, uncertain, simple, challenging, hesitant, excitement, fear, and overwhelming.

MDPQ-16 Tool

The 16-item short-form MDPQ is a validated tool designed to assess an individual's proficiency with mobile devices across 8 key domains: mobile device basics, communication, data and file storage, internet, calendar, entertainment, privacy, and troubleshooting and software management [26]. Each item is rated on a 5-point scale with the following options: never tried (1), not at all (2), not very easily (3), somewhat easily (4), and very easily (5). Scores are averaged across the domains and summed to calculate a total proficiency measure, ranging from 8 (lowest proficiency) to 40 (highest proficiency).

AFPI Tool

The AFPI is a validated tool designed to evaluate an individual's ability to perform everyday tasks that can be facilitated by MSHT to enhance performance and participation [2]. The AFPI comprises a 46-item task bank categorized into 6 domains: environmental control (9 tasks), ADL (5 tasks), IADL (20 tasks), communication and planning (6 tasks), leisure activities (4 tasks), and emergency management (2 tasks). Participants respond to a series of questions indicating how they typically complete each task and the level of assistance or effort required.

Their responses are coded on a scale from 1 to 11, as detailed in Table 1. While higher codes generally indicate greater independence, it is important to note that certain paired codes (ie, 2 and 3, 4 and 5, 6 and 7, 8 and 9, and 10 and 11) distinguish whether the individual uses technology for support or not, without implying a difference in overall independence.

Table 1. Autonomy, Safety, and Social Integration via Smart Technologies Functional Performance Index codes.

Code	Responses
1	Task not completed (due to lack of ability or resources) but has the desire to complete it
2	With complete assistance from another person and technology
3	With complete assistance from another person
4	With partial assistance from another person and technology
5	With partial assistance from another person
6	On my own with support from technology—hard
7	On my own without support from technology—hard
8	On my own with support from technology—some effort
9	On my own without support from technology—some effort
10	On my own with support from technology—easy
11	On my own without support from technology—easy

Self-Perceived Task Performance and Satisfaction

Participants were asked to rate their self-perceived task performance and satisfaction using a 10-point scale. For task performance, they were instructed to rate how well they currently complete the task, with 1 indicating "not able to do it at all" and 10 indicating "able to do it extremely well." Similarly, for satisfaction, they were asked to rate their level of satisfaction with how they currently complete the task, with 1 indicating "not satisfied at all" and 10 indicating "very satisfied."

Intervention Feasibility

The feasibility of the ASSIST intervention was evaluated across several key areas.

Participation and Attendance

This area evaluated the proportion of participants who completed the intervention and attended all scheduled sessions.

Tasks, Technology Solutions, and Costs

Tasks addressed covered the number of tasks successfully addressed compared with those that could not be addressed.

Categories of tasks included a detailed breakdown of the types of tasks addressed by the intervention (eg, environmental control, ADL, and IADL) and the specific tasks commonly addressed within each category.

Technology solutions included a classification of the types of technology solutions implemented to support the identified tasks.

Costs included the total costs incurred, including both technology costs and installation expenses.

Training Effectiveness

Participants' progress in achieving their identified goals during the training sessions was assessed using GAS [27]. Participants collaborated with the study OTs to develop personalized goals based on the identified tasks. The OTs ensured that all goals

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adhered to the specific, measurable, achievable, relevant, and time-bound criteria [30]. For each goal, 5 levels of attainment were defined to measure progress. Level 0 indicated that the participant achieved the goal at the expected level. Positive levels, +1 and +2, reflected that the participant exceeded expectations, with +2 representing significant improvement beyond what was anticipated. Conversely, negative levels, –1 and –2, indicated outcomes that fell short of expectations, with –2 representing a much worse result than anticipated. At the beginning of the training, participants' baseline levels were established, typically at –2 or –1. Progress was then reassessed periodically throughout the training sessions. The overall GAS score was computed at baseline and after the training using the following formula:



where w represents the weight assigned to each goal and X is the level achieved for each goal. In this study, as the goals were based on prioritized tasks, they were considered equally important, and equal weights were assigned.

Intervention Outcomes

Of the tasks addressed, the percentage that resulted in a shift from requiring assistance to achieving independence, the percentage that resulted in a change from complete to partial assistance or reduced effort if originally performed independently, and the percentage that resulted in no measurable change were covered in task outcomes.

Participant feedback included changes in self-perceived task performance and satisfaction between baseline and posttraining assessments.

Data Preparation and Analysis

All study data were retrieved from the study REDCap site. Descriptive analyses were conducted to summarize participant characteristics, tasks addressed, costs, GAS, AFPI performance, and self-perceived task performance and satisfaction. Changes in GAS, self-perceived task performance, and satisfaction before and after the intervention were analyzed using a paired sample 2-tailed t test or its nonparametric equivalent if assumptions were violated. All statistical analyses were performed using SPSS (version 28; IBM Corp).

Ethical Considerations

This study was approved by the Institutional Review Board at the University of Pittsburgh (STUDY19100361). All participants provided written informed consent before enrollment. All data were anonymized for analysis. Participants did not receive monetary compensation; instead, they were allowed to keep the technology devices recommended to them as part of the study.

Results

Overview

The study began in October 2021 with the enrollment of the first participant. From October 2021 to October 2022, the ASSIST protocol was trialed with 2 (11%) of the 18 participants to refine and streamline the process. Key adjustments included the addition of the MDPQ-16, self-perceived task performance and satisfaction measures on a 10-point scale, and finalizing the administration of the AFPI. Participants were asked to review the AFPI item bank to identify tasks they could not perform independently but wished to or tasks they found challenging or required assistance with. Then, they collaborated with the OT to prioritize tasks for intervention.

The remaining 16 (89%) of the 18 participants were enrolled starting in November 2022. One participant from this group withdrew after the first assessment session due to resistance to changes in their apartment or daily routine and a lack of readiness for the intervention. The remaining 15 participants completed the posttraining evaluation in December 2024. In total, 18 participants enrolled in the study. Of these, 17 (94%) completing the full study protocol and attending all scheduled sessions. As follow-up data collection is still ongoing, this study only reported results from baseline to posttraining evaluation. Results from follow-ups, monthly interviews, and exit interviews will be included in a future manuscript.

Participant Characteristics

Demographic details for the 17 participants who completed the study are presented in Table 2. The participants in this study were aged between 23 and 80 years, with an average of 47.9 (SD 15.6) years. In total, 14 (82%) of the participants received paid assistance, either from professionals, family members, friends, or a combination of these, while 3 (18%) of them relied solely on unpaid caregivers. Weekly caregiving hours varied widely, ranging from 10 to 168 hours, with an average of 74.7 (SD 43.7) hours per week, highlighting the participants' diverse support needs. All (n=17, 100%) participants had upper extremity motor deficits, and additional functional challenges were common. Some (n=7, 41%) participants reported visual challenges, with 6 (35%) retaining functional vision and 1 (6%) being legally blind. Some (n=7, 41%) participants experienced speech difficulties, and 1 (6%) reported auditory challenges. Moreover, some (n=8, 47%) participants faced sensory limitations.

All (17/17, 100%) participants used powered wheelchairs for mobility. Most controlled their wheelchairs using joysticks (15/17, 88%), while 12% (2/17) of the participants used alternative methods: chin control and head array. Smartphones were widely used among participants. In addition, 59% (10/17) of the participants owned iPhones, while 18% (3/17) of the participants used Google Pixel phones, and another 18% (3/17) used Samsung phones. Moreover, 6% (1/17) of the participants did not own a smartphone and used a family member's phone when needed. For smartphone interaction, 47% (8/17) of the participants used a combination of touch, joystick, switch, or voice control; 35% (6/17) relied solely on touch or joystick; and 18% (3/17) exclusively used voice control. Beyond smartphones, 65% (11/17) of the participants had adopted at least 3 types of MSHT, 12% (2/17) had 1 or 2 pieces of MSHT, and 24% (4/17) participants did not own any MSHT products but possessed a tablet, a computer, or both.

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Table 2. Participant demographics (N=17).

Demographic variables	Values
Age (y), mean (SD)	47.9 (15.6)
Sex, n (%)	
Male	9 (53)
Female	8 (47)
Race[a], n (%)	
Asian American	1 (6)
White	17 (100)
Ethnicity, n (%)	
Non-Hispanic	17 (100)
Education, n (%)	
High school diploma	2 (12)
Some college credit; no degree	3 (18)
Associate's degree (eg, AA[b] and AS[c])	2 (12)
Bachelor's degree (eg, BA[d] and BS[e])	6 (35)
Master's degree (eg, MA[f] and MS[g])	2 (12)
Doctorate degree (eg, PhD[h] and EdD[i])	2 (12)
Primary diagnosis, n (%)	
Cerebral palsy	8 (47)
Quadriplegia spastic	5 (29)
Diplegia spastic	1 (6)
Hemiplegia spastic	1 (6)
Quadriplegic	1 (6)
Cervical spinal cord injury	7 (41)
C2[j]-C4[k] complete (AIS[l] A)	2 (12)
C2-C4 incomplete (AIS B or C)	2 (12)
C6[m] incomplete (AIS B)	2 (12)
C4 (nontraumatic)	1 (6)
Multiple sclerosis (primary progressive)	1 (6)
Congenital myasthenic syndrome	1 (6)
Living situation, n (%)	
Alone	5 (29)
With others	12 (71)
Housing status, n (%)	
Own	14 (82)
Rent	3 (18)
Medicaid home- and community-based services, n (%)	10 (59)
Caregiving arrangement (some may select multiple options), n (%)	
Paid professionals	14 (82)
Paid family members or friends	6 (35)
Unpaid family members or friends	3 (18)

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[a]One participant reported both races.
[b]AA: associate of arts.
[c]AS: associate of science.
[d]BA: bachelor of arts.
[e]BS: bachelor of science.
[f]MA: master of arts.
[g]MS: master of science.
[h]PhD: doctor of philosophy.
[i]EdD: doctor of education.
[j]C2: the second cervical vertebra.
[k]C4: the fourth cervical vertebra.
[l]AIS: American Spinal Injury Association Impairment Scale.
[m]C6: the sixth cervical vertebra.

Participants reported varying levels of comfort with technology. Of the 17 participants, 1 (6%) described feeling very uncomfortable, while most felt more at ease, with 7 (41%) participants identifying as being very comfortable and 9 (53%) as being comfortable. In terms of attitudes toward technology, the most commonly chosen descriptors used by the participants included satisfied (n=10, 59%), frustration (n=9, 53%), confident (n=8, 47%), and enjoyment (n=7, 41%). Some participants described their experiences as challenging (n=6, 35%), uncertain (n=6, 35%), or overwhelming (n=4, 26%). Fewer participants chose terms such as dissatisfied (n=2, 12%) or fear (n=1, 6%). Some (n=5, 29%) participants selected only positive descriptors, 2 (12%) selected only negative descriptors, and 10 (59%) described a mix of positive and negative experiences.

Mobile device proficiency, as measured by the MDPQ-16, showed a wide range of abilities. The average score (excluding the first 2, 12% of the 17 participants whose data were not collected) was 29.8 (SD 9.5), with 3 participants scoring below 20, indicating significant challenges; 3 scoring between 20 and 30, reflecting moderate proficiency; and the remainder (n=9) scoring between 30 and 40, representing higher proficiency.

Tasks, Technology Solutions, and Costs

Overview

Each participant was asked to identify up to 10 tasks, resulting in 155 tasks being identified (mean 9.1, SD 1.4 tasks per participant). Of these, 127 (81.9%) tasks were addressed (mean 7.5, SD 2.0 tasks per participant). Table 3 provides a detailed breakdown of the 127 tasks addressed across domains, including 64 (50.4%) for environmental control, 8 (6.3%) for ADLs, 37 (29.1%) for IADLs, 12 (9.4%) for emergency management, 3 (2.4%) for communication, and 3 (2.4%) for leisure.

In total, 28 (18.1%) of the 155 tasks were not addressed due to various factors, such as the absence of appropriate technology solutions, insufficient infrastructure, and the need to prioritize tasks for digital literacy training.

Some tasks could not be addressed due to the absence of appropriate technology solutions. For example, a smart shower controller was not implemented because the available products override manual controls, potentially leaving users unable to adjust the shower manually if the device malfunctions. Similarly, no suitable smart or standard scale was available for home weight monitoring for individuals who use powered wheelchairs. Side-to-side bed position adjustments were not possible with the smart bed frames currently on the market. In addition, while medication dispensers could help organize and dispense medications, they were not suitable for individuals with upper extremity motor impairments who could not reach and retrieve the medications independently.

Environmental constraints further posed challenges. For instance, the lack of nearby outlets prevented the installation of devices, such as bidets and air conditioners, in participants' homes.

In other cases, tasks had to be reduced to allow participants sufficient time to improve their digital literacy and prevent them from feeling overwhelmed.

In terms of technology solutions, participants were first guided to select at least one smart home ecosystem to integrate their MSHT devices. A total of 6 (35%) of the 17 participants opted to use 2 smart home ecosystems, and the rest (11/17, 65%) chose a single ecosystem, as shown in Table 4.

A variety of MSHT devices were provided to address participants' identified tasks. Products were selected based on compatibility with the participants' chosen smart home ecosystems, the desired features, and environmental compatibility. These devices leveraged AI and IoT capabilities to enhance automation, remote control, and accessibility. An overview of the provided technologies and their functionalities is given in the subsequent sections.

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Table 3. Tasks addressed (n=127).

Tasks addressed	Tasks, n (%)
Environmental	
Lock and unlock doors	11 (8.7)
Control lights	10 (7.9)
Answer doors	9 (7.1)
Open and close doors	8 (6.3)
Control fans	8 (6.3)
Control window treatments	8 (6.3)
View inside or outside for surveillance	5 (3.9)
Adjust thermostat	4 (3.1)
Building access	1 (0.8)
ADLs[a]	
Bed mobility	4 (3.1)
Clean oneself after toileting	2 (1.6)
Hand washing	1 (0.8)
Tooth brushing	1 (0.8)
Operate TV	3 (2.4)
Emergency management	12 (9.4)
Communication	4 (3.1)
IADLs[b]	
Vacuum or mop floors	6 (4.7)
Charge technology devices	6 (4.7)
Medication management	3 (2.4)
Pet care	3 (2.4)
Manage health care supplies	3 (2.4)
Pay for purchase	3 (2.4)
Shop in person	2 (1.6)
Determine needed grocery or items	2 (1.6)
Self-manage health	2 (1.6)
Other tasks	6 (4.7)

[a]ADL: activities of daily living.

[b]IADL: instrumental activities of daily living.

Table 4. Smart home ecosystems chosen by study participants (N=17).

Smart home ecosystems	Participants, n (%)
Amazon Alexa	5 (29)
Google Home	3 (18)
Samsung SmartThings	2 (12)
Apple Home	1 (6)
Amazon Alexa and Google Home	4 (24)
Amazon Alexa and Apple Home	2 (12)

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Lighting Control

Participants required flexible solutions for diverse lighting conditions, including ceiling lights, lamps with either standard or atypical bulbs, multiway switch configurations, and motion sensor controlled lights with extended illumination. The provided devices integrated IoT connectivity and AI-driven automation, allowing for application and voice control as well as automation tailored to user preferences and routines.

Smart in-wall dimmers and switches provided remote and automated lighting control while allowing manual operation without disrupting application or voice control. Companion switches for multiway installations maintained smart lighting functionality across multiple switch locations. Retrofit smart switches and button actuators provided remote control for nonsmart lighting fixtures without replacing existing wiring. Smart bulbs and plugs enhanced flexibility by enabling customizable lighting scenes and automation without modifying existing fixtures. Smart dimmer switches that were attached to existing light switches prevented accidental switch offs that would disable the functionality of smart light bulbs while allowing for local manual control.

Home Access

Participants received automated door and lock solutions that integrated with smart home ecosystems for enhanced safety and security. These devices leveraged AI-based access control, object recognition, and IoT-enabled remote operation, allowing for hands-free entry and real-time monitoring.

Automatic door openers with voice control modules or smart garage door openers enabled hands-free operation through voice assistants, allowing individuals with mobility limitations to open doors effortlessly.

Smart locks (retrofit and permanent solutions) provided keyless entry via mobile apps, biometric authentication, or voice commands, offering secure and customizable access.

Video doorbells (wired or battery-powered video doorbells with solar options) provided real-time video streaming, 2-way communication, and motion-triggered or object recognition–based notifications, with some models offering facial recognition to identify known visitors. When integrated with other smart home devices, video doorbells could trigger automated routines, such as turning on lights to enhance accessibility.

Window Treatment Control

AI-enhanced motorized solutions were provided to automate curtain and blind adjustments for improved accessibility. They could also automate adjustments based on time of day, room temperature, or sunlight exposure.

Retrofit curtain bots motorized existing curtain rods for voice and mobile app control. Retrofit options for tilt wand control adjusted blind slats via voice and mobile app control. Retrofit options for horizontal or vertical blinds or shades with continuous loop controls adjusted the blind tilt or lift or lowered the blind or shade via voice and mobile app control. Smart blinds (roller, cellular, and top down or bottom up) adjusted blinds via voice and mobile app control.

Climate Control

AI-enabled thermostats and fans automated temperature regulation, with some models featuring adaptive learning to adjust based on user routines.

Smart thermostats enabled temperature control via mobile apps or voice commands, with some models featuring occupancy sensors and learning algorithms for adaptive adjustments. Smart ceiling fans and standing fans provided scheduled automation and IoT integration to adjust airflow based on temperature sensors and voice or mobile app control. Smart bridges for existing fans converted nonsmart fans into IoT-compatible devices, enabling voice or mobile app control and automated control.

Surveillance and Inventory Management

Smart cameras, designed for indoor and outdoor use, provided surveillance and security, with some models featuring voice-controlled pan, tilt, and zoom functions and object recognition features. In addition, when paired with mobile apps such as Sortly (Sortly Inc), they helped participants manage health care supplies. When placed inside a refrigerator, they also facilitated the tracking of stored items.

Wearables for Emergency Support and Daily Assistance

Smartwatches, including Apple Watch (Apple Inc) and Google Pixel Watch (Google LLC), supported multiple tasks, such as accessing emergency services or contacts, making in-store payments, and managing personal health.

In addition, a variety of AI-driven and IoT-enabled solutions further supported participants' independence and home automation. Textbox 1 provides a list of such solutions.

In terms of costs, all participants stayed within the US $5000 allowance. The overall cost of devices and installation services by the contractor averaged US $3308 (SD US $1192) per participant. Notably, 8 (47%) of the 17 participants selected "open or close door" as a desired task, which required relatively expensive automatic door openers that are not typically classified as MSHT. Excluding the cost of automatic door openers, the average cost per participant decreased to US $2234 (SD US $984).

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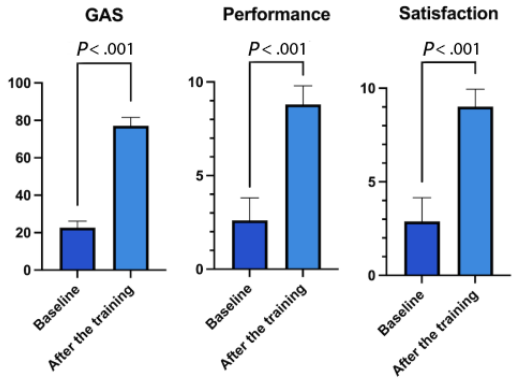
Textbox 1. Solutions that supported participants' independence and home automation.

- Robotic vacuums: used artificial intelligence–powered navigation to optimize cleaning paths, avoid obstacles, and automatically lift mops based on floor type; features such as autoemptying bins and self-washing mop systems reduced maintenance needs
- Smart home hubs: centralized control for all Internet of Things–enabled devices, allowing seamless automation
- Smart button actuators: converted standard appliances into smart-enabled devices by automating button presses
- Smart power strips: enabled remote control of multiple devices with artificial intelligence–driven energy consumption tracking
- Smart smoke and CO detectors: provided real-time alerts and remote monitoring for safety
- Smart bed frames and voice-controlled bed systems: allowed users to adjust positions via voice commands or mobile apps
- Smart faucets and bidets: touchless control enhanced hygiene and accessibility
- Smart pet feeders and water fountains: enabled individuals to independently manage their pets' feeding and hydration through automated schedules, with mobile app or voice control for portion adjustments and monitoring
- Streaming devices: provided access to digital media, enabling voice and mobile app control for seamless navigation of entertainment and news
- Smart Sensors (water leak sensors, contact sensors, etc): enhanced independence by providing real-time alerts for leaks, open doors or windows, or unauthorized access; these Internet of Things–enabled sensors could integrate with smart home systems for automated responses
- Essential Accessories: enhanced independent use of smart devices, including smartphone mounting systems for beds and wheelchairs, charging solutions for independent device charging, and mesh Wi-Fi systems to improve connectivity

Training Effectiveness

Participants completed an average of 5.6 (SD 1.7) training sessions. Working with the study OTs, they collaboratively established 117 goals, averaging 6.9 (SD 2.3) goals per participant. This number is slightly smaller than the total number of tasks identified, as some tasks were combined for efficiency, for example, combining "open or close doors" with "lock or unlock doors." Nearly all goals (114/117, 97.4%) achieved at least level 0 (met expectations) on the GAS, and most (99/117, 84.6%) reached level 2 (significantly exceeded expectations). The average baseline GAS score of 22.6 (SD 3.5) increased to 77.2 (SD 4.5) after training (Figure 2), indicating substantial progress across participants. Paired sample *t* tests showed statistically significant improvements in GAS scores after training (t_{16}=37.6; *P*<.001; Cohen *d*=6.0).

Figure 2. Baseline and posttraining comparisons. GAS: Goal Attainment Scale.



Intervention Outcomes

On the basis of the AFPI results, 74.8% (95/127) of the tasks showed a shift from requiring assistance to achieving independence. An additional 18.9% (24/127) of the tasks demonstrated a transition, either from requiring complete assistance to partial assistance or, for tasks performed independently, a reduction in the effort required. Only 6.3% (8/127) of the tasks showed no measurable change.

Self-perceived task performance (excluding the first 2 participants whose data were not collected) improved significantly from a baseline mean of 2.6 (SD 1.2) to 8.8 (SD 1.0) after training, while satisfaction with task performance increased from an average of 2.9 (SD 1.3) to 9.0 (SD 0.9; Figure 2). Paired sample *t* tests indicated statistically significant improvements in both self-perceived performance (t_{14}=13.8; *P*<.001; Cohen *d*=1.7) and satisfaction (t_{14}=13.8, *P*<.001; Cohen *d*=1.7) after the intervention.

Discussion

Principal Findings

This study introduced ASSIST, a comprehensive intervention that leverages off-the-shelf MSHT to support individuals with complex physical disabilities. The findings demonstrated the intervention's feasibility in improving functional performance and supporting independent living. Participants reported transitioning from relying on caregiver assistance to independently completing 74.8% (95/127) of their identified tasks, reducing the level of assistance or effort required for

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18.9% (24/127) of the tasks, and significantly improving perceived task performance and satisfaction.

ASSIST uses a client-centered approach through 2 comprehensive assessment sessions aimed at identifying each individual's unique needs, abilities, and context. This approach is essential not only because of the wide range of MSHT available and its potential to address numerous daily tasks but also because selecting the appropriate devices requires careful consideration of multiple factors, such as the user's functional abilities, preferences, technology experience and comfort, and home environments. For example, we prioritized retrofit options for renters, provided mesh Wi-Fi systems to resolve connectivity issues, and selected devices with mobile apps that ensure accessibility for participants relying solely on voice control. We also addressed the concerns of others in the home. For example, parents of a participant were hesitant about installations in shared spaces, such as the living room and kitchen, fearing they would look "obvious." After the OT showed them permanent solutions that matched their wall color, they approved. We also developed an environment checklist for different types of MSHT to streamline the selection process, ensuring compatibility and efficiency. Many of the factors addressed in ASSIST align with the 59 key features of a smart home modification program for individuals with physical disabilities identified in the Delphi survey by Mun and Kim [23]. This client-centered approach is further supported by the findings of Ripat et al [19], who emphasized the importance of addressing unique goals, circumstances, and contexts in their case series on the identification and assessment of electronic aids for daily living among individuals with high-level tetraplegia. Their work stressed the necessity of tailoring interventions to meet the distinct needs of each individual, even among those with similar injury levels.

The client-centered approach in ASSIST extends to its training sessions, where individualized plans are developed based on participants' technology experience, comfort, attitudes, and mobile device proficiency. For example, 2 (12%) of the 17 participants with similar functional profiles, both relying exclusively on voice control for smartphones, had different technology attitudes and MDPQ-16 scores (16.5 vs 36). One described their attitude as "dissatisfied, frustrated, uncertain, and excited," while the other chose "simple." As a result, the study OT designed tailored plans, with the first participant starting with basic voice control training and the second covering advanced skills, such as creating routines. This approach aligns with Arthanat et al [7], who emphasized using GAS for individualized training in their MSHT intervention for individuals with Alzheimer disease and their care partners.

Notably, our client-centered approach was supported by several tools. First, many individuals are not familiar with or do not keep up with technological advancements. This issue was highlighted in our previous work on developing and validating the AFPI tool [2] and by Arthanat et al [7], who found that participants' unfamiliarity with the technology was a major challenge in their MSHT intervention. Similarly, a UK policy report based on roundtable discussions and interviews highlighted low awareness of MSHT as a significant barrier, affecting both individuals with disabilities and professionals [5]. To address this gap, we used the AFPI tool to identify performance challenges clients were interested in addressing, which could be facilitated by MSHT, even if they had no previous knowledge of these technologies. This tool streamlined the task prioritization process. Although participants were informed that they could suggest tasks beyond the AFPI task bank, only a few additional tasks were proposed. Second, we used a demo station to facilitate device trials, focusing on selecting a suitable smart home ecosystem. Trialing mainstream smart home ecosystems is crucial, as they offer limited customization compared with traditional AT products. The hands-on experience provided participants with new information and helped them make more informed choices. For example, 2 participants, despite owning Amazon Echo devices, preferred Google Home after testing both systems. They found Google Home's simple interface and well-spaced control buttons easier to navigate and use for selecting smart home device controls. In addition, they appreciated the seamless integration with the hands-free Google Assistant on their Android (Google LLC) phones. Similarly, another 2 participants who owned Amazon Echo devices expressed interest in also using Apple Home, as they were already using Siri (Apple Inc) for other tasks on their iPhones.

It was encouraging to find that 76% (13/17) of the participants in this study already owned at least 1 MSHT device. However, their attitudes toward technology, as reflected in the descriptors they selected, revealed mixed experiences. While 5 (29%) participants selected only positive descriptors, such as "satisfied," "confident," or "enjoyment," most (n=12, 71%) participants chose either negative or a mix of descriptors. "Frustration" emerged as the most frequently selected negative descriptor, chosen by 9 (53%) participants. This aligns with our observation that, despite owning MSHT devices, some (3/17, 18%) participants had stored them away due to difficulties during setup, and most (10/17, 59%) were unsure how to integrate their devices into a smart home ecosystem. These findings suggest a need for targeted support to bridge the gap between ownership and effective use of MSHT, especially among populations with diverse abilities and needs.

It is also worth noting that more than half (10/17, 59%) of the participants in the study were enrolled in the US Medicaid home- and community-based services (HCBSs). Although the HCBS waiver definitions in the state of Pennsylvania include provisions for MSHT, such as electronic communication aids; mobile apps; hubs; software; and devices that control appliances, lights, telephones, and security systems, none of the participants were aware that they could request MSHT through their service providers. Furthermore, our investigation revealed a lack of clear processes for the provision of such technologies under the AT services in HCBS waiver programs.

This finding emphasized the need for better education and guidance for both service providers and participants to ensure these technologies are effectively integrated into care plans.

Barriers to Implementation

The intervention faced several challenges, including factors related to participants, technology, training, and context.

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Lack of Digital Literacy and Accessibility Knowledge

Some (7/17, 41%) participants faced challenges with digital literacy and accessibility, which created significant barriers to implementing MSHT effectively. These limitations impacted participants' ability to interact with the technology, requiring study OTs to address these issues as part of the training. For example, 12% (2/17) of the participants were taught to use Amazon Alexa by clearing clutter around the Amazon Echo speaker, enabling audio cues, and pausing after the wake word to confirm the device's responsiveness. OTs also provided guidance on password management, application organization, and accessibility features, such as voice control settings and voice assistants for participants relying on voice commands, as well as assistive touch settings for those needing improved touch interaction. While the MDPQ-16 assessed mobile device proficiency, it did not account for physical abilities or appropriate phone mounting on wheelchairs or bedside setups, which are critical factors for successful MSHT implementation for individuals with complex physical disabilities.

Technology Selection, Installation, and Customization

Selecting, installing, and customizing MSHT presented various challenges and often required significant time and effort. In some cases, it was difficult to find technology that fully met participants' needs, as noted in the Results section, and in other instances, the technology only partially addressed their requirements. Device installation posed additional barriers. While Best Buy Geek Squad provided valuable services, it did not carry all the products provided to participants, necessitating the involvement of a general contractor. However, finding contractors knowledgeable about MSHT proved challenging. Beyond installation, pairing and integrating devices required substantial effort and often took longer than anticipated due to pairing complexities. Customizing solutions to meet participants' unique needs added another layer of complexity. For example, one participant with both motor and visual impairments required a solution to respond to visitor calls and grant building access. To address this, we adapted a smart control button, linking it with the Tasker application (Crafty Apps Ltd) on his Android device. The button was configured for easier activation using his elbow and programmed via Tasker to simulate pressing "6" on his phone, enabling him to independently let visitors into the building. Another participant with a weaker voice experienced difficulties using a Fire TV Cube (Amazon.com, Inc) to control the television. This issue was resolved by adding a high-definition multimedia interface extension cable and an infrared blaster, positioning the device closer to the client to enhance speech recognition for voice commands.

Training

A significant barrier to implementation was the overlap between device setup and participant training during training sessions. The study OTs were tasked with pairing, configuring, and customizing devices to meet participants' needs during the training sessions. The complexities of pairing for some devices and the time required for troubleshooting sometimes extended these sessions beyond 90 minutes. Ideally, all devices should be fully installed and configured before training begins to allow sessions to focus solely on skill development and effective use of the technology. This challenge highlights the need for a clear separation between device setup and training phases to streamline the implementation process.

Contextual Factors

Environmental and contextual limitations posed significant barriers to implementing MSHT. As noted in the Results section, environmental issues, such as missing electrical outlets, prevented the installation of devices needed to address participant needs. For 2 (12%) of the 17 participants living in subsidized housing, obtaining permission to install technology added delays and required additional effort, including writing justification letters and educating building contractors on MSHT installation. Caregivers also play a crucial role in sustaining the use of MSHT, particularly for devices requiring maintenance or caregiver collaboration. While caregivers were encouraged to participate in training sessions, their presence was not mandatory, which sometimes hindered effective implementation. For instance, 2 (12%) participants were provided similar technological solutions to manage their health care supplies, requiring caregivers to use a recommended tracking application; one participant found the solution effective for accurate tracking and timely ordering, while the other found it ineffective due to the caregiver not using the application to update supply information, highlighting caregiver engagement as a barrier.

In general, the findings of this study highlight significant opportunities to use MSHT to support a wide range of activities at a cost substantially lower than traditional AT, such as ECUs. MSHT offers versatility and affordability, making it a promising option for enhancing the independence and participation of individuals with complex physical disabilities. However, MSHT alone is not a complete solution. These individuals and their families often require ongoing support, including education on the available options, assistance with device selection, proper installation and setup, and training to ensure users feel confident and empowered. As emphasized in the Global Accessibility Reporting Initiative report [31], the concept of AT in the digital world must evolve to integrate mainstream technology into AT provision and include training on how to use these devices, their features, and associated services for professionals, caregivers, and end users with disabilities. Without the support, barriers such as lack of digital literacy, difficulty with setup, and underuse of features can limit the effectiveness of MSHT. Addressing these gaps is essential to ensuring that MSHT fulfills its promise of providing cost-effective, inclusive solutions for individuals with disabilities.

Limitations

The study had several limitations. First, it reported only the quantitative results from the ASSIST intervention and excluded the 3-month follow-up data intended to evaluate continued use, performance, and satisfaction with MSHT after 3 months of independent use. As the study is ongoing, we chose to focus this paper on the immediate outcomes of the intervention due to the substantial volume of information collected, with plans to publish a subsequent paper addressing sustained use, qualitative feedback, and caregiver perspectives.

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Second, the study primarily focused on participants with disabilities, with limited emphasis on caregiver involvement. While MSHT has the potential to significantly support caregivers, this aspect was not fully explored. Only 2 caregivers were enrolled in the study, and their experiences will be detailed in the follow-up paper. Future research should prioritize caregiver recruitment to comprehensively examine the dual impact of MSHT on individuals with disabilities and their caregivers.

Third, the study focused on participants with complex physical disabilities and had a small sample size. Future research should include a larger, more diverse sample to better assess the broader applicability of MSHT interventions.

Fourth, this study focused on commercial smart home technologies and did not evaluate open-source options for free alternatives. Further research should explore cost-effective options to enhance accessibility for individuals with disabilities.

Fifth, the intervention provided funding for MSHT devices and installation services to ensure a focus on evaluating their impact. However, this approach does not reflect real-world practices, where financial and logistical barriers can significantly affect access and use. Future studies should explore strategies for addressing funding and installation barriers in practical, real-world settings. In addition, the cost analysis did not account for clinicians' time spent on device setup or delivering the intervention. A more comprehensive cost-benefit analysis would provide greater insights into the feasibility and sustainability of such interventions.

Finally, the study used a single-group pre-post design, which limits the ability to draw definitive conclusions about the causal effects of the intervention and understand the effects of its various components. A future comparative effectiveness study could incorporate a control group receiving either minimal support or specific subsets of the intervention components. This approach would enable researchers to evaluate the impact of individual elements within the intervention and identify which ones are most critical to achieving successful outcomes while still ensuring all participants derive some benefit. In addition, the treating OTs collected intervention outcomes, such as AFPI and self-perceived performance or satisfaction, which could bias responses due to social desirability or reluctance to give negative feedback. Future studies should use independent evaluators and observation-based tools to ensure objectivity and reduce bias.

Conclusions

This study demonstrated the immediate benefits of the ASSIST intervention in promoting functional independence and improving satisfaction with MSHT among individuals with complex physical disabilities. The findings showed MSHT's potential to address diverse daily living needs at a lower cost than traditional AT. However, challenges such as digital literacy and accessibility gaps, device setup barriers, and limited caregiver involvement present significant obstacles to broader implementation. Future work should prioritize overcoming these barriers by developing scalable models that incorporate funding solutions, caregiver engagement, and enhanced training programs. This study laid a strong foundation for advancing MSHT integration into the lives of individuals with disabilities and emphasized the need for a comprehensive, tailored approach to maximize its benefits and address implementation challenges.

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Authors' Contributions

DD was responsible for conceptualization, formal analysis, funding acquisition, methodology, project administration, resources, writing the original draft, and reviewing and editing the manuscript. LM was responsible for conceptualization, data curation, investigation, methodology, and reviewing and editing the manuscript. GN was responsible for data curation, investigation, and reviewing and editing the manuscript. AF was responsible for conceptualization, investigation, methodology, and reviewing and editing the manuscript. KR was responsible for investigation, writing, reviewing, and editing the manuscript. PF was responsible for data curation, writing, reviewing, and editing the manuscript. JB was responsible for resources, writing, reviewing, and editing the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ADL: activities of daily living
AFPI: Autonomy, Safety, and Social Integration via Smart Technologies Functional Performance Index
AI: artificial intelligence
ASSIST: Autonomy, Safety, and Social Integration via Smart Technologies
AT: assistive technology
ECU: environmental control unit
GAS: Goal Attainment Scale
HCBS: home- and community-based service
IADL: instrumental activities of daily living
IoT: Internet of Things
MDPQ: Mobile Device Proficiency Questionnaire
MSHT: mainstream smart home technology
OT: occupational therapist
REDCap: Research Electronic Data Capture

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Original Paper

Stakeholders and Contextual Factors in the Implementation of Assistive Robotic Arms for Persons With Tetraplegia: Deductive Content Analysis of Focus Group Interviews

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Abstract

Background: Tetraplegia imposes significant challenges on affected individuals, caregivers, and health care systems. Assistive technologies (ATs) such as assistive robotic arms have been shown to improve the quality of life of persons with tetraplegia, fostering independence in daily activities and reducing caregiver burden. Despite potential benefits, the integration of AT innovations into daily life remains difficult. Implementation science offers a systematic approach to bridge this know-do gap.

Objective: This study aimed to (1) identify and involve relevant stakeholders; (2) identify relevant contextual factors (barriers and facilitators); and (3) suggest a general outlook for the implementation of AT, specifically an assistive robotic arm, into the everyday private lives of individuals with tetraplegia in Switzerland.

Methods: A qualitative design was used, involving 3 semistructured online focus group interviews with 8 stakeholder groups, including persons with tetraplegia as well as those who could provide perspectives on engineering or technology, legal matters, nursing or care, therapy, social counseling, social insurance, and political considerations. The interviews were analyzed using the Focus Group Illustration Mapping tool, and the data were aligned with the domains of the Consolidated Framework for Implementation Research.

Results: 3 focus group interviews comprising 22 participants were conducted, and data were mapped onto 21 constructs across the Consolidated Framework for Implementation Research domains. Identified barriers were customization to users' needs, safety concerns, and financing issues for the high AT costs. The collaboration with different stakeholders, including those who provided perspectives on political engagement, proved crucial. Identified facilitators included the enhancement of autonomy for persons with tetraplegia, improvement of quality of life, reduction of caregiver dependency, and addressing health care labor shortages. The implementation outlook involved the formation of an experienced team and the development of an implementation plan using hybrid type 1 and type 2 designs that incorporate both qualitative and quantitative implementation and innovation outcomes.

Conclusions: Robotic arms offer promising benefits in terms of improved participation for users, while high costs and regulatory complexities as to who will assume these costs limit their implementation. These findings highlight the complexities involved in implementing AT innovations and the importance of addressing contextual factors. A specific framework for the implementation of AT is needed to ensure the successful integration in Switzerland and other countries with comparable social and health insurance systems.

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KEYWORDS

assistive technologies; robotic arm; implementation; barriers; facilitators; Consolidated Framework for Implementation Research

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Introduction

Background

Recent technological advancements have led to the proliferation of assistive technologies (ATs), including assistive robotic arms, improving the quality of life for individuals with spinal cord injury (SCI) [1]. SCI is a profound, life-altering condition that affects approximately 15.4 million people worldwide [2], with significant impacts on individuals, caregivers, and health care systems [3-6]. Tetraplegia, the partial or complete loss of motor and sensory function in all 4 extremities and the trunk, is a common manifestation of cervical SCI [7]. Upper extremity function ranks highest in importance among individuals with tetraplegia, often prioritized over functions such as bowel, bladder, sexual, or walking abilities [7]. Disabled upper extremities not only diminish independence and social participation but hinder employment prospects, leading to increased care costs [8,9]. Comparatively, individuals with SCI often experience lower quality of life levels than their able-bodied peers [10,11], and regardless of the specific nature of their impairments, they frequently depend on caregivers to meet their daily needs [12,13]. Paid caregiving services can impose a significant financial burden on either the individual or the funding agency [14], whereas unpaid caregiving, provided mainly by family members, results in significant psychological implications [11,15,16].

Persons with impaired upper extremities, whether due to tetraplegia or other causes, such as multiple sclerosis or cerebral palsy [17], heavily depend on ATs to enhance independence and participation in activities of daily living (ADLs) [18,19]. ATs augment individuals' capabilities and broaden the range of activities they can engage in. Commonly used adaptations include cutlery, environmental control systems, writing orthoses [20], wheelchairs, prosthetics, and orthotics [21]. The application of AT not only aids the user but also indirectly benefits caregivers, notably family caregivers. Atoyebi et al [22] emphasize the potential of AT in reducing caregiver burden and alleviating stress. Specifically assistive robots, as defined by Kyrarini et al [17], serve as compensatory ATs and offer external assistance controlled by the user through an interface [23,24]. They facilitate a wide range of activities for persons with upper extremity disabilities, enhance care and promote independence across different areas [25,26]. One example is the Functional Robot with Dexterous Arm and User Friendly Interface for Disabled People (FRIEND) system, a wheelchair-mounted robotic manipulator designed to assist users with tetraplegia in tasks such as drinking and eating. The FRIEND IV, the latest iteration, integrates a 7-degree of freedom robotic arm and a 2-finger gripper and has been tested in a use-scenario, achieving a 95% success rate for cataloging books (of a performed 100 runs) with the end user's intervention [27]. The Jaco 2 robotic arm (Kinova Inc), a widely used commercially available system, offers 6- or 7-degree of freedom configurations and can be equipped with 2- or 3-finger grippers. It has been applied in various contexts, such as adaptive feeding systems that integrate force sensors and cameras to detect and manipulate food for users. In an efficacy study with 31 participants, the Jaco robotic arm has demonstrated the potential to reduce caregiving time by approximately 41% [28]. Beyond feeding and drinking tasks, assistive robotic systems have also been implemented in other ADLs. The Baxter humanoid robot, for example, has been used to provide personalized dressing assistance, using force-minimizing methods to help users with upper-body impairments wear sleeveless jackets [29]. Other experimental systems have explored applications such as beard shaving, hair brushing, and bathing, although these tasks remain in early stages of development and require further research to ensure safety and usability [17]. However, most robotic systems are still in the research phase and require significant customization and personalization to effectively assist persons with impaired upper extremity in their daily life.

There have been efforts to promote high-performance AT as prototypes, such as international contests like the CYBATHLON hosted by the Swiss Federal Institute of Technology Zurich in Switzerland [30,31]. Nonetheless, the need [32,33], the transfer, and the adaptation of AT in everyday life remain a transnational challenge [1,34,35], and many robotic innovations fail to reach the market [36]. This discrepancy can be attributed to various factors, including a focus on technical feasibility over user needs, complexity, cost, and the need for technical assistance for use [36,37]. For effective market integration, factors such as reliability, cost-effectiveness, esthetics, functionality, and usability must be carefully considered, with user-centered design principles playing a relevant role [23,38,39].

Objectives

The need of structured knowledge transfer, reimbursement strategies, and the assessment of the readiness of the AT market to successfully transition a prototype into a market-ready product [30] can be met with implementation sciences, offering valuable methods for the systematic uptake of evidence-based practices [40]. The implementation sciences acknowledge the relevant influence of economic, political, professional, and sociohistorical context factors on the adoption of evidence in practice [40]. The aim of this study is to investigate and reduce the research translation gap of implementing ATs into social and health insurance systems, with a specific focus on integrating a user-centered designed assistive robotic arm into the everyday private lives of individuals with tetraplegia in Switzerland [41]. The study's objectives are (1) identifying and involving relevant stakeholders, (2) assessing contextual factors (barriers and facilitators), and (3) proposing an implementation strategy for the robotic arm.

Methods

Qualitative Design

A qualitative design was applied, conducting 3 online focus group interviews with representatives from 8 stakeholder groups relevant to the robotic arm's implementation, aiming to identify barriers and facilitators. This study was performed from a constructivist or interpretivist point of view using a general deductive approach. This research was reported in accordance with the Standards for Reporting Qualitative Research by O'Brien et al [42].

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Conceptual Framework

The Consolidated Framework for Implementation Research (CFIR) serves as a widely used guide in implementation research, comprising 39 constructs synthesizing existing theories applicable across all implementation phases, allowing researchers to select the most relevant constructs for their specific study setting [43-45]. It aims to identify and explain factors influencing implementation outcomes, consisting of 5 major domains: innovation, outer setting, inner setting, individuals involved, and implementation process [45]. The innovation is related to the characteristics of the innovation being implemented into a particular setting. Outer and inner settings represent a dynamic interface, where the outer setting generally includes the political, social, and economic context, such as community and state factors, while the inner setting comprises the structural and cultural context. Individuals involved represents the individuals involved with the innovation and the implementation process. In this domain, cultural, organizational, and professional aspects as well as individual mindsets and norms are considered. The implementation process includes the development needed during implementation. According to Damschroder et al [46], researchers should choose the most relevant constructs from the 39 offered in the CFIR to suit their specific study context. These constructs can guide diagnostic evaluations of the implementation environment, monitor implementation progress, and interpret findings in the research studies or qualitative improvement initiatives.

Context

The robotic arm at the center of the focus groups was a prototype developed by the Bern University of Applied Sciences in Switzerland. It competed in the Assistance Robot Race at the CYBATHLON 2024, mastering 10 different tasks of daily life, such as removing a parcel from the mailbox or navigating a touch screen. However, it has not yet been subjected to trials beyond this competition [47]. The robotic arm system consists of a Kinova Gen3 robotic arm with 7 joints, which can be mounted on an electric wheelchair. A 3D camera positioned near the gripper provides visual input for the current task. The vision system uses machine learning algorithms to identify objects, enabling the robot to approach and grasp them in a semiautomated manner, thereby saving time in completing the task. A graphical user interface displayed on a tablet near the user presents live and processed images from the camera. Users with some arm mobility can interact with the system by using the tablet's touch screen to issue commands, while those without sufficient mobility rely on speech recognition powered by Whisper (OpenAI) [48]. The robotic arm system is designed to ensure simple operation and intelligent robotic behavior. The architecture of the system itself is independent of the robotic arm, allowing for flexibility in implementation. For instance, while the current configuration uses the Kinova Gen3 robotic arm, it could be replaced with an alternative model, such as the BATEO (ACCREA Engineering) arm, without compromising the system's functionality. In addition to the existing literature on different robotic arm systems, a cross-sectional study focusing on the identification of needs for ATs for upper limbs in persons with tetraplegia was considered for the design of the robotic arm (N Hutmacher, unpublished data, March 2025). An overview of the robotic arm system can be found in Multimedia Appendix 1.

Representatives from 8 stakeholder groups (affected persons, as well as those who could provide perspectives on engineering or technology, legal matters, nursing or care, therapy, social counseling, social insurance, and political considerations) participated in the focus group interviews. The nursing or care stakeholder group included professional caregivers and family members who provided caregiving, the therapy group comprised occupational and physical therapists, and the social insurance group included representatives from various Swiss social insurance organizations (Swiss social insurers according to Federal Accident Insurance [UVG], Federal Military Insurance [MVG], and Federal Law on Invalidity Insurance [IVG]). Inclusion criteria required stakeholders to have specific professional roles or specialized knowledge, be aged >18 years, and have a good understanding of German.

Sampling Strategy

Stakeholders were organized into focus groups, each consisting of 6 to 9 participants, with a minimum of 4 stakeholder groups represented in each focus group. This approach aimed to facilitate discussions and ensure diverse perspectives were represented among stakeholders in a heterogenous group composition [46,47].

Purposive sampling aimed to achieve maximum variation in specialty by using a snowball approach to contact official representatives from insurance institutions, government offices, medical clinics specializing in SCI, assistive product retailers, and personal contacts. Recruiting involved contact via email or phone by the main researcher [42].

The researchers found consistent discussion of similar barriers and facilitators after 3 focus group interviews, confirming data saturation.

Data Collection Methods

To avoid increased time expenditure with long journeys, the 120-minute focus group interviews were conducted online via Microsoft Teams during January 2024 to February 2024.

Data collected for the general implementation outlook were informed by extensive literature research.

Data Collection Instruments and Technologies

Data collection followed a semistructured interview guide (Multimedia Appendix 2) developed by the research team based on literature review. The interview guide was refined in 3 one-on-one online interviews with participants (including a representative of engineering or technology, legal perspective, and social insurers) who did not participate in the focus groups. The guide was supplemented by the discussion and answers from the participants in the one-on-one meetings. The final guide contained the areas first impressions, opportunities, barriers, dealbreakers, and outlook or solutions.

Ground rules, a schedule, and a photograph of the robotic arm as stimulus material (Multimedia Appendix 3) were introduced at the start of each focus group interview. Participants identified themselves by role and name, with sessions being video and

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audio recorded using the Microsoft Teams application. Moderation was handled by the main researcher, and note-taking was handled by a note-taker.

Units of Study

A total of 3 focus group interviews were conducted with 6 to 9 representatives of the different stakeholder groups shown in Table 1 (focus group 1: 9/22, 41%; focus group 2: 6/22, 27%; and focus group 3: 7/22, 32%). A total of 7 stakeholder groups were represented in at least 1 focus group; no participant engaged in more than 1 group. Family caregivers from the nursing or care and political perspective groups did not participate in the study. Most study participants (13/22, 59%) were female. Participants appeared to be highly experienced in their professional roles; they had worked on average 15 (SD 9.23) years in the current professional function.

Table 1. Units of study in total and stratified per focus group (N=22).

	Participants, n (%)	Experience in years, mean (SD; minimum/maximum)	Participants in focus group 1, n (%)	Participants in focus group 2, n (%)	Participants in focus group 3, n (%)
Affected persons[a]	4 (18)	—[b]	2 (22)	1 (17)	1 (14)
Engineering or technology	5 (23)	14 (6.34; 6/20)	0 (0)	3 (50)	2 (29)
Legal matters	1 (4)	5 (—; 5/5)	1 (11)	0 (0)	0 (0)
Nursing or care	2 (9)	18 (19.80; 4/32)	1 (11)	1 (17)	0 (0)
Therapy[c]	5 (23)	14 (9.98; 5/25)	3 (33)	0 (0)	2 (29)
Social counseling	2 (9)	17 (4.24; 14/20)	2 (22)	0 (0)	0 (0)
Social insurance[d]	3 (14)	20 (11.72; 11/33)	0 (0)	1 (17)	2 (29)
Total	22 (100)	15 (9.23; 4/33)	9 (100)	6 (100)	7 (100)

[a]Disability years for the affected persons: mean=27; minimum/maximum: 5/46.

[b]Not applicable.

[c]Therapy included physiotherapists and occupational therapists.

[d]Swiss social insurers according to Federal Accident Insurance, Federal Military Insurance, and Federal Law on Invalidity Insurance.

Data Processing

The Focus Group Illustration Mapping tool, as outlined by Pelz et al [49], facilitated a comprehensive summary of focus group interview content by combining survey methods with content evaluation. It used the semistructured interview guide as its framework, with key aspects first impressions, opportunities, barriers, dealbreakers, and outlook or solutions serving as central nodes. Relationships between concepts were represented using connecting arrows, with color codes distinguishing stakeholder groups. Visualizations were created using the web-based tool Miro [50], and PDF versions were sent to participants for consensual validation (Multimedia Appendices 4-6). The illustration maps were translated from German to English (Multimedia Appendices 7-9).

Data Analysis

The CFIR constructs were selected after intensive examination of all 39 constructs according to the time of the study. A deductive approach was used to code data from the illustration maps, which were aligned with domains 1 to 4 of the CFIR framework.

For the implementation outlook, a similar deductive approach was used to code data extracted from literature research, focusing exclusively on the implementation process domain.

Techniques to Enhance Trustworthiness

To ensure credibility of the findings, participant validation was used. A link to a Microsoft Forms survey allowed the validation of the illustration map by each participant anonymously, where either the option "I agree with the visual summary" or the option "I do not agree with the visual summary," followed by an open text field for feedback, could be chosen (Multimedia Appendices 10 and 11). The response rate for the validation was 77%, with 17 participants completing the survey. The illustration maps were translated from German to English using 3 translation programs: DeepL (DeepL SE), LEO (LEO GmbH), and Dict.cc (dict.cc GmbH). Data triangulation was achieved through semistructured interviews and document analysis of online research, converging multiple data sources to validate identified themes and patterns [42].

Ethical Considerations

Written informed consent was obtained from all participants outlining the investigation's purpose, the use of data, and their publication (Multimedia Appendix 12). Given the design of the study and the nature of the data collected, formal ethics approval was not required. According to Risk Category A as defined in Article 7 of the Swiss Human Research Ordinance (HRO), studies involving noninvasive procedures and fully anonymized qualitative data, such as focus group interviews, are exempt from requiring ethics approval [51]. The research was conducted in accordance with ethical principles respecting the dignity, privacy, and autonomy of the participants.

Results

The selected constructs of the 39 CFIR constructs for all 5 domains are displayed in Figure 1.

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Figure 1. Overview of the selected Consolidated Framework for Implementation Research constructs.



Barriers and Facilitators to Implementation

Overview

Multimedia Appendix 13 summarizes the barriers and facilitators across 21 constructs within the CFIR domains innovation, outer setting, inner setting, and individuals domain. In the following, quotation marks are used to mark direct phrasing from the illustration maps.

Domain I: Innovation

Innovation Evidence Base

Facilitators that were mapped on the innovation evidence base could be supported with published literature. Overall, participants noted the robotic arm to enhance "self-care" and the facilitating aspect of increased quality of life through more autonomy [28,52]. In addition, it was reported that the robotic arm "saves on skilled labor" in the health care system, supporting its effectiveness [52]. Moreover, the robotic arm represented an "opportunity in the second labor market" [52].

Innovation Relative Advantage

According to participants, the robotic arm allowed an advantage over caregiver dependency, where simultaneously "autonomy is enabled." Regarding this, one participant mentioned a potential negative aspect, namely, "there may be fewer human interactions." The robotic arm's inability to support critical activities such as transfers was noted, rendering users dependent on caregiver support. Participants mentioned reduced dependence on social insurance benefits, potentially enabling "work ability and integration."

Innovation Adaptability

Identified barriers included the robotic arm's inability to fit both electric and active wheelchairs and the challenge of customizing it to each user's environment. Recognized opportunities to overcome these barriers were customization through the interface and the integration of a "combination with existing wearables," noted as a facilitator by a technical stakeholder.

Innovation Trialability

Testing the robotic arm in everyday life and then having the opportunity to decide in favor of it was seen as necessary by the participants.

Innovation Complexity

The complex requirement for the robotic arm to replace the human arm function was seen as a challenge, where "technical limitations," such as "recognizing material" and adjusting gripping force, were noted. However, one affected person emphasized functionality over speed of execution. Although the decision-making would always remain with the user when using the robotic arm, cognitive limitations were seen as a factor, highlighting the importance of the arm's intuitiveness and ease of operation. The introduction of differing user profiles and operating modes, as well as the automatization of the robotic arm, were seen as facilitators for innovation complexity. This

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would allow for shared use of the robotic arm, for example, in "residential homes." The interaction of the robotic arm with a dynamic human instead of a static object presented another barrier, with safety concerns, particularly regarding "spasticity" adding complexity to the innovation.

Innovation Design

he size and the one-sided weight of the robotic arm were perceived to affect the maneuverability of the electric wheelchair, potentially obstructing proximity to objects and hindering activities such as approaching a table. Concerns about the robotic arm's "robustness" and "sensitivity" were raised due to potential damage from impacts or road conditions. The life expectancy of the robotic arm was considered a possible barrier, and features such as "material resistance to temperature, dust, and moisture" were mentioned as decisive. Environmental settings such as "car or taxi transport" or interactions with "young children" were also seen as potential hindrances to the innovation design. One participant noted that a "noisy environment" could affect the voice control of the robotic arm. The power regulation and dependency of the robotic arm were additional barriers identified. Some stakeholders found the robotic arm to be conspicuous, particularly when added to the already large wheelchair. However, affected persons prioritized practicality over aesthetics.

Innovation Cost

High costs of the robotic arm emerged as a significant barrier across all focus group interviews. The current estimated cost of the robotic arm system is around 50,000 Swiss francs (US $55,000), with additional expenses for customization, maintenance, repair, and indemnity insurance. "Savings on structural measures or technical aids" and the saving of resources as well as increasing work ability were noted as facilitators, potentially offsetting costs in the long term. Participants suggested expanding the target group to "other disorders with impaired upper extremity" or healthy individuals simplifying market entry and potentially lowering prices. However, this change in scope could affect assumptions about cost bearers.

Domain II: Outer Setting

Critical Incidents

Participants identified user involvement in both the development and financing processes, as well as public acceptance, as key factors that facilitate successful implementation. However, general dependency on technology and user helplessness in emergencies were seen as barriers, emphasizing the need for robust safety protocols and self-help capabilities. "WWarranty and availability of materials and spare parts" were critical barriers, and one stakeholder noted that "success depends on retention services, service intervals, duration of use, and guarantee pages." "High costs" emerged as a significant barrier across all focus group interviews, emphasizing economic considerations and financial implications.

Local Attitudes

While some participants viewed technology, including robotics, as the future, concerns were raised about potential stigmatization. Furthermore, the need of political engagement to enhance social inclusion was stated by the participants, and it appeared relevant to manage expectations and clarify the robotic arm's role as an assistive product.

Local Conditions

One facilitating factor noted was the possibility of using the robotic arm on public transportation in Switzerland, similar to how an electric wheelchair is used. Concerns were raised about potential damage to the robotic arm or injury to others during its use. In addition, it was mentioned that international travel with the robotic arm could be limited.

Partnerships and Connections

Collaborative opportunities, including partnerships with universities and "media partners," and the involvement of therapists were seen as facilitating for the robotic arm's implementation. One stakeholder representing the engineering or technical perspective emphasized the importance of involving specialist retailers and technology partners. Furthermore, the political involvement and collaborations with specialized foundations, such as "Swiss Paraplegic Foundation," were seen as a facilitating aspect to the robotic arm's implementation. The collaboration with already existing applications was seen as enhancing; however, reliance on third-party providers for services such as "servers and applications" was also identified as a barrier.

Policies and Laws

Participants identified various legal barriers to the implementation of the robotic arm, including authorization processes and compliance with European regulations. Stakeholders emphasized the need for compliance with Swiss laws, particularly regarding data protection and the use of integrated cameras in public spaces. Additional concerns arising with the assumption of costs by the Swiss Invalidity Insurance (IV) were noted as barriers to the robotic arm's implementation.

Financing

During the focus group interviews, potential funding sources discussed included the IV, the Swiss National Accident Insurance Fund (SUVA), indemnity insurance, and foundations. Concerns were raised that the robotic arm might cover activities already provided with other ATs, reducing its relevance and likelihood of financing. The reallocation of resources from other services, if IV covered costs for items such as "door openers," was seen as another barrier, as it could potentially limit the autonomy of the affected persons. The absence of a specific category for robotics in IV regulations posed a barrier to financing, despite "federal court judgments" indicating otherwise. Conflicting motives between cost bearers and developers were further identified as a barrier to financing efforts. Establishing a clear application area for the robotic arm was deemed necessary but challenging, although a "step-by-step approach" was identified as a facilitating factor.

External Pressure

Participants noted the duplicating and commercializing of prototypes as barriers. The existing competition from robots, such as "comparable robot arm Lio" in the Swiss market, was

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cited as a barrier, while Switzerland's small market size posed challenges in effectively meeting demand.

Domain III: Inner Setting

Structural Characteristics

The range of the field of application of the robotic arm from personal household of the user to public space was seen as a facilitator by the participants. However, the individuality of the user and the environmental settings also represented a barrier, where, for example, the variety of door handles could be limiting. Furthermore, the discrepancy between indoor and outdoor settings was perceived as a barrier.

Relational Connections

The enhancement of autonomy by the robotic arm was perceived to have a positive influence on the users' state of mind, reducing tension in the immediate vicinity and improving relationship quality.

Tension for Change

The "reduction of shortage of skilled labor" within the Swiss care setting was perceived as a facilitator to the implementation of the robotic arm.

Domain IV: Individual Domain

Opinion Leaders

The current "wheelchair-bound Swiss National Councilor" was mentioned as a facilitator by an engineering stakeholder.

Innovation Deliverers

Physical and occupational therapists, as well as specialist retailer and distribution centers, were identified by the participants as innovation deliverers. Here, "Swiss Med Tech, Ortho Reha Suisse, Otto Bock, and the United States Military" were mentioned to enrich the project with expertise and possible resources.

Innovation Recipients

Persons with tetraplegia were identified as innovation recipients, where living independently was seen as a facilitator, while for users requiring 24-hour care, such as those dependent on a tracheostomy, the robotic arm was considered unsuitable.

Characteristics Subdomain: Need

The "desire for independence" was seen as the main need for the innovation across all focus group interviews. The fact that the robotic arm enabled additional autonomous activities was seen as a facilitator by the participants. Activities such as applying makeup, "eating meals while still warm," "scratching the face," and "blowing the nose" were mentioned. In addition, dressing, shopping, and pursuing hobbies such as "art" and "playing games" were cited. However, with additional functions, safety concerns were emphasized. Furthermore, it was seen as a barrier that other supplementary services would still be required and should not be excluded for the user when using the robotic arm.

Implementation Outlook

The implementation outlook was structured on the fifth domain of the CFIR (implementation process) displayed in Table 2; the included data came from literature research. The formation of an experienced implementation team is proposed to lead the implementation [40], while the needs for ATs for individuals with tetraplegia have been identified in a cross-sectional study (N Hutmacher, unpublished data, March 2025). As the project progresses, insights will be mapped to CFIR constructs, and an implementation plan will be developed, including pilot testing. The use of hybrid type 1 and type 2 designs will allow to assess both effectiveness and implementation within real-world contexts [53].

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Table 2. Implementation outlook mapped on the fifth Consolidated Framework for Implementation Research (CFIR) domain (constructs with no barriers or facilitators were omitted).

Constructs	Propositions
Domain V: Implementation process	
Teaming	• An implementation team with experienced representatives from Switzerland [37]
Assessing needs	• A cross-sectional study assessing the needs for assistive technologies for individuals with tetraplegia (N Hutmacher, unpublished data, March 2025) • Stakeholder representatives from the focus groups for ongoing dialogue and refinement of understanding the needs of both innovation deliverers and recipients • Stakeholder groups identified in the focus group interviews to ensure comprehensive understanding of needs
Planning	• With project advances, mapping of further insights on context with identified and omitted CFIR constructs • The rating of identified constructs within the CFIR reflects both their valence and magnitude [54] • An implementation plan developed by the implementation team, including specific steps such as pilot testing and measures • Use of hybrid type 1 design (effectiveness within real-world contexts), preceded by a hybrid type 2 design [53]
Engaging	• Possible key players for engagement: the SCI[a] community in Switzerland and the Swiss Paraplegic Centre and its foundation (national and international scope) [49,55]
Reflecting and evaluating: implementation outcomes	• Combination of qualitative and quantitative measurements • Fidelity: fidelity of implementation assessment and stages of implementation completion [53], including self-reporting • Feasibility: surveys • Acceptability: surveys and interviews • Appropriateness: surveys and focus groups • Sustainability: sustainment measurement system and RE-AIM[b] framework [52,53] • Readiness for innovation and implementation: stages of implementation completion tool (postimplementation sustainment outcomes [53]
Reflecting and evaluating: innovation outcomes	• Combination of qualitative and quantitative measurements • Innovation effectiveness: used cases and controlled trial design • Functional independence for ADLs[c]: Functional Independence Measure • Quality of life: Short Form 36 Health Survey not only for users but also caregivers and ISCoS[d] quality of life questionnaire [54] • User satisfaction: Quebec User Evaluation of Satisfaction with Assistive Technology [56] • Specific function outcomes: mobility and communication subscores of Spinal Independence Measure [57]

[a]SCI: spinal cord injury.

[b]RE-AIM: Reach, Efficacy, Adoption, Implementation, and Maintenance.

[c]ADLs: activities of daily living.

[d]ISCoS: International Spinal Cord Society.

Discussion

This study aimed to explore the research translation gap in integrating ATs into social and health insurance systems. It specifically focused on identifying stakeholders, assessing contextual factors, and proposing an implementation outlook for introducing an assistive robotic arm into the everyday private lives of individuals with tetraplegia in Switzerland.

Stakeholders

Throughout all focus group interviews, there was agreement that the present stakeholder groups were relevant to the implementation of the robotic arm. A stakeholder group that was frequently discussed among the interviews was individuals providing a political perspective, which is also emphasized by Wolfenden et al [54]. According to a recent study by MacLachlan et al [56], AT policy should be grounded in evidence, but its foundational framework must go beyond rigid scientific criteria and be more inclusive. This is an important consideration for governments because the capacity to implement can be hindered by the volume of concurrent initiatives, potentially leading to low prioritization of the implementation, which could cause the implementation to fail [57]. In this context, stakeholder perspectives, contextual factors, cultural nuances, available resources, and systemic viewpoints should be systematically evaluated and synthesized in a transparent manner to enhance their credibility and inform policy decisions. MacLachlan et al [56] even propose the role of policy entrepreneurs, translating technical content into compelling information to engage politicians, to network and interact with the key stakeholders. Involving the current wheelchair-bound Swiss national councilor, as discussed in the focus group interviews, could facilitate cross-sector collaboration and have positive effects on the implementation of the robotic arm [58].

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Barriers and Facilitators

All stakeholder groups agreed that the innovation addresses the needs of the recipients, specifically the desire for greater autonomy among individuals with tetraplegia. The robotic arm would allow for improvement in daily life participation, and although some activities may still be challenging or time consuming [59], addressing the impairment of the upper extremities and the autonomy provided was valued by the users [7]. Because the robotic arm may not allow complete independence for affected persons, partial or continuous assistance from a caregiver might still be needed, which was perceived as negative in the focus group interviews. Similar results were found by Gelderblom et al [24] assessing the MANUS robotic arm, where the continued dependence on caregivers was perceived as stressful to the user. Nevertheless, according to the focus group interviews, users' quality of life was expected to improve with the use of the robotic arm. This is reflected in the observations of Maheu et al [28], where the empowerment of the user enables an improvement in the quality of life, not only of the user but also of the caregiver. This facilitator must be emphasized as an important contribution of the robotic arm [60]. Specific assessment of how ATs, more precisely robotic arms, influences the quality of life of affected persons and of caregiver needs to be addressed in future research.

The complexity of the requirements of the innovation and the need for individuality with each user were perceived as barriers to the implementation of the robotic arm. The involvement of users in the development and implementation process was emphasized across the focus group interviews. This not only provides valuable insights that can enhance the effectiveness of the innovation [61,62] but also leads to higher user satisfaction. According to Martin et al [63], users that possess a greater understanding of ATs and feel more informed tend to exhibit higher satisfaction with the devices. Likewise, when their requirements are unmet, the users tend to express less satisfaction levels with the technology. It is anticipated that if usability limitations, such as use efficiency and overall satisfaction, remain unaddressed, users are prone to abandon their AT shortly after acquiring it [30,64]. This is an important factor to consider when assessing the readiness of the AT market and the implementation of the robotic arm moving forward. Furthermore, piloting, as mentioned in the focus group interviews, would allow users to gain experience and further adapt the innovation based on their feedback [65].

According to Nicolet et al [66], it is crucial to involve not only users but also other diverse stakeholders in the early stages. This facilitates the dissemination and transfer of findings, while also enhancing credibility and acceptance within the population. This is relevant as the implementation of the robotic arm could be further facilitated by support from the population. The general positive attitude among the focus groups toward technology as the future presents an optimal prerequisite for this aspect. The favorable view of robots was also shown among the older adult population in Switzerland, although concerns about personal connection and data privacy were raised, supporting similar statements from the focus groups [67]. Understanding patient needs and resources and effectively prioritizing them in combination with the involvement of the public, strongly correlate with successful implementation and are seen as a way to secure the acceptance and implementation of policies [57,68]. These are relevant aspects to consider as we move forward with the implementation of AT, specifically the robotic arm.

A relevant barrier discussed across all the focus group interviews was the financing of the robotic arm. Its current costs as a prototype exceed individual financial resources of affected persons, making it unaffordable. In Switzerland, the governmental social or health insurance system is expected to reimburse costs for ATs. The primary focus of social insurers lies in the cost-effectiveness of the assistance they are considering reimbursing, which according to Romer et al [69] specifically refers to the extent of cost savings achievable through the acquisition of the AT in relation to the overall cost of care for the user (cost of labor of the caregiver and cost of technical aids), which the robotic arm could replace. Additional indirect economic advances of the robotic arm encompass various benefits, such as reductions in unemployment compensation expenses, as users regain employment opportunities or increased workload can be allowed or area of application of work be expanded [69]. According to Bensi et al [56], cost savings of €290 (US $319) per individual over a span of 5 years resulted from enhanced autonomy through ATs and decreased reliance on personal assistants. The delicate balance between affordable supply of needed assistive products and high quality to foster social benefits alongside financial profitability remains a challenge. However, evidence on the effectiveness and cost-effectiveness of assistive robotic arms is limited [70], necessitating further research contributing to the implementation process [71].

In addition, determining the cost bearer within Switzerland's social insurance system is crucial for the implementation of ATs and was mentioned as a barrier across the focus group interviews. Laws in Switzerland require the IV to provide rehabilitation services, while the SUVA covers the economic consequences of accidents or occupational diseases [72,73]. The complexity and fragmentation of the Swiss social insurance system [74] could hinder the implementation process. This is supported by Schusselé Filliettaz et al [75], who found in a survey on integrated care initiatives in Switzerland between 2015 and 2016 that chronic care integration presents a notable challenge due to issues with the allocation of responsibilities, payment structures for health care professionals and institutions, and financing mechanisms. This is further complicated by the different conditions that apply to the assumption of costs by the various cost bearers within the social insurance system. The assumption of costs by the IV, which was emphasized in the interviews, requires the robotic arm to fulfill the criteria effectiveness, appropriateness, and economic efficiency [76]. In addition, the List of Remedies and Equipment (MiGeL) outlines the device categories eligible for coverage and specifies the maximum reimbursement amounts, including approximately 20 groups of approved devices [77]. Currently, no category that includes robotics as an AT is listed in the MiGeL. Without a designated category, similar ATs listed on the MiGeL may receive compensation, potentially leading to higher costs or inadequate support compared to the robotic arm. According to

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MacLachlan et al [78], the absence of a clear framework for ATs such as robotics hinders implementation efforts, further compounded by a lack of familiarity and knowledge regarding disability and impairment. The clarification of competence and the assumption of costs among the various cost bearers need to be addressed for AT and the robotic arm in the Swiss context.

Moving forward with the implementation of the robotic arm, a focused approach targeting the identified barriers is necessary. The key recommendations from the authors for addressing the most relevant barriers currently identified are listed below:

- Conduct a detailed cost-effectiveness study to demonstrate the robotic arm's long-term financial savings (e.g., reduction of reliance on personal assistance, improvement of workability, and saving unemployment benefits).
- Perform pilot studies, where individuals with tetraplegia can trial the robotic arm in real-world settings. Continuous feedback should be collected to identify potential issues with usability, fit, and comfort. Furthermore, caregivers should be involved in the trial process of the robotic arm. This will help to construct the robotic arm to meet the user's needs and make it more effective.
- Clarify cost assumptions with insurers and enter into dialogue with the IV, SUVA, and other relevant insurance bodies to establish clear guidelines for the reimbursement of the robotic arm and comparable ATs. Here, the demonstration of the robotic arm's cost-effectiveness will help justify reimbursement.

Implementation Outlook

Moving forward, an implementation team overseeing and facilitating key activities in the selection and implementation is needed [79]. Representatives of implementation teams should encompass various viewpoints, including those of practitioners, supervisors, administrative leaders, and policy makers. The relevance of implementation teams was also acknowledged by Metz and Bartley [79], stating that in a survey of implementation frameworks, 17 (68%) of 25 frameworks emphasized the formation and use of implementation teams as essential elements of the implementation framework to ensure high-quality implementation. Furthermore, a stakeholder analysis by Reed et al [80] would allow a thorough investigation of relevant stakeholders for overall stakeholder engagement and their change over time [40,81-83] for the implementation of ATs.

In addition to the implementation context, successful evaluation of innovation and implementation is needed. In this research, the combination of innovation and implementation outcomes was given as an implementation outlook, as suggested by Hung et al [84]. According to Albers et al [40], clinical outcomes may be inaccurate or poorly understood if implementation outcomes are not measured, making it crucial to combine both types of assessments. Previous research emphasizes the construct relative advantage of the CFIR as a decisive factor for successful adoption and implementation of the innovation [85]. This suggests that successful implementation is more likely when users recognize a clear advantage in the innovation's effectiveness. Stakeholders must clearly observe the benefits of the innovation, emphasizing the importance of efforts to demonstrate these benefits [57]. Therefore, giving early attention to the relative advantages in implementation planning could be a strategic approach and should be considered as we move forward with the robotic arm and its implementation.

The use of a hybrid design, combining elements of clinical effectiveness and implementation research to explore not only what works but also how, where, and why, was further proposed in the implementation outlook. This would allow to incorporate complexity to establish external validity and gain insights on scaling up and disseminating [86]. The use of mixed methods designs would enable exploratory and confirmatory research, according to Palinkas et al [87], incorporating the perspectives of potential consumers, practitioners, and clients. To assess innovation effectiveness, standardized ADLs were suggested in this research. Integrating outcomes with the International Classification of Functioning, Disability, and Health could further refine functional evaluation tasks, ensuring a comprehensive assessment that goes beyond basic activities and allows for better comparison across research groups [88]. These considerations for methodology, including design and data collection techniques, need to be incorporated in the future research on the robotic arm's effectiveness and implementation and comparable ATs.

Strength and Limitations

Some limitations should be considered together with the results of this research. First, although efforts were made to include a broad coverage of stakeholder groups, the distribution of representatives varied, potentially introducing bias with certain perspectives dominating the discussion [42]. To decrease this group dynamic bias, sampling procedures were used to group similar perspectives together in focus groups. However, the absence of a family caregiver representative within the nursing or care stakeholder group and representatives from the political perspective group was acknowledged as a limitation, as this may have led to missed important insights. Second, the study focused on implementation within the Swiss social insurance system, limiting its generalizability in terms of governmental financing of the robotic arm and similar ATs. Furthermore, the direct end users of the robotic arm considered in this study are persons with impaired upper extremity due to tetraplegia. However, the target population could be broadened to include individuals with upper extremity impairments caused by congenital conditions, such as cerebral palsy, as well as other medical conditions. Expanding the target group will require further research to address the specific needs and challenges associated with these conditions.

The analysis of the contextual factors was conducted early in the development of the robotic arm. This is a strength, as it provides valuable insights and identified barriers and facilitators that should be considered moving forward. However, further exploration and development may highlight additional aspects influencing context, and identified contextual factors need to be reassessed with the process. Another strength of this research is its potential applicability to future AT implementation processes in Switzerland and countries with comparable social and health insurance systems. The use of the CFIR framework allows for building on these results and integrating findings from other studies, contributing to knowledge about the

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interaction between innovations and context. Another strength of this study is the contribution of valuable insights to the implementation of ATs, specifically assistive robots.

Conclusions

This research explored the current contextual factors influencing the implementation of an assistive robotic arm in the everyday lives of individuals with tetraplegia in Switzerland. As an example of AT, the robotic arm offers promising benefits in terms of autonomy and improved participation for users, positively influencing their quality of life. Challenges such as high costs and regulatory complexities regarding cost coverage in its implementation need to be addressed, highlighting the need for a framework for implementing ATs. The need for political lobbying, stakeholder engagement, and user involvement throughout the implementation process were identified to facilitate the widespread adoption of ATs in Switzerland and other countries with comparable social and health insurance systems.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Participant recruitment and data collection were conducted by VF; all authors (VF, MR, and AMR) analyzed and interpreted the data and contributed to writing the manuscript, with VF playing the lead role overall. Each author read and approved the final manuscript to be submitted to *JMIR Rehabilitation and Assistive Technologies* and agreed both to be personally accountable for the author's own contribution and to ensure adequate investigation and resolution of questions related to the accuracy or integrity of any part of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of the robotic arm system.
[DOCX File , 226 KB - rehab_v12i1e65759_app1.docx]

Multimedia Appendix 2
Semistructured interview guide for focus groups (German).
[DOCX File , 19 KB - rehab_v12i1e65759_app2.docx]

Multimedia Appendix 3
Stimulus material for robotic arm system.
[DOCX File , 1363 KB - rehab_v12i1e65759_app3.docx]

Multimedia Appendix 4
Illustration map for focus group 1 (German).
[DOCX File , 474 KB - rehab_v12i1e65759_app4.docx]

Multimedia Appendix 5
Illustration map for focus group 2 (German).
[DOCX File , 540 KB - rehab_v12i1e65759_app5.docx]

Multimedia Appendix 6
Illustration map for focus group 3 (German).
[DOCX File , 477 KB - rehab_v12i1e65759_app6.docx]

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Multimedia Appendix 7
Illustration map for focus group 1 (English).
[DOCX File , 470 KB - rehab_v12i1e65759_app7.docx]

Multimedia Appendix 8
Illustration map for focus group 2 (English).
[DOCX File , 202 KB - rehab_v12i1e65759_app8.docx]

Multimedia Appendix 9
Illustration map for focus group 3 (English).
[DOCX File , 467 KB - rehab_v12i1e65759_app9.docx]

Multimedia Appendix 10
Example of participant validation of the illustration map in Microsoft Forms (German).
[DOCX File , 337 KB - rehab_v12i1e65759_app10.docx]

Multimedia Appendix 11
Example of participant validation of the illustration map in Microsoft Forms (English).
[DOCX File , 124 KB - rehab_v12i1e65759_app11.docx]

Multimedia Appendix 12
Patient information and informed consent form.
[DOCX File , 2932 KB - rehab_v12i1e65759_app12.docx]

Multimedia Appendix 13
Barriers and facilitators identified (constructs with no barriers or facilitators were omitted).
[DOCX File , 22 KB - rehab_v12i1e65759_app13.docx]

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Abbreviations

ADLs: activities of daily living
AT: assistive technology
CFIR: Consolidated Framework for Implementation Research
FRIEND: Functional Robot with Dexterous Arm and User Friendly Interface for Disabled People
IV: Swiss Invalidity Insurance
MiGeL: List of Remedies and Equipment
SCI: spinal cord injury
SUVA: Swiss National Accident Insurance Fund

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Original Paper

Lessons Learned From the Integration of Ambient Assisted Living Technologies in Older Adults' Care: Longitudinal Mixed Methods Study

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Abstract

Background: COVID-19 has given impetus to an already growing trend around the use of ambient assisted living (AAL) technologies to support frail older adults who live alone. However, the challenge is that systematic research on the long-term use of AAL technologies remains in its nascent stages, leaving gaps in the understanding of the predictors that contribute to the routine embedding of AAL technologies in older adults' care.

Objective: This paper aims to share key lessons from a longitudinal study on the routine embedding of AAL technologies in older adults' care within a hitherto under-studied Southeast Asian context. Our objective was to design and deploy an AAL system termed Ubiquitous Service Management and Reasoning Architecture (Ubismart), evaluate its impact on older adults' quality of life (QOL), and distill lessons to inform the sustainable and culturally sensitive adoption of AAL technologies in similar settings.

Methods: We conducted an in-depth case study using a mixed methods design. First, we designed and deployed Ubismart to unobtrusively monitor and visualize older adults' activities of daily living. To assess changes in QOL, we administered a simplified, gamified version of the validated Older People's Quality of Life Questionnaire. Finally, we conducted semistructured interviews with older adults and their caregivers to triangulate the quantitative findings and explore evolving perceptions of the technology and its integration into daily routines.

Results: Quantitative analysis revealed significant improvements in (1) psychological and emotional well-being (P=.01) and (2) leisure and social activities (P=.03) following the AAL intervention. Other QOL dimensions showed no statistically significant change. Qualitative findings reinforced the improvement in psychological and emotional well-being, with many participants describing a heightened sense of safety and peace of mind, often likening the technology to "insurance" or a silent companion. However, the impact on social relationships was paradoxical; some older adults felt more cared for, while others perceived a decline in in-person visits. This paradox highlighted the complexities of technology's role in caregiving, as it might simultaneously enhance feelings of safety while unintentionally diminishing social connection for some older adults.

Conclusions: AAL technologies such as Ubismart enhance older adults' psychological and emotional well-being and sense of safety but may inadvertently reduce social interaction. Sustainable integration requires balancing these benefits with efforts to maintain meaningful caregiver connections, supporting both safety and social engagement for older adults.

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Trial Registration: ClinicalTrials.gov NCT06486935; https://clinicaltrials.gov/study/NCT06486935

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KEYWORDS

ambient assisted living; Internet of Things; IoT; normalization process theory; older adults; quality of life

Introduction

Background

"I am afraid of dying alone at home" [1]; this fear, expressed by an older woman in Singapore, underscores a growing global phenomenon. As health care advances have prolonged life expectancy [2], demographic projections suggest that by 2030, 1 in 6 people worldwide will be aged ≥60 years, thus entering older adulthood. Unfortunately, many factors, including declining birth rates, changing norms, urbanization, and migration, have led to the evolution of family structures, causing a considerable proportion of these older people to live alone. In the United States, about 28% of the people aged ≥65 years live by themselves, including slightly <6 million men and slightly >10 million women [3]. Similar trends are seen across the globe, such as in Canada [4], Singapore [5], and France [6]. While living alone as an older adult is not inherently problematic and can be an indicator of robust health [7], it remains challenging for some individuals, particularly impoverished older adults who rely on government or not-for-profit organizations' support.

In response, developments in the Internet of Things (IoT) technologies and computational data science have introduced novel digital health interventions, such as ambient assisted living (AAL) technologies. AAL technologies are a type of smart home technology that enables individuals to remain socially connected while living independently [8]. Smart homes denote residences equipped with a high-technology network, linking sensors and other IoT-based domestic devices, appliances, and features that can be remotely monitored, accessed, or controlled and provide services that respond to the needs of the inhabitants [9]. The use of AAL technologies among older adults started to gain increasing research attention around the early 2000s [10,11]. These technologies hold an innovative promise in providing support for older adults, offering tools that enhance safety, independence, and overall quality of life (QOL) for those facing challenges associated with living alone [12,13].

However, end-user adoption and continued use of AAL technologies are still very low [8]. We believe that a significant obstacle to the sustainable use of AAL technologies lies in the absence of a robust, theory-driven approach to understanding how AAL technologies become routinely integrated and normalized in their social contexts. Intervention development and evaluation require a strong theoretical foundation [14]. Because social distancing protocols implemented during the COVID-19 pandemic have given impetus to an already growing trend in the adoption of AAL technologies [15,16], we believe that work theorizing the processes by which AAL technologies become routinely embedded in the care of older adults is both timely and relevant. Thus far, 3 distinct bodies of literature on AAL technologies have emerged: technical, human, and integrative perspectives [17]. The technical perspective primarily addresses design challenges and the implementation of AAL technologies. In contrast, the human perspective concerns the sociopsychological factors influencing adoption and shaping the use of AAL technologies.

While a great deal of good work has been done, recent research still highlights a lack of richer contextual and long-term approaches to understanding technology use among older adults requiring assisted living [18]. Indeed, most theoretical tools researchers use in the humanistic perspective of AAL technologies imply a psychological approach focusing on older adults as a unit of analysis. This is exemplified by the use of rational choice theories and theories of individual motivation, such as the theory of planned behavior, the technology acceptance model, and self-determination theory [19-21]. Such psychologizing of AAL technologies' use greatly curtails an understanding of how sociopsychological factors shape the routinization of these technologies in the care of older adults. It neglects that technology acceptance in this context is culturally dependent and will vary from one society to another [18,22]. Indeed, older adults cannot be studied in isolation, especially those requiring assisted living, because they live in interdependence with one another, their caregivers, and technological interventions [17,18].

Aims

Against this background, the aim of this paper is to promote the sustainable use of AAL technologies in the care of older adults by sharing a qualitative narrative and lessons learned from a longitudinal mixed methods study involving 19 older adults in Southeast Asia, a hitherto under-studied context. In doing so, we contribute to an emerging agenda of a rich sociological understanding of how older adults adopt and continue using AAL technologies by investigating an assemblage of sociotechnical linkages between different actors, including older adults, their caregivers, and the AAL technologies [18,23]. Such a focus is vital because AAL technologies can significantly impact the QOL for both older adults and caregivers if and only if they can be effectively integrated into routine practice [14].

To this end, we draw on 2 longitudinal AAL technology deployment studies to address the following research questions:

- How can AAL technologies be integrated and embedded into the care of older adults in context-dependent ways?
- What factors facilitate or impede the routine embedding of AAL technologies in the care of older adults?

In this paper, we first review related literature and introduce the theoretical framework guiding our narrative and proposed recommendations. Next, we detail the study's context and the specific AAL technology implemented. Finally, we share key lessons from the technology deployment process.

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Prior Work

As mentioned earlier, a lot of great work has been done, and some researchers have also shared personal narratives and lessons learned. While these lessons learned by other researchers provide valuable insights, they lag in 3 important ways that motivate our work.

First, a few of these studies have used quantitative methods and found that several barriers, including usability concerns, a lack of perceived usefulness, and low technological efficacy, impede the routine integration of AAL technologies in older adults' care [24-26], and indeed, these are helpful. However, richer contextual insights are difficult to capture through quantitative data [27]. Beyond their contributions to specific areas of empirical research, qualitative narratives can also serve to reorient theories. They may influence theories not only relating to individual AAL technology users but also regarding the society within which the use occurs. This is done by bringing attention to the social and cultural dynamics through which the routinization of these technologies occurs [28]. There are surely exceptions. Drawing insights from an ethnographic case study, Doyle et al [29] presented recommendations on the 4 interrelated and dynamic life cycles of independent living technology development: ethnographic inquiry, design, deployment, and ongoing evaluation. However, this differs from our objective to investigate sociopsychological and cultural dynamics that facilitate or impede the integration of AAL technologies into older adults' care.

Second, some personal narratives lack an overarching theoretical framework to organize the key recommendations. For example, Consolvo et al [30] highlighted design insights supported by practical experiences, such as keeping the ambient sensors out of older adults' view and providing a "human touch." "Human touch" here refers to capturing qualitative details, such as the reasons behind specific actions or feelings, to create a more empathetic and personalized understanding of older adults' experiences instead of focusing solely on sensor data. However, there is a lack of an overarching theory to create a complete and meaningful picture by linking their work to existing theories and previous research [31], which is understandable, as their work is design oriented and not psychosocial in nature. Still, to build a cumulative body of knowledge, personal narrative studies should be theoretically driven [32], as this will provide valuable support to the identification of patterns, themes, and connections in the narratives.

Third, only a handful of these studies were conducted in Southeast Asia. Most of those conducted in Southeast Asia used rational choice theories and quantitative approaches [9,33,34]. As indicated earlier, we believe qualitative research is more suited to understanding how AAL use evolves over time and why it evolves this way. The use of rational choice theories, with older adults being the primary data source, assumes that the decision to adopt and use a technology lies with the individual older user. However, the reality is far different because AAL technologies are better understood as complex adaptive systems, which are systems composed of interacting agents described in terms of rules [35]. Agents include the IoT components, older adults, and caregivers [35]. Such a view of AAL technologies' use focuses attention on the fundamental mechanisms of emergence [36]; that is, the interactions between users and AAL technologies, along with their caregivers, are intricately linked and shape the overall context of AAL use [37]. Therefore, adoption, acceptance, and use are culture dependent and will vary from one society to another [18,22]. From such a perspective, the use of AAL technologies is viewed as (1) socially and culturally situated and (2) determined by the interactions of multiple actors, including older adults, their caregivers, and the AAL technologies themselves, who engage in nonlinear and, at times, chaotic ways [38].

Organizing Theoretical Framework

It is recommended that personal narratives be shared within the confines of extant theoretical frameworks to better organize the lessons presented [32,38]. Therefore, we anchor our narrative and present our lessons based on normalization process theory (NPT) [14,39] because a fundamental theoretical and empirical puzzle in the complex health care interventions literature relates to how the use of these technologies can transcend conscious behavior and become part of normal routine in care activities [14,36]. NPT is a sociological theory explaining key mechanisms that facilitate or impede the implementation, embedding, and integration of new health techniques, technologies, and other complex interventions [39]. It is based on the premise that health care interventions are complex social interventions that require multiple people to work together to achieve a desired outcome [14]. It identifies 4 key mechanisms of the normalization process.

First, "coherence" pertains to target users' sensemaking or understanding of the nature and purpose of the intervention. It is related to the notion of perceived usefulness in the information systems and human-computer interaction literature [40]. The intervention must make sense to the target users and be compatible with their values and expectations to be perceived as useful [41]. Second, "cognitive participation" means that the intervention must engage and include everyone at every health care system level, from patients and their families to health care professionals and administrators. Third, "collective action" means that the intervention needs to be integrated into routine practice and be supported by the necessary resources, infrastructure, and training. Finally, "reflexive monitoring" means that the intervention needs to be evaluated and monitored regularly to ensure that it remains effective and sustainable over time.

Methods

Ethical Considerations

This study received ethics approval from the institutional review board of the National University of Singapore (A-16-349; protocol title: "City for All Ages: Elderly friendly City Services for Active and Healthy Aging") and is registered with ClinicalTrials.gov (NCT06486935). All participants were referred to the study by their caregivers. No reimbursement was offered for participation. Informed consent was obtained from each participant prior to enrollment, including consent for the future use of their data in research. All data used for analysis were deidentified to preserve participant confidentiality.

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Study Context

We situated our research within the context of older adults living alone in Singapore's subsidized public housing, relying on professional caregiving services provided by government-supported care centers, specifically senior activity centers (SACs). Currently, SACs are expanding their reach and services under the newly adopted designation of active aging centers. The SACs provide various services, including social activities, monitoring homebound older adults, befriending them, and responding to emergency alerts. As with any other care facility, a daunting challenge for SACs is a shortage of workforce. Therefore, AAL technologies were found to be an innovative promise to help older adults age in place, which can be defined as remaining in the community, with some level of independence, rather than in residential care [42].

Recruitment and Data Collection

Overview

Given the limited theoretical insights available, we adopted a mixed methods case study approach to explore the use of AAL technologies in this hitherto underexplored context. Our mixed methods approach consisted of semistructured interviews, a quantitative survey, and the AAL technology described in the subsequent sections.

We collected data at the individual level of analysis from 19 older adults and 2 caregivers. Drawing from our ethics review, the inclusion criteria for the older participants were (1) cognitively abled older adults living alone or with no more than 2 roommates; (2) English, Mandarin, or Cantonese speakers; and (3) members of the SAC. For ethical reasons, we excluded older adults with (1) severe disabilities, (2) reduced mobility (those who used a wheelchair), and (3) severe dementia. Older participants' demographics are presented in Table 1, with most (10/19, 53%) participants in their 70s. Participants primarily spoke Mandarin or a combination of Mandarin and English, with varied educational backgrounds ranging from no formal education to secondary schooling. Most (16/19, 84%) were widowed and lived alone, although a few (3/19, 16%) resided with 1 or 2 family members.

Table 1. Demographic characteristics of older adults in this study.

ID	Sex	Age (y)	Language	Education	Marital status	Living arrangements
ID1	Female	65	Mandarin	None	Widowed	Alone
ID2	Female	70	English	Primary	Widowed	Alone
ID3	Female	74	Cantonese and Mandarin	None	Separated	Alone
ID4	Male	79	English	Primary	Married	Family
ID5	Female	86	Mandarin	Secondary	Single	Alone
ID6	Female	67	Mandarin and English	Primary	Widowed	Family
ID7	Female	67	Mandarin	None	Widowed	Alone
ID8	Male	72	Mandarin	Secondary	Married	Alone
ID9	Male	69	Mandarin and English	Secondary	Divorced	Alone
ID10	Female	70	English	Secondary	Widowed	Alone
ID11	Female	67	Mandarin and English	Secondary	Widowed	Alone
ID12	Female	71	Mandarin and English	Primary	Widowed	Alone
ID13	Female	70	Mandarin and English	Secondary	Widowed	Family
ID14	Female	90	Mandarin and English	None	Widowed	Alone
ID15	Female	70	Mandarin and English	None	Widowed	Alone
ID16	Male	83	Mandarin and English	Primary	Divorced	Alone
ID17	Male	77	Mandarin and English	None	Single	Alone
ID18	Female	73	Mandarin and English	Secondary	Widowed	Family
ID19	Female	82	Mandarin and English	None	Widowed	Alone

Quantitative Survey

Our primary dependent variable was older adults' QOL. To assess this, we adopted the Older People's Quality of Life Questionnaire (OPQOL) [43], which captures key dimensions of QOL relevant to older adult populations. Specifically, we focused on six core domains: (1) health, (2) independence and freedom, (3) psychological and emotional well-being, (4) social relationships, (5) home and neighborhood safety, and (6) leisure and social activities.

Semistructured Interviews

To complement and build on the quantitative findings, we conducted semistructured interviews with older adults. These interviews explored 3 key areas: Older adults' perceived QOL, expectations of the AAL technology, and overall satisfaction with the AAL system following installation. First, perceived

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QOL was captured at baseline and throughout the study (Table 2). Perceived QOL included questions as follows: (1) How would you describe your QOL as a whole? (2) To what extent do you feel safe, given that you live alone? and (3) How is your relationship with the SAC caregivers? Questions related to expectations of the technology were as follows: (1) What are your expectations of this technology? (2) What do you think this technology can do for you? and (3) What would you like this technology to do for you? Questions related to satisfaction with the AAL technologies were as follows: (1) Overall, how satisfied are you with the sensor technology? (2) Would you recommend this technology to a friend or a relative? (3) What else would you like the technology to do for you? and (4) How has your relationship with the SAC caregivers changed since the technology implementation?

Table 2. Ubiquitous Service Management and Reasoning Architecture deployment details.

Region	Duration (mo)	Starting date	Homes, n	Sensors
Geylang Bahru, Singapore	1	August 2016	3	×10[a]
Geylang Bahru, Singapore	>6	March 2017	5	×10
Geylang Bahru, Singapore	>6	March 2017	5	Z-Wave
Ang Mo Kio, Singapore	>9	May 2018	6	Z-Wave

[a]10 sensors deployed throughout the 2 homes.

We included caregivers who were full-time staff members at the SAC and fluent in English, Mandarin, or Cantonese. Both caregivers were male, held the position of senior executive at the SAC, and were actively involved in caregiving responsibilities across 2 centers.

Our questions for the caregivers covered aspects of their job and how AAL technologies could help (ie, gauging expectations at baseline) and have helped (ie, gauging experiences following deployment and the older adults' perceptions of the technology). Examples of questions are as follows: (1) What aspects of your job do you like, and what aspects of your job do you find fulfilling? (2) What prospective improvements do you wish to see in your work? (3) What technologies are currently available to you in your daily work? (5) How do you think sensor-based technology can facilitate your work? (6) How do you think sensor-based technology can hinder your work? (7) To your understanding, what are some of the older adults' concerns pertaining to technology? and (8) What were some of the reasons for some individuals not providing consent to participate? All interviews were recorded and transcribed.

The AAL Technology Intervention

Overview

We developed an AAL technology platform termed Ubiquitous Service Management and Reasoning architecture (Ubismart), a live web-based platform with multiple interfaces and communication channels that are continuously expanded [44,45]. The platform has been deployed in real homes in France and Singapore. In this paper, we focused on Singapore deployments, which occurred in 3 waves with incremental features in 2016, 2017, and 2018 (Table 2).

The entire process that was organized using the NPT spanned, on average, 14 months, from ethics approvals and development to reflexive monitoring (Table 3).

Table 3. Global timeline from user needs to deployments.

Months	Activities	
	NPT[a] phase	Descriptions
1-5	Development and approvals	• Observations, discussions, and prototyping • Validation and demo • Applications for ethics approval • Initial trial and field test
5	Coherence	• Briefing sessions
6	Cognitive participation	• Recruitment sessions and baseline interviews
7	Collective action	• AAL[b] intervention deployment
8-12	Reflexive monitoring	• Feature updates and maintenance • Follow-up interviews • Data analysis and feedback
13-14	Feedback on AAL normalization	• Interviews and impact on validation

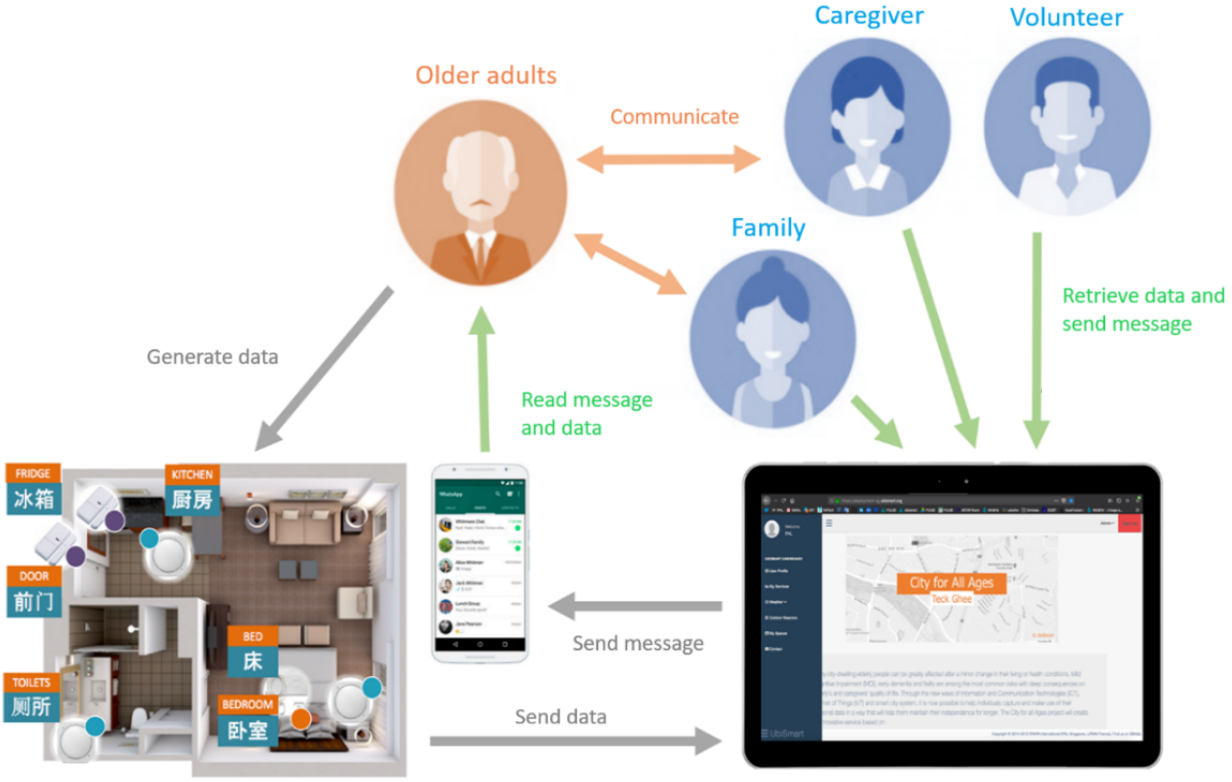
[a]NPT: normalization process theory.

[b]AAL: ambient assisted living.

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We subsequently present the components of the Ubismart system depicted in Figure 1. The system unobtrusively monitored older adults' activities of daily living (ADLs) and generated data through sensors placed in key areas of their homes. These data were then accessible to caregivers through a connected platform, allowing for remote communication, data retrieval, and message exchange to support the older adults' well-being. Ubismart consisted of 3 key modules, discussed in the subsequent sections.

Figure 1. Overview of the Ubiquitous Service Management and Reasoning Architecture setup and stakeholder interactions.

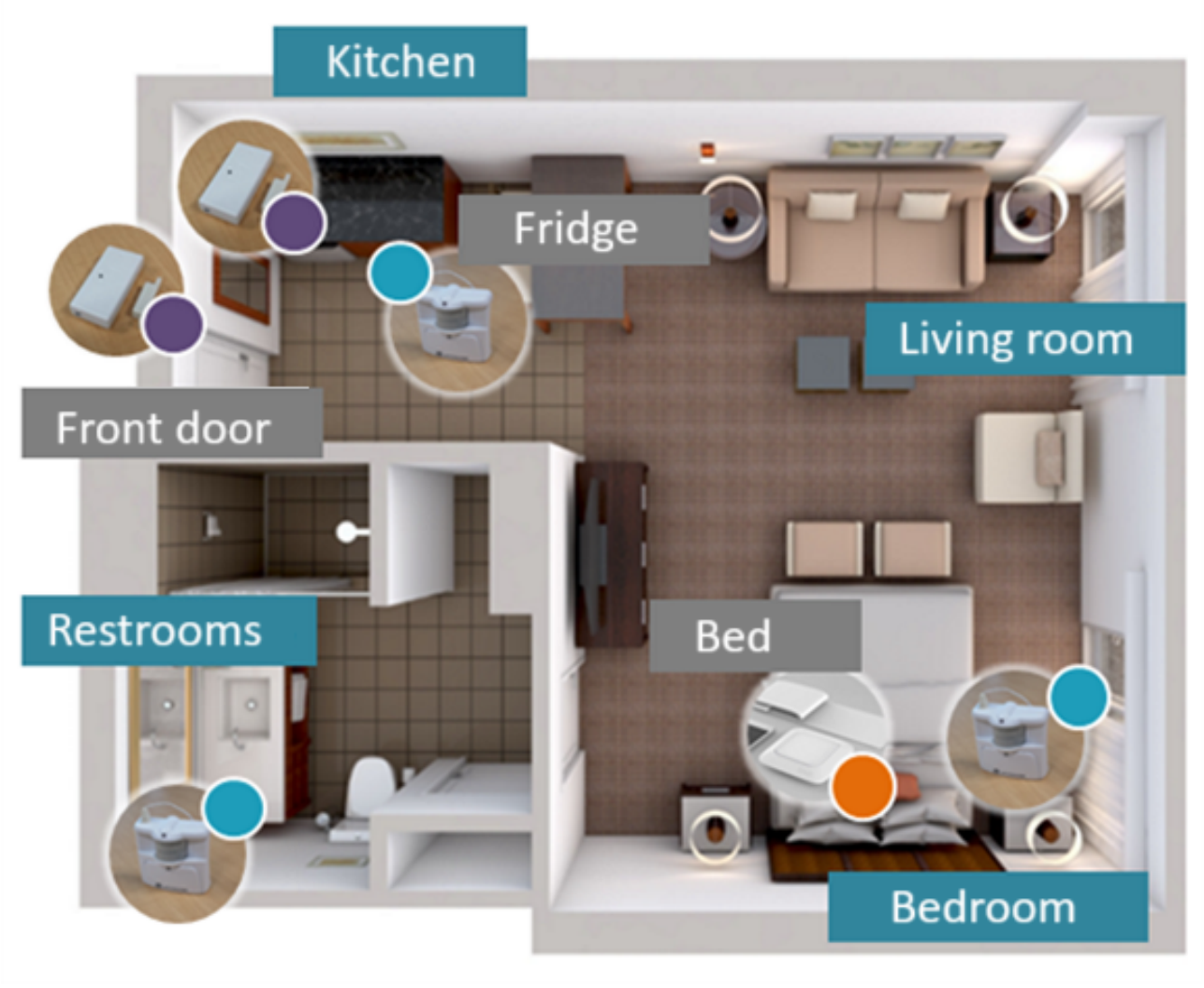


Module 1: Multimodal Sensors

Multimodal sensors with wireless data transmission capability were installed at different locations (eg, bedroom, kitchen, toilet, bathroom, and living room) to monitor and detect the activities performed by individual older adults, such as cooking, sleeping, going to the bathroom, going out of the apartment, etc. As illustrated in Figure 2, we installed (1) contact sensors on the fridge and house doors; (2) motion sensors in the kitchen, bedroom, and toilet; and (3) bed sensors under the mattress.

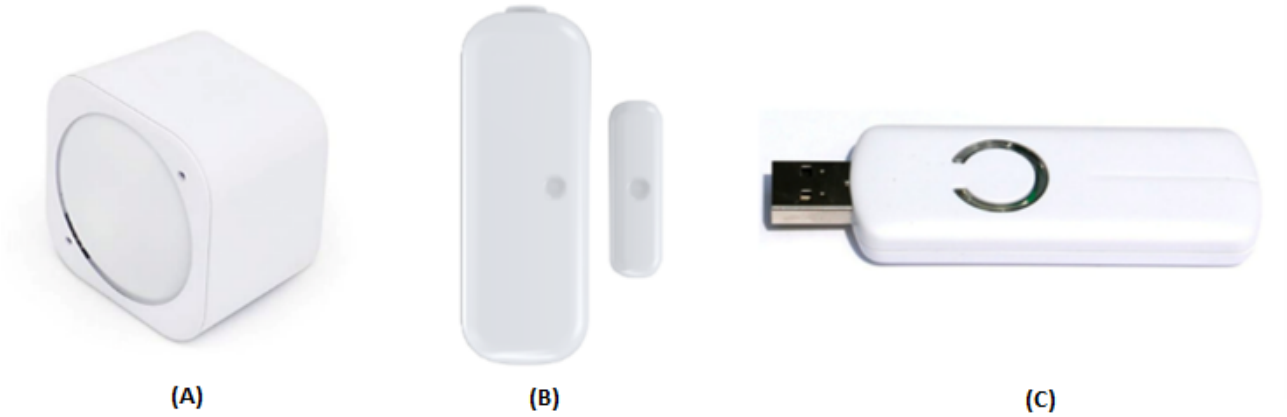
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Figure 2. Deployment layout in older adults' apartments.



Contact sensors capture when doors are opened and closed [46]. Motion sensors emit a signal when there is a significant change in the infrared spectrum; therefore, they are used to detect movement (Figure 3). The technical specifications of the sensors are discussed elsewhere [47].

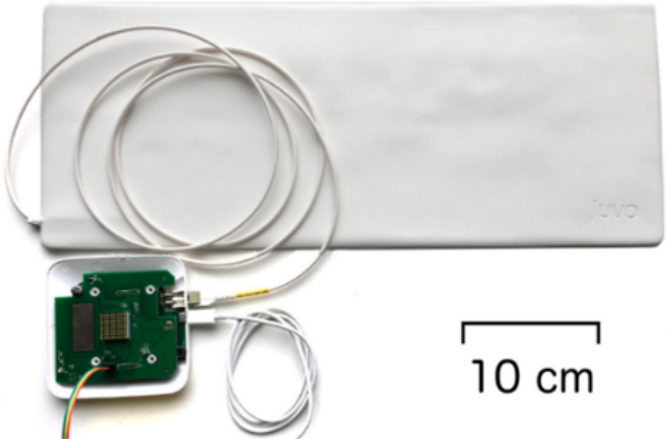
Figure 3. Z-Wave equipment—multisensor (eg, motion and humidity temperature), contact sensor, and Z-Wave receiver (from left to right).



The microbend fiberoptic pressure sensor mat, developed by Juvo Labs Pte Ltd (Figure 4), was placed unobtrusively below the bed mattress or sheet to measure heart rate and respiratory rate during sleep. This mat provides information on sleep parameters, such as sleep-wake rhythms, and can be used to detect sleep disorders. Technical specifications of this mat and related algorithm development are published elsewhere [47-50].

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Figure 4. Sleep mat from JUVO.



The collected data were transferred through a secure gateway with a Raspberry Pi (Raspberry Pi Foundation) to a dedicated server for data processing and analysis. A Raspberry Pi is a pocket-sized computer commonly used in IoT applications because of its small size and ability to run Unix-like systems that ease the portability of algorithms (Figure 5). Our installation was strictly devoid of any video and audio processing or recording to respect the privacy of our participants.

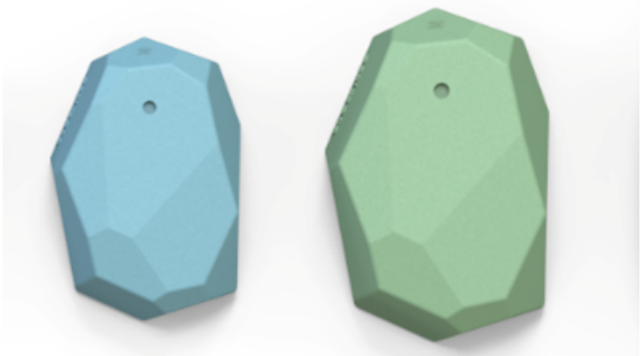
Figure 5. Raspberry Pi 3 Model B.



Module 2: Bluetooth Beacons

We strategically placed Bluetooth beacons from Estimote (Figure 6) in public areas to track the engagement of older adults in outdoor events organized by the SAC. These activities included gardening sessions, bingo games, and various social gatherings. It is important to note that the beacons do not receive or process any data, and they are not aware of any detections. They are placed at specific locations, and at regular intervals, they emit their own identifiers. The tracking is performed using a custom-made smartphone app that detects these signals and sends data to our servers.

Figure 6. Bluetooth beacons.



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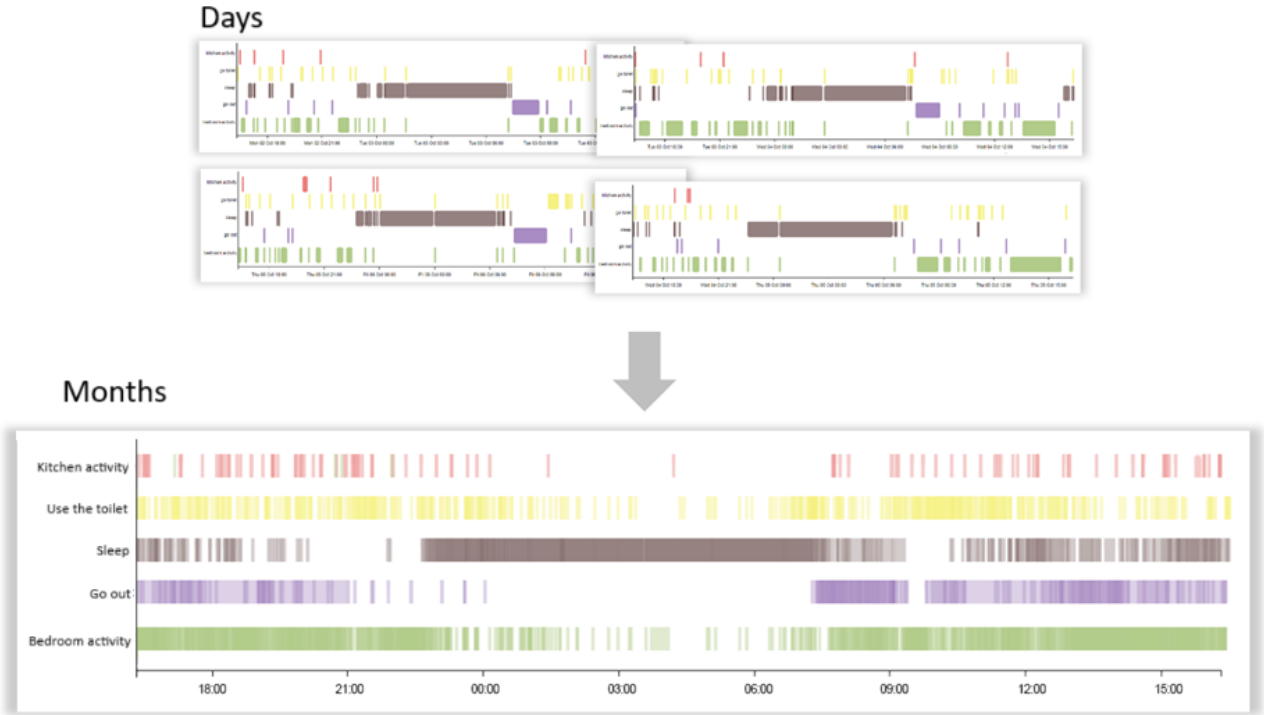
Module 3: Mobile App

The data from the sensors were processed in real time to provide a visualization of older adults' activities on a mobile app, as schematized in Figures 7 and 8. This app was accessible to the local staff at the SAC and the adults' relatives (if applicable). The goal of the app was to provide information on older adults' QOL in a cognitively efficient manner. As shown in Figures 7 and 8, visualized data included sleep duration, relative duration spent indoors and outdoors, and washroom and kitchen activities [51,52]. Caregivers received notifications of any irregularities (ie, deviations from the established baseline) through the mobile app. The baseline ADLs for the older adults were established through comprehensive semistructured interviews before deployment (Table 3). Risk alerts were activated when there were indications of significant and concerning behavioral changes. These could be detected through various parameters, including reduced participation in social events (as recorded by SAC data); noticeable deterioration in performing basic ADLs, including mobility or challenges in preparing meals during regular hours; and a decrease in sleep quality or sleep-related concerns.

Figure 7. Screenshot of an older adult's activities of daily living in Ubiquitous Service Management and Reasoning Architecture.



Figure 8. Personalized processing to detect deviations from older adults' baseline data.



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Shortcomings of Previous AAL Technologies Versus This Study's Approach

Having described the Ubismart system, we turn to how it deviates from systems in previous literature. As mentioned, the number of studies on AAL technologies started to soar around 2015 [53], meaning that our deployment was one of the first studies to use AAL technologies in the care of older adults, with our first deployment in August 2016 (Table 2). Previous and current AAL technology deployments made use of audio or visual input. This is an increasingly pressing issue that our deployments avoided by excluding these sources of information. Privacy and fear of recordings are important aspects during deployments. From a technical perspective, we realized the concept of a "smart home in a box" by developing a system that can be deployed in any environment within 30 minutes. This was achieved through efforts to streamline sensor registration and create an easily extensible system built on semantic web principles [54,55]. In addition, our proprietary algorithms enabled noninvasive sleep tracking and could detect potential respiratory issues [56].

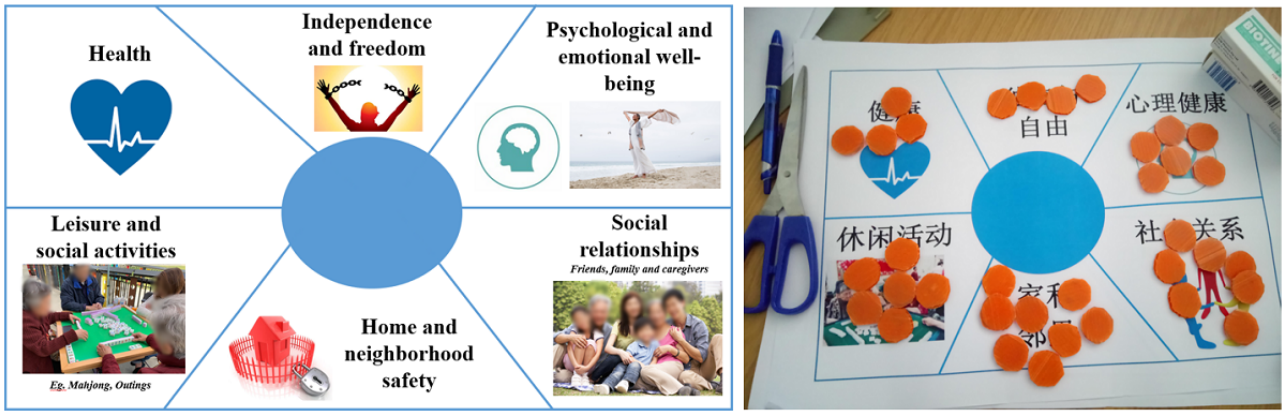
Results

Quantitative Survey: the Impact of Ubismart on QOL

As outlined earlier, we had initially planned to assess QOL using the validated OPQOL instrument. However, pilot testing revealed significant difficulties. Many participants, especially those with no formal education (7/19, 37%) or only primary schooling (6/19, 32%), struggled to meaningfully differentiate between points on the Likert scale, even when the survey was translated into local dialects. These challenges posed a risk of introducing measurement error and participant disengagement.

To ensure comprehension and more meaningful self-expression, we developed a gamified version of the QOL assessment (Figure 9). Participants were given 35 coins and asked to allocate those across 6 core QOL dimensions. The root question was simplified to "How do you feel you are doing in each of these areas?" The number of coins assigned to each domain served as an intuitive proxy for participants' self-assessed well-being in that area.

Figure 9. The gamified quality of life measurement tool.



We selected 35 coins to strike a balance between simplicity and sensitivity. The number was large enough to allow participants to express meaningful variation across the 6 domains while still being cognitively manageable for older adults with limited numeracy.

Using data collected through the gamified QOL assessment tool, we conducted a paired sample, 2-tailed *t* tests to examine whether the installation of AAL technology led to significant changes in the distribution of perceived well-being across QOL domains. Because the total number of coins (n=35) was fixed at all time points, our focus was not on changes in overall QOL scores but rather on how participants reallocated their perceived well-being across individual dimensions. Because the assessment was simplified to the domain level, we interpreted any meaningful shifts in specific domains as indicative of potential changes in participants' overall QOL.

When we analyzed QOL across its individual dimensions, 2 areas showed statistically significant gains. For leisure and social activities, participants reported a significant increase in scores following the intervention (before: mean 2.67, SD 2.29; after: mean 4.67, SD 1.22; *P*=.03), indicating enhanced social engagement and participation. Similarly, psychological and emotional well-being improved significantly (before: mean 5.44, SD 1.51; after: mean 6.78, SD 1.48; *P*=.01), suggesting a positive impact on emotional stability and mental wellness.

No statistically significant changes were observed in the dimensions of health, independence and freedom, social relationships, or home and neighborhood safety (all *P*>.05). The absence of change in "independence and freedom" was expected, given that the system was designed to be unobtrusive and did not alter participants' physical mobility or routines. Similarly, "health" was largely outside the scope of the AAL system, which did not provide direct medical interventions. However, the lack of significant changes in "social relationships" and "home and neighborhood safety" was unexpected. These findings are further explored in the A Qualitative Narrative of the Impact of Ubismart on Older Adults' QOL section, which offers deeper insight into how participants perceived and experienced these domains beyond what was captured through quantitative measures.

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A Qualitative Narrative of the Impact of Ubismart on Older Adults' QOL

Overview

Triangulating findings from the quantitative analysis, our semistructured interviews likewise did not reveal any perceived impact on health and independence and freedom. As mentioned earlier, this was not unexpected. First, participants might have attributed their health status primarily to age-related conditions, and the system itself did not offer medical functions or interventions. In addition, no major health events occurred during the 14-month study period that would have activated the system's monitoring features. Second, participants continued to age in place, and the unobtrusive nature of the intervention meant their autonomy and routines remained unchanged, factors that likely contributed to a stable sense of independence and freedom.

In the subsequent sections, we have presented qualitative findings for the remaining 4 QOL dimensions: emotional well-being, safety, leisure and social activities, and social relationships. We highlighted how participants described the intervention's perceived impact in each area.

Home and Neighborhood Safety

Safety emerged as one of the most frequently discussed and emotionally resonant themes in the qualitative narratives, even though it did not register as statistically significant in the quantitative analysis. Participants consistently described a heightened sense of home-based safety, citing reassurance during emergencies, confidence in being monitored, and peace of mind while sleeping alone.

While the quantitative instrument combined home and neighborhood safety into a single construct, participants' narratives overwhelmingly emphasized in-home safety, suggesting that this specificity may have been masked in the statistical findings. These qualitative accounts highlighted that, even without measurable shifts in coin allocations, participants experienced the intervention as increasing their sense of security within their living spaces. The following quotes illustrate these perceptions:

> *I feel safer...* [Participant 2]

> *I feel that it [Ubismart] is very good for its sense of safety. If anything happens to me, [the caregivers] would know...If nothing is happening for the time being, then all is good...While we sleep at night, we feel safer.* [Participant 10]

Psychological and Emotional Well-Being

The deep-seated fear of dying or struggling alone, reflected in the Introduction section [1] and echoed by many older adults in our study, was a central theme in participants' narratives about psychological and emotional well-being. While the AAL system was not designed to provide emotional care, its unobtrusive presence appeared to ease anxieties and offer a sense of psychological reassurance. Indeed, both quantitative and qualitative data pointed to improvements in psychological and emotional well-being, making this one of the strongest areas of alignment across methods. Participants frequently described feeling calmer, more secure, and less fearful since the installation of Ubismart. The system was perceived not just as a technological safeguard but as a "silent companion" that offered comfort in the absence of continuous human presence. The following excerpts illustrate this enhanced psychological and emotional state:

> *Without your [the team's] help, my troubles will still persist. As [a senior], I have so much to be fearful of. But with these sensors, I feel so much at ease. I need not fear anything. It's better than not having the sensors...It's like having someone by my side...Without the sensors, there's nothing else I have; who else other than God can I ask?* [Participant 5]

> *It's psychology. You feel more confident, you feel more secure. It's the psychology.* [Participant 6]

> *It is like having insurance for us. If anything happens to us, the [caregivers] will know, for example, if we have a fall. So, the sense of safety is very good...It is like my personal insurance, which is very good for me.* [Participant 7]

These individual accounts were echoed by caregivers, who also observed shifts in the participants' sense of security:

> *They feel that there is a heightened sense of security, meaning that even when they are at home, they have a better peace of mind with this technology.* [Caregiver 1]

Leisure and Social Activities

Quantitative analysis showed a statistically significant improvement in leisure and social activities, suggesting increased participation or engagement following the intervention. However, this domain was not particularly salient in older adults' qualitative narratives. When probed, most participants did not mention any changes in their social routines or activity levels that they attributed to Ubismart. To better understand this discrepancy, we consulted the caregivers, who offered a potential explanation:

> *...the whole deployment doesn't really affect their sense of independence and [SAC activities]. Those who before this research project are regular participants continue to be regular participants for the SAC's activities or community events. Those who are mostly home-bound continue to stay home-bound.* [Caregiver 2]

Social Relationships

Surprisingly, our findings revealed a mixed impact on the domain of social relationships. While some participants described strengthened bonds with caregivers following the deployment of Ubismart, others expressed feelings of being overlooked or less visible. One older adult noted that caregivers had become more attentive:

> *They have become more caring, clearer, and more understanding.* [Participant 10]

In contrast, another participant conveyed a sense of isolation:

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> *I just hope that those downstairs [the caregivers] will look up to the old people more often. I am lonely in this flat and should have someone come up to visit me, right...Here is [senior] who cannot conveniently move her hands and legs, and yet there is no one to visit.* [Participant 5]

These divergent perspectives reflected the nuanced reality of digitally supported care in a low-income, high-need setting. In this study, most (16/19, 84%) older adults lived alone in subsidized rental housing and had limited or no regular contact with close family. For many, SAC caregivers represented their most consistent and trusted source of support not only for physical well-being but also for emotional connection and social presence. In such a context, even subtle shifts in caregiver engagement were felt acutely.

It is important to note the clear differences among these older adults. Participant 10 was relatively frail, while participant 5 was healthier and more independent. According to the caregiver, standard protocol required visiting older adults who needed more support 3 times a week, while healthier older adults received 2 visits per month. The caregiver further explained that if the Ubismart app showed no anomalies and the older adults remained active at the SAC, they sometimes forwent additional visits due to limited resources:

> *So, [participant 5] is not exactly frail and vulnerable, so it is a subjective comment, but I should say that sometimes this thing about home visits is because [participant 5] and [participant 10] are the more regular participants in the center. They come to the center on a weekly basis, at least three or four times. So, as long as the center gets to see them, interact with them, and understand whether they are okay or good for that day or that week. That is also a form of outreach.*

While some older adults interpreted Ubismart as a sign of care, others perceived it as a potential substitute for relational presence, a perception that risks reinforcing feelings of abandonment if not accompanied by continued in-person interaction. However, caregivers also highlighted that Ubismart facilitated deeper relational exchanges. The mobile app served not only as a monitoring tool but also as a conversational catalyst:

> *We have a more in-depth understanding of the [older person's] daily condition. We will use [the app] as a conversational starter so that we will get into a more in-depth interaction with them and be more able to care for particular characteristics.*

In fact, the technology was especially welcomed in light of staffing limitations. One caregiver explained the following:

> *So currently, we have five [full-time caregivers] as per headcount, so it's [divided with the other] SAC...so it's just two staff per center. Our latest estimate is slightly more than 800 [older people]; about 400 belong to the rental units, and the rest are all from the nearby blocks.* [Caregiver 1]

Against this backdrop, caregivers appreciated Ubismart's ability to extend their reach while maintaining dignity and privacy for older adults:

> *We are very supportive of this because we feel this approach is nonintrusive. It respects the seniors' privacy...and we are able to ensure that they are okay at home.* [Caregiver 2]

These reflections reinforced the view that AAL technologies, when thoughtfully implemented, could serve as a bridge rather than a barrier to meaningful human connection, especially in contexts where caregiving capacity is stretched thin.

Concerns of the AAL Technologies

Although our primary focus was on QOL, we also explored participants' broader experiences with the Ubismart system, including any concerns that arose during its use. As with many technological interventions, older adults expressed several reservations. Through open coding of the interview data, we identified 5 key concerns. The first related to electricity consumption, which was raised both during interviews with the research team and in conversations with SAC caregivers:

> *I asked them, "Why [is] my electric bill very high?" [The caregiver said] "No, you got a sensor, but this one is like a battery."* [Participant 2]
>
> *I think one of the most common [questions] is whether it consumes a lot of electricity. But right now, based on the 19 participants, they are aware that these things don't take much electricity.* [Caregiver 2]

Second, privacy violation was a major concern in the beginning. The older adults suspected that the sensors might have video recording capabilities. Some took afternoon naps on their chairs instead of the bed out of fear that the bed sensor would capture it, and they might be judged for unproductivity. However, we explained to the older adults that the goal is to keep them safe and not judge their sleep patterns. In addition, privacy concerns waned over time as the older adults understood that the sensors did not have video recording capabilities. This is reflected in the following quote:

> *I was initially concerned about the sensors taking videos in the toilet. But later I got used to it.* [Participant 6]

Third, physical harm was a major concern for one of the frail participants. She suspected that the sensors were the cause of her body pain:

> *I'm scared [that] maybe the [sensors] are affecting my whole legs...now my legs cannot go up, [it's] very painful* [Participant 2]

As a result, she wanted to uninstall the sensors. After reassurance from her nurse that the pain was not attributable to the sensors and that the sensors would be beneficial in case of an emergency, the participant chose to continue using the technology:

> *I asked if it's better for them [the team] to take out [the sensors], but the nurses said, "No, no need, no need because it is better for you." They're scared [if*

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> *anything happens] when I go to the toilet and fall down or sleep and cannot wake.*

Fourth, two participants had concerns about the inconveniences caused by technology in some ADLs, such as cleaning:

> *I personally don't like the sensors under the bed. Every time I clean under the bed, it drops, and I do not know how to put it back. If I lay it on the floor, it looks untidy as well.* [Participant 3]

> *[It is already difficult] to clean the floor. Last time, I could clean. But with the sensors, I cannot [clean].* [Participant 2]

After a closer look at the sensors, we found that the bed sensor required an extension cable, which we informed the older adults could be elevated to not obstruct the cleaning. This resolved the issue. Once the aforementioned concerns were addressed, most of the participants were satisfied with the system. They seemed happy to have something new in their home. We believe that they felt special to have been chosen to participate in this study because the older adults consistently asked if the sensors could be left at their homes after the study had ended.

Fifth, fears about radiation exposure unexpectedly emerged as a key barrier to participation. Although we had addressed more common concerns, such as electricity consumption, privacy, and cleaning inconveniences, our initial planning did not anticipate that some participants might associate ambient sensors with radiation risk. During the initial briefing, one older adult who appeared to be an informal leader among peers voiced this concern and declined to proceed with installation. His decision significantly influenced others, some of whom had previously agreed to participate, leading to a noticeable drop in participation.

Lessons Learned and Recommendations

Overview

The subsequent sections present lessons learned at different phases of the AAL technologies' integration and normalization process. Before outlining specific insights, we reiterate the distinctiveness of the study context to make it salient for interpreting the recommendations mentioned subsequently. As previously described, our participants were older adults living in heavily subsidized rental housing in Singapore. Many (16/19, 84%) lived alone, had little or no regular contact with close family, and depended heavily on staff at the SACs as their primary source of emotional and social support. In this context, caregiving relationships were not merely transactional. They were deeply relational and, for many participants, irreplaceable. This high-need, low-resource environment shaped how the Ubismart intervention was introduced, understood, and integrated into daily life. The recommendations presented in this section are thus grounded in and should be interpreted through this unique caregiving and social ecosystem.

Coherence

Coherence refers to how individuals and collectives make sense of a new intervention, that is, what it is, why it matters, and how it fits into their lives [14,39]. In this study, fostering coherence required more than technical explanation; it demanded sensitivity to the lived realities of older adults who relied heavily on SAC caregivers for trust, translation, and emotional anchoring. Recognizing that caregivers played a pivotal role in participants' day-to-day lives, we engaged SAC staff members early and invited them to colead participant briefings. Their presence not only facilitated translation because many (16/19, 84%) older adults communicated in Hokkien, Mandarin, or Cantonese but also lent credibility to the project. Because SAC caregivers were often viewed as family-like figures, their involvement helped older adults feel reassured and respected during the introduction of Ubismart. On the basis of these insights, we present some recommendations.

The first recommendation is to engage trusted caregiving intermediaries early and include them in participant briefings, as their involvement plays a critical role in fostering coherence by translating, legitimizing, and contextualizing the intervention.

The second recommendation is to deliver briefings in linguistically and culturally appropriate formats, such as using translated materials, visual aids, and caregiver-facilitated discussions, to ensure understanding among older adults with diverse language abilities and educational backgrounds.

Cognitive Engagement

Cognitive engagement focuses on individuals' active participation in the intervention [14,39]. Routine integration of AAL technologies into older adults' care hinges on their willingness to actively engage in field deployment and commitment to maintaining the presence of ambient sensors within their homes. In our context, we initially assumed that older adults' trust in SAC caregivers, coupled with a clear understanding of the AAL system's benefits, would translate into widespread acceptance. However, our experience revealed that this assumption overlooked the layered dynamics of peer influence and perceived risk, which proved critical to engagement.

Despite initial enthusiasm, a subset of participants opted out of deployment due to fears surrounding radiation exposure, a concern introduced by one particularly influential older adult. This individual's withdrawal prompted others to follow suit. Notably, this occurred even after the system's safety and privacy features were explained. While the Ubismart system used only low-power, off-the-shelf electronics, technical reassurance alone was insufficient to counteract socially transmitted anxieties. This experience highlighted that engagement depended not only on formal information channels but also on informal social dynamics. Surfacing and addressing these perceived risks (however unfounded) required relational attentiveness and not just technical accuracy. Drawing from this, we make further recommendations.

The third recommendation is to identify and engage both formal (eg, SAC caregivers) and informal (eg, respected peers at the SAC) influencers early in the process. For older adults who spend much of their time in communal settings, peer relationships significantly shape perceptions and decisions. Addressing perceived risks requires not only technical transparency but also relational attentiveness and messaging that resonates with these trusted figures.

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The fourth recommendation is to provide ample time for reflection on the proposed intervention. Although we asked the older adults about their concerns at the joint briefing, we may not have given them sufficient time to reflect. Therefore, it would be best to allow older adults sufficient time (eg, a few days) for reflection, encouraging them to document their apprehensions for a thorough concern mitigation process.

The fifth recommendation is to facilitate low-pressure, small-group discussions at SACs where participants can share thoughts with peers and caregivers. These informal settings encourage open dialogue and can serve as early warning systems for surfacing emerging concerns or misinformation. They also provide a trusted space for gently debunking myths, such as health risks from sensors, through respectful, peer-sensitive conversation.

Collective Action

Collective action addresses how stakeholders within an ecosystem work together to enact the new intervention [14,39]. In the context of this study, successful deployment of Ubismart required not only technical infrastructure but also thoughtful collaboration between older adults and SAC caregivers to ensure the system was meaningfully integrated into everyday life. While our team gleaned many general insights about sensor placement, connectivity, and troubleshooting (eg, SIM card recharging, battery drain, and optimal sensor placement), we focused on lessons uniquely shaped by our study context—a dense, low-income housing estate in Singapore where older adults often lived alone, had limited family interaction, and relied heavily on SAC caregivers for daily support.

A critical insight that emerged during early deployment was the influence of “saving face,” a deeply rooted cultural value in many Asian societies. Face is the social esteem accorded by others or the respectability or deference that a person can claim for themselves from others by the degree to which they are judged to have behaved appropriately [57]. To avoid losing face, one participant reported napping on a chair rather than on the bed so her rest would not be captured by the bed sensor. She feared that being seen as inactive during the day might reflect poorly on her. The technology itself did not drive this concern but a broader social anxiety around appearing unproductive or burdensome did.

This behavior underscored a central challenge in the era of big data, namely data accuracy. Sensor-based systems like Ubismart generate large volumes of behavioral data that, if interpreted without cultural context, can misrepresent reality. Inaccuracies, especially those stemming from altered behavior due to social pressure, pose a serious threat to the quality and utility of big data in AAL systems. Ensuring data integrity requires building environments where users feel safe to act naturally. To support this, clear and culturally sensitive messaging is essential. Repeatedly emphasizing that the system is not intended to evaluate or penalize routine behaviors but instead to detect deviations that may signal distress can prevent compensatory behaviors that compromise data fidelity. Therefore, we make some recommendations mentioned subsequently.

The sixth recommendation is to reinforce early and often that the goal of the AAL system is to detect anomalies and not to surveil or judge daily behavior. This framing supports cultural values like dignity and reduces compensatory behaviors that compromise data quality.

The seventh recommendation is to leverage peer-led and caregiver-facilitated discussions at SACs to build trust and clarify how sensor data are used. These relational channels help reduce fear, promote natural behavior, and improve data reliability in a context where both peer influence and caregiver relationships are central.

Along the same vein of data accuracy, one of the core challenges in big data systems like AAL is maintaining reliable sensor performance over time. In our context, many (16/19, 84%) older adults lived alone and lacked the technical know-how to detect or report sensor issues, while SAC caregivers were already operating at full capacity. This made routine manual checks unfeasible. However, regular interactions with peers and caregivers at the SACs present a culturally grounded opportunity. By integrating informal sensor checks into existing social routines, such as weekly visits or group activities, we can support data reliability without adding strain to caregiving staff. Therefore, we make the recommendation mentioned subsequently.

The eighth recommendation is to leverage trusted peer and caregiver networks to identify sensor issues. SAC caregivers and socially influential peers should be equipped with simple cues to detect malfunctions, and informal checks during regular interactions should be encouraged. These efforts should be paired with automated alerts for a hybrid approach to reliability.

Reflexive Monitoring

This phase of the NPT is concerned with how users will perceive the intervention once it has been in use for a while [14,39]. In our study, both older adults and SAC caregivers perceived Ubismart as a helpful, dignified addition to daily routines. Caregivers reported that the system facilitated more personalized and proactive care, while older adults described a growing sense of safety, particularly within the home environment. This perceived security appeared to catalyze subtle behavioral improvements, including increased confidence and reduced anxiety, aligning with the statistically significant gains observed in psychological and emotional well-being.

However, the same system also revealed unintended consequences. As the technology assumed a more active monitoring role, some participants perceived a decline in relational contact. While caregivers relied on Ubismart to allocate limited resources and prioritize high-need cases, this shift risked reinforcing feelings of neglect or abandonment among older adults who previously received more frequent visits. In the context of this study, where most (16/19, 84%) participants lived alone and SAC caregivers served as their main source of emotional support, the reduction in in-person interactions carried emotional weight.

These dynamics underscored a core tension in digitally supported care; while ambient technologies might improve efficiency and safety, they could inadvertently diminish the

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very human connections older adults value most. Therefore, reflexive monitoring requires ongoing attentiveness not only to technical metrics but also to lived experiences and shifting care relationships. Drawing from the aforementioned lessons, we present two recommendations.

The ninth recommendation is to embed structured opportunities for older adults and caregivers to share how technology affects their care experiences and relationships. These feedback mechanisms not only surface unintended consequences (eg, reduced visit frequency) but also provide a relational check on system use, reinforcing dignity, trust, and care continuity.

The 10th recommendation is that in high-need, low-resource settings, where caregivers are the primary source of support, AAL technologies should augment relational care and not replace it. To address capacity gaps, caregivers should partner with community volunteers, students, or nonprofits to ensure older adults' emotional and social needs are met.

Discussion

Principal Findings

Motivated by the shortage of longitudinal studies on the integration of AAL technologies in older adults' care, especially in Southeast Asia, we used an in-depth case study to explore the deployment and impact of an AAL technology, which we termed Ubismart, on older adults' QOL. Our study revealed that AAL technologies positively impacted certain QOL dimensions for older adults, particularly enhancing psychological well-being and a sense of security. Many participants reported feeling safer with the technology, describing it as a reassuring presence in their homes. However, the impact on social relationships was mixed; while some older adults felt more cared for due to the technology, others experienced fewer in-person visits and a sense of isolation, as caregivers increasingly relied on AAL systems for monitoring.

Key lessons emerged regarding the integration and normalization of AAL technology. First, to establish coherence, it is essential to prioritize culturally grounded and relationally sensitive strategies that help older adults understand the purpose and relevance of AAL technology. Involving caregivers (ie, trusted figures in participants' lives) in joint briefings would be especially effective in building trust and reinforcing the system's value within existing care relationships. Second, to support cognitive engagement, it is crucial to recognize that adoption is shaped not only by formal caregivers but also by influential peer networks within the ecosystem. In our study, a single participant's concern about radiation led others to withdraw, demonstrating how quickly skepticism can spread in tightly connected communities. Third, collective action requires sensitivity to cultural norms such as saving face. Some participants altered their behavior, such as napping on a chair, to avoid perceived judgment. Reinforcing that the system monitors for anomalies, not habits, is key to preserving data accuracy. Finally, reflexive monitoring brought attention to an important unintended consequence; while the technology promoted safety, it also inadvertently reduced social interactions for some older adults, highlighting the need for vigilance in balancing AAL technology's benefits with ongoing human connection.

Comparison With Prior Work

As mentioned earlier, much good work has been done on the use of AAL in the care of older adults. Similar to other projects, including HomeAssist [58] and NESTORE [59], both conducted in the European Union, our intervention supported aging in place by offering unobtrusive monitoring. Overall, our findings align with previous AAL studies that reported improved QOL among older adults [60,61]. However, our work contributes novel insights into several key areas.

First, as Taramasco et al [60] mentioned, data pertaining to QOL are scarce. They highlighted the methodological challenge of having to adjust for baseline imbalances in QOL measures before detecting a significant effect, underscoring how sensitive and complex this construct can be to capture. Our study contributes to this conversation not only by examining QOL outcomes but also by reflecting critically on the measurement process itself. We document the challenges of using standard Likert-based tools with older adults who have limited formal education and propose a culturally adapted, gamified alternative that offers a more accessible way for participants to express their perceived well-being. This approach enables us to surface meaningful shifts in specific QOL domains while also contributing to a broader methodological discussion on how best to measure QOL in underserved populations.

Second, recent works have shown that about 5 countries (ie, the United States, the United Kingdom, France, Canada, and Japan) have been leading research in AAL technologies thus far, and of these 5, only Japan has a collectivistic culture [62]. Answering the call for more research from diverse cultures [62], our study offers rare empirical insights from a subpopulation within a collectivistic culture. Specifically, we focused on older adults in Singapore who, despite living in a society that values familial interdependence, often experience social isolation due to impoverishment, limited education, and estrangement from close family. These older adults reside in heavily subsidized housing and depend primarily on caregiving staff at community-based SACs for emotional and social support. Unlike the typical AAL studies conducted in individualistic, high-resource settings, our work surfaces how the adoption and routinization of AAL technologies are mediated by unique cultural and relational dynamics, including peer influence, saving face [57], and the central role of institutional caregivers. These findings highlight the importance of designing AAL systems not only for technical robustness but also for cultural fit and relational integration within the lived caregiving ecologies of susceptible older adults.

Third, the OPQOL is one of the most widely used and validated instruments for assessing QOL in older adult populations, offering a multidimensional perspective that includes domains such as health, independence, social relationships, emotional well-being, and home and neighborhood safety [43,63]. However, our findings suggest that this latter domain, particularly in both the full [43] and brief versions [63] of OPQOL, may mask intervention-specific effects when home and neighborhood safety are treated as a single construct.

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Although our quantitative analysis using a gamified proxy of the OPQOL did not show a statistically significant change in the aggregated safety domain, qualitative narratives consistently revealed an increased sense of home-based safety. Participants described feeling reassured knowing help would be available during emergencies, especially at night or when living alone. In contrast, neighborhood safety was rarely mentioned and remained largely unaffected by the intervention. While the OPQOL-brief includes the item "I feel safe where I live," this phrasing still conflates 2 distinct contexts. On the basis of our findings, we suggest that future studies consider explicitly separating this domain into "I feel safe at home" and "I feel safe in my neighborhood" to more accurately detect the localized effects of AAL interventions and avoid measurement dilution.

Taken together, these contributions reinforce the need for culturally sensitive, relationally grounded, and methodologically flexible approaches to designing and evaluating AAL technologies, particularly in diverse, underrepresented populations.

Limitations

As with all research, this study is not without its limitations. We highlight 3 limitations that we believe are particularly important. First, a potential limitation of this study is that we focused on one context, Singapore. While the findings of our study may be generalizable to similar cultures (ie, collectivistic), some of our findings, especially pertaining to the relationship between older adults and caregivers, may not be applicable in individualistic cultures. However, our goal was to explore a context-specific understanding of the routinization of AAL technologies in this hitherto under-studied context. In doing so, we answer calls for research that redirects focus from general theories of technology use to context-specific theorizing [64]. Second, even though we explored our study context comprehensively, by having 19 older adults in this study, we are again unable to claim broad generalizability of the proposed recommendations. More research is needed before such claims can be made. However, we note that our sample size is comparable to similar studies with sample sizes ranging from 9 to 20 [24,29], owing to the cost of deployment. Third, we used a validated measure of QOL that is largely used in Western contexts [43]; therefore, our participants struggled to understand it, and we had to improvise and create the "gamified QOL measurement tool" as a conversation starter. Indeed, QOL may be experienced differently based on demographic differences [65].

Future Directions

Future research should address the aforementioned limitations to enhance the study's robustness and applicability. First, cross-cultural studies that examine AAL technology use in both collectivistic and individualistic contexts could provide insights into the role of cultural values in shaping older adults' and caregivers' dynamics. This would help determine the extent to which our findings apply beyond Singapore. Second, while our sample size aligns with similar studies, larger and more diverse samples would strengthen the generalizability of our recommendations. Future studies could partner with health care organizations to increase sample size and diversity. Finally, developing culturally responsive QOL measurement tools would mitigate the challenges we encountered with Western-centric QOL assessments, allowing a more accurate understanding of well-being across diverse populations.

Conclusions

In conclusion, this study highlights the promise of AAL technologies in addressing the challenges faced by older adults living independently; however, it underscores that no technology is a panacea. While AAL tools can enhance safety, social connection, and QOL, they cannot fully substitute for the support systems that older adults need. Future research should continue to explore these technologies' potential across different cultural contexts and emphasize the importance of complementary social and familial support in promoting older adults' well-being.

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Conflicts of Interest

None declared.

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Abbreviations

AAL: ambient assisted living
ADL: activity of daily living
IoT: Internet of Things
NPT: normalization process theory
OPQOL: Older People’s Quality of Life Questionnaire
QOL: quality of life
SAC: senior activity center
Ubismart: Ubiquitous Service Management and Reasoning Architecture

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Original Paper

Enhancing Self-Efficacy Through Robotic Safety Support in Balance-Challenging Reach Tasks: Feasibility Study in Young Adults

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Abstract

Background: Falls and fear of falling adversely affect the quality of life and independence of older adults. Although various robotic systems have been developed for fall prevention, their psychological effects, particularly on self-efficacy, remain underexplored. A ceiling-mounted fall impact mitigation robot offers continuous protection with almost no limitations on the range of movement; however, its impact on users' psychological state and functional performance is unclear.

Objective: This study aimed to evaluate the effect of a fall impact mitigation robot on psychological reassurance and task performance during dynamic balance tasks in healthy young adults, with a focus on self-efficacy and functional reach capacity.

Methods: Twenty-four healthy adults (age: mean 28.9, SD 7.9 years) were randomly assigned to experimental (n=12) or control (n=12) groups. All participants performed a baseline functional reach test, followed by a series of progressively challenging reach tasks (starting at 98% of maximum reach and increasing by 2% until failure). The experimental group performed tasks while wearing the fall impact mitigation robot; the control group performed without it. Self-efficacy ratings (–5 to +5 scale) were recorded before each trial. Center of pressure (COP) data were continuously collected. Statistical analyses included Mann-Whitney *U* tests for self-efficacy, Kaplan-Meier survival analysis for task performance, and *t* tests for functional reach test and COP changes.

Results: During reach trials ≥102% of baseline, the experimental group (median 1.0, IQR 0.0 to 3.0) reported significantly higher self-efficacy ratings than did the control group (median 0.0, IQR –1.0 to 2.0; U=1292.5; P=.047). However, no significant differences were observed in changes in functional reach capacity (experimental: mean 104.2%, SD 3.8%; control: mean 103.6%, SD 2.5%; P=.62) or COP displacement (experimental: mean 108.9%, SD 10.4%; control: mean 114.1%, SD 9.8%; P=.23). Survival analysis revealed a nonsignificant trend toward greater task persistence in the experimental group (χ^2_1=0.36, P=.55).

Conclusions: The fall impact mitigation robot significantly improved self-efficacy during challenging balance tasks, despite providing no active physical support. These findings underscore the role of psychological reassurance in modulating balance-related behavior and suggest that robotic safety systems may influence motor performance through psychological mechanisms. Integrating psychological support into robotic fall prevention strategies may enhance their effectiveness.

Trial Registration: UMIN Clinical Trials Registry UMIN000049284; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000056126

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KEYWORDS

robotics; self-efficacy; fall-related self-efficacy; preventing falls; postural balance; assistive technology; human–robot interaction; functional reach test; psychological reassurance; rehabilitation

Introduction

The rapid aging of the global population presents major challenges to health care and social security systems. Among these, age-related declines in physical function, particularly mobility limitations, adversely affect the quality of life and independence of older adults [1]. To address these challenges, assistive robotic technologies are being developed for various domains, including mobility, transfer, bathing, and communication [2-6]. These systems are anticipated to play a key role in promoting healthy longevity by supporting physical, social, and psychological well-being [7,8].

Fall prevention is a central concern in the context of age-related functional decline, as falls compromise both safety and independence. Approximately one-third of older adults experience at least one fall annually [9,10], and the risk of fall-related injuries increases due to age-associated impairments in musculoskeletal, cardiovascular, visual, vestibular, and proprioceptive functions [11-15]. Beyond physical injury, the fear of falling contributes to a cycle of reduced mobility, decreased activity, and social withdrawal [16,17]. This fear can negatively influence balance control and movement behavior [18], particularly in older adults with physical disabilities, thereby limiting social participation and increasing the risk of future falls [19-21].

To mitigate these risks, various robotic solutions for fall prevention have been proposed. These include “smart robotic walkers” that anticipate movement patterns to provide proactive support [22] and “robotic canes” that adapt to users’ gait characteristics [23-25]. While promising, these systems are often optimized for clinical settings and may be impractical for home use due to space and mobility constraints [26]. Moreover, their potential psychological benefits remain poorly characterized, despite the crucial role of fall-related self-efficacy in fall prevention outcomes.

Recent studies have emphasized the importance of psychological factors in fall prevention. Self-efficacy, as defined by Bandura [27], refers to an individual’s belief in their ability to carry out actions necessary to achieve specific outcomes. Tinetti et al [28] introduced the concept of falls efficacy as a domain-specific form of self-efficacy, meaning the confidence to perform daily activities without falling. Building on this, Powell and Myers [29] developed the Activities-specific Balance Confidence Scale, which assesses confidence in maintaining balance during a range of activities. More recently, Soh et al [30-32] proposed a multidimensional framework for fall efficacy, encompassing 4 distinct domains across the fall continuum: balance confidence (pre-fall), balance recovery confidence (near-fall), safe-landing confidence (fall-landing), and post-fall recovery confidence (post-fall). This expanded model highlights the need for psychological resilience not only to prevent falls but also to manage their occurrence. Clinical findings suggest that such psychological constructs can directly modulate balance control mechanisms, potentially masking or compensating for physical impairments [18]. As such, effective fall prevention strategies should integrate both physical safeguards and psychological reinforcement.

Motor learning theory provides a framework for understanding how to effectively provide such psychological reinforcement. Self-efficacy influences task engagement, and learning is optimized when difficulty appropriately matches ability [27,33]. However, people naturally tend to be conservative, using only a portion of their available stability capacity due to inherent safety mechanisms [34]. This suggests that effective balance training must address both the physical and psychological barriers that limit engagement with appropriately challenging tasks.

The present study focuses on a ceiling-mounted fall impact mitigation robot designed to address both physical and psychological aspects of fall prevention. This suspended system provides continuous support during daily activities in home environments, with almost no limitations on the range of movement. While the system was primarily designed to reduce the physical risk of fall-related injuries, its impact on psychological factors, particularly fall-related self-efficacy, has not been fully elucidated. Specifically, it remains unclear whether the constant presence of such a safety system influences users’ psychological state, and if so, whether this influence translates into measurable changes in motor performance when facing such challenging tasks.

This study aims to examine the effect of the fall impact mitigation robot on psychological reassurance and task performance during dynamic balance challenges. Young healthy adults were selected as participants to establish a baseline understanding of these mechanisms, unconfounded by age-related impairments. We used the functional reach test (FRT), a validated tool for assessing dynamic balance and fall risk across age groups [35]. The FRT was particularly suited to this study, as it provides a quantitative measure of physical reaching ability and reflects the confidence required to perform challenging balance tasks [34]. Participants were asked to perform progressively demanding reaching tasks that exceeded their maximum capacity, either with or without robotic safety support depending on their group assignment. Prior to each attempt, participants were asked the self-efficacy ratings to quantify how perceived safety influences both confidence and motor performance. By investigating this relationship, we aim to elucidate how robotic safety systems modulate human movement behavior, thereby informing the development of comprehensive fall prevention strategies that promote safe, independent living among older adults.

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Methods

Participants

Twenty-four healthy adults (12 men and 12 women; age: mean 28.9, SD 7.9 years; height: mean 1.64, SD 0.09 m; weight: mean 59.1, SD 12.5 kg) participated in this study. Participants were randomly assigned to either the experimental group (n=12; 7 men, 5 women; age: mean 27.5, SD 7.9 years; height: mean 1.65, SD 0.08 m; weight: mean 59.9, SD 13.8 kg) or the control group (n=12; 5 men, 7 women; age: mean 30.3, SD 8.1 years; height: mean 1.62, SD 0.10 m; weight: mean 58.3, SD 11.6 kg). There was no significant association between grouping and gender distribution (χ^2_1=0.67; *P*=.41). Statistical analysis showed that the randomization achieved an adequate gender ratio, and this slight demographic variation does not represent a methodological flaw. All participants provided written informed consent prior to the study.

Ethical Considerations

The study protocol was approved by the Ethics and Conflict of Interest Committee of the National Center for Geriatrics and Gerontology (approval number 1636).

Apparatus and Protocol

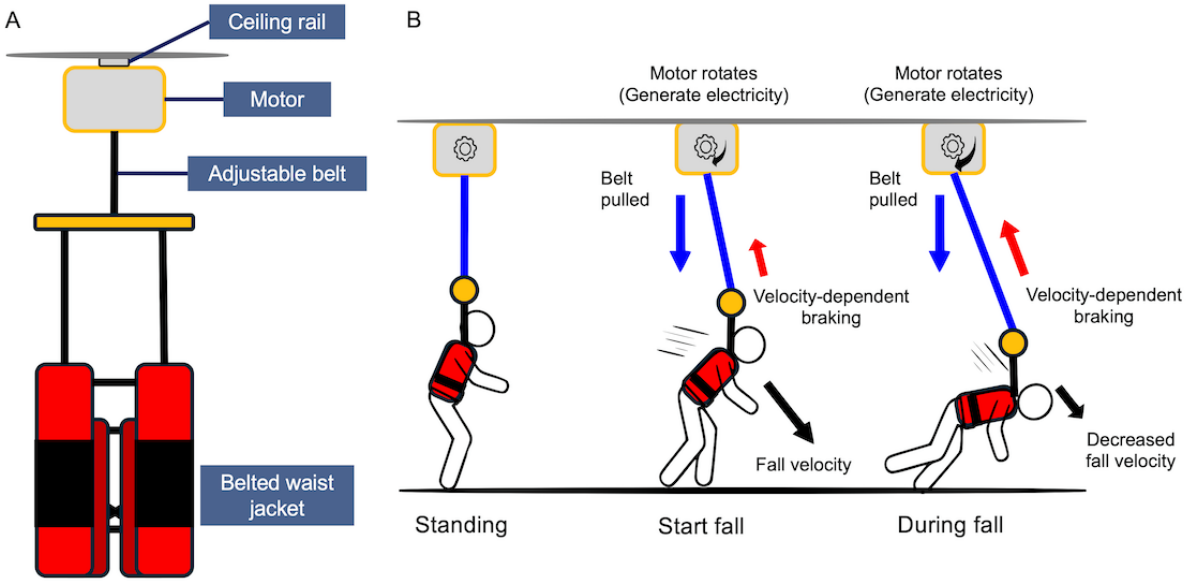
Measurement Equipment

FRT distance was measured using a dedicated device (T-2795, TOEI LIGHT Co., Ltd.). Center of pressure (COP) data were acquired using 2 force plates (BP400-600, Advanced Mechanical Technology, Inc.) operating at a sampling frequency of 1000 Hz. Data acquisition was managed via A-Cap, an AD conversion system and its accompanying software (version 1.26.1, 4Assist, Inc.).

Fall Impact Mitigation Robot

The experimental group used a ceiling-mounted fall impact mitigation robot (Yorisoi Robot, Sanyo Homes Co., Ltd.) equipped with a high-performance DC motor (model SS40E8; Figure 1). The system is permanently installed in the Living Lab, a real-world simulation environment designed for evaluating daily activities [36]. The robot remains inactive during normal movement and activates only upon detecting accelerations consistent with falling, engaging a braking mechanism to mitigate impact without interfering with normal movement.

Figure 1. Fall impact mitigation robot system. (A) System configuration showing ceiling rail, motor unit, adjustable belt, and belted waist jacket. (B) Fall response mechanism: when a fall occurs, the adjustable belt around the motor shaft is pulled, causing motor rotation that generates electricity for velocity-dependent control to reduce fall impact during the descent sequence.

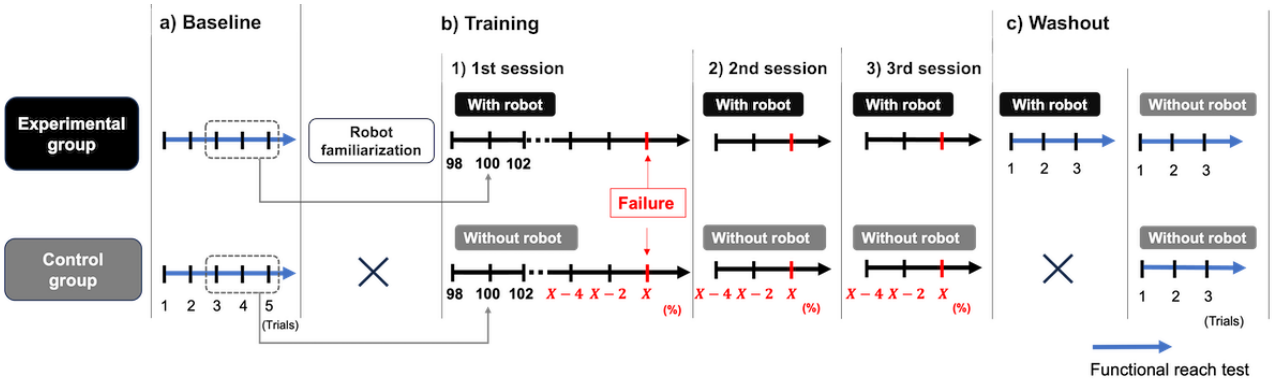


Experimental Procedure

The intervention consisted of three sequential phases (Figure 2): (1) a baseline phase to determine individual maximum reach capacity, (2) a training phase for robot familiarization and dynamic reaching tasks, and (3) a washout phase to assess residual effects without robotic assistance. To ensure participant safety throughout the experiment, a research assistant was positioned in close proximity to provide manual support if necessary, and shock-absorbing mats were placed on the floor in the forward reaching direction as a further precaution.

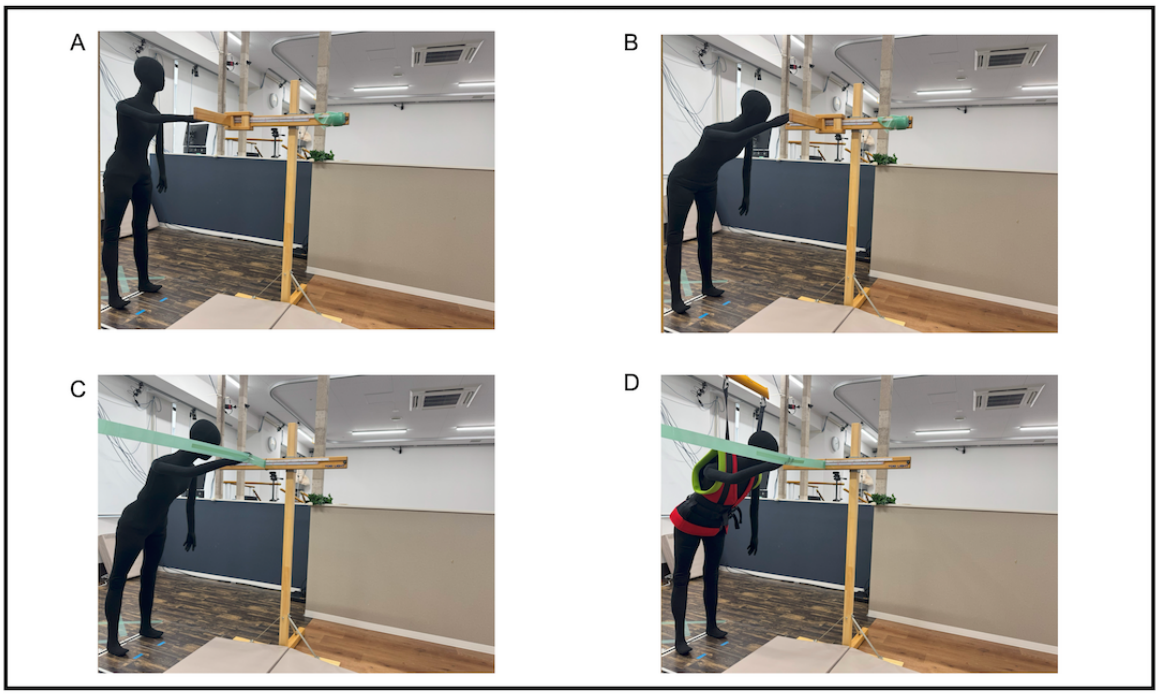
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Figure 2. Schematic overview of the experimental procedure comparing reaching tasks performed with and without the fall impact mitigation robot.



Baseline phase: All participants first completed a standard FRT to establish baseline performance (Figure 3A). Participants stood barefoot with feet shoulder-width apart on the force plates (right foot on right plate, left foot on left plate). The measuring device was adjusted to acromion height. From this standardized position, participants extended the right arm horizontally and pushed the measuring device forward using the extended fingers (Figure 3B). A trial was considered successful if the participant returned to the starting position without foot displacement; heel lift was permitted. After 5 trials, the average distance from the third through fifth attempts was recorded as the maximum reach distance (defined as 100%).

Figure 3. Experimental setup for the functional reach and challenging reaching tasks. (A) Initial posture for the functional reach test, with the participant standing on force plates and the measuring device aligned to acromion height. (B) Standard reach assessment, with the participant extending the right arm horizontally. (C) Challenging functional reach test, in which the participant attempts to reach beyond their baseline maximum distance. (D) Challenging reach task with the participant wearing the fall impact mitigation robot.



Training phase: The control group performed the training tasks without the robot (Figure 3C), while the experimental group performed with robotic support (Figure 3D). Participants in the experimental group were introduced to the robot's functionality, with emphasis on its passive operation during normal movement and its role in fall impact mitigation. A researcher conducted a forward fall demonstration while wearing the robot to illustrate activation of the braking mechanism. Participants then wore the device and performed 3 controlled forward falls with robot safety support to familiarize themselves with the system's protective function. The control group did not participate in this familiarization procedure.

Subsequently, all participants performed a series of challenging reach tasks designed to exceed the maximum reach capacity established during baseline. The same posture and setup were maintained. The task began at 98% of the individual's maximum reach distance, increasing by 2% with each successful attempt until failure. Task failure was defined as inability to reach the target distance, any foot movement, or loss of balance preventing return to the starting position. Targets were marked with tape and reached using the extended right arm.

Before each trial, participants rated their confidence in their ability to perform the forward reaching task to the specified target distance without losing balance or moving their feet,

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using an 11-point scale from –5 (completely unconfident) to +5 (completely confident), with negative values indicating low confidence and positive values indicating high confidence. Upon failure, participants completed 2 additional sets of 3 trials at the failure distance and 2 easier levels (–2% and –4%). One-minute rest intervals were provided between sets to minimize fatigue.

Washout phase: After the challenging reach task, the experimental group completed 3 standard FRT trials (shown in Figures 3A and 3B) while still wearing the robot. Subsequently, both groups performed another 3 standard FRT trials without the robot to assess any residual effects (washout) of robotic support.

Data Analysis

Statistical Analysis

Outliers in the FRT and COP datasets were identified and excluded using the Smirnov-Grubbs test. Data distribution was assessed using the Kolmogorov-Smirnov test for normality, followed by the Bartlett test to evaluate the homogeneity of variance across groups. Based on these preliminary assessments, parametric tests (independent samples *t* tests) were applied to normally distributed data with equal variances. When these assumptions were not met, nonparametric alternatives were used as appropriate. Statistical analyses for FRT variables were conducted using EZR software (version 1.55; Saitama Medical Center, Jichi Medical University) [37]. COP data were preprocessed in MATLAB 2022b (MathWorks) prior to statistical analysis in EZR. Analyses of the challenging reach task and self-efficacy ratings were performed using Python 3.12. A significance level of $P<.05$ was adopted for all statistical comparisons.

Self-Efficacy Analysis

To evaluate psychological responses, self-efficacy ratings were analyzed for all trials conducted at or beyond 102% of each participant's baseline maximum reach. Given the ordinal nature of the self-efficacy scale (–5 to +5) as described above, between-group comparisons were performed using the Mann-Whitney *U* test.

Functional Reach Test Analysis

To assess the effects of the intervention on functional reach capacity, percent changes in reach distance from baseline to washout were calculated for each participant. Between-group differences in these percent changes were analyzed using independent samples *t* tests.

Challenging Reach Task Analysis

Performance during the challenging reach task was analyzed using Kaplan-Meier survival analysis. Reaching distances, expressed as percentages of baseline maximum, were treated as the time variable. Task failure, defined as an inability to reach the target distance, foot movement, or loss of balance, was designated as the event of interest. Survival curves for the experimental and control groups were compared using the log-rank test to determine differences in performance persistence.

COP Analysis

Composite COP coordinates were calculated from ground reaction force components recorded by 2 force plates. COP data were filtered using a fourth-order Butterworth low-pass filter with a 6.0 Hz cutoff frequency. The analysis window for each FRT attempt was defined by synchronizing COP trajectories with corresponding video recordings. Anteroposterior COP displacement was computed as the difference between minimum and maximum positions during baseline and washout measurements. Changes in COP displacement from baseline to washout were expressed as percentages of baseline values. Between-group comparisons of these percent changes were conducted using independent samples *t* tests.

Results

Self-Efficacy Analysis

Self-efficacy ratings during challenging reach trials (≥102% of baseline maximum reach) were significantly higher in the experimental group (median 1.0, IQR 0.0 to 3.0, range: –3.0 to 5.0; trials: 62) than in the control group (median 0.0, IQR –1.0 to 2.0, range: –4.0 to 5.0; trials: 53) (Figure 4). This between-group difference in Figure 4 was statistically significant (Mann-Whitney *U* test: $U=1292.5$, $P=.047$). The mean self-efficacy ratings from all participants are shown in Figure 5. Self-efficacy was higher in the experimental group (ie, when using the robot), mainly in reaching trials of 110% or more.

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Figure 4. Box-and-whisker plots of self-efficacy ratings during challenging reaching tasks (≥102% of baseline maximum reach) in the experimental (red) and control (blue) groups. The y-axis represents self-efficacy scores on an 11-point scale from –5 (completely unconfident) to +5 (completely confident).

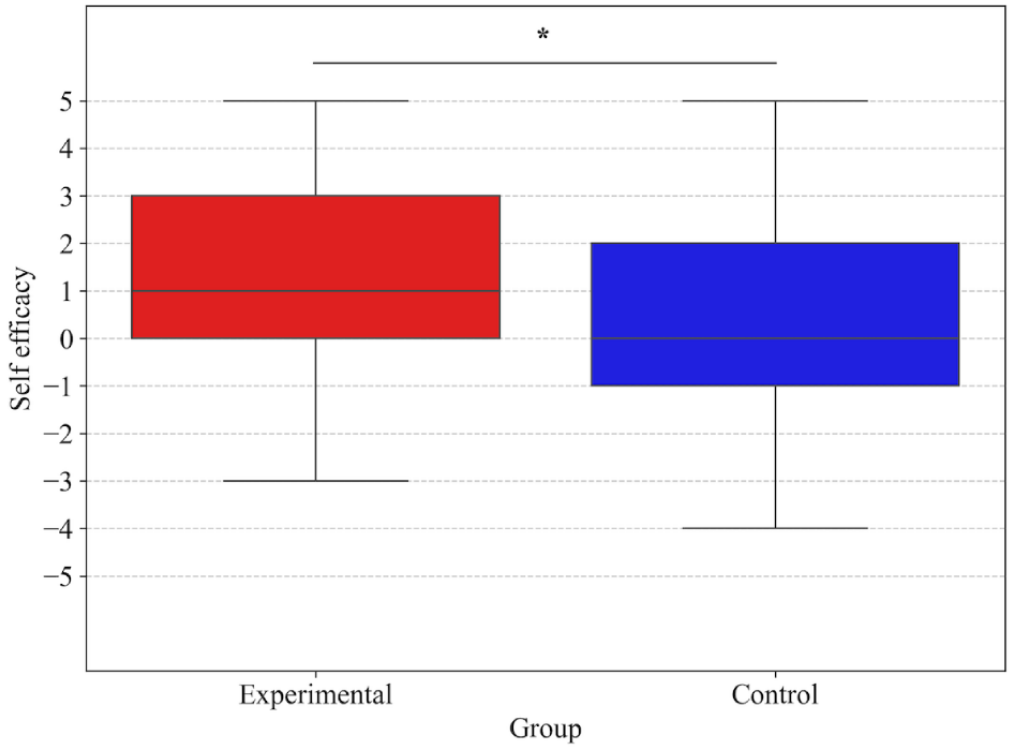
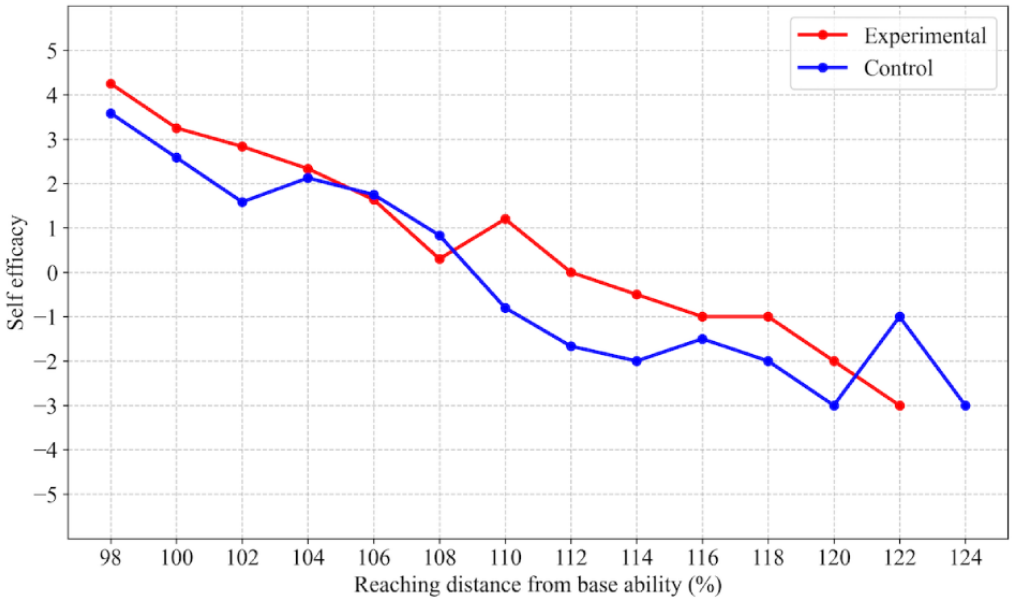


Figure 5. Self-efficacy ratings across different reaching distances during the challenging task for the experimental (red) and control (blue) groups. The x-axis shows reaching distance as a percentage of baseline maximum reach (100% = participant's baseline maximum). The y-axis displays mean self-efficacy scores on an 11-point scale from –5 to +5.



The standard FRT

There were no significant between-group differences in percent changes in functional reach capacity from baseline to washout (experimental: mean 104.2%, SD 3.8%; control: mean 103.6%, SD 2.5%; $t_{22} = 0.510$, P=.62; Table 1). Both groups exhibited modest improvements in maximum reach distance following the intervention protocol.

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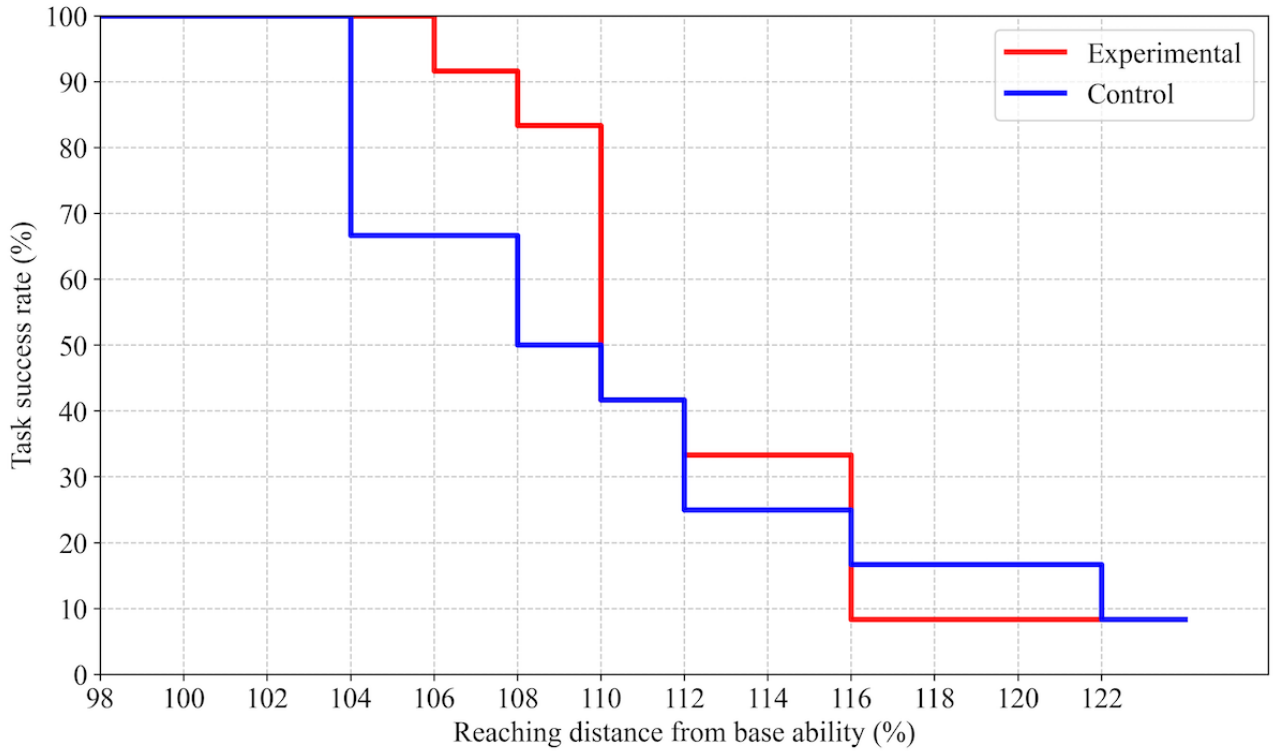
Table 1. Comparison of physical performance measures between experimental and control groups. Data are presented as mean ± standard deviation and reflect percentage changes from baseline to washout for the functional reach test (FRT) distance and center of pressure (COP) displacement.

Outcome Measure	Experimental (n=12), mean (SD)	Control (n=12), mean (SD)	*t* value	*P* value
FRT (%)	104.2 (3.8)	103.6 (2.5)	0.510	.62
COP (%)	108.9 (10.4)	114.1 (9.8)	1.244	.23

Challenging Reach Task

Kaplan-Meier survival analysis of maximum reaching distances revealed no significant difference between groups (log-rank test: χ^2_1=0.36, *P*=.55), although the survival curve suggested a trend toward greater task persistence in the experimental group (Figure 6).

Figure 6. Kaplan-Meier survival curves comparing maximum reaching distances achieved during the challenging task in the experimental (red line, with fall impact mitigation robot) and control (blue line) groups. The x-axis denotes reaching distance as a percentage of baseline maximum reach. The y-axis indicates the proportion of participants able to successfully complete each reach distance.



COP Analysis

No significant differences were observed between the groups in anteroposterior COP displacement from baseline to washout (experimental: mean 108.9%, SD 10.4%; control: mean 114.1%, SD 9.8%; t_{22}=1.244, *P*=.23; Table 1), indicating that COP dynamics during the functional reach task were not differentially influenced by the intervention.

Discussion

Principal Findings

This study investigated the psychological effects of a fall impact mitigation robot, focusing on its influence on self-efficacy and physical performance during balance-challenging tasks. Participants in the experimental group who wore the robot exhibited significantly higher self-efficacy ratings, particularly prior to reaching tasks that exceeded their individualized maximum reach thresholds (Figures 4 and 5). Although survival analysis suggested a trend toward greater task persistence in the experimental group (Figure 6), no statistically significant differences were observed in physical performance metrics, such as FRT scores or COP displacement (Table 1). These findings indicate that the fall impact mitigation robot provided psychological reassurance and enhanced self-efficacy, even in the absence of active robotic assistance.

Implications for Fall Prevention

The observed enhancement in self-efficacy has direct implications for fall prevention strategies. Fear of falling contributes to activity restriction and social withdrawal, which in turn negatively impact balance control and motor behavior [18]. Among older adults, fear of falling is associated with reduced social participation and elevated risk of subsequent falls [19]. Robotic interventions that bolster self-efficacy may help interrupt this deleterious cycle. Existing evidence links higher self-efficacy with increased motivation for activities of daily living and outdoor mobility [16], suggesting that such

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interventions could support long-term improvements in physical activity and social engagement. However, further longitudinal research is needed to substantiate these potential benefits.

Integration With the Falls Self-Efficacy Framework

To contextualize our findings within current theoretical models, we refer to the framework proposed by Soh et al [32], which delineates falls self-efficacy into 4 domains: balance confidence (pre-fall), balance recovery confidence (near-fall), safe-landing confidence (fall-landing), and post-fall recovery confidence (post-fall). While the fall impact mitigation robot was designed to enhance safe-landing confidence, the observed increase in self-efficacy suggests a broader psychological effect, potentially extending toward balance confidence. This cross-domain influence implies that perceived protection during potential falls may generalize to increased confidence during pre-fall activities, offering a novel direction for fall prevention strategies.

Dissociation Between Psychological and Physical Outcomes

A key observation in this study was the dissociation between psychological and physical outcomes, namely, significant improvements in self-efficacy without parallel changes in FRT or COP displacement. As suggested by Bandura [27], enhancements in self-efficacy typically precede measurable behavioral changes, which may emerge over longer timeframes. The use of healthy young adults likely introduced ceiling effects, limiting the detection of performance-related differences. Moreover, the single-session intervention design may have been insufficient to elicit observable physical adaptations. Longitudinal studies incorporating diverse populations are needed to clarify the temporal relationship between self-efficacy and physical performance.

Insights Into Motor Learning and Human-Robot Interaction

Our findings provide a new perspective on the application of the challenge point framework [33] to balance training. The framework posits that learning is most effective at the edge of a person's ability. Modulating the level of physical assistance is a common approach to guide learners to this optimal state. Our results, however, demonstrate that psychological safety is a powerful, alternative modulator. The increase in self-efficacy without a change in physical performance indicates that the robot enabled participants to perform closer to their true physical limits, not by making the task easier, but by removing the fear of falling. This suggests a potential model for effective training, where psychological barriers are addressed first to allow a learner to safely engage with their optimal challenge point.

Furthermore, the enhancement of self-efficacy in the mere presence of the robot contributes to the growing body of literature on human-robot interaction. Broadbent et al [7] found that robots can fulfill both physical and psychological roles. Our results support this dual-function hypothesis, demonstrating that robotic presence alone can provide psychological reassurance and influence behavior.

Limitations and Future Directions

Several limitations of this study warrant consideration. First, the small sample size limited statistical power and generalizability. Second, the focus on healthy young adults constrains the applicability of findings to clinical or older populations. Third, only short-term effects were assessed, leaving the long-term psychological and behavioral impacts unexamined. Fourth, the interaction between fear of falling and physical function may differ across age groups, underscoring the need for population-specific studies. Future work should incorporate validated scales aligned with the multifactorial model of falls self-efficacy proposed by Soh et al [32]. Finally, our analysis of motor behavior was restricted to coarse indicators such as COP displacement. Future investigations may benefit from high-resolution, markerless motion capture technologies, already implemented in our Living Lab environment [38], to enable fine-grained analysis of postural and movement strategies associated with robotic safety systems.

Conclusions

These findings demonstrate that a fall impact mitigation robot can enhance self-efficacy via psychological reassurance, even in the absence of active physical assistance. This indicates that psychological support enhances self-efficacy, but that physical assistance is also necessary, highlighting the need for fall prevention strategies that integrate both. The observed enhancement in self-efficacy may promote greater engagement in physical activity and, in turn, contribute to improved functional capacity, a hypothesis that warrants validation through longitudinal investigation.

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Conflicts of Interest

None declared.

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Abbreviations

COP: center of pressure
FRT: functional reach test

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Original Paper

Ankle Bracelet Laser as a Novel Portable Device to Improve Walking in Patients With Parkinsonism: Randomized Crossover Controlled Trial

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Abstract

Background: Freezing of gait (FOG) is a common and debilitating symptom of parkinsonism. Although visual cues have proven efficacy in alleviating FOG, most current visual cues are fixed in place, restricting their use to controlled environments such as clinics or homes. Mobile open-loop cueing devices have been developed to address this limitation; however, they typically require manual activation to deliver the visual cues, which can be particularly challenging for patients with attention or cognitive impairments, leading to equivocal results in improving gait performance.

Objective: The aim of the study is to assess the efficacy of an ankle bracelet laser, a new mobile visual cue designed for practical use, in improving gait performance in patients with parkinsonism and FOG.

Methods: A randomized controlled 2-period crossover trial was conducted from June 15, 2020, to October 1, 2020, at Ramathibodi Hospital. In total, 10 patients with parkinsonism and FOG were enrolled in 2 conditions: walking with laser-off first and walking with laser-on first. Gait speed, the timed up and go test, stride length, and the locomotor rehabilitation index were assessed twice in each trial with a 10-minute washout period.

Results: The results showed favorable improvement in all parameters. Gait speed and stride length improved by 0.07 m/s (95% CI 0.04-0.09 m/s; *P*<.001) and 0.17 m (95% CI 0.11-0.23 m; *P*<.001), respectively, with laser-on. The timed up and go test duration was reduced by 7.69 seconds (95% CI 2.82-12.55 seconds; *P*=.002). The locomotor rehabilitation index improved by 4.46% (95% CI 2.56%-6.36%; *P*<.001). When using the device, there were no adverse effects, such as dizziness or blurred vision.

Conclusions: The ankle bracelet laser cue produced immediate improvements in gait speed, stride length, and balance in patients with parkinsonism and FOG, suggesting that the device can acutely enhance gait performance. Further research is needed to determine whether these benefits are sustained and applicable to daily life activities.

Trial Registration: Thai Clinical Trials Registry TCTR20210511001; https://www.thaiclinicaltrials.org/show/TCTR20210511001

(JMIR Rehabil Assist Technol 2025;12:e70209) doi:10.2196/70209

KEYWORDS

parkinsonism; gait disorders; cues; self-help devices; lasers

Introduction

Background

Individuals with parkinsonism walk with a slower gait speed, shorter stride length, and higher cadence, resulting in an asymmetrical gait and increased energy expenditure compared to healthy people [1,2]. Freezing of gait (FOG) is one of the most common debilitating symptoms of parkinsonism and leads to multiple falls, related injuries, mobility limitations, functional dependence, restrictions in social activities, as well as psychological effects such as anxiety and depression.

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Pharmacological and surgical interventions do not always provide satisfying outcomes [3-5]. External cueing has been used as a nonpharmacological intervention to alleviate FOG and improve gait parameters [6-8]. Visual cues may have more advantages in improving spatial parameters than auditory cues [9]. Fixed visual cues, such as taping a line on the floor to step over, have shown good immediate outcomes. However, this method is limited because it can only be used in environments where a fixed visual cueing line has been placed.

Currently, mobile visual cues mostly take the form of open-loop cueing (constant stimulus) [10] systems, such as laser light incorporated with a gait aid such as a walker or cane. Several studies have reported favorable outcomes regarding the immediate effect of reducing FOG and improving gait parameters; however, some results were equivocal [11], and some studies did not demonstrate improved outcomes [12]. In addition, gait speed as a predictor of ambulation ability [13] did not always improve with this method [14] and even slowed with the use of the device [15]. This may be because the open-loop system uses manual control to project the laser light and requires attention to project the cues at a constant distance in front of the foot. This dual-task process may be difficult for some patients to perform, especially for patients with some attention or cognitive impairment. Because cognitive impairment is commonly related to FOG in parkinsonism, this could be one of the factors leading to negative outcomes [16,17]. In addition, patients with parkinsonism and FOG showed greater sequence learning deficits than nonfreezers [18], and these deficits worsened further under dual-task conditions.

The long-term effect of visual cueing devices remains unclear. Some studies showed that these devices could not provide carry-on or retention effects [15], resulting in cue dependency for patients with FOG. This may be because of cognitive overload when using the device, which could distract attention away from walking [8,16], reducing the neural reserve for the motor relearning process [17].

Physical exercise could improve the motor function in parkinsonism. Nordic walking (NW) [2] is one of the exercise techniques using a specialized pole, working with arm swing to coordinate the rhythmic movement of the lower extremities and enhance the body's ability to move forward with an increased range of motion in the upper and lower extremities. NW training could improve gait performance and reduce energy expenditures in patients with Parkinson disease (PD). However, studies of the efficacy of NW were limited to patients with mild to moderate PD, Hoehn and Yahr (H&Y) stage 1-1.5 [2], or H&Y stages 1-3 [19], and only 1 person experienced FOG. Another trial [20] also showed improvement of gait speed, timed up and go (TUG), and the locomotor rehabilitation index (LRI) in patients with PD with an average of H&Y stage 1.5, but only 3 of 16 participants had FOG. Additional research has shown mixed results. One study reported that following an individualized and progressive NW training intervention, significant improvements were observed in walking function, daily activity level, and motor function, with participants sustaining independent NW exercise over 3 months and showing increased serum brain-derived neurotrophic factor levels after 5 months [21] Conversely, a systematic review and meta-analysis [22] found that NW did not lead to clinically significant changes in global motor impairment, functional mobility, balance, or physical fitness in patients with PD. However, it suggested that NW may improve walking ability and quality of life, though further research is needed to confirm these outcomes.

Recently, we developed ankle bracelet lasers as a new visual cueing device [23] aimed for ease and practical use to reduce cognitive overload. The ankle bracelet laser was designed as a closed-loop (intermittent stimulus) cueing system that provides a laser cue automatically following individual walking steps, so each patient can walk naturally. However, the device cost is too expensive for most people in our country due to the motion sensor and the software program that detects the gait motion to command the laser cue.

Therefore, we created another new version using ultrasonic sensors to detect the motion during the stance and swing phases. The command is simpler and fits with the low-income insurance cost. This device is currently a prototype. Electrical safety testing has been conducted by our engineering team to ensure safe operation; however, the device has not yet received formal medical device certification. The current version is planned to be sold at approximately US $185, reduced from US $490 in our earlier design.

The ankle bracelet laser operates intermittently, activating during the stance phase when the foot touches the floor, as detected by the integrated sensor. Once the foot contacts the floor, the laser line automatically projects in front of the patient's contralateral foot, providing a target to step to or over. This cycle of laser line projections repeats alternately and continuously throughout the walking period without the need for manual control or additional commands. The use of a mobile, laser-guided system might also promote neuroplasticity and motor relearning. This is achieved through a sensory-motor cycle in which an individual's own movement triggers intermittent sensory cues. This repeated feedback loop reinforces ongoing motor performance and may lead to long-term training effects [10,11]. The Velcro strap at the ankle position is easy to wear for a patient with a stiff back or tremors, which are commonly found in parkinsonism, because they do not need good hand function or to bend their back to put on the device. In addition, this device can be used with bare feet, which is suitable for Asian cultures, or with any kind of shoes.

Objective

The aim of the study is to study the efficacy of the ankle bracelet laser in improving walking performance in parkinsonism.

Methods

Study Design

We conducted a randomized crossover design study to lessen the between-patient variation. The study was conducted between June 15, 2020, and October 1, 2020. Patients with parkinsonism and FOG were enrolled in 2 conditions: walking with laser-off first and walking with laser-on first. The washout period was set at 10 minutes between the 2 conditions to avoid carryover effects.

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Participants

Patients with parkinsonism were recruited from the Physical Medicine and Rehabilitation Outpatient Clinic of Ramathibodi Hospital. The inclusion criteria were as follows: (1) patients with parkinsonism diagnosed by a neurologist, (2) aged 18-90 years, (3) ability to walk at least 16 m with or without a gait aid, (4) no medication adjustment within the previous 3 months, and (5) H&Y stages 1-4. The exclusion criteria were as follows: (1) unable to see the laser line projection on the floor, (2) other neurological disorders, (3) unable to communicate well, (4) unable to use the device, and (5) denied or rejected from the study.

Ethical Considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki. The protocol was reviewed and approved by the Human Research Ethics Committee, Faculty of Medicine, Ramathibodi Hospital, Mahidol University (approval COA. MURA2020/702). Written informed consent was obtained from all participants prior to enrollment, including consent for data collection and publication of deidentified results. To ensure confidentiality, all data were anonymized before analysis, and no personal identifiers were collected or stored in the dataset. Participants received compensation for their time as well as reimbursement for transportation costs related to study visits. This study was retrospectively registered with the Thai Clinical Trials Registry (TCTR20210511001) [24].

Intervention

The ankle bracelet laser was designed as a closed-loop cueing system that provides a laser cue automatically following an individual's walking steps. The ankle bracelet lasers were attached to both tibial areas. The device size was 4×5×2 cm, weighed 200 g, and is shown in Figure 1. The device uses an ultrasonic sensor to detect foot position from the ground and is integrated with a microcontroller to control the laser line projection correlated with an individual's walking steps. Once a patient performed a heel or foot strike, the laser line was projected in front of the contralateral foot to step on or over when entering the swing phase. The laser line disappeared once the foot was lifted off the ground. These cycles repeat alternately and automatically, following each individual's walking step.

Figure 1. Ankle bracelet laser attached to both tibias.



Experimental Design

The participants were informed of the objective and procedure of the study and provided signed informed consent before starting the trials. Each participant was randomized using a sealed envelope into 1 of 2 conditions: walking with the laser-off first or walking with the laser-on first. There was a 10-minute washout period between each condition.

Each participant walked a 10-m path twice at a comfortable speed, taking a break for a few minutes or until they felt ready to perform the TUG test twice. Gait speed and related spatiotemporal parameters were analyzed using a 6-m segment located in the middle of the total 10-m walking distance, excluding the initial and final 2 m. The start and end points of the 6-m segment were marked with striped floor lines to clearly identify the first and last strides.

A digital single-lens reflex camera, the Canon EOS 500D equipped with a Canon EF-S 18-55mm f/3.5-5.6 IS II kit lens, was used to record videos at 60 frames per second. The camera was positioned 4 m laterally from the walkway in a sagittal (lateral) view and was aligned to capture the entire 6-m measurement segment. This setup, which follows standard observational gait analysis techniques [25], enabled accurate visual identification of foot contact at both the start and end of

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the measurement zone. The camera angle, zoom, and position, as well as the floor markers, were kept fixed and consistent across all participants to ensure uniformity and reduce variability in gait analysis, including for calculations of the LRI and optimum walking speed (OWS).

Gait Analysis and Parameter Calculation

To ensure objectivity and reliability, all video recordings were independently analyzed by 2 experienced physiatrists who were blinded to the study conditions and not involved in the recording process. Initial foot contact was defined as the moment the heel of the leading foot touched the ground on or beyond the starting line of the 6-m segment. The first completed step was then counted, followed by subsequent steps until the final foot contact on or beyond the end line of the segment. All identifications of foot contacts and steps were based on visual inspection of individual video frames, using heel strike as the reference point, in accordance with standard gait analysis protocols [25].

Gait parameters were calculated as follows: average gait speed (m/s) was calculated by dividing the 6-m distance by the time difference between the first foot contact and the last completed footstep, average cadence (steps per minute) was calculated as the number of completed steps divided by the total walking time (from the first foot contact to the last completed step), and average stride length (m) was calculated as average gait speed (m/s)×2×60/cadence (steps per minute) [25].

To ensure proper use of the device, all participants were given a standardized 5-minute familiarization period. During this time, they adjusted the distance of the laser line projection in front of their foot according to their personal preference, such as stride length or visual comfort. Participants were considered ready to begin the intervention once they reported feeling comfortable with the laser projection and could consistently step to the indicated distance. The same 5-minute period and readiness criteria were applied to all participants to ensure consistency across the intervention. Then, each patient would sit still for 10 minutes before starting the experiments to wash out the movement effect. Before beginning each trial, each participant took 10 alternating steps with both feet to warm up. One of the examiners followed the participants to prevent falls during all the tests.

Outcome Measures

Efficacy was primarily measured by the improvement in gait speed between the laser-off and laser-on conditions. Secondary measures included changes in stride length, TUG test results, and the LRI. The LRI is a method to determine the relationship between self-selected gait speed and the OWS, which is the speed that uses the lowest metabolic energy expenditure [26]. The OWS (m/s) was calculated from $\sqrt{(0.25\times9.81\times0.54}$ of height). The LRI (in percentages) was equal to 100× walking speed/OWS. We chose gait speed as the primary outcome because it is a reliable and sensitive tool to represent individual mobility and functional status and is easy to follow up clinically [13].

Statistical Analysis

Statistical analysis was performed using STATA (version 17; StataCorp LLC). A mixed linear regression model with adjusting the sequence effect was used to analyze the differences in gait speed, stride length, the TUG test, and the LRI between 2 conditions: walking with laser-off and walking with laser-on. Statistical significance was set at $P<.05$. Effect sizes were calculated using Hedges *g* to correct for small sample size bias, with values of 0.20, 0.50, 0.80, and 1.20 indicating small, moderate, large, and very large effects, respectively.

Sample Size and Analysis

The sample size was calculated based on the improvement of gait speed from comparable studies [27], with $\alpha=.05$ and $\beta=0.8$, equal to 10 patients. Therefore, we recruited and randomized 10 participants to see the feasibility and efficacy of this device.

This trial was conducted and reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines (Multimedia Appendix 1).

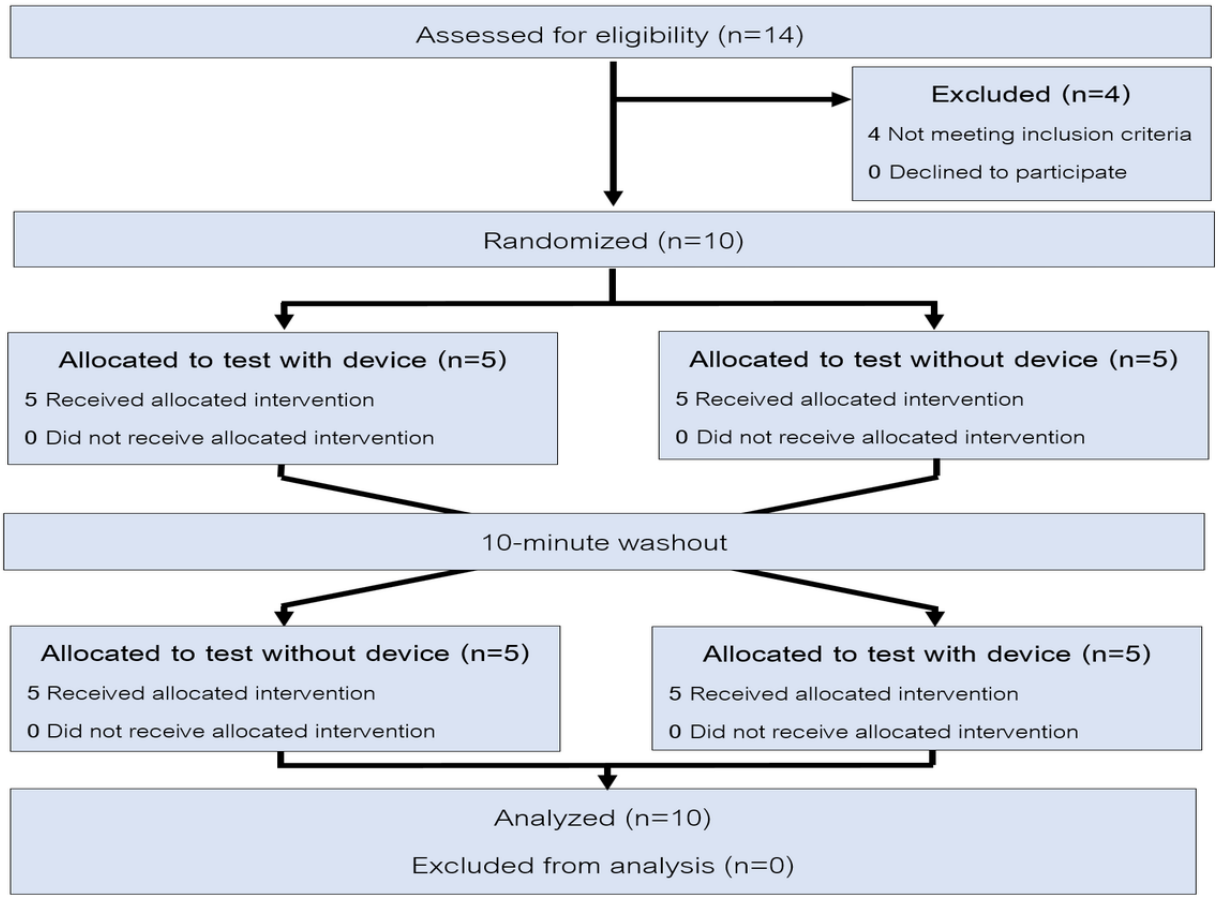
Results

Participant Flow

The flow diagram of this trial is shown in Figure 2.

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Figure 2. Flow diagram for crossover trials.



Participant Characteristics

In total, 10 of the 14 screened patients with parkinsonism who met the inclusion criteria were included in the study. Among these participants, 6 (60%) were diagnosed with PD, while the remaining 4 (40%) had nonprimary parkinsonism—specifically, 2 (20%) with secondary parkinsonism and 2 (20%) with atypical parkinsonism.

In total, 6 (60%) participants were able to walk without the use of a gait aid. A total of 9 of the 10 participants had not previously used any cueing devices. In total, 1 (10%) participant with vascular parkinsonism had created her own visual cue by attaching a piece of wood to her cane; however, she was unable to concentrate and use the device effectively. The participants' clinical characteristics are summarized in Table 1.

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Table 1. Demographic data of participants.

Data	Values
Age (years)	
Mean (SD)	69 (7.2)
Disease duration (years)	
Median (IQR)	5 (2.8-12.3)
Sex, n (%)	
Male	5 (50)
Female	5 (50)
Hoehn and Yahr, n (%)	
2	2 (20)
3	5 (50)
4	3 (30)
Parkinsonism (n=10), n (%)	
Parkinson disease	6 (60)
Atypical parkinsonism	
Progressive supranuclear palsy	1 (10)
MSA-C[a]	1 (10)
Secondary parkinsonism	
Vascular parkinsonism	1 (10)
Normal pressure hydrocephalus	1 (10)
BMI (kg/m^2)	
Mean (SD)	24.42 (5.9)
Gait aid, n (%)	
Tripod cane	3 (30)
Walker	1 (10)
None	6 (60)

[a]MSA-C: multiple system atrophy cerebellar type.

Gait Measures

Before comparing the results, the mixed linear regression model was used to test for a sequence effect—AB (laser-on followed by laser-off) versus BA (laser-off followed by laser-on)—for each parameter. Across all outcomes (gait speed, stride length, TUG, and LRI), no significant sequence effects were observed in patients with parkinsonism or within the PD and atypical parkinsonism subgroups, indicating that the order of laser-on and laser-off interventions had no impact on the results (Table S1 in Multimedia Appendix 2).

The results with the ankle bracelet laser showed statistically significant improvements in all parameters, with clinically meaningful differences in gait speed, stride length, and TUG test results. With the laser-on, gait speed and stride length improved by a mean of 0.07 m/s (95% CI 0.04-0.09 m/s; P<.001) and 0.17 m (95% CI 0.11-0.23 m; P<.001), respectively. The TUG test time decreased by a mean of 7.69 seconds (95% CI 2.82-12.55 seconds; P=.002). The LRI improved by a mean of 4.46% (95% CI 2.56%-6.36%; P<.001). The mean cadence with the laser-off was 98.55 (95% CI 81.32-115.78) steps per minute, whereas with the laser-on, it was 88.80 (95% CI 74.13-103.47) steps per minute. The overall results of the study are presented in Table 2.

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Table 2. The outcomes comparison between laser-off and laser-on in 10 patients with parkinsonism.

Outcomes	Laser-off, mean (95% CI)	Laser-on, mean (95% CI)	Mean difference (95% CI)	*P* value
Gait speed (m/s)	0.60 (0.48-0.72)	0.66 (0.54-0.78)	0.07 (0.04-0.09)	<.001
Stride length (m)	0.73 (0.61-0.86)	0.90 (0.78-1.03)	0.17 (0.11-0.23)	<.001
TUG[a] (seconds)	34.76 (19.68-49.84)	27.08 (12.00-42.16)	7.69 (2.82-12.55)	.002
LRI[b] (%)	40.75 (32.57-48.93)	45.21 (37.02-53.39)	4.46 (2.56-6.36)	<.001

[a]TUG: timed up and go.

[b]LRI: locomotor rehabilitation index.

Subgroup and Effect Size Analysis

After separating the participants into Parkinson and atypical Parkinson groups, improvements in all parameters were also observed, as detailed in Tables 3 and 4. Furthermore, Table 5, which shows the coefficient and effect size (Hedges *g*) for all parameters, indicates a large effect size for stride length (Hedges *g*=0.81). The other parameters showed small to medium effects.

Table 3. The outcomes comparison between laser-off and laser-on in 6 patients with typical Parkinson disease.

Outcomes	Laser-off, mean (95% CI)	Laser-on, mean (95% CI)	Mean difference (95% CI)	*P* value
Gait speed (m/s)	0.62 (0.43-0.82)	0.68 (0.49-0.88)	0.06 (0.01-0.10)	.01
Stride length (m)	0.73 (0.54-0.91)	0.92 (0.74-1.10)	0.20 (0.13-0.26)	<.001
TUG[a] (seconds)	40.85 (16.85-64.86)	32.31(8.30-56.31)	8.55 (1.8-15.30)	.01
LRI[b] (%)	42.53 (29.33-55.72)	46.43 (33.23-59.62)	3.89 (0.85-6.94)	.01

[a]TUG: timed up and go.

[b]LRI: locomotor rehabilitation index.

Table 4. The outcomes comparison between laser-off and laser-on in 4 patients with atypical Parkinson disease.

Outcomes	Laser-off, mean (95% CI)	Laser-on, mean (95% CI)	Mean difference (95% CI)	*P* value
Gait speed (m/s)	0.55 (0.48 to 0.62)	0.63 (0.57 to 0.70)	0.08 (0.07 to 0.09)	<.001
Stride length (m)	0.74 (0.67 to 0.83)	0.88 (0.80 to 0.96)	0.13 (0.03 to 0.23)	.01
TUG[a] (seconds)	25.62 (20.11 to 31.14)	19.23 (13.71 to 24.75)	6.40 (–0.16 to 12.96)	.050
LRI[b] (%)	38.07 (33.26 to 42.88)	43.38 (38.56 to 48.19)	5.30 (4.60 to 6.01)	<.001

[a]TUG: timed up and go.

[b]LRI: locomotor rehabilitation index.

Table 5. The coefficients and effect sizes (Hedges g) for all parameters.

Outcomes	Coefficient	Effect size, Hedges *g*
Gait speed (m/s)	0.07	0.33
Stride length (m)	0.17	0.81
TUG[a] (seconds)	7.69	0.31
LRI[b] (%)	4.46	0.33

[a]TUG: timed up and go.

[b]LRI: locomotor rehabilitation index.

Subjective Aspects

There were no adverse effects while using the device, such as dizziness while looking at the laser line or blurred vision.

Discussion

Principal Findings

We developed the ankle bracelet laser as a new closed-loop visual cueing device to improve gait performance in patients with parkinsonism and FOG. Our study revealed the improvement of gait speed and stride length and a decrease in

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TUG time in the laser-on condition compared to the laser-off condition. No participants experienced walking difficulties or adverse effects while using the device.

Efficacy and Clinical Significance

The improvement of gait speed by an average of 0.07 (95% CI 0.04-0.09) m/s reached the minimal clinically important difference for minimal change (0.06 m/s) in persons with PD [28]. Furthermore, in patients with H&Y stage 3, gait speed was improved by an average of 0.1 m/s, reaching this same minimal clinically important difference with a large effect size (Hedges g=0.75; Table S2 in Multimedia Appendix 2).

Gait speed is a key indicator for independent living and life in the community and is related to objective measures of balance such as the Berg balance, TUG, and severity in H&Y [29]. Slow gait speed and short stride length are related to falling and fragility in people with PD [1]. Therefore, increasing gait speed is related to greater mobility, increased independence, and improved balance for patients with parkinsonism. Stride length with laser-on showed a clinically significant average improvement of 0.17 m [1]. Increasing the stride length [1,30] also improves walking performance and reduces shuffling gait in FOG, which might help reduce the risk of falls. This study also showed the improvement in gait speed and stride length but decreased cadence after laser-on. These results are related to the walking characteristics of people with PD, in which gait speed is more related to stride length than cadence [1].

Our study found a clear change in these spatiotemporal parameters. In contrast, previous studies produced controversial or negative results [12,14,15,31]. Most previous mobile cueing devices need manual control and require attention and cognitive function to use the devices effectively. These may be impractical to some patients, especially those with cognitive impairments, which are commonly found in parkinsonism. Our ankle bracelet laser could project cues that automatically follow each walking step. Therefore, the demands on executive function and attention are lower [10,11] and may be the reason for the results in our study. In addition, the movable laser line following tibial movement might increase sensory input and improve motor performance, especially by increasing stride length [32]. This device also acts as a proof of concept for ease of use by leading to an immediate improvement in inexperienced participants; a total of 9 of 10 had no experience with visual cues, and only 1 person had a history of unsuccessful use of a self-made cue attached to a walking stick.

In the TUG test, the mean difference of 8.55 seconds reached the minimal detectable change in PD (3.5 seconds) [33,34]. The TUG test is one of the tools used to evaluate the risk of falls with good reliability and validity [35]; however, there was less evidence regarding visual cues and the TUG test [36]. Some studies have focused on sit-to-stand ability [37,38] and did not represent the dynamic balance in turning, which is usually impaired in patients with parkinsonism and FOG.

Our results suggest that the reduction in TUG time reflects improved balance and overall function by addressing the crucial phases—sit-to-stand, walking, turning, and stand-to-sit. Because FOG often occurs during initiation, turning, or directional changes, a shorter TUG time, particularly in the turning component, may have a direct and clinically meaningful impact on FOG reduction, since turning impairments are a frequent trigger for FOG and a common cause of falls [10,39]. These findings are consistent with improvements seen in previous studies using NW training [20] and align with recent research identifying TUG time and turning velocity as early indicators of gait abnormalities in parkinsonism [40]. Together, our results support the use of TUG time, alongside gait speed, as a primary outcome in future FOG intervention studies and highlight the potential for smartwatch-based monitoring to capture real-world events outside the clinic [41].

The higher LRI represents the improvement of the metabolic economy [26]. The LRI in our study was also improved, similar to the NW training, and reflected that walking speed in laser-on is closer to OWS and has a lower metabolic cost. However, the degree of improvement in our study was less than the 6-week NW training. In our study, 80% of the participants were in H&Y stages 3-4 with FOG episodes. On the other hand, the people in NW training were in an average H&Y stage of 1.5, with only a few individuals (3/16) experiencing FOG. Therefore, disease stage may influence the degree of improvement observed. The ankle laser may be more appropriate for individuals with advanced parkinsonism, whereas NW training appears most beneficial for improving walking economy in those with mild PD [2].

Due to the small sample size in each stage, further study should be done with a larger sample size in different H&Y staging to prove this hypothesis. Further study should also include coordinating the exercise training with the device, adjusting to each stage to see the different effects.

This study found significant improvements in patients with H&Y stages 2-4, with patients with H&Y stage 3 showing marked improvement in gait speed, TUG test, and the LRI with a large effect size, shown in Table S2 in Multimedia Appendix 2.

Our sample size of 10 was determined a priori based on power calculations from a previous study (α=.05 and β=0.8), which was sufficient to detect statistically significant improvements in all primary and secondary outcomes of this study. While we acknowledge that larger trials are ultimately necessary to achieve greater statistical power, this study was designed as an exploratory trial to evaluate the efficacy and feasibility of a novel device. Because of the small number of patients with each H&Y stage, future studies should examine these groups separately to identify any different outcomes, including long-term effects, between each stage. Based on sample size calculations from this study, a total of 39 participants would be required for a future crossover trial comparing the effects of this device in moderate to severe parkinsonism (H&Y stages 3-4).

Our device led to improvement in all 4 patients with atypical and secondary parkinsonism, which is very interesting because these patients have smaller responses to anti-parkinsonism drugs than patients with primary parkinsonism [42,43], and there is less evidence on the use of cueing devices in these groups. We

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should conduct further studies with a larger sample size of patients with different types of parkinsonism.

Pathophysiology and Cognitive Considerations

Currently, the pathogenesis of FOG is still unclear. The basal ganglia are a group of nuclei that controlled the movement, such as walking from initiation to walk and maintain the walking process, by providing the internal cue via the connection pathway with the supplementary motor area [9]. It has been proposed that FOG is caused by frontal lobe dysfunction or a lack of connectivity between frontal lobe and the basal ganglia [27].

Visual cues could activate the dorsolateral premotor control system by bypassing the brain network via the cerebello-parieto-premotor loops instead of the usual route via the hypoactive basal ganglia-supplementary motor area. The single-photon emission computed tomography study [44] also showed more enhancement of cerebral blood flow in the right lateral premotor cortex, which is mainly influenced by cerebellar input [44], and middle frontal gyrus, as well as reduced left dorsolateral prefrontal cortex activity in patients with PD and FOG while walking on treadmills with visual cues compared to control.

The frontostriatal pathways [45] that connect the shifting between cognitive and motor control are less efficient in freezers than in nonfreezers [11]; thus, individuals with parkinsonism who experience FOG often have reduced cognitive reserve [16] and deficits in sequence learning [18]. These underlying cognitive issues lead to difficulties with dual-tasking and limit their ability for motor relearning.

Our ankle bracelet laser focuses on ease of use and natural walking to minimize cognitive overload, allowing patients to focus on gait training. This study did not compare the device directly with other visual cueing systems. Future trials should evaluate its efficacy relative to other systems to identify potential differences or add on data values.

The Closed-Loop Ankle Bracelet Laser System

Similar to the systems described in Ginis et al [11] and Muthukrishnan et al [46], our device is a closed-loop cueing system that uses wearable sensors to detect leg motion and automatically activates a laser cue via a microcontroller. Through this process, the external (visual) cue was projected based on real-time movement, which was considered the motor feedback. The combination of the feedback from the user's movement and the feedforward of the sensory stimuli may enhance the neuroplasticity and motor relearning. Therefore, incorporating the ankle bracelet laser into gait training or exercise programs should be investigated to determine its potential role in sensory feedback and motor relearning.

Study Limitations and Future Directions

This study found an immediate and significant improvement with less than 5 minutes of trials, which suggests the ease and practical use of the ankle bracelet laser system. However, we still lack a study of using the device in a home setting, which should be further done to prove this concept in daily living. Cognitive impairment is an important factor related not only to the efficacy of visual cues but also to the degree of FOG. Future studies should also investigate different degrees of cognitive impairment and evaluate correlations between gait improvement, the benefits of visual cues, and cognitive function.

The other limitation of using a visual cue is the need to look down at the laser line while walking, which the ankle bracelet laser projects continuously. This device could be programmed to project the laser cue on demand, providing feedback to the user only when FOG occurs. However, there is still controversy when comparing the efficacy of continuous cueing with on-demand cueing. Although previous studies have reported better results with continuous cueing, the patients also reported greater fatigue while using continuous cues than when using on-demand cues [38]. Because the long-term effects of the 2 methods remain unknown, future studies should compare results using the ankle bracelet laser with on-demand cues, such as determining the optimal time to project the laser line and comparing the results with continuous laser projection [47].

Conclusions

The ankle bracelet laser cue produced immediate improvements in gait speed, stride length, and balance in patients with parkinsonism and FOG, suggesting that the device can acutely enhance gait performance. Further research is needed to determine whether these benefits are sustained and applicable to daily life activities.

Acknowledgments

The authors would like to thank Dr Chareon Tangtrongbenchas for designing and building the first prototypes of the ankle bracelet laser.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT 2010 checklist.
[PDF File (Adobe PDF File), 67 KB - rehab_v12i1e70209_app1.pdf]

Multimedia Appendix 2

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Table S1. Sequence effects from the mixed linear regression model for all outcome parameters (gait speed, stride length, Timed Up and Go [TUG], and lateral rhythmicity index [LRI]) in patients with Parkinsonism, Parkinson's disease, and atypical Parkinsonism. AB = Laser-On followed by Laser-Off; BA = Laser-Off followed by Laser-On. Table S2. Outcomes comparison between laser-off and laser-on conditions for 5 patients with H&Y stage 3 Parkinsonism. This table includes the mean, mean difference, *P* value, Hedge g effect size, and interpretation for each outcome parameter.
[DOCX File , 17 KB - rehab_v12i1e70209_app2.docx]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
FOG: freezing of gait
H&Y: Hoehn and Yahr
LRI: locomotor rehabilitation index
NW: Nordic walking
OWS: optimum walking speed
PD: Parkinson disease
TUG: timed up and go

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Original Paper

A Technology-Aided Program to Help People With Intellectual and Multiple Disabilities Access Leisure Stimuli and Engage in Cognitive and Physical Activity: Development and Usability Study

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Abstract

Background: People with moderate to severe intellectual disability can have difficulties accessing leisure stimuli and engaging in basic cognitive and physical activity independently. These difficulties may be even more marked in individuals with a combination of intellectual disability and sensory or sensory-motor impairments.

Objective: This study assessed a new program relying on touch screen technology, which was set up to support access to leisure stimuli and the performance of a simple form of cognitive activity and basic physical exercise for adults with intellectual or intellectual and hearing disabilities, lack of functional speech, and poor motor dexterity.

Methods: The program alternated access to preferred stimuli (ie, songs, comic sketches, or cartoons) with cognitive activity (ie, matching-to-sample tasks) and physical exercise (ie, body movements). The touch screen technology was modified to ensure that people with poor motor dexterity would be effective in their responding regardless of the accuracy of their responses. The program was implemented with 7 participants. Its impact was assessed through the use of single-case research methodology.

Results: During the baseline (when standard technology was used), the mean percentage of songs, comic sketches, or cartoons accessed; match-to-sample responses provided; and body movements performed correctly and independent of research assistants' help was 0% for all participants with a single exception. During the intervention (when the new program with modified touch screen technology was used), the participants' mean percentage of songs, comic sketches, or cartoons accessed correctly and independent of research assistants' help per session was virtually 100%. Their mean percentage for correct match-to-sample responses provided and correct body movements performed independent of research assistants' help was within the 90% to 100% range.

Conclusions: The findings suggest that the program may constitute a useful tool for helping people with intellectual and multiple disabilities access leisure stimuli and engage in cognitive and physical activity.

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KEYWORDS

intellectual disability; deafness; touch screen technology; leisure; cognitive activity; physical exercise

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Introduction

Background

People with moderate to severe intellectual disability can have difficulties accessing leisure stimuli and engaging in basic cognitive and physical activity independently [1-7]. For example, their reduced manual dexterity and unfamiliarity with technological gadgets may limit their opportunities to operate standard devices available to select and activate preferred leisure stimuli, such as songs, comic sketches, and cartoons [8-12]. Their tendency to remain fairly isolated and their low motivation and self-determination may interfere with their possibility to (1) engage in cognitive activities such as listening to and answering questions related to their interest areas or performing stimulus discrimination and stimulus matching tasks [11-16] and (2) perform simple, beneficial body movements involving the arms, legs, or head and neck [17-20]. These difficulties may be even more marked in individuals with a combination of intellectual disability and sensory or sensory-motor impairments (eg, hearing loss and reduced ambulatory skills) [11,21-25].

The use of staff supervision to help people with intellectual and multiple disabilities access leisure options and practice cognitive activities and physical exercise may present 2 drawbacks. First, such supervision would be rather costly in terms of staff time and not always feasible in contexts in which staff availability is limited [3,7]. Second, the use of staff supervision would be unlikely to promote participants' independence [3,7,10,11]. A possible alternative to staff supervision may be the use of technology-aided programs [26-30]. A variety of technology-aided programs have been developed over the years to enable people to independently perform multistep tasks [3,6,7,31-33], engage in physical exercise [34-38], and produce verbal (easy-to-understand) requests for preferred events [39-45].

Programs have also been developed that have the objective of helping people engage in combinations of activities. The activities combined could include leisure and communication via telephone calls or messages [46]; leisure, communication, and occupational (functional) tasks [47]; or leisure, communication, and cognitive exercises via stories and related questions or series of questions [11,48]. In the last one of those studies [48], a program was assessed with 6 adults who were diagnosed with moderate intellectual disability, motor impairments, and lack of (functional) speech. The program relied on a tablet fitted with internet connection, a SIM card, WhatsApp Messenger, and the MacroDroid app and interfaced with pairs of response sensors. Every session started with the tablet presenting music and a telephone image and asking the participants whether they wanted to listen to music or call somebody. If the participants activated the sensor in front of the music image, the tablet presented the photos of 2 singers. Activating the sensor in front of one of the singers led the tablet to play a song by that singer for 1.5 minutes. The end of the song led the process to be repeated once or twice more. If the participants chose the telephone image, the tablet presented the photos of 2 preferred persons. Choosing one of them led to the start of a video call with that person.

Following the choice period, the tablet presented a series of 5 questions suitable to the participants' skills. For example, the tablet could present the image of a girl and the image of another person and ask, "Which one is a girl?" If the participants answered correctly by activating the sensor in front of the right image, the tablet provided verbal approval followed by the next question. If participants were incorrect, the tablet remained idle. Once all the questions had been answered, a new choice period started. A session included 4 choice periods and 3 series of questions. The results showed that, during the baseline, the participants were unable to use a standard tablet. During the intervention, they were successful in accessing songs, making video calls, and answering questions.

In light of (1) the encouraging results obtained with the program described previously and other programs targeting combinations of activities and (2) the positive implications of those results for participants and rehabilitation contexts, new research efforts in this area would appear quite relevant. Those efforts should be aimed at designing and evaluating new technology-aided programs for enabling people with intellectual and multiple disabilities to engage in different forms of activities (ie, activities promoting their enjoyment and vitalizing their intellectual and physical functions) independent of staff supervision.

Objectives

This study assessed a new program relying on touch screen technology that was designed to support access to leisure stimuli and the performance of a simple form of cognitive activity and basic physical exercise for adults with intellectual or intellectual and hearing disabilities, lack of functional speech, and poor motor dexterity. The program alternated access to preferred stimuli (ie, songs, comic sketches, or cartoons) with cognitive activity (ie, matching-to-sample tasks) and physical exercise (ie, series of body movements). The alternation was intended to motivate the participants to successfully manage the latter (presumably less preferred) forms of engagement [49,50]. The touch screen technology was modified to ensure that people with poor motor dexterity would be successful in their responding regardless of the accuracy of their responses. The program was implemented with 7 participants. Its impact was assessed through the use of single-case research methodology.

Methods

Participants

Table 1 lists the 7 participants involved in the study using pseudonyms and reports their chronological ages and their Vineland age equivalents obtained using the second edition of the Vineland Adaptive Behavior Scales [51,52]. The participants had a diagnosis of congenital or perinatal encephalopathy with intellectual disability. Three of them (Adriel, Lilah, and Wyatt) also presented with hearing loss, and one of these 3 (Wyatt) was nonambulatory. All participants had functional vision with or without glasses correction but lacked functional speech (ie, could only emit a few sounds or words) and had poor motor dexterity. Their chronological ages ranged from 24 to 64 years. Their Vineland age equivalents varied between 2 years and 3 months and 5 years and 9 months for daily living skills (the *personal* subdomain) and between 3 years and 1 month and 4

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years and 8 months for receptive communication. No IQ scores were available for them. Psychological records of the rehabilitation and care centers that they attended reported their level of intellectual disability to be in the moderate or moderate to severe range.

The participants were recruited through direct contact with the centers that they attended. Their selection was based on a number of conditions, which were verified through preliminary observations or staff interviews. First, they did not access preferred stimuli and did not engage in forms of cognitive activity and physical exercise without staff supervision. Second, they were considered unfit to use standard technology because they had difficulties following the multiple operational steps required for that and because they also had difficulties in activating a touch screen monitor given their poor motor dexterity and erratic response patterns (eg, heavy pointing, tapping, and touching with the fingernails). Third, they seemed to enjoy music, comic sketches, or cartoons and, thus, were thought to be strongly motivated to access these stimuli. Fourth, they could engage in basic forms of cognitive activity, such as carrying out simple match-to-sample tasks with various types of stimuli, when staff arranged those tasks for them. Fifth, they were able to imitate body movements considered to be suitable forms of physical exercise (eg, raising their arms and bringing them down to their knees) both when shown by a person in front of them and when presented on a computer screen. Sixth, staff considered the program and the technology used for it (shown to them in advance) functional for the participants and supported the study.

Table 1. Participants' chronological ages and Vineland age equivalents for daily living skills (personal subdomain; DLSP) and receptive communication (RC).

Participant pseudonym	Chronological age (y)	Vineland age equivalent[a]	
		DLSP	RC
Paisley	61	2 years 3 months	4 years 3 months
Adriel	51	4 years 7 months	3 years 1 month
Lilah	63	4 years 11 months	3 years 8 months
Jade	64	5 years 9 months	4 years 3 months
Lainey	48	4 years 4 months	4 years 3 months
Jayden	24	4 years 2 months	3 years 4 months
Wyatt	49	2 years 3 months	4 years 8 months

[a]Age equivalents are based on the Italian standardization of the Vineland Adaptive Behavior Scales [51].

Ethical Considerations

Regular staff members and research assistants showed the participants the technology (ie, touch screen monitor and the options it contained) and asked them whether they would like to use it. Their positive vocal or behavioral (head nodding) response to the question was taken as consent to the study. However, to make their recruitment highly transparent, their legal representatives were involved in the consent process. Specifically, the legal representatives were asked to read and sign a written consent form on the participants' behalf authorizing their inclusion in the study. No compensation was available for the participants whose privacy was protected through de-identification. This study was approved by the ethics committee of the Lega del Filo D'Oro, Osimo, Italy (P031020252). All procedures performed were in accordance with the national and international ethical standards and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Setting, Sessions, and Research Assistants

Quiet rooms at the rehabilitation and care centers that the participants attended constituted the setting for this study. This study included baseline and intervention sessions. The baseline sessions were carried out without the use of the technology system developed for this study. The intervention sessions involved the use of the technology system. The sessions were implemented by research assistants, typically once a day, 4 to 6 days a week. Four research assistants were employed to carry out the sessions and collect the data. They held university psychology degrees, had experience applying technology-aided intervention programs with people with disabilities, and were familiar with different data recording methods.

Technology System: Components

The technology system included a touch screen monitor of 27-48 cm, which was linked to a PC. The computer had internet connection, which allowed for the use of a specific web application. This application controlled the presentation of the leisure options (ie, songs, comic sketches, or cartoons), the cognitive activity (ie, match-to-sample tasks), and the physical exercise (ie, body movements) on the touch screen monitor (see the following section). Moreover, the web application enabled the touch screen monitor to (1) recognize different response configurations (eg, standard input responses, heavy touch, prolonged touch, tap or taps, and scrolling movements) and, thus, (2) react to those responses in a manner consistent with the content of the program [53]. The web application is freely available [54].

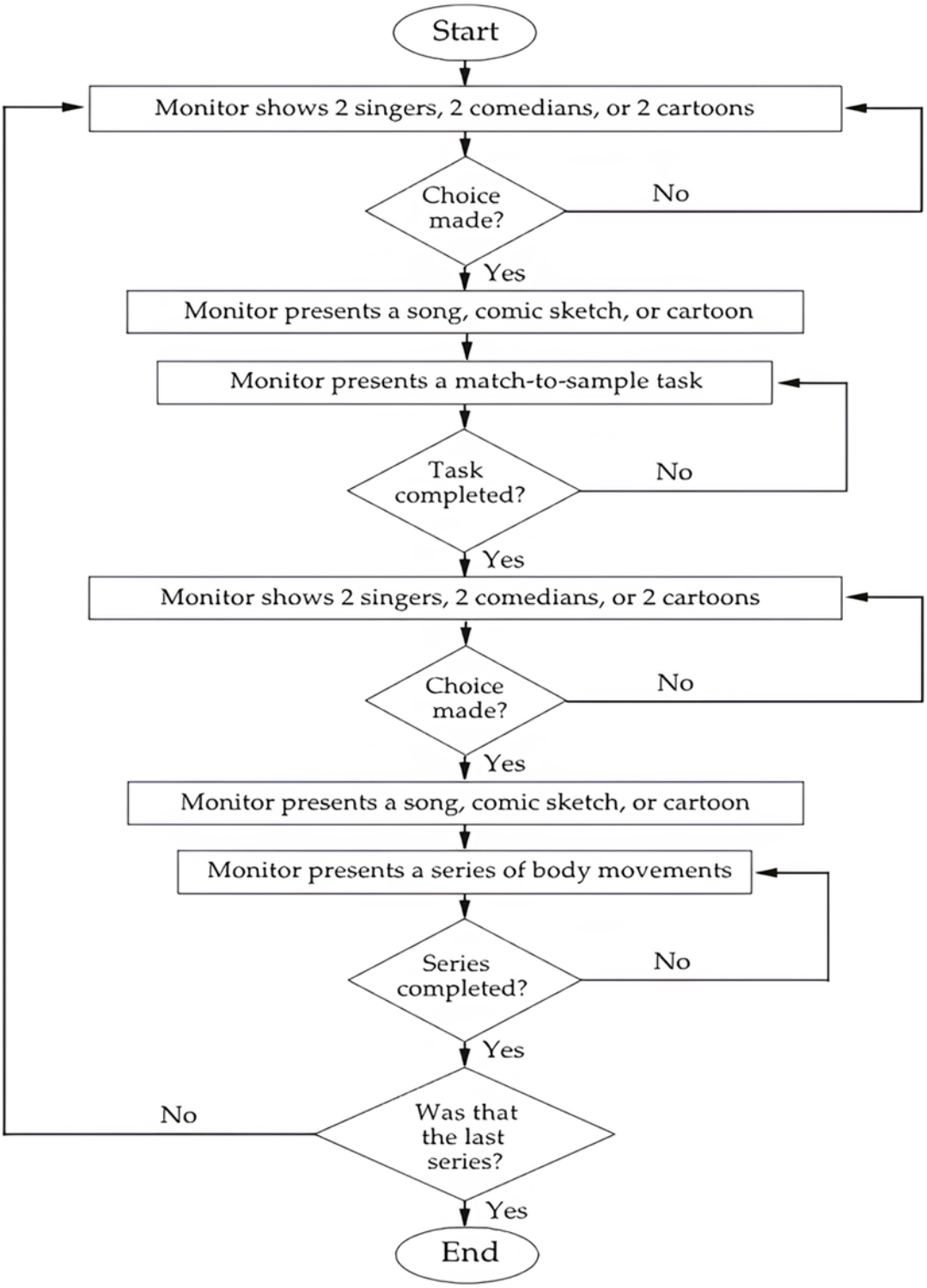
Technology System: Functioning

At the beginning of a session, the touch screen monitor showed 2 leisure options (ie, the images of 2 singers, 2 comedians, or 2 cartoons depending on the participants' preferences and

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hearing condition). The participants could choose 1 of the 2 alternatives by touching it. This caused the touch screen monitor to show a 2-minute video of a song, comic sketch, or cartoon consistent with the choice made by the participants. The only exception to this was Lilah, for whom comic sketches or cartoons lasted 1 minute. Observations indicated that her positive attention to those stimuli tended to decrease after 1 minute. Figure 1 provides a summary of the technology system's functioning.

Figure 1. Flowchart summarizing the technology system's functioning.

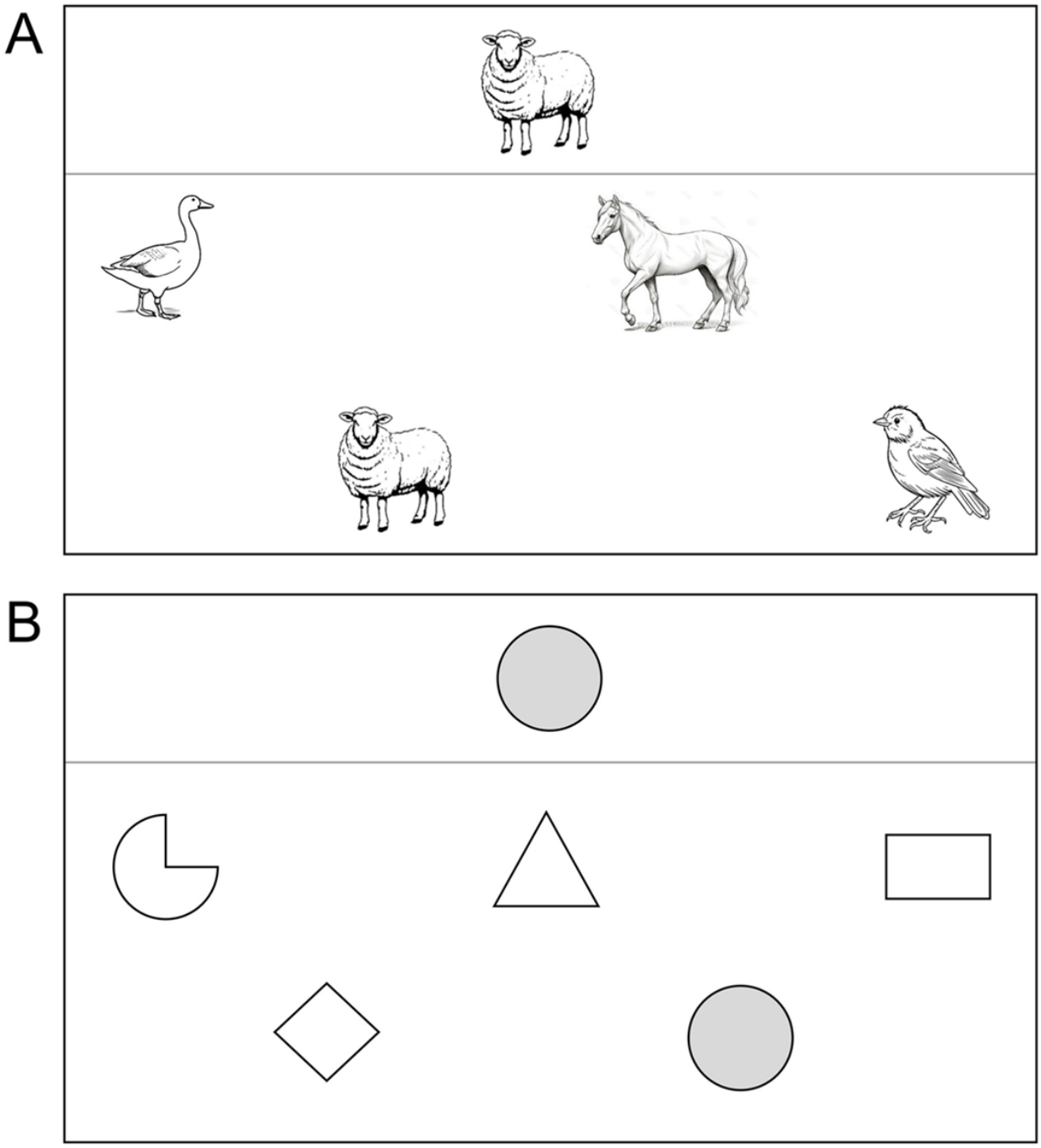


At the end of the song, sketch, or cartoon, the touch screen monitor presented a match-to-sample task consisting of 5 or 8 different pages (images), each of which represented a sample stimulus (eg, a colored animal or geometric shape) and 4 other colored stimuli, including the correct match (Figure 2A-B). The pages were presented individually so that the participants could see only 1 page at a time. In each of the pages, the participants were to touch the stimulus that correctly matched the sample.

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Touching the correct match caused the appearance of a picture showing approval for the response (eg, a woman with thumbs up). This was followed by the appearance of the next page of the task with the next set of stimuli, in which the participants were to identify and touch the correct match. Touching the incorrect match led to the permanence of the same page on the monitor. Progress to the next page occurred only after the participants touched the correct match or a preset interval of 20 to 30 seconds elapsed.

Figure 2. Schematic representation of 2 possible pages (A and B) of a match-to-sample task. Each page shows the sample (top) and the match stimuli available (bottom), which are shown in gray and white in this figure.



Once the match-to-sample task was completed (ie, with answers provided for each of the 5 or 8 pages), the touch screen monitor showed 2 new leisure options (ie, images of 2 singers, 2 comedians, or 2 cartoons), and all conditions were as those described previously. At the end of the song, sketch, or cartoon, the touch screen monitor presented a video in which the research assistants modeled a series of body movements that the participants were to reproduce. For example, the series could consist of the research assistants standing and sitting 10 or more times or raising their arms and bringing them down to their knees for 10 or more times. The research assistants movement modeling was combined with verbal instructions and encouragements to reproduce those movements. Background color changes (eg, red for arms up and white or green for arms

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down) could be used for the participants with hearing loss to foster their attention and movement discrimination.

Once the series of body movements had been completed, a new 4-stage sequence (ie, singers, comedians, or cartoons; match-to-sample task; singers, comedians, or cartoons; and body movements) started. The new sequence included different singers, comedians, or cartoons; a different match-to-sample task; and new body movements or new combinations of them. A session included 3 sequences so that the participants had to (1) make 6 choices between singers, comedians, or cartoons (thus accessing 6 songs, 6 comic sketches, or 6 cartoons); (2) complete 3 match-to-sample tasks; and (3) perform 3 series of body movements.

Data Recording

The measures recorded were (1) the songs, comic sketches, or cartoons accessed correctly and independent of research assistants' help; (2) the match-to-sample responses carried out correctly (ie, those targeting the correct match in the first attempt) and independent of research assistants' help; (3) the body movements reproduced correctly and independent of research assistants' help; (4) the instances of research assistants' help; and (5) the length of the sessions. The research assistants recorded all 5 measures during the baseline and intervention sessions.

Interrater agreement was checked in 22.4% (15/67; Adriel) to 26.0% (20/77; Jade) of single-participant sessions through the use of a reliability observer. Agreement on songs, comic sketches, or cartoons accessed; correct match-to-sample responses; and instances of research assistants' help were recorded when the research assistants and the reliability observer had the same scores. Agreement on body movements and session length was recorded when the research assistants and reliability observer had scores that differed by no more than 3 units and 2 minutes, respectively. The percentage of agreement (computed for each participant by dividing the number of sessions in which agreement was reported for all measures by the total number of sessions involving the reliability observer and multiplying this by 100%) was 90% or above for all participants.

Experimental Conditions and Data Analysis

Overview

This study was implemented according to a nonconcurrent multiple baseline design across participants [55,56]. Initially, there was a baseline phase in which the participants were provided with a touch screen monitor that worked in a standard manner. This phase included different numbers of sessions for the participants as required by the design. Two intervention phases were then implemented, during which the participants were provided with the technology system described previously.

To guarantee that the research assistants would implement the sessions accurately (ie, to foster procedural fidelity [57]), familiarization and feedback strategies were used. Familiarization consisted of 2 preliminary meetings in which the research assistants were to practice the baseline and intervention conditions under supervision. Feedback consisted of comments provided to the research assistants after the sessions to inform them as to whether their performance was accurate or needed corrections. Feedback was delivered by a study coordinator who had access to videos of all the sessions.

The baseline and intervention data were reported in graphic format. The percentage of nonoverlapping data (PND), a data analysis method commonly used in single-case experimental research [58], served to determine the impact (effect size) of the intervention on (1) songs, comic sketches, or cartoons accessed; (2) correct match-to-sample responses provided; and (3) body movements reproduced. Specifically, the PND method served to calculate the percentage of intervention sessions with a score higher than the highest baseline score for each measure.

Baseline

The baseline phase included 5 to 11 sessions, during which the technology system described previously was not available and the touch screen monitor worked in a standard manner. Initially, the monitor showed the Google icon. Touching (activating) this icon led the monitor to show a web page with 3 separate folders on the favorites bar: one concerning preferred leisure events (ie, songs, comic sketches, or cartoons), a second one concerning match-to-sample tasks, and a third one concerning body movements. Touching (opening) the first folder led to websites containing videos of preferred songs, comic sketches, or cartoons. Touching (opening) the second folder led to websites containing specific match-to-sample tasks. Touching (opening) the third folder led to websites containing videos of different body movements. Initially, the research assistants modeled the response to access a preferred song, comic sketch, or cartoon (depending on the participants), that is, touching the Google icon; touching (opening) the leisure folder; and touching (opening) the website containing a video with a preferred song, comic sketch, or cartoon. The video was stopped shortly thereafter, and the participants were asked to produce the response on their own. If the participants did not manage to do so for 20 to 30 seconds (ie, an interval considered sufficient for them to produce a response), the research assistants repeated the sequence to allow them to access a song, comic sketch, or cartoon for 2 minutes (1 minute in the case of Lilah).

At the end of the song, sketch, or cartoon, the research assistants modeled the response to access a match-to-sample task (ie, cognitive activity). The response consisted of (1) touching the Google icon, which led to the appearance of the leisure, match-to-sample, and body movement folders; (2) touching (opening) the match-to-sample folder, which led to websites containing match-to-sample tasks; and (3) touching (opening) one of these websites showing a specific match-to-sample task. The task remained visible only briefly. The participants were then asked to proceed on their own. If they did not manage to do so for 20 to 30 seconds, the research assistants repeated the sequence to allow them to access a task and helped them (if needed) to provide match-to-sample responses.

After the match-to-sample responses, the research assistants modeled the response for accessing a song, comic sketch, or cartoon. All steps and conditions were identical to those described previously. Once the song, comic sketch, or cartoon had ended, the research assistants modeled the response for accessing the body movement (ie, physical activity) option. The

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sequence involved (1) touching the Google icon; (2) touching (opening) the body movement folder; and (3) touching (opening) one of the websites, in which a video with 10 repetitions of specific body movements (eg, moving arms up and down) was presented. The video was soon halted, and the participants were asked to proceed on their own. Conditions for research assistants' help in case of participant failure were as described previously.

The session was interrupted (to reduce frustration) once the participants had received 4 instances of research assistants' help for opening the websites and accessing songs, comic sketches, or cartoons; match-to-sample tasks; and body movements. The scoring for songs, sketches, or cartoons accessed; match-to-sample responses provided; and body movements performed was negative if the participants required research assistants' help to open the websites leading to them. Negative scoring was also used in relation to the songs, sketches, or cartoons; match-to-sample responses; and body movements missed due to session interruption.

Intervention Phase 1

During the first intervention phase (including 28-40 sessions), the participants were provided with the technology system that worked as described in the Technology System: Functioning section and Figure 1. At the start of a session, the touch screen monitor showed the pictures of 2 leisure stimuli, and the participants were to touch one of them to start a song, comic sketch, or cartoon depending on the pictures displayed. A song, comic sketch, or cartoon lasted 2 minutes (1 minute in the case of Lilah). Thereafter, the touch screen monitor showed (one at a time) the 5 pages of the first match-to-sample task available. For each page, the participants were to touch the stimulus that matched the sample. Once the participants had completed the match-to-sample task, the touch screen monitor presented 2 new leisure stimuli. The participants were to choose one of them as mentioned previously. At the end of the leisure event (ie, song, comic sketch, or cartoon), the touch screen monitor presented a video with the research assistants showing a series of 10 to 18 body movements. The participants were to imitate (reproduce) those movements. Completion of the body movement series led to the beginning of a new 4-stage sequence (ie, leisure stimuli, match-to-sample task, leisure stimuli, and body movements). A session included 3 of those sequences, which differed in terms of the leisure events, match-to-sample tasks, and body movements presented.

The phase was introduced by 4 to 6 practice sessions in which the participants were provided with research assistants' help to manage their access to leisure events, responses to the match-to-sample tasks, and imitation (reproduction) of body movements. During the regular sessions that followed, research assistants' help would only be available if the participants failed to access a leisure event for 20 to 30 seconds.

Intervention Phase 2

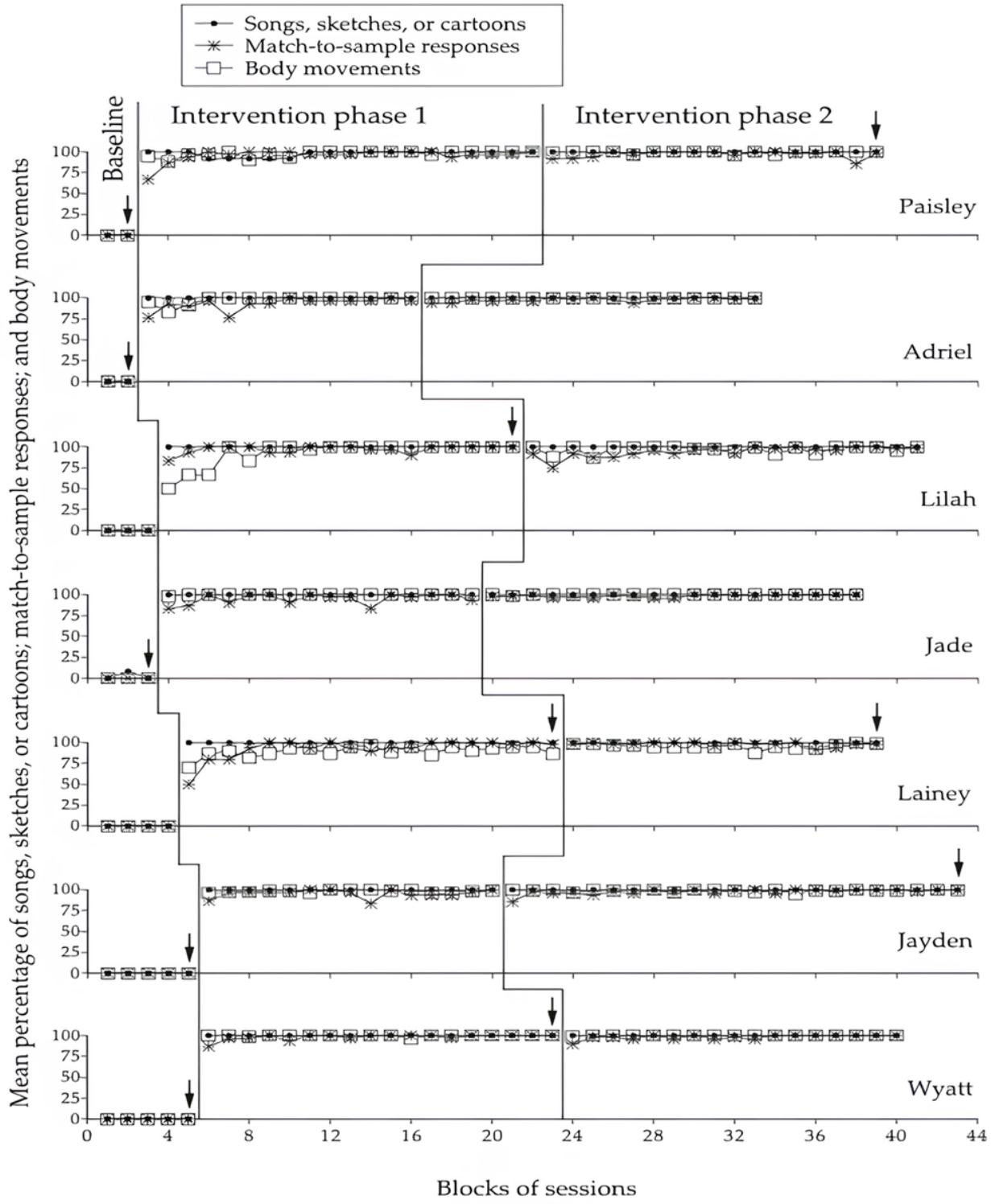
During the second intervention phase (including 33-47 sessions), all conditions were as in intervention phase 1 except that (1) the match-to-sample tasks included 8 (rather than 5) pages and (2) the series of body movements included 14 to 30 (rather than 10-18) movements.

Results

Figure 3 summarizes the baseline and intervention data for the 7 participants. The dots represent the mean percentage of songs, comic sketches, or cartoons accessed independent of research assistants' help per session over blocks of 2 sessions. The asterisks and the empty squares represent the mean percentage of correct match-to-sample responses provided and correct body movements performed per session over the same blocks of sessions, respectively. The arrows mark blocks of 3 sessions that took place at the end of the baseline and intervention phases. The practice (familiarization) sessions preceding the start of intervention phase 1 do not appear in the figure.

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Figure 3. Dots, asterisks, and empty squares represent the mean percentage of songs, comic sketches, or cartoons accessed; match-to-sample responses provided; and body movements performed over blocks of 2 sessions, respectively. Blocks of 3 sessions are marked with an arrow.



During the baseline phase, the mean percentage of songs, comic sketches, or cartoons accessed; match-to-sample responses provided; and body movements performed correctly and independent of research assistants' help was 0% for all participants except Jade. She managed to access 1 song throughout the 7 baseline sessions available to her. Participants were largely characterized by inactivity and failed to produce effective touch screen responses on those occasions in which they took the initiative to follow the research assistants' modeling on how to activate the Google icon and open the 3 basic folders and the related websites. The aforementioned inactivity and difficulties (causing dependence on research assistants' help) led to the interruption of all baseline sessions. The length of those sessions was always below 15 minutes.

During intervention phase 1, the mean percentage for songs, comic sketches, or cartoons accessed correctly and independent of research assistants' help per session was 100% for all participants except Paisley, whose mean percentage was 97.9%

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(SD 3.7%). The mean percentage of correct match-to-sample responses provided and correct body movements performed independent of the research assistants' help ranged between 92.7% (SD 12.1%; Lainey) and 98.2% (SD 3.5%; Wyatt) and between 90.1% (SD 6.5%; Lainey) and 99.9% (SD 0.4%; Jade), respectively. The mean session length varied between slightly over 15 minutes (Lilah) and 23 minutes (Lainey).

During intervention phase 2, the mean percentage for songs, comic sketches, or cartoons accessed correctly and independent of the research assistants' help per session was 100% for all participants. The mean percentage for correct match-to-sample responses provided and correct body movements performed independent of the research assistants' help ranged between 94.2% (SD 6.0%; Lilah) and 98.6% (SD 1.7%; Jade) and between 95.6% (SD 3.1%; Lainey) and 100% (SD 0%; Adriel), respectively. The mean session length varied between approximately 16.5 minutes (Lilah) and 27.5 minutes (Lainey).

The PND method showed an index of 1 on each of the aforementioned 3 measures for all participants. Indeed, the data values of the intervention sessions were always higher than the baseline data values on each of the measures. This evidence confirms the strong impact of the intervention with the technology system across participants and measures.

Discussion

Principal Findings

The results suggest that participants with intellectual or intellectual and sensory-motor disabilities could use the technology system introduced in this study to access songs, comic sketches, or cartoons; provide correct match-to-sample responses; and perform correct body movements independent of research assistants' help. These results confirm previous findings showing that technology-aided programs can be set up to help people with intellectual and multiple disabilities engage in functional activities independent of staff [3,7,11,41]. These results also extend previous evidence. In fact, this study (1) included a form of cognitive (match-to-sample) activity and basic physical exercise adjustable to people with intellectual and multiple disabilities and (2) introduced a new, modified touch screen system. In light of the aforementioned results, several considerations may be in order.

First, enabling people with intellectual and multiple disabilities to remain constructively busy for practically relevant time periods independent of staff supervision may be considered a meaningful achievement for the participants and their rehabilitation context. Indeed, participants can develop and strengthen self-determination and initiative, reach a higher (more satisfactory) level of functioning, and experience a better quality of life in line with their rights [59-64]. The rehabilitation context may be able to include extra opportunities for constructive engagement in the participants' daily schedules without significant investment of staff time [7,65,66].

Second, access to preferred leisure stimuli may be considered important for the participants' enjoyment and possibly their level of satisfaction with the sessions [50,67]. Engaging in cognitive activity and physical exercise may be important for the participants' intellectual and physical stimulation and contribute to their rehabilitation progress and well-being [11,14,68,69]. Combining (interspersing) access to preferred leisure stimuli with cognitive and physical activities, as was done in this study, might help (motivate) the participants to constructively engage in the latter types of activities as well irrespective of the fact that these activities may not necessarily be preferred by them [49,50]. While no formal data are available to confirm the accuracy of the aforementioned statement, the participants' positive and stable performance throughout the intervention sessions may be taken to suggest that they remained motivated to engage in each of the activities available, thus making their involvement in the study constructive and profitable.

Third, the participants' motivation and positive performance during the intervention phase may be ascribed not only to the presence of preferred leisure events among the options available but also to other factors. For example, the cognitive (match-to-sample) tasks and physical exercises (body movements) were tailored (adjusted) to their skill level in terms of the stimuli and movements included, thus minimizing difficulties, failures, and frustration. The participants received positive feedback for the cognitive (match-to-sample) responses completed, and it is possible that such feedback represented a mild form of reinforcement [50]. The body movements were supported by instructions and encouragements for the participants with typical hearing and were cued (emphasized) through background color changes for the participants with hearing loss. The touch screen monitor reacted promptly and consistently to the participants' touch responses, minimizing any risk of failures.

Fourth, the web application included in the technology system ensured that the participants could make their touch responses successful (ie, choosing and activating a preferred leisure stimulus and selecting a matching stimulus) regardless of the accuracy (quality) of their contact with the touch screen monitor. Specifically, they could be successful irrespective of whether their contact consisted of a standard input touch, a heavy touch, a prolonged touch, taps, or scrolling movements. The use of such an application was considered critically important (necessary) based on the preliminary assessment of the participants' response characteristics and their baseline performance. Whether the application was still strictly necessary for all participants by the end of the study is not clear as no data were collected on that. Informal observations seemed to suggest that the participants' response schemes did not show particular changes over time.

Limitations and Future Research

The 3 main limitations of this study involve the lack of assessment of participants' satisfaction with the touch screen technology system and the intervention sessions, the lack of social validation of the program and the related technology, and the absence of maintenance and generalization data on the effects of the program. Regarding the participants' satisfaction, 2 basic points can be made. First, the fact that the participants remained constructively engaged throughout the intervention sessions seems to suggest that they were comfortable (and

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possibly satisfied) with the sessions and their content [49,50,67]. Moreover, anecdotal reports provided additional support for this view. Second, future studies are expected to include a formal assessment of participant satisfaction. The assessment could involve two approaches: (1) measuring the participants' indices of happiness during and outside of the sessions and (2) having the participants choose between the sessions and other types of daily occupation [70,71].

The lack of social validation of the program and the technology used can be amended by future studies through surveys of staff and caregivers on these points. In practice, staff and caregivers could be (1) shown videos of the program (intervention) sessions with the participants using the technology and (2) asked to rate the program and technology in terms of impact, user-friendliness, and usability [72-74]. The lack of maintenance and generalization data can be amended by (1) extending the data collection period to verify whether the participants' performance remains stable over time and (2) implementing the program across different settings to ascertain whether the participants continue to be successful irrespective of the context [50,75].

The lack of assessment of whether the cognitive activity and physical exercise had an impact on the participants' functioning in those areas may be considered a fourth limitation of this study. Future research may need to address this limitation and find ways (ie, identify appropriate measures) to carry out such an assessment. The relatively small number of participants might not be considered an additional limitation as far as the internal validity of the data reported is concerned. In fact, the single-case research design used in this study is admittedly adequate to ensure such validity [55,56,76]. To test the external validity of those data, one would need to implement single-case replication studies and possibly group studies including experimental and control conditions [77-79].

Conclusions

The results suggest that the intervention program with the support of the technology system was effective in enabling participants with intellectual and multiple disabilities to independently access leisure events, manage match-to-sample tasks, and perform series of body movements. These findings can be considered encouraging as to the possibility of helping people with serious disabilities reach relevant levels of independent occupation through technology-aided programs. However, no conclusions about their implications can be drawn given the limitations of this study discussed previously. New research will need to counter those limitations and assess the generality and robustness of these data. New research might also seek to upgrade the technology system to make it simpler and more easily available.

Acknowledgments

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Data Availability

The datasets generated during this study are available on OneDrive repository [80]

Authors' Contributions

GEL was responsible for setting up the study, acquiring and analyzing the data, and writing the manuscript. GA and CF collaborated in setting up the study and the technology system and contributed to acquiring and analyzing the data and editing the manuscript. NNS, MFO, and JS collaborated in setting up the study, analyzing the data, and writing and editing the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

PND: percentage of nonoverlapping data

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Use of Socially Assistive Robots in Physiotherapy: Scoping Review

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Abstract

Background: Socially assistive robots (SARs) are robotic technology platforms equipped with sensing (eg, through audio or visual) and acting (eg, speech and movement) capabilities to interact socially with users. SARs are increasingly adopted in physiotherapy to aid patients in their rehabilitation journey by providing feedback, motivation, and encouragement. However, while many studies have explored SAR implementation in physiotherapy, research involving clinical populations remains scarce, and the overall state of SAR deployment is unclear.

Objective: This scoping review aimed to explore the use of SARs in physiotherapy with clinical populations, how the effectiveness of these interventions has been evaluated, and identify limitations and new areas of application and future work.

Methods: Following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Review) reporting guideline extension, comprehensive searches based on SARs and physiotherapy were conducted in various databases. Title and abstract screening were performed by 1 reviewer, with full-text screening conducted by 2 reviewers. Data extraction, synthesis, and analysis were completed by 1 reviewer. Data on SAR roles were categorized and synthesized using content analysis. Other descriptive texts were summarized to improve readability.

Results: Our findings suggest that SARs are commonly used in rehabilitation clinics and hospital inpatient settings, primarily for neurological conditions. In these interventions, SARs typically serve roles, such as coaching, demonstration, monitoring, and peer support. Their effectiveness is generally evaluated through clinical outcomes, user performance, functional measures, and metrics assessing the robots' acceptability, usability, and perception.

Conclusions: This scoping review highlighted SARs' potential to address challenges faced by human therapists due to the demands of time-extending coaching and monitoring and the limited availability of therapists. Future research should focus on addressing the limitations identified in this scoping review, including small sample sizes, technical issues in both the robot and intervention design, sufficient involvement of key stakeholders in the design and development of SAR-based interventions, and conducting more clinical trials to investigate SAR intervention effectiveness.

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KEYWORDS

socially assistive robots; robotics; physical therapy modalities; rehabilitation; human-robot interaction

Introduction

Socially assistive robots (SARs) are designed to provide support to users primarily through social interaction and engagement. SARs were first defined and introduced in the field of physiotherapy in a foundational publication by Feil-Seifer and Mataric [1]. Unlike physically assistive robotic systems, SARs can achieve their primary function without performing any physical work or physically interacting with the environment or the intended user [2]. SARs are endowed with unique capabilities in human-social interactions, such as recognizing patterns of human interactions and engaging users through various forms of communication, including verbal and nonverbal cues, such as motion, and visual or tactile aids [1,3]. By emphasizing noncontact social interaction, SARs have shown promise in enhancing patient adherence, motivation, and engagement in rehabilitation exercises [4]. These merits in SAR application are the key to assisting physiotherapists in fostering active participation in health care programs [5].

In rehabilitation, where time spent engaging in interventions is a key dosage parameter, SARs play an important role by offering verbal encouragement, coaching, feedback, reminders, and continuous monitoring to enhance the overall therapeutic intervention or self-directed therapy [5,6]. For instance, for

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children diagnosed with cerebral palsy (CP), conventional therapy approaches may benefit from novel strategies to increase motivation and thus achieve optimal outcomes [7]. A previous review has found that children and young adolescents with CP generally interact positively with SARs, leading to improved motivation and engagement [8]. Furthermore, SARs can be tailored to conduct gamified motor training sessions, capturing the attention of children with CP and encouraging active participation [9]. SARs' ability to address barriers to participation in therapy, such as motivation and self-efficacy, aligns with goals recognized by the International Classification of Functioning, Disabilities and Health (ICF) [10] developed by the World Health Organization (WHO), which serves as the most encompassing taxonomic model to describe an individual's functioning and disability [11].

While existing literature indicates that SARs show promise for improving outcomes across health and social care settings for diverse populations, their specific applications in physiotherapy remain poorly characterized [12]. Despite the growing interest in integrating SARs into rehabilitation settings, the full breadth of usage in physiotherapy practice remains unclear, partly due to a current lack of literature summarizing SAR-assisted physiotherapy studies directly involving clinical populations. Existing reviews of SAR-assisted therapy in physiotherapy have primarily focused on interventions for children living with CP, providing valuable yet constrained perspectives on the potentially broader usage of SARs in physiotherapy practice [9,13,14]. A scoping review exploring the use of robot-assisted therapy for upper limb impairments in children with CP identified 1 type of SAR (CosmoBot) [14]. This SAR was used in a small sample size (n=6) study investigating effects on functional movement quality, thus providing a limited view of the state of SAR deployment in physiotherapy practice.

This paper aims to fill this gap and advance the field by presenting a scoping review of the current state of the art of SAR deployment in physiotherapy with clinical populations [15]. Specifically, this scoping review seeks to identify how SAR systems are implemented and operationally integrated into interventions and activities reported in physiotherapy contexts and describe the methods used to evaluate the effectiveness of interventions that integrate the use of SARs. In addition, the review aims to identify current limitations to SAR integration within physiotherapy interventions and explore new potential application areas suggested in research to date. The findings of the scoping review will guide future interdisciplinary collaboration between physiotherapy, roboticists, and human-robot interaction researchers interested in investigating SAR applications in clinical populations.

Methods

Study Design

This review was a systematic scoping review that followed the methodological steps first described by Arskey and O'Malley [16] and subsequently refined by Levac et al [17], Peters et al [18] and Pollock et al [19]. A scoping review was determined to be the most appropriate review methodology given the paucity of clinical trials investigating the effectiveness of SAR interventions in clinical physiotherapy, which precludes the conduct of a systematic review [20]. As such, our review question was "What is known about the use of SARs within physiotherapy interventions and activities with clinical populations?"

The advantages of a scoping review approach are the development of a systematic and reproducible search strategy, with clear inclusion and exclusion criteria to comprehensively identify and chart existing evidence related to our review question and identify gaps and potential avenues for future research. This scoping review report follows the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Review) [21]. Given the nature of the scoping review being a type of systematic review, no ethical approval was needed.

Search Strategy

The scoping review search terms were structured using the population, concept, context (PCC) framework [18]. For this review, the population was any clinical population, the concept of interest was SARs, and the context of interest was the conduct of physiotherapy interventions or activities. To ensure a balanced and comprehensive yield of existing publications related to robotics in physiotherapy, a combination of health and engineering literature databases was systematically searched. The engineering databases searched for this scoping review were the Association of Computing Machinery (ACM) and the Institute of Electrical and Electronics Engineers (IEEE) databases. The health databases searched were Ovid MEDLINE, Ovid Emcare, Ovid EMBASE, Ovid Cochrane Library, Scopus, and the CINAHL.

A primary database search string was developed in consultation with an academic librarian as recommended for scoping reviews [18]. The first search was constructed for execution in MEDLINE using Medical Subject Headings (MeSH), database-specific thesaurus equivalent words and keywords for SAR (eg, "social* assist* robot") and physiotherapy (eg, "physiotherapy"). Details of complete syntax are listed in (Multimedia Appendix 1).

The primary search string was then adapted for use in all other electronic databases by modifying syntax and using database-specific subject headings (ie, MeSH). In cases where a database did not use subject headings (such as Scopus, ACM, and IEEE), only keywords were used. A study date limit filter was applied to restrict the search for publications since the foundational 2005 publication of Feil-Seifer and Mataric [1]. All databases were searched up to November 23, 2023. Complete search strings for all databases searched are presented in (Multimedia Appendix 2).

Identified records from all databases were uploaded to reference manager software Endnote (Clarivate; [22]) and imported into systematic review software Covidence (Veritas Health Innovation; [23]) for screening. Records were automatically deduplicated in Covidence before conducting title, abstract, and full-text screening. Further manual identification and removal of duplicates were conducted during the screening stages to ensure no duplicate records appeared in the final yield.

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Inclusion and Exclusion Criteria

Population

All studies involving clinical populations interacting with SARs were included.

Concept

Only studies reporting on SARs as an intervention, a medium to deliver an intervention, or both were considered. As defined in the introduction, the SARs reported must be capable of providing noncontact social interaction with users. Therefore, studies involving surgical or physically assistive robotics, artificial intelligence software, and virtual intervention without focusing on SARs were excluded.

Context

Studies conducted using physiotherapy as an intervention or cotherapy in various settings, such as hospitals, clinics, community health care centers, and residential aged care facilities, were included.

Types of Studies

Only full-text peer-reviewed primary studies written in English and published from 2005 to the present were included. Peer-reviewed conference papers and proceedings reporting completed studies were considered for inclusion, as in the engineering literature, these undergo a peer review process akin to that of journal papers in the medical field. Any unfinished studies and gray literature, including short technical reports and workshop papers, were excluded. Only studies that reported clinical studies were considered. Publications that solely described robot design and development or evaluated system feasibility, system features, or user perception were excluded.

Selection of Relevant Publications

All references were imported into Covidence [23]. One reviewer (JH) screened all records at the title and abstract stage against the eligibility. To confirm reviewer accuracy in applying the eligibility criteria, a subset of 25 studies was randomly selected for independent evaluation by all 3 review team members. The outcome of the 3 independent reviews of the 25 studies was compared and agreement on the screening outcome was confirmed.

Two reviewers independently screened all papers at the full-text screening stage. One reviewer (JH) screened all papers while the second independent review was conducted by either MF or PCM. Meetings between all 3 reviewers occurred at regular intervals during all screening stages, ensuring close supervision of JH's screening progress and a unified and consistent interpretation of the criteria. Conflicts identified at the full-text screening stage were resolved by an initial discussion between the reviewing pair (JH and MF or JH and PCM) until a consensus was reached. If a consensus could not be reached by the reviewing pair, the third reviewer was consulted and discussion continued until a consensus was reached. Included studies advanced to data extraction, while exclusion reasons were documented for excluded studies.

Data Extraction

A data-charting form was developed in Covidence [23] to extract relevant data from the included studies [4,24-35] . The types of data extracted are shown in (Table 1). The review team piloted the data-charting form with the first 2 records and revised it before charting the data from the rest of the included studies [4,24-35].

One of the reviewers (JH) completed the remaining data extraction process to ensure data extraction consistency. Two reviewers (MF and PCM) audited the extracted data from 4 included studies [26,30,34,35] (approximately 30% of the final yield) and identified negligible errors in the data extracted. Extracted data were then exported from Covidence [23] to a spreadsheet for synthesis.

Table . Template for extracting information from the included studies.

Topic	Extraction details
Study	Title, author name, publication year, country, study duration, study design, study aim, and sample size.
Population	Age and condition or diagnosis.
Concept	Physiotherapy setting, physiotherapy goal, type of training, specific exercise prescribed to patients, length of each session in minutes, number of sessions, and intensity of training.
Context	Name of the robot, level of autonomy, if the robot was being controlled during the intervention, technical support presence during the intervention, area of physiotherapist and patient or client involvement in the protocol or robot design phase, robot model, the function of robot, the behavior of the robot, the communication channels between robot and users, presence of physiotherapist during the intervention, role of physiotherapist and presence of a control group.
Outcome and finding	Construct investigated and associated outcome measure, key finding, study and robotic limitation, and area of application.

Data Analysis and Synthesis

Data synthesis and analysis was led by JH with regular review meetings with MF and PCM to confirm the accuracy of the synthesis process and devise a shared interpretation of the data synthesized. Charted data were first categorized into groups related to the scoping review questions: study and participant

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characteristics (population), features of physiotherapy (context), features of SARs (concept) used in interventions, robot design features, evaluation methods, key findings, limitations, and areas of application. Patterns were identified within each group and categorized, which aided the comparison and interpretation of data.

Subsequently, a more detailed analysis of the data extracted from included studies [4,24-35] by applying content analysis [36] was performed. Descriptive text extracted from studies relating to robot function and behavior was condensed, and patterns related to robot functions were coded and grouped into categories. Similarly, descriptive text concerning the role of physiotherapists, physiotherapists, and patient or client involvement in the protocol and robot design phase, key findings, limitations, and application areas were condensed, coded, and categorized. Throughout the data analysis process, all data were directly linked to the source material, and where necessary, the original text was revisited to confirm context or meaning if extracted data segments were ambiguous when being analyzed in isolation.

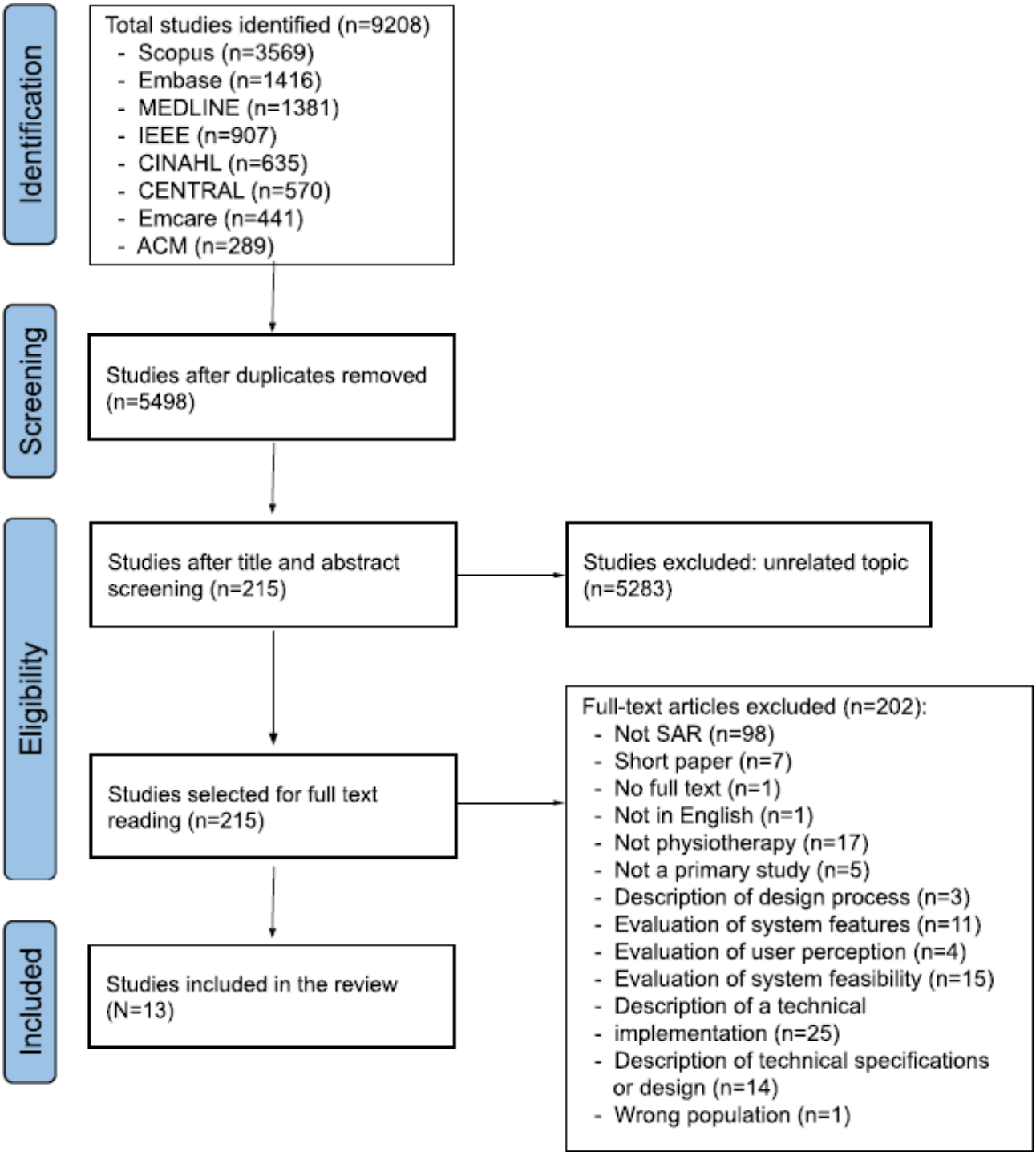
Results

Description of Included Studies

The database searches identified 9208 studies. After removing duplicates (3710 studies) and title and abstract screening, 215 studies were included for full-text screening. Of those, 202 studies were excluded with main reasons shown in Figure 1. Seven short papers related to our review question were identified at the full-text screening stage. A citation linkage search using Google Scholar was conducted to establish if any subsequent full-text reports had been published. No additional records meeting the inclusion criteria were identified by citation tracking of the studies included at the full-text stage. A final yield of 13 studies [4,24-35] met the criteria for inclusion in the review (Figure 1).

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Figure 1. Flowchart of study selection process adapted from the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Review) flowchart for this review.



SAR-Related Interventions and Activities in Physiotherapy

In this section, we begin by summarizing the general characteristics and demographic details of the selected studies. Following that, we provide an overview of the specific physiotherapy interventions, including prescribed exercises, dosage, and objectives.

Physiotherapy Settings and Participant Groups

Table 2 lists the main characteristics, demographic details, and countries where the SAR interventions took place. For studies that did not explicitly report their country of implementation, we derived the location from the institutional affiliation of the first or corresponding author, treating this as the proxy country of study. Among the included studies, the geographical distribution was as follows: Colombia hosted the largest number (3/13, 23%) [24-26], followed by 2 studies each in Spain [27,28], Israel [29,30], and Australia [4,31]. Single studies were reported from Belgium [32], France [33], and Saudi Arabia [34].

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Table . Description of included studies with information is categorized by physiotherapy settings where socially assistive robotics were used.

Article and Year	Country	Study duration	Study design	Sample size	Study group (s) and age in years (mean, SD)	Diagnosis or Condition
Hospital inpatient						
Pulido et al [27], 2019	Spain	4 months	Quasi-experimental small-N design	8	• Traditional group: 3-10 • Robot group: 3-10	Obstetric brachial plexus palsy or infantile cerebral palsy
Salas-Monedero et al [28], 2023	Spain	Not reported	Prospective observational study	10	• Patients with tetraplegia: 9.7 (4.0) • Patients with paraplegia: 10.6 (2.1)	Pediatric-onset chronic spinal cord injury
Meyns et al [32], 2019	Belgium	8 months	Cohort study	89 (typical developing children: 75; children with oncological disorders: 14)	• Typical developing children: 4-13 (mean 7.9, SD 2.3), • Children with oncological disorders: 3-15 (mean 7.0, SD 3.8)	Neutropenia and cancer
Both inpatient and outpatient						
Butchart et al [31], 2021	Australia	2 months	Not reported	10 (children: 5; parents: 5)	• Children: 6-12 • Parents: 38-47	Cerebral palsy, hemispherectomy, or hereditary spastic paresis
Rehabilitation center						
Buitrago et al [24], 2020	Colombia	8 weeks	Case report	1	• 8	Dyskinetic cerebral palsy
Feingold Polak and Tzedek [29], 2020	Israel	5-7 weeks	Not reported	4	• 51-75 (mean 64, SD 10)	Stroke
Cespedes et al [25], 2020	Colombia	Not reported	Not reported	4	• Between 20 and 60	Stroke, spinal cord injuries, and Guillain-Barré syndrome
Blanchard et al [33], 2022	France	19 months	Randomized controlled trial	27 (robot: 15; control group: 12)	• Robot group: 42.9 (12.8) • Control group: 43.8 (9.7)	Nonspecific low back pain
Rehabilitation clinic						
Carrillo et al [4], 2020	Australia	23 months	Not reported	9	• Not reported	Cerebral palsy
Feingold-Polak et al [30], 2020	Israel	5-7 weeks	Randomized controlled trial	24 (robot group: 11; computer group: 13)	• Robot group: 30-76 (mean 54.8, SD 13), • Computer group: 40-77 (mean 62.6, SD 15)	Stroke
Irfan et al [26], 2020	Colombia	18 weeks	Longitudinal case study	• 1	• 6	Myocardial infarction

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Article and Year	Country	Study duration	Study design	Sample size	Study group (s) and age in years (mean, SD)	Diagnosis or Condition
Al-Shahry and Al-Shehri [34], 2020	Saudi Arabia	5 trials on different days	Not reported	5	• 20-65	Patients with musculoskeletal conditions diagnosed with pain in muscles or joints or both
Private nursing home						
Bäck et al [35], 2013	Finland	7 months	Not reported	34	Median age greater than 85	Residents of the nursing home

SAR interventions were implemented across various physiotherapy settings, with the most common being rehabilitation clinics [4,24-26,29,33-35] (8/13, 62%) and hospital inpatient settings [27,28,32] (3/13, 23%). One study [31] reported rehabilitation in both inpatient and outpatient settings (1/13, 8%). Inpatient physiotherapy takes place when the patient is admitted to the hospital, while outpatient physiotherapy occurs outside of hospital admission, typically in outpatient departments of hospitals, rehabilitation centers, or private clinics. In addition, 1 study reported SAR interventions in a private nursing home [35].

Regarding the context of application, we found that the reported SAR interventions were predominantly applied in the treatment of neurological conditions, such as CP, obstetric brachial plexus palsy, spinal cord injury, hemispherectomy, hereditary spastic paresis, stroke, and Guillain-Barre syndrome [4,24,25,27,29-32] (8/13, 62%). Musculoskeletal conditions (eg, low back pain, muscle or joint pain) were next in frequency [33,34] (2/13, 16%), followed by cancer [32] (1/13, 8%) and cardiovascular conditions (eg, myocardial infarction) [26] (1/13, 8%). One study's participants were residents in an older care facility [35].

The age range of SAR intervention recipients varied from 3 years old to more than 85 years. Specifically, 4 studies [24,27,28,32] targeted children (younger than 18 years of age), including those in early childhood and adolescence. Notably, 7 studies [25,26,29,30,33-35] focused on adults (18 years and older), encompassing a broad range of ages within this group. Overall, 1 study [31] included both children and parents in the intervention. In addition, 1 study [4] did not report the age of the intervention recipients.

Out of 13 included studies [4,24-35], only 5 studies [27,28,30,32,33] reported using a control group. This distinction is important, as control groups are critical to determining whether the observed effects are truly due to the inclusion of SARs.

Features of Physiotherapy Intervention

Table 3 lists all the physiotherapy interventions extracted from the studies. Interventions encompassed various types of training, specific exercises or programs, frequency, timings, and intensities of training, as well as physiotherapy goals tailored to specific patient populations.

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Table . Description of physiotherapy intervention with information is categorized by the type of physiotherapy training.

Author and year	Specific exercises	Physiotherapy goals	Frequency and time	Intensity
Endurance training				
Irfan et al [26], 2020	Warm-up (stretching), exercises on a treadmill, and cool-down (low-intensity exercises)	Accelerate recovery and reduce the risk of recurrent events.	35×20 - 30-minute sessions for 18 weeks.	Relative intensity of the sessions, determined by the treadmill speed and inclination, was progressively increased over time.
Salas-Monedero et al [28], 2023	Warm up, seated upper extremity muscle exercises (shoulder abduction, shoulder flexion-extension, elbow flexion-extension, and elbow elevation), and cool down	Enhance strength and endurance requirements in preparation for repetitive movements, such as those used in neurorehabilitation to acquire movement patterns for activities of daily living.	30-minute sessions, 2-3 times per week for a maximum of 5 weeks (10 sessions in total).	Not reported
Carrillo et al [4], 2018	Sit-to-stand exercise, exercise from a lying down position, and toy relay game	Delivery and participation in exercise programs in pediatric rehabilitation.	1 session of up to 30 minutes per participant.	Not reported
Strength training				
Bäck et al [35], 2013	Arm and leg exercise in sitting	Delivery and participation in a group exercise program.	4 sessions of 10-20 minutes each.	Not reported
Al-Shahry and Al-Shehri [34], 2020	Strengthening exercise	Improve back strength.	5 sessions of 30 minutes each.	Not reported
Butchart et al [31], 2021	Strengthening exercises in supine (such as bridges) and side-lying (such as hip abduction), relay games with obstacles	Delivery and participation of exercise programs in pediatric rehabilitation.	Up to 3 sessions, average session length of 33 minutes.	Not reported
Functional task training				
Feingold-Polak et al [30], 2021	Reach-grasp-and-place, or reach-grasp-and-manipulate movements, using real everyday objects, such as cups, jars, keys, wallets, and drawers.	Use functional task training to practice force regulation and retraining coordination.	30-50 minutes per session, 2-3 times per week for 5-7 weeks (15 sessions in total).	Not reported
Feingold Polak and Tzedek [29], 2020	Kitchen game (arrange jars on shelves at 3 different heights), cup game (ordering a set of colored cups in a row according), target game (ordering a set of colored cups in a circle), keys game (ordering a set of colored keys on a board), drawer game (take objects out of drawers located at different heights), card game (manipulation of cards), and wallet game (take the keys out of zipped wallets)	Retraining coordination of reach-to-grasp movements.	40-60 minutes per session, 2-3 times per week for 5-7 weeks (15 sessions in total).	Not reported
Gait training				
Cespedes et al [25], 2020	Walking using Lokomat	Promote functional locomotor recovery; retrain gait through neuroplasticity stimulation.	SAR[a]-assisted therapy: 1x45-minute session; conventional therapy: 1x 45-minute session	Not reported
Gross motor and motor control training				

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Author and year	Specific exercises	Physiotherapy goals	Frequency and time	Intensity
Meyns et al [32], 2019	Gross motor movement exercises, such as raising arms, squats, lunges, and walking forwards and backwards	Participating in physical exercises.	1-minute set of exercise, 1-3 sets for each of the 4 conditions (each participant was asked to perform in all 4 conditions).	Not reported
Buitrago et al [24], 2020	Walking	Improve functional movement and cognitive skills.	16×45-minute sessions over 8 weeks.	Not reported
Flexibility and proprioception training				
Pulido et al [27], 2019	Mirror game (imitate different poses) and imitation game (imitate a sequence of poses in a specific order)	Training proprioception and improving joint mobility ranges	SAR-based therapy: 30 minute session, twice per week for 2 months, maximum of 15 sessions for each participant; traditional therapy: same as above	Not reported
Blanchard et al [33], 2022	Stretching	Promote participation and adherence to long-term exercise therapy for people with chronic low back pain	30-minute sessions, 5 times per week for 3 weeks (15 sessions)	Not reported

[a]SAR: socially assistive robotic.

SARs were used across a range of training modalities, including endurance training [4,26,28] (3/13, 23%), which focused on improving cardiovascular fitness; strength training [31,34,35] (3/13, 23%), aimed at increasing muscle strength; functional task training [29,30] (2/13, 15%), which helped patients practice real-life activities; gait training [25] (1/13, 8%), targeting walking ability and balance; gross motor and motor control [24,32] (2/13, 16%), which improved muscle movement and coordination; and flexibility and proprioception training [27,33] (2/13, 16%), aimed at enhancing joint range of motion and the body's ability to sense movement and position.

The specific exercises described in the interventions varied based on the targeted condition and goals. Setting clear goals is crucial for guiding interventions toward desired outcomes and requires a thorough understanding of the patient's activities, needs, limitations, and strengths [37]. The goals in SARs interventions can be grouped into 2 main categories: increasing activity and participation, as seen in studies by Carrillo et al [4], Back et al [35], Butchart et al [31], Meyns et al [32], and Blanchard et al [33]; and targeting underlying impairments in patients' physical function, such as improving strength and endurance [28], enhancing back strength [34], and retraining coordination [29,30], gait [25], and proprioception [33].

In addition to the conventional therapeutic exercises (eg, treadmill exercise, robot-assisted gait training, and stretching) reported in the majority of the studies [4,24-26,28,32,34,35], SARs were also involved in gamification programs, as reported in 3 studies [27,29,30]. While all studies provided sufficient details on the exercise programs' frequency and time parameters, only 1 study [26] specified exercise intensity. Reporting on these parameters, such as frequency, duration, and intensity is crucial, as it helps track progress and ensures that programs are tailored to the individual's needs and capabilities.

Furthermore, 7 studies [24,26-30,33] implemented relatively long-term physiotherapy interventions, with session numbers ranging from 10 to 35 and total duration spanning from 3 to 18 weeks. In contrast, 3 studies [31,34,35] conducted 5 or fewer sessions, and 3 studies [4,25,32] administered only 1 therapy session per participant.

Finding on SARs Characteristics

To answer the question of how SARs are integrated into physiotherapy contexts, we categorized the information on SARs characteristics based on 4 subquestions.

1. What SAR platforms are most used in physiotherapy?

2. How do SARs and users interact with each other?

3. What roles do these robots serve within physiotherapy contexts?

4. What was the involvement of key stakeholders in the design and development process of SARs and intervention protocols, as well as the presence of technical support and the role of physiotherapists during interventions?

This information aims to provide insights into the relationship we seek to build between robots and users, and how to ensure that SAR interventions are designed with the needs of target users in mind, thereby promoting broader community adoption.

Types and Levels of Autonomy of SARs in Physiotherapy

All reported SARs were humanoid robots, designed to mimic the human body in shape and capable of precise movements for tasks, such as demonstration. Among these, NAO was the most frequently used robot platform (10/13) [4,24-28,31,32,34,35]. NAO is a programmable humanoid robot developed by Aldebaran Robotics (SoftBank Robotics) [27]. Pepper, also developed by Aldebaran Robotics (SoftBank Robotics), was the second most commonly used robot [29,30]. One study [33] used Poppy, an open-source humanoid robot developed based on the Poppy project [38].

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Using the classification by Beer et al [39], we identified 3 categories of robot autonomy from the included studies: "fully autonomous," "semiautonomous," and "tele-operated." One study [26] reported that the SAR was "fully autonomous," indicating that the robot operated independently without human intervention. In contrast, 2 studies [29,30] reported that the SAR was "semi-autonomous," as the robot required some degree of human input or supervision during the intervention. However, the majority of studies [4,24,25,27,28,31-35] (10/13, 77%) did not provide a specific description of the level of autonomy or how the robot was operated.

Interaction Between SARs and Users

Eleven studies [4,24-27,29-31,33-35] reported several communication channels from robots to users during the physiotherapy interventions and activities. The use of speech or verbal feedback was the most commonly reported communication method [4,24-27,29,31,33-35] (11/13, 85%). In most studies, the robot used audible phrases with a synthetic voice or prerecorded instructions to engage patients, communicate with the physiotherapist, or provide verbal feedback on the timing or success of tasks [25,29,35]. Motion or gesture was also commonly used, reported in 10 studies [4,24-27,29,31,33-35] (10/13, 77%). For instance, the robot could bow to demonstrate correct spinal posture [25], imitate the patient's movements to demonstrate exercises [27], or perform physical gestures, such as hand clapping or head nodding, to motivate patients [29]. In addition, visual feedback was provided by displaying messages or images on the robot's tablet screen [30,33], and LED outputs were used to prompt inputs [4].

Users were able to command the robots through various methods, including touching the robot's head-based tactile sensors [4,24,26], using voice commands to stop, resume, and restart the exercise program [34], pressing a physical button on a table to indicate completion of exercises [29,30], and interacting with a tablet interface [26]. However, 7 studies [25,27,28,31-33,35] did not specify the communication channels used by users to interact with the robots.

Functions and Roles of SARS

Content analysis identified and categorized 4 functions of SARs in physiotherapy interventions and activities: coaching, demonstration, peer support, and monitoring. However, this was based on data from the 12 included studies [4,24-31,33-35], as 1 study did not explicitly report the function of the SARs [32].

Coaching was identified as a prominent function of SARs in physiotherapy interventions, emphasizing their capacity to provide instructions and feedback. For example, in the study by Buitrago et al [24], the coaching role of SARs was as "[robot] gives feedback to the child by saying positive sentences for having completed the task' and '[robot] verbally indicated him [user] extending an arm that he had to go to where the therapist was to bring another toy." In some studies, the robots delivered game instruction and feedback to users using both verbal and visual feedback, encouraging users to improve their performance [29]. In other studies, the robot encouraged users during sessions using motivational phrases such as "Let's go! You can do it!" [26].

Demonstration was identified as the second most common function reported (6/13, 46%), highlighting the role of SARs in physically showing or modeling exercises, techniques, and movements. This function was often described as leveraging the robot's humanoid embodiment to demonstrate gestures and motions. In 5 studies [4,27,31,33,34], SARs like NAO or Poppy demonstrated exercises or performed them alongside patients. In a study by Cespedes et al [25], the robot provided posture feedback to a patient during gait training and demonstrated corrective cervical or thoracic posture techniques.

Monitoring, 2 studies [25,26] highlighted the role of SARs in monitoring and assessing safety warnings and reporting emergencies to human therapists. In the study by Irfan et al [26], NAO could request the study participant report their level of physical exertion using the Borg scale [40], a numerical scale that measures perceived exertion during physical activity, and issue warnings about a high heart rate during treadmill exercises for patients with a history of myocardial infarction. Similarly, Cespedes et al [25] reported that when a heart rate alert was detected, NAO verbally confirmed the patient's condition and alerted the therapist promptly.

The role of peer support provided by SARs involves the robot engaging with the patient as a supportive companion during therapy sessions, often providing positive reinforcement and encouragement. Most studies described this role through various forms of motivational feedback, such as verbal motivation or encouragement and positive feedback [25,31]. Examples of supportive messages included phrases like "I'm so happy to see you again" and "It is so nice that you came back" [30]. Irfan et al [26] also personalized feedback by including the patient's name in supportive statements aiming to enhance the robot's perceived sociability. In addition, Carrillo et al [4] reported that NAO incorporated humor and preprogrammed dialogue to build rapport with patients.

Key Stakeholder Involvement in SAR Design and Development

Out of the 13 studies [4,24-35] reviewed, 7 (54%) studies [4,26,27,29,31,33,34] reported involving physiotherapists or other health care professionals in the design of SARs or intervention protocols. Physiotherapists specifically contributed to designing exercise programs [27,31,34], patient selection [34], and robot vocal feedback messages [33]. Feingold-Polak and Levy-Tzedek [29] reported system improvements based on recommendations from a focus group of expert clinicians who work with stroke survivors, the intended target users of the SARs. Carrillo et al [4] highlighted the active engagement of therapists in both the design and development phases of the robot, allowing them to critique and explore the system's physical and clinical capabilities and limitations.

Only 2 studies [4,35] involved clinical populations in the design of SARs or intervention protocols. Back et al [35] mentioned the continuous development of an exercise program based on user feedback. Carrillo et al [4] described several early robot-patient interactions during the design and development

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to obtain structured feedback for protocol refinement. However, most included studies either did not report clinical population involvement [24,25,27-33](9/13, 69%) or did not include clinical populations in the design process [26,34](2/13, 15%).

Involvement of Technical Support and Physiotherapist During the Intervention

Three studies [4,30,35] reported providing technical support during interventions. In the study by Back et al [35], a therapist was present to ensure the robot functioned properly. In Feingold-Polak et al's study [30], a clinician was present during the intervention to address technical problems, such as replacing a malfunctioning tag reader. Carrillo et al's study [4] required engineer intervention to restart the system due to battery drainage. While 1 study [27] explicitly reported no technical support, 9 studies [24-26,28,29,31-34] did not provide any information regarding technical support required during the SAR intervention.

Eleven studies [4,24-31,33,35] identified various roles of physiotherapists and medical staff during physiotherapy sessions. In some instances, physiotherapists directly participated in therapy by coordinating activities with the robots [24,25] or providing physical support to patients with neurological impairments [31]. Five studies [4,28,30,33,35] explicitly mentioned physiotherapists ensuring the proper operation of SARs [30,35], setting parameters [28,30,33], or arranging the environment to facilitate smooth sessions [4,30]. In the study by Pulido et al [27], the therapist configured personalized exercises based on patient profiles and monitored sessions via a graphical interface. Similarly, Salas-Monedero et al [28] described monitoring through sensors to facilitate timely interventions. In the study by Irfan et al [26], medical staff present during cardiovascular rehabilitation sessions provided immediate assistance during emergencies, monitored vital signs, and interacted with the robot. In another study, physiotherapists played an educational role by introducing patients to robots and explaining system capabilities and interactions before sessions [33].

Methods of Evaluation and Outcome

Table 4 summarizes the evaluation methods for treatment effectiveness reported in the included studies [4,24-35]. The outcomes are categorized into 2 groups. The first group includes clinical outcomes, user performance, or functional measures, which assess the direct impact of interventions on the user's health and functional abilities, as well as their ability to perform tasks related to their functional goals. For example, Buitrago et al [24] used Goal Attainment Scaling [41] to evaluate the extent to which the patient with CP achieved his goals, with positive results indicating that the user successfully met the objectives during robotic training. Salas-Monedero et al [28] assessed upper extremity dexterity in patients with tetraplegia and paraplegia using metrics like the Box and Block Test [42]. Irfan et al [26] monitored physiological parameters, such as heart rate, the Borg scale [40], and blood pressure in a patient with a history of heart attack to observe the intervention's effects.

The second group encompasses metrics that evaluate the acceptance, usability, and perception of robots. Among these, acceptance was the most frequently assessed construct, typically measured through subjective evaluations, such as interviews and questionnaires, with reports indicating a positive trend toward acceptance of SARs [4,26,29-31,33]. In addition, studies focusing on user perception reported positive feedback regarding the overall robot experience [35], usability [27], and increased user motivation and adherence to therapy [4,26,27,32]. However, 1 study found no improvement in adherence [33].

Although most of the included studies assessed the acceptance, usability, and perception of robots, 7 studies [4,29-32,34,35] did not report any clinical outcomes, user performance, or functional measures. This may limit the understanding of the actual therapeutic benefits of the robotic interventions.

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Table . Methods of evaluation and key findings from included studies.

Author and year	Measures (clinical outcomes, user performance, or functional measures)	Measures (acceptance, usability, or perception of robots)	Key findings
Meyns et al [32], 2019	• Not applicable	• Motivation: Fun Toolkit (the Again table, the Smileyometer, and the Fun Sorter)	• Humanoid robot instructors, like using music, enhance children's initial motivation for physical activity programs.
Bäck et al [35], 2013	• Not applicable	• Feedback on robot experience: Survey questions	• Positive feedback supports using NAO robots as exercise trainers and in nursing home rehabilitation for older adults.
Al-Shahry and Al-Shehri [34], 2020	• Not applicable	• Robot-patient performance: Clarity, therapy sequences, interaction, voice, timing, independence, operation and technical performance, and degree of freedom	• Robot therapy shows highly satisfactory performance with good patient acceptance.
Butchart et al [31], 2021	• Not applicable	• Perceptions of acceptability and therapeutic value: Semistructured in-depth interview	• NAO robot is an acceptable complement to rehabilitation therapies. • NAO robots have perceived therapeutic value through their potential to enhance engagement and rehabilitation program delivery, particularly in the absence of a physiotherapist.
Feingold-Polak et al [30], 2021	• Not applicable	• User acceptance of the novel system: User satisfaction evaluation questionnaire and open-ended questionnaire • Evaluation of technical limitations: Custom-made questionnaire	• Long-term stroke rehabilitation with robotic platforms in clinical settings is feasible and shows strong acceptance among patients with post-stroke.
Feingold Polak and Tzedek [29], 2020	• Not applicable	• Acceptance: Robot Acceptance Survey (RAS), a custom-made user-acceptance questionnaire based on the User Satisfaction Evaluation Questionnaire (USEQ)	• Patients with poststroke demonstrate acceptance trends toward SAR after long-term interaction.
Martí Carrillo et al [4], 2018	• Not applicable	• Acceptance: Robot acceptance questionnaire from physiotherapists, acceptance questionnaire for guardians	• Despite its limited capabilities, NAO's robust minimalist system deployment provides valuable patient engagement insights for ongoing clinical deployment, especially for a formal clinical evaluation.
Buitrago et al [24], 2020	• Effectiveness of intervention: Objective evaluation of intervention using the Goal Attainment Scale (GAS)	• Not applicable	• Participant showed increased continuous steps during training with a humanoid robot.

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Author and year	Measures (clinical outcomes, user performance, or functional measures)	Measures (acceptance, usability, or perception of robots)	Key findings
Salas-Monedero et al [28], 2023	• User performance: Length of the hand trajectory (mm), peak number detected in the velocity profile of hand during the execution of the task (units), Box and Block Test (blocks)	• Compliance: Record the number of sessions for each participant	• Intervention benefited patients with tetraplegia by improving hand motor accuracy and dexterity. However, patients with paraplegia showed no improvement with intensive short-term training.
Irfan et al [26], 2020	• Physiological parameters: Heart rate, Borg scale, gait parameters (step length, cadence, and speed), cervical posture, systolic blood pressure	• Social interaction: Gaze and patient's verbal and nonverbal feedback • Technology use and acceptance: Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire	• Improved physiological progress observed. • Patient adherence to the cardiac rehabilitation program may have been enhanced with personalized robot attendance.
Cespedes et al [25], 2020	• Patient performance: Heart rate, Borg scale • Poor posture time (cervical and thoracic): The total time during the session when the posture inclination overcomes the good posture threshold	• User perception: Questionnaire to the patient and the therapist	• SAR[a] had a positive effect on patient encouragement, intrinsic motivation, and adherence to the therapy and was well-received by patients and therapists, with reported benefits in gait rehabilitation sessions.
Pulido et al [27], 2019	• Motor performance: Manual Ability Classification System (MACS), Motor scale of Mallet, Quality of Upper Extremity Skills Test (QUEST) scale	• Usability and compliance: Record the number of sessions for each participant • User perception on satisfaction and usability: Questionnaires for patients, relatives, and clinical staff, Likert scale (5 items), open questions	• Patients showed slight motor skill improvement with robotic platform training compared to conventional therapy (where no improvements were detected) • Deemed useful and easy to operate by patients, relatives, and health care professionals.
Blanchard et al [33], 2022	• Change in lumbar pain: Visual analog scale (VAS) • Change in disability: Roland Morris Questionnaires (RMQ), the Dallas Pain (DPQ) Questionnaires • Adverse events: Reported by physiotherapists during therapy sessions and by investigators during evaluation visits	• Adherence: Record number of movements performed by the participants during each robot-led session • Change in fears and beliefs: Fear-Avoidance Beliefs Questionnaire (FABQ) • Usability: System Usability Scale (SUS) • Therapist's acceptance of robot: Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire	• Adherence to robot sessions declined over time, limiting physical activity supervision. • No negative impact is shown on clinical outcomes, but the system was deemed not yet ready for rehabilitation applications.

[a]SAR: socially assistive robotic.

Reported Limitations and Areas of Improvement

Overall, 4/13 (31%) included studies [28,29,31,35] reported a limitation related to small sample sizes, thus limiting the generalizability of their findings. Selection bias was identified as a potential limitation in 1 study [31], where researchers may have been inclined to select participants they had previous positive interactions with. Other study limitations identified included slow recruitment rates due to strict inclusion criteria [33] and the homogeneity of participants from the same facility [29]. Technical issues and limitations in robot design were reported in 3/13 (23%) studies [33-35], such as system readiness issues and malfunctions leading to missed robot sessions [33], pelvic movement readiness and system heating concerns [34], and limited exercise variety due to robot size constraints [35].

In addition, 3/13 (23%) studies [4,24,34] highlighted limitations in intervention design. For instance, Buitrago et al [24] noted that, although the objective measured by the Goal Attainment Scaling was achieved during the training, neither the robot nor the therapist adjusted the task or the environment to reflect the

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new goal. Carrillo et al [4] reported that the therapist performed tasks for the robot as they were not informed of the robot's capabilities. Other reported limitations included a limited range of friendly interactions, the need for refreshment breaks, and limited flexibility in exercise sequences [34].

Other identified limitations included robotic technology expenses [35] and uncertainty regarding the impact of color blindness in users [30]. Identified limitations in evaluation methodologies included difficulty in measuring motivation in very young children [32], a lack of assessment of the robot's impact on physical health [33,35], and the absence of cognitive ability data to indicate acceptability [31]. Three studies [25-27] did not report any limitations.

The areas of application proposed by the authors of the included studies spanned the domains of rehabilitation, such as cardiac rehabilitation [26], pediatric oncology, and neurorehabilitation [24,28,30,32], and applications in older adult care facilities [35]. Other identified applications included supporting exercise, progress monitoring, and maintaining motivation and adherence [26]. In addition, studies' authors suggested integrating SARs into existing robot-assisted gait rehabilitation [25], using SARs to address gaps in telehealth care by enabling real-time program adjustment based on robot-patient interactions [34], and supporting long-term home exercise programs for people with chronic conditions who may not have access or resources for prolonged therapist contact to assist with managing their condition [33]. One study [29] did not propose any specific areas of application.

Discussion

Main Findings

This scoping review aimed to explore the usage of SARs in physiotherapy contexts with clinical populations. Across the 13 studies [4,24-35] identified, SARs' roles and functions were tailored to suit the specific needs of patients and the objectives of physiotherapy interventions. These findings indicate that, in current applications, the primary objective of integrating SARs into health care is therapeutic augmentation [43].

Numerous studies reported that the use of SARs led to repetitive exercises and sessions [44]. This issue may stem from simplistic programming or a lack of personalized adaptation, which can result in a loss of user interest [44]. To address this, efforts have increasingly focused on complementing SAR interventions with devices like Lokomat or incorporating more advanced gamified exercises [4,25,27,29,30]. This review identified several SAR capabilities, including coaching, demonstration, monitoring, and peer support. Currently, SARs seem to be prioritized for roles, such as time-extending coaching and monitoring, functions that are considered unfeasible for human therapists due to the mismatch between the number of available therapists and the size of clinical populations [43].

Robots Used

The dynamics of socially assistive interaction are elucidated through the roles that SARs take on and the communication channels used between robots and users. In all but 2 studies [28,32], where communication methods were not reported, verbal communication channels were used to deliver feedback, encouragement, or instructions (along with visual and motion-related communication). Verbal praise to users is considered positive feedback and thus has the potential to enhance users' intrinsic motivation for task performance [43].

Of the SAR models discussed in the review, the humanoid robot NAO is the most frequently used. Although there is limited evidence guiding the selection of the most suitable SAR model for physiotherapy applications, NAO has been commonly adopted in aged care and pediatric rehabilitation contexts, noted for its good acceptance by users and physiotherapists and movement capabilities [13,45]. The prevalent use of NAO in clinical settings may stem from its perceived usefulness in prior feasibility tests [46], its commercial availability and its well-established functional and technical capabilities [47].

Stakeholder Involvement in the Design of SARs and Intervention Protocols

The involvement of domain experts (physiotherapists) and end users (clinical populations) in the design of the SAR system and the intervention protocols was investigated, with a focus on understanding whether the systems adequately meet the needs of important stakeholders. The findings show a lack of participation from key stakeholders in both processes. Among the 13 included studies [4,24-35], only 2 studies [4,35] appeared to have involved end users in the design and development phase, while the remaining studies either did not report or did not engage stakeholders during these stages. In Back et al's study [35], participants provided feedback on exercise programs to improve their effectiveness. In Carrillo et al's study [4], the authors emphasized the early engagement of patients and physiotherapists in the design and development of SARs, highlighting the benefits of overcoming technological limitations, fostering effective engagement with end users, and facilitating the development of the robot's demonstration function. A previous study has identified the value of stakeholder input in robot development, as it aids in identifying potential uses for developers, pinpointing flaws in current robot designs to avoid, and suggesting improvements to ensure usability, particularly in health care settings [48].

Limitations in the Current Deployment of SARs With Clinical Population

The majority of studies reported limitations within their findings, particularly regarding small sample size [28,29,31,35], challenges in patient recruitment [31,33], the robot's design and technical capabilities [33-35], intervention protocol design [4,24], and evaluation methods [24,32,33]. Meanwhile, despite significant efforts in the application of SARs in physiotherapy, many of the studies are primarily pilot studies intended to pave the way to clinical trials with end users. However, they often fail to progress into larger studies due to the various limitations highlighted in Lo's [49] paper, such as the inappropriate selection of control groups to assess therapeutic benefits, the absence of power calculations to detect minimally clinically important differences, and insufficient detail in robot rehabilitation protocols, hindering reproducibility. The current included studies have flaws, such as slow patient recruitment processes [31,33] and small sample size [28,29,35]. This could

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potentially compromise the validity of these trials and their impact on the clinical evaluation of the effect of SARs on patient outcomes.

Other limitations stem from the shortcomings of the current SAR designs and technological limitations, such as pelvic movement robustness, system overheating [34], robot size that affects exercise variety [35], and system readiness and malfunction [33]. This aligns with a study that investigated NAO-assisted pediatric CP rehabilitation, where most physiotherapists considered system or hardware failures during sessions as crucial features needing improvement [50].

In addition, the personalization of the robots to adapt to the user's mood, fatigue, and performance variations during long-term involvement, such as in rehabilitation, remains a major challenge. In a review analyzing patients' and clinicians' opinions on the use of SARs in rehabilitation, the loss of user interest frequently arose as a concern [51]. This could pose a challenge in applying SARs when working with vulnerable user populations, supporting self-rehabilitation, or long-term exercise programs for chronic conditions [33].

Previous papers have described several barriers to the integration of SARs in clinical settings [44,49]. When recruiting end users (clinical populations) in clinical trials, several ethical issues must be carefully considered regarding patient physical and psychological safety, especially when involving vulnerable clinical populations (eg, children or people with cognitive impairments) [52]. Another significant hurdle is justifying the investment in clinical SAR research without clear economic or clinical evidence of its cost-effectiveness, which may impede the adoption of SARs in clinical settings. In addition, conducting research in the clinical setting can be time-consuming, as it requires multidisciplinary collaboration between robotics and health science experts who are rarely co-located [43]. These factors may indeed contribute to the high budget requirements of robot research in clinical settings.

Strengths and Limitations of This Scoping Review

A strength of this scoping review is the interdisciplinary review team with expertise in the fields of physiotherapy (JH and MF), robotics (PCM), and scoping review methodologies (MF). This interdisciplinary perspective was important for identifying relevant locations to search, terms to use, and knowledge of disciplinary publication conventions. While numerous medical and engineering databases were comprehensively searched, citation tracking was limited to short reports that otherwise met the inclusion criteria for pragmatic reasons. This may have resulted in the omission of potential studies suitable for inclusion, but this risk is considered minimal given that the citation tracking found no further eligible studies for inclusion.

Furthermore, one team member led the majority of title and abstract screening, data extraction, synthesis, and analysis. This approach may introduce bias into the study exclusion, data extraction, and synthesis processes, potentially leading to incomplete data capture due to the risk of overlooking relevant information and nuances [53]. The primary reviewer's limited experience in scoping review methodology may further compound these potential biases [53]. However, this risk was counterbalanced in this review through the auditing of processes and data, the use of collaborative review tools with clear audit trails, and regular meetings for confirmation of decisions and team endorsement to progress after each review stage.

Conclusions

This scoping review identified what is currently known about the usage of SARs in physiotherapy interventions and activities with clinical populations. Despite the limited publications on this topic, the review offers insights into SAR design and application areas in physiotherapy interventions. This review has highlighted the future potential of SARs to be increasingly applied in health care settings. Future research should prioritize addressing the limitations in intervention design and evaluation methods to enhance the quality of evidence in this field. There is a critical need to resolve technical issues associated with SARs, such as system readiness, malfunction, size restriction, and overheating, to enhance the quality of interventions. Engaging key stakeholders, including physiotherapists and clinical populations, at all stages of SAR design and development is essential to overcoming technical challenges and promoting user acceptance. In addition, conducting more clinical trials and using reliable and valid clinical outcome measures are essential steps to investigate the effectiveness of SARs in promoting health outcomes.

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Authors' Contributions

MF and PCM defined the scope of the review. JH conducted the article search, screening, and data extraction from selected publications. MF and PCM validated the screening and data extraction processes of the selected articles. JH wrote the original draft and MF and PCM reviewed and edited the manuscript.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Complete search terms for socially assistive robotics and physiotherapy.
[XLSX File, 9 KB - rehab_v12i1e69908_app1.xlsx]

Multimedia Appendix 2
Overview of used search strings and number of publication 'hits' (Results).
[XLSX File, 10 KB - rehab_v12i1e69908_app2.xlsx]

Checklist 1
PRISMA Checklist.
[DOCX File, 115 KB - rehab_v12i1e69908_app3.docx]

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Abbreviations

ACM: Association of Computing Machinery
CP: cerebral palsy
ICF: International Classification of Functioning, Disabilities and Health
IEEE: Institute of Electrical and Electronics Engineers
MeSH: Medical Subject Headings
PCC: population, concepts, context
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Review
SARs: Socially Assistive Robots
WHO: World Health Organization

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Original Paper

User Acceptance of a Home Robotic Assistant for Individuals With Physical Disabilities: Explorative Qualitative Study

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Abstract

Background: Health care is shifting toward 5 proactive approaches: personalized, participatory, preventive, predictive, and precision-focused services (P5 medicine). This patient-centered care leverages technologies such as artificial intelligence (AI)–powered robots, which can personalize and enhance services for users with disabilities. These advancements are crucial given the World Health Organization's projection of a global shortage of up to 10 million health care workers by 2030.

Objective: This study aimed to investigate the acceptance of a humanoid assistive robot among users with physical disabilities during (1) AI-powered (using a Wizard of Oz methodology) robotic performance of predefined personalized assistance tasks and (2) operator-controlled robotic performance (simulated distant service).

Methods: An explorative qualitative design was used, involving user testing in a simulated home environment and individual interviews. Directed content analysis was based on the Almere model and the model of domestic social robot acceptance.

Results: Nine participants with physical disabilities aged 27 to 78 years engaged in robot interactions. They shared their perceptions across 7 acceptance concepts: hedonic attitudes, utilitarian attitudes, personal norms, social norms, control beliefs, facilitating conditions, and intention to use. Participants valued the robot's usefulness for practical services but not for personal care. They preferred automation but accepted remote control of the robot for some tasks. Privacy concerns were mixed.

Conclusions: This study highlights the complex interplay of functional expectations, technological readiness, and personal and societal norms affecting the acceptance of physically assistive robots. Participants were generally positive about robotic assistance as it increases independence and lessens the need for human caregivers, although they acknowledged some current shortcomings. They were open to trying more home testing if future robots could perform most tasks autonomously. AI-powered robots offer new possibilities for creating more adaptable and personalized assistive technologies, potentially enhancing their effectiveness and viability for individuals with disabilities.

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KEYWORDS

physical artificial intelligence; physical AI; health care robotics; assistive technology; content analysis; qualitative; health care; robotics; assistive; robot interaction; physical disabilities; readiness; amputations

Introduction

Background

Health care is evolving to adopt a more proactive approach through the principles of personalized, participatory, preventive, predictive, and precision-focused services (P5 medicine). This approach to patient-centered care uses technologies such as robots. Artificial intelligence (AI) is central in the development of these robots to enhance care and treatment processes [1]. AI refers to "the application of computer technology to mimic

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human intelligence and critical thinking" [2]. Through machine learning, AI systems can autonomously enhance their algorithms by learning from data and cognitive inputs without specific programming. This research field is rapidly expanding and becoming increasingly interdisciplinary, attracting a growing number of researchers.

AI techniques can enhance the management of comprehensive health services by supporting medical professionals such as physicians, nurses, and administrators [3]. For example, AI can provide timely access to medical information, streamline hospital operations, and ensure patient safety by improving medication management and care engagement [4]. Furthermore, AI may optimize logistics, such as the just-in-time delivery of drugs and equipment, and improve training for health care personnel, potentially reducing disparities between urban and rural health care services [3]. Furthermore, AI systems have shown promising results within health care in predicting conditions such as sepsis, cancer, and cardiovascular risk and monitoring vital signs in intensive care units [5-7].

Physical AI (PAI) [8-10] encompasses the application of AI technologies within physical systems, devices, and environments, enabling the performance of tasks that involve physical interaction or manipulation in the real world. In contrast to software-based AI, which functions in digital settings, such as data analysis, natural language processing, and web-based recommendation systems, PAI is evident in concrete, real-world applications. Examples of PAI include robotics, intelligent sensors, autonomous vehicles, and other cyberphysical systems that merge computational intelligence with physical functionalities [8-10].

AI-powered robotics in health care may offer a range of potential benefits that could revolutionize the field [11]. These systems provide precision and consistency in tasks, often surpassing human capabilities. Precision is particularly vital in surgeries to avoid adverse events and harm to patients. AI-powered robotics also facilitate telemedicine, allowing health care professionals to conduct consultations and services remotely, thus extending medical services to underresourced areas [12]. Such developments are crucial as the World Health Organization has highlighted global staffing challenges, projecting a potential shortage of up to 10 million health care workers by 2030 [13]. To address these challenges, the health care sector is increasingly adopting robotics and AI to mitigate workforce shortages. AI-powered robots may not only support complex medical procedures but could also assist in daily care activities, potentially reducing the workload on health care staff. In addition, robots integrated with AI could play a pivotal role in personalizing, adapting, and improving services to users with disabilities [12]. Despite the high initial costs of implementing AI-powered robotics in health care, the long-term benefits, streamlined processes, and overall cost savings could significantly improve the efficiency and accessibility of health care delivery [14].

Related Work

The field of scientific robotics is advancing the development of social assistive robots capable of adapting to local social norms, interpreting human emotions and desires, and learning by emulating human behavior. While these socially assistive robots primarily offer companionship and facilitate basic exercises, their capabilities in carrying out a variety of physical assistance tasks, such as carrying and delivery, are still limited. Robots able to assist people physically (carrying and delivery) include robots such as Care-O-bot, Doro, TIAGo, Lio, EVE, and Hobbit. They can be remotely controlled via home services or preprogrammed to operate autonomously, performing tasks primarily ordered through a tablet [15-17].

Research indicates that older adults generally perceive socially assistive robots as enjoyable, friendly, and safe [18,19]. However, studies by Wu et al [20] and Lee et al [21] highlight that older individuals without functional impairments find little relevance in these robots. The domain of assistive robotics for individuals with physical disabilities, whether young or old, remains nascent. Sørensen et al [22] concluded in their review that robots designed to assist with a variety of physical tasks currently demonstrate an inadequate level of technical readiness for home use, particularly due to their lack of personalization and overall preparedness for everyday assistance. A key challenge for effective assistive robots is managing a wide variety of assistive situations and tailoring robots' interactions to the living contexts and preferences (or habits) of the individuals they assist [23]. So far, assistive robots that provide physical assistance have had limited capabilities for detailed personalization, which is essential for effectively serving their users [15]. However, recent advances in AI may enable these robots to adapt to their users' environments and offer services in a more personalized manner [22].

Previous studies highlight that robot personalization is crucial for user acceptance as it aligns robots with the users' preferences and needs, thereby enhancing their willingness to use them [19,24,25]. Rather than taking over enjoyable activities that contribute to physical activity, robots should assist with challenging or energy-draining tasks, thus allowing users to focus on preferred activities [15]. However, personalization can be costly and time-consuming and requires ongoing technical support as users' needs evolve with their health status. Given these challenges, multidisciplinary research, including participatory design in PAI, is essential [26]. PAI combines insights from technical and human sciences to develop robots that intelligently interact with their physical environment, adapt to malfunctions, and integrate with existing systems. This approach fosters innovation and ensures that robots are practical, safe, and effective in dynamic real-world settings [4].

Currently, there is a lack of knowledge about user acceptance of robots able to assist physically or of PAI among individuals with physical disabilities. In this paper, we present the results of a multidisciplinary study investigating individuals with physical disabilities' acceptance of a humanoid robot (EVE) providing personalized assistance in a simulated home setting.

Theoretical Frameworks for Assessing Acceptance of Technology

In total, 2 models have frequently been used to assess acceptability in users of assistive and social robots: the Almere model [27] and the model of domestic social robot acceptance (DSRA) [28]. The Almere model by Heerink et al [27] extends

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the unified theory of acceptance and use of technology [29] by including factors related to social interaction. The model's effectiveness has been evaluated through controlled experiments and longitudinal data collection involving 3 different assistive social robots in older adult care facilities and homes. The findings demonstrated significant support for the model and, thereby, contribute to the understanding of the factors influencing the acceptance of assistive social robots among older users. Heerink et al [27] highlight the importance of considering both functional and social variables in the design and implementation of these technologies.

DSRA [28] is rooted in the theory of planned behavior and extends it by incorporating factors specific to the context of domestic social robotics. These include utilitarian and hedonic attitudes, social and personal normative beliefs, and control beliefs. The study's [28] findings underscore the importance of considering these factors in the design and development of social robots to ensure their acceptance and integration into domestic settings.

In this study, we used these models as frameworks in a qualitative investigation of acceptance in potential future users of humanoid robots that are able to assist their users physically. We use the term *physically assistive robots* in this paper.

Objectives

People with physical disabilities, whether from disease or injury, encounter obstacles in their everyday activities and social participation. Many rely on formal or informal caregivers for assistance with activities of daily living. Upcoming demographic shifts pose significant challenges to the availability of home care services and assistants, potentially affecting individuals' ability to access necessary support [15].

The aim of this study was to investigate the acceptance of the prototype humanoid assistive robot EVE in individuals with physical disabilities during (1) AI-powered (using a Wizard of Oz methodology [30,31]) robotic performance of predefined personalized assistance tasks and (2) operator-controlled robotic performance.

In addition, we explored potential users' perspectives on how physical robotic assistance might impact their independence and autonomy.

On the basis of the models used as frameworks, we also suggested changes to the concepts we found more prominent when investigating acceptance of robots primarily designed for physical assistance rather than social interaction.

Methods

Study Design

This study used an explorative qualitative design, with data collection consisting of user testing in a simulated home environment and individual interviews. We used human-centered design (HCD), a creative approach to problem-solving that starts with understanding the needs of the people one is designing for and ends with solutions tailored to their needs. HCD emphasizes incorporating the end user at the center of the design process, ensuring that products or services are tailored to meet their needs and enhance usability [15,32]. The process is iterative, involving multiple stages of prototypes and tests to refine and validate the service based on user feedback, ensuring that the service is usable in real-world scenarios [33]. As recommended for HCD, we worked iteratively and in a multidisciplinary manner with robot engineers; robot operators; and, most importantly, the potential future users we targeted—individuals with physical disabilities [34]. We define usability as "the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (ISO9241) [35].

Before the user test, we asked the participants for which tasks they would find it most useful to receive physical assistance from a robot. We then shared these insights with the robot engineers, enabling the robot operators to practice performing these specific tasks and make necessary adjustments to align with the robot's current technical capabilities.

First, user testing [36] of the robot was conducted in a simulated home environment, allowing participants to interact with the robot in a realistic setting. This was followed by video-stimulated interviews with the participants approximately 1 week later, providing them with an opportunity to reflect on their experiences. For data collection and analysis, we used a directed approach [37] based on the 2 theoretical frameworks: the Almere model and the model of DSRA. These frameworks guided the evaluation of how users with disabilities accepted robot home assistance.

The Robot

This project is part of a broader project conducted at the University of Agder focusing on exploring humanoid robotic applications in health care. The university has acquired a state-of-the-art humanoid robot named EVE (Figure 1) specifically for research purposes.

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Figure 1. The humanoid robot EVE in the user testing scenario (pictures by LS).

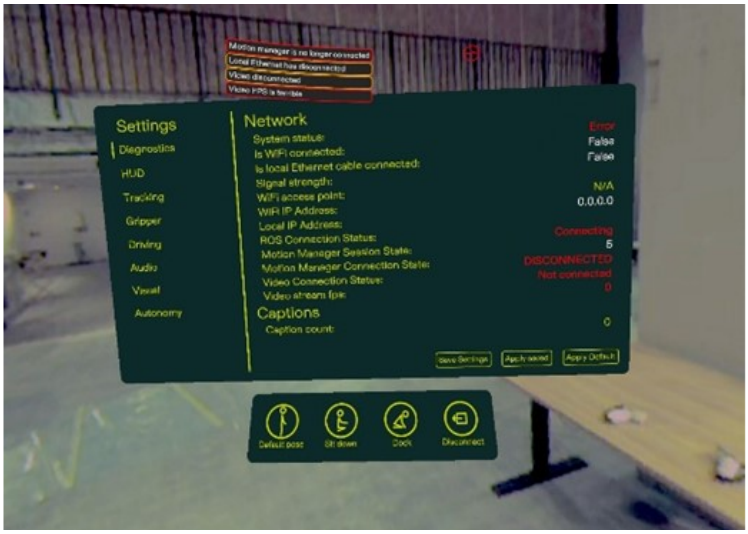


EVE is a full-size humanoid robot designed for research and logistic applications. Standing at a height of 186 cm and weighing 80 kg, EVE maneuvers on 3 wheels, equipped with grippers enabling it to manipulate objects of varying sizes. The robot is equipped with cameras and sensors to perceive and interact with its surroundings. Its mobility, dexterity, and balance allow it to navigate complex environments and manipulate objects effectively [38].

The robots' AI-powered movements are trained using a diverse dataset from 30 EVE robots, enabling it to perform a wide range of tasks, from tidying to social interactions. This base model is then fine-tuned for specific capabilities, such as door manipulation or warehouse tasks. Using data instead of code, robot operators train (using virtual reality glasses and controllers) and expand the robot's abilities to increase flexibility in the robot's functions [38].

In this study, the robot was controlled using Meta Quest 3 glasses. Operators were given a stereoscopic view through 2 fish-eye lenses calibrated to provide depth perception. The Meta Quest 3 controllers were used to manipulate the robot's wrist, whereas an algorithm (self-developed Sync/Robot Control; Figure 2) translated these movements into more complex actions, enabling the robot to mimic human motion based on wrist inputs.

Figure 2. Sync/Robot Control (picture by 1X Technologies, reused with permission).



Recruitment

Participants were recruited through purposive sampling by coordinators of health services at a spinal cord ward at a rehabilitation hospital in the eastern region of Norway and a municipality in the southern region of Norway. The inclusion criteria for this study were individuals aged ≥16 years with physical disabilities, living at home, and receiving formal or informal care.

The coordinators suggested relevant candidates to the researcher based on the inclusion and exclusion criteria (Textbox 1). The first author, LS, then contacted the candidates with information about the study with an invitation to participate. Seven of the participants had previously taken part in a focus group activity [15] where they received information about the robot and saw videos of the robot performing different activities before their interaction with it (although not in the context of health care). The 2 remaining participants received information about the robot and watched the same videos after agreeing to take part in this study.

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Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Aged ≥16 years
- Having physical disabilities requiring physical assistance with personal care or activities of daily living

Exclusion criteria

- Cognitive challenges or language challenges that would make commanding the robot or answering questions in Norwegian difficult

Data Collection and Procedure

The user tests took place in a hospital room designed as an apartment that is used for patients to practice becoming independent before discharge. The apartment has a living room with a table, chair, closet, and television. It also includes an accessible kitchen and bathroom. The control room for controlling the robot through virtual reality was set up in the adjacent room. It included live video feeds displayed on a screen, live audio from the robot, and an additional speaker system (Jabra speakers) to enhance sound quality. The participant-robot interaction was video recorded using 2 cameras in the room (Multimedia Appendix 1). The participants' interaction with the robot had 3 parts (Textbox 2). First, participants watched EVE perform 5 tasks. The tasks were identified as useful in a previous study investigating users with physical disabilities' needs for assistance [15]. We used a Wizard of Oz approach [30,31], in which EVE appeared to perform tasks autonomously while a human operator discreetly controlled the robot behind the scenes unbeknownst to the participants to simulate its functionality. This technique is often used in developing and testing technologies such as health care robots and enables researchers to evaluate interactions, collect user feedback, and identify improvement areas before fully automating the system [30,31,39]. The presence of the operator was revealed to participants at the conclusion of the study.

Second, the participants were instructed to ask the robot to bring a drink of water. Before the user testing, LS had asked each participant how they would need and prefer to have a drink of water served. After the participants had asked the robot to bring the water, the robot nodded for confirmation and went to the kitchen to bring water (Wizard of Oz methodology). Details of the personalized service are described in Textbox 2.

In the third part of the interaction, the participants were instructed to call the operator of the robot to request assistance with a chosen task. This part was designed to simulate a scenario in which a remote operator could control the robot for tasks that were not yet automated (human in the loop). Participants selected tasks that they often needed help with, such as picking up an item from the floor (Textbox 2). The participant first called out "Hallo," prompting the operator to connect to the robot via voice and ask how they could assist. After retrieving the requested item, the operator asked (through the robot) if any further assistance was needed before saying, "just call again if there is anything you need. Have a nice day." The robot then returned to its parking space, which was chosen by the participant. Some preferred the robot to be parked in the living room, whereas others wanted it out of sight, in which case it returned to the kitchen. The user test was facilitated by LS and the second author, DTSJ, in collaboration with the operators of EVE.

Approximately 1 week after the interaction, participants were interviewed at a time and place of their choosing. Seven interviews took place in the participants' homes, whereas 2 were conducted at a hospital due to the participants' short-term admissions. The first author used video-stimulated recall, a retrospective think-aloud interview technique, to help participants recall, discuss, and reflect on their robot interaction [40].

The interviews were conducted by LS, an occupational therapy specialist with knowledge of the participants' functional impairments and daily challenges but no clinical relationship with them. The semistructured interviews were guided by acceptance concepts from the Almere model and the model of DSRA, with additional questions focusing on independence and autonomy (Multimedia Appendix 2).

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Textbox 2. The robot-participant interaction in 3 parts.

Demonstration of robot tasks

- Tidying up, including picking up trash from the table and placing it in the garbage bin
- Retrieving a towel from the floor and placing it in the laundry basket in the bathroom
- Pulling down a roller curtain using a string
- Verbally announcing the day's schedule
- Opening a bag of potato chips and pouring them into a bowl

Bringing the participant a drink of water, tailored to each user's specific needs

Four participants received a water bottle that the robot obtained from the fridge:

- For one participant, the robot placed the water bottle on the table (participant 6).
- Three participants received the water bottle in their hand (participants 1, 2, and 7). One participant had paralysis, which required the robot to hold the bottle still for some time until the participant managed to get a grip around the bottle. The robot released the grip as the participant said thank you.
- One participant who also had paralysis had a glass delivered to his hand in a similar way (participant 3).
- Two participants had their glasses placed on a table in front of them. The robot then filled a mug of water in the kitchen, came to the living room, and filled the glass of water. One was a regular glass (participant 4), and the other was a wineglass. This participant preferred a wineglass to be able to grip and hold it by the stem (participant 8).
- One participant who was not able to move their arms had the robot deliver a glass with a straw to a stand in front of their face that was mounted on the electric wheelchair (participant 5).
- One patient was served the drink of water in a bottle with a straw and drank from the straw as the robot held the bottle (participant 9).

A task of the participants' own choosing

- Picking up an object that was dropped on the floor (participants 1, 8, and 9)
- Bringing the participant a newspaper (participant 6)
- Bringing a blanket to lay over the participant's legs (participant 2)
- Taking something out and down from a top cupboard in the kitchen (participant 7)
- Taking out a bag of snacks from a kitchen drawer, opening it, and bringing it to the participant (participant 3)
- Scratching the back of the participant's head using a scratching stick (participant 5)
- Bringing the television remote control and placing it in the participant's lap (participant 4)

Analysis

The interviews were transcribed verbatim by the first author, omitting minor speech hesitations to improve readability. For the analysis, we used the 16-step process described by Assarroudi et al [41] in a combination of deductive and inductive approach [37,42]. First, in the directed approach, the data were coded deductively using a structured categorization matrix [41] based on the predetermined codes from the Almere model and the model of DSRA (Multimedia Appendix 3 [43-51]). According to Hsieh and Shannon [37], directed content analysis is useful when a theory exists about a phenomenon that needs further refinement or development through qualitative research [37]. Second, inductive coding was performed to search for additional concepts that might affect the acceptance of the assistive robot and concepts that needed to be modified or could be excluded. All data analysis was performed using the NVivo software application (version 14; Lumivero). The initial coding was performed by LS. An extract from the coding was then reviewed by and discussed with all authors until an agreement was reached about categories and subcategories. The findings were finally organized into 7 categories with 13 subcategories. Table 1 shows an example from the analysis process.

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Table 1. Example of the analysis process.

Participant statement	Codes	Category
"I tend to drop my phone on the floor. If the robot could pick it up, that would definitely be a useful task for me."	• Pick up an item	Usefulness
"...no, giving it verbal commands would not be hard for me, if you have a pet you're quite used to it."	• Voice commanding; not perceived difficult	Ease of use
"I wonder a bit about the monitoring, if people can see and hear what's happening in my house through the robot, I wouldn't like that."	• Distant controlling • Monitoring	Privacy

Ethical Considerations

All methods were carried out in accordance with relevant guidelines (Helsinki Declaration) and national laws. This study was approved by the Research Ethics Committee at the Regional Committees for Medical and Health Research Ethics (467937), the University of Agder- Norway's ethical board, and Sikt—Norwegian Agency for Shared Services in Education and Research (343362). All participants gave their written informed consent to take part in the study, with the possibility to withdraw at any time. To ensure confidentiality and anonymity throughout the analysis, identifiable details in the interviews were anonymized, and participants and other mentioned persons were assigned numbers. As the robot continuously records picture and sound input and stores these data, participants signed an additional consent form for this data collection. All data stored in the robot were deleted 1 week after the robot-participant interaction. Participants were not compensated for participation, but travel expenses were compensated.

Results

Overview

Eleven persons (Table 2) with physical disabilities (3 women, 8 men) agreed to participate in the user tests. Of these 11 individuals, 2 withdrew (1 woman and 1 man), 1 because of illness and 1 because the assistant called in sick that day. The participants were aged between 27 and 78 years, with a median age of 59 years. One participant had muscular dystrophy, 7 had a cervical spinal cord injury (SCI; paralysis to arms and legs), 1 had a thoracic SCI (paralysis to the legs), and all were wheelchair users (full time).

Table 2. Participant characteristics.

Participant ID	Sex	Age (years)	Diagnosis	SCI[a] level	Assistance (h/wk)	Source of assistance
1	Male	69	SCI	C5-6	31.5	Assistants and partner, parents, or children
2	Male	42	SCI	C5-6	3	Home nursing services; assistants; partner, parents, or children; and friends
3	Male	37	SCI	C6-7	45	Home nursing services; assistants; partner, parents, or children; and friends
4	Male	27	SCI	C5	91	Home nursing services; assistants; partner, parents, or children; and friends
5	Male	59	SCI	C3	154	Assistants; partner, parents, or children; and friends
6	Male	78	SCI	Th4-5	31.5	Home nursing services and partner, parents, or children
7	Male	31	SCI	C5	52	Home nursing services; assistants; partner, parents, or children; and friends
8	Female	78	SCI	C6	90.5	Home nursing services; assistants; and partner, parents, or children
9	Female	60	Muscular dystrophy	Lim girdle	168	Assistants; partner, parents, or children; and friends

[a]SCI: spinal cord injury.

Although many of the participants had the same diagnosis, the group was heterogenous in terms of level of independence. Table 3 shows the participants' level of independence according to the Barthel Index for Activities of Daily Living [52], which assesses independence on a summarized scale from 0 to 20, where 20 is independent. All participants received various degrees of assistance with activities of daily living (Table 3). All participants considered themselves above average in being familiar with technology, such as smart house technology, computers, apps, and technical assistance devices. Two participants lived in accessible apartments (one rented and one owned). Seven of the participants lived in private accessible houses that were adapted for their particular needs, with automatic doors or windows, wider doors, ramps, elevators, and no thresholds.

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Table 3. Barthel index[a].

Participant ID	Feeding (0-2)	Bathing (0-1)	Grooming (0-1)	Dressing (0-2)	Bowels (0-2)	Bladder (0-2)	Toilet use (0-2)	Transfers (0-3)	Mobility (0-3)	Stairs (0-2)	Total (0-20)
1	1	0	1	1	2	2	2	2	2	0	13
2	1	0	1	1	2	2	0	2	1	0	10
3	1	0	1	1	2	2	0	2	1	0	10
4	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	1	0	1
6	2	0	0	0	0	0	0	3	1	0	6
7	2	0	1	2	2	2	0	3	1	0	13
8	2	0	1	0	0	0	0	0	0	0	3
9	0	0	0	0	0	0	0	0	0	0	0

[a]The Barthel Index for Activities of Daily Living assesses the level of independence on a scale from 0 to 20, where 20 is independent.

The extracted main categories based on the concepts from the Almere model and the model of DSRA were hedonic attitudes, utilitarian attitudes, personal norms, social norms, control beliefs, facilitating conditions, and intention to use (definitions can be found in Multimedia Appendix 3). These concepts with subcategories are shown in Table 4. The results related to each category and subcategory will be presented in the following sections. We made some smaller changes to the subcategories from the theory based on the statements from the participants. This is further elaborated on in the Discussion section.

Table 4. Acceptance model categories and subcategories—used, modified, excluded, and added.

Category	Hedonic attitudes	Utilitarian attitudes	Personal norms	Social norms	Control beliefs	Facilitating conditions	Intention to use
Subcategories used	• Enjoyment	• Perceived usefulness • Ease of use • Perceived adaptiveness	• Privacy • Trust	• Social influence • Perceived sociability • Societal impact	• Anxiety • Safety	• No subcategories	• No subcategories
Modified subcategories used	• Attractiveness • Appearance, including animacy	—[a]	—	—	—	—	—
Excluded subcategories	• Social presence • Companionship	—	—	• Status	• Self-efficacy • Cost	—	—
Added subcategories	—	—	• Independence • Autonomy	—	—	—	—

[a]Not applicable.

Altogether, 573 statements were coded from the transcripts. Of these 573 statements, 109 (19%) were used more than once as they fit in more than one subcategory. Of the subcategories, the participants spent most time talking about the robot's functions and how it could assist with their needs. The usefulness category included 123 statements, with the most frequently mentioned tasks being picking up items dropped on the floor and bringing a drink of water. We used the International Classification of Functioning, Disability, and Health (ICF) to organize the findings (Table 5). The ICF is a framework developed by the World Health Organization for measuring health and disability at both the individual and population levels. Other authors have previously used the ICF concerning socially assistive robotics to evaluate assistive technologies' impact on users' lives and group activities that humans perform [15,53,54].

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Table 5. Assistive tasks that would make the robot useful.

ICF[a]	Useful assistance categories and tasks

Activity and participation	• Bringing items
	  • Water
	  • Snacks
	  • Preheated food
	  • Medication
	  • Blanket
	  • Newspaper
	  • Glasses
	  • Urine drainage bag
	  • Phone
	  • Clothes
	  • Shoes
	  • Remote control
	• Picking up an object dropped to the floor
	• Calendar reminders
	• Assisting with transfers
	• Emergency alerts
	• Housework
	  • Tidying
	  • Wash windows
	  • Putting things in or taking things out of the dishwasher
	• Assisting with technical aids
	  • Moving technical aids; bringing, for example, wheelchair, toilet chair, or walking frame
	  • Putting on tarpaulin
	  • Changing the position of the bed
	  • Controlling the lift and car lift
	• Opening doors
	• Charging phones or tablets

Self care	• Scratching • Putting on or taking off a comforter

[a]ICF: International Classification of Functioning, Disability, and Health.

Hedonic Attitudes

Appearance (Attractiveness) and Animacy

The participants' statements about the robot did not relate to its attractiveness and, thus, did not fit the predefined subcategory of attractiveness from the model of DSRA. However, they were concerned with how the robot should look and its human likeness. Therefore, we named this subcategory Appearance and Animacy. Half of the participants perceived the robot as overly large and described it as bulky and masculine. Others valued the robot's ability to reach levels inaccessible to them, stating that this was particularly beneficial for those using wheelchairs. Participants offered no specific comments about the robot's hands, which featured very mechanical grippers. They did not express a preference against more humanlike fingers, recognizing the functionality of the grippers as paramount. All but 1 participant appreciated the robot's humanlike appearance. They did not desire a greater human likeness, explaining that they preferred it to retain its robotic nature to avoid a "creepy" overly humanlike appearance:

> *They have made a friendly design on it and stylish in relation to color and so you should not make it more human-like than that really. There is something about the fact that with a robot being a robot...you should not pursuit more resemblance to humans, but in relation to meeting a robot it's easier if it looks like a human than not at all. But maybe not too much.* [Participant 2]

However, they were interested in the robot having a humanlike voice and the option to personalize this voice according to their preferences. While some participants appreciated the robot's mobility on wheels, others expressed a preference for a smaller, lighter robot with legs capable of walking in stairs. One participant expressed a wish for the robot to have a humanlike mask and even hair:

> *No, first of all, it could have had completely different colors, been a little neater, smaller, not so dominant in the surroundings and then I think maybe you could also make a more human mask, get hair on the head, more human details, as human as possible for a robot.* [Participant 1]

Enjoyment

As the primary focus of the user interaction was the robot providing practical assistance and not being a social figure, we did not particularly ask about the participants' level of enjoyment. Still, 3 participants mentioned that they enjoyed the encounter and that they believed that it would be fun to have a robot assisting them:

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> *I've actually always liked [technology] and I liked it better 10-20 years ago than I do now...I think this is great fun, but it will probably also vary, but I just think it would be fun.* [Participant 9]

Another participant stated the following:

> *...yes, it's very funny this robot helping out, this is the future, but it still seems far ahead...I thought it had come further. It would have been really fun to test the robot when it was fully AI powered. I'm very excited to see how smart it will be to understand its surroundings.* [Participant 2]

Utilitarian Attitudes

Perceived Usefulness

All except 1 participant expressed being impressed by the robot's functionality, particularly as the robot picked up a bag of chips, opened the bag, poured it into a bowl without spilling anything, and then served the bowl to the participants. During this task, the participants could see both finer and grosser movement skills from the robot. The one participant being most skeptical referred to the robot as an early-stage prototype, relating this mainly to its speed:

> *No, putting aside that I found it looking scary, I thought it might be only the second version at best, and its movements were very slow.* [Participant 1]

Another participant stated the following:

> *I was skeptical about what he could pick up...but I was very impressed when he picked up that bag, and no spilling at all, then I was very impressed with it, yes thought it worked really well.* [Participant 6]

All the participants mentioned that tasks such as tidying, bringing them things, and picking up things they dropped on the floor would be particularly beneficial for them. The tasks that they chose for the interaction with the robot were of such character and were personalized to each participant's needs (Textbox 2). The participants appreciated that the robot could serve a drink specifically aligned to their needs and respond to their commands for a particular action. Several of the participants chose for the robot to pick up an item from the floor. Most of the participants were not able to do this if they, for example, accidentally dropped their phone or other items.

The participants mentioned other assistance tasks that would make the robot useful for them: turning lights off and on, answering the door, reading and answering mail, helping write signatures and other notes, scratching when itching, attaching iPads to charging cords, putting cutlery in and out of the dishwasher, serving guests with drinks and snacks, turning on and filling the washing machine, adjusting the comforter if they were too hot or cold, supporting them when transferring to the toilet, and adjusting the electric bed.

The interaction with the robot also led the participants to expect more advanced tasks, including tasks that would require the robot to function outside the home. A few participants mentioned assistance with their technical aids. One expressed that, if the robot could follow him to his car and then roll his walking frame back to the apartment, that would be very useful for him. Taking the tarpaulin off his outdoor electric wheelchair and then putting it back on when he returned would also be highly beneficial. One participant wished for the robot to be her walking partner. She wanted the robot to assist with minor repositioning of her hand so that she could control the joystick of her wheelchair without fear of her hand falling off the armrest. Another participant wanted the robot to control his car lift for more effective boarding, and one suggested that the robot could serve him water outside on his veranda during the summer.

Apart from physical assistance tasks, all but 1 participant appreciated that the robot reminded them of their agenda. They suggested integrating the software with their phones, noting that registering appointments and activities in multiple digital calendars would be cumbersome:

> *That [robot giving reminders] would have been useful for me, just ask my wife (laughter).* [Participant 4]

During the user test, the participants interacted with the robot both in an automated mode (using a Wizard of Oz methodology) and a mode in which the robot was operator controlled, simulated as "municipality services-personnel" controlling the robot. They found the ability to operate the robot remotely to respond to emergencies or perform actions that the robot had not yet learned to be both useful and necessary. However, they preferred the robot to be automated for most tasks. One participant stated the following:

> *It's good to have the opportunity to do that [distant operating], but then, you should be told that "now we can see into your home."* [Participant 4]

Another said the following:

> *Yes, so it has to have that function...well there will always be some challenging tasks, there are no homes or institutions that are the same, so there may be physical things that make it possible for it to mess up.* [Participant 2]

When discussing how the robot could be useful for fulfilling their needs, the participants that received assistance in personal care stated that the robot could never replace their human carers completely. By watching the robot in action, they realized that it could not assist them in tasks such as using a breathing mask or catheterization. One participant stated that, the previous year, she could have benefitted from the practical assistance that was demonstrated by the robot, but as her function had deteriorated, especially her breathing and the risk of having something stuck in her throat, she could only be without her human helpers for very short periods of the day.

Several of the other participants stated that they already had assistants or home services attending to most of their needs. Still, the participants sometimes experienced pressure ulcers or infections, which forced them to bed rest. They suggested having the robot present during these periods to assist in fulfilling the tasks they needed.

However, most participants agreed that such a robot could replace some of their assistants' time and be particularly useful in the gaps when they did not have a human helper:

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> *As a backup, they [the assistants] are out driving a lot with the kids to training and so on, and they are shopping for me, it's nice for me to be at home, but during summer I have to drink a lot of water, so then it could be nice [to have a robot assisting].* [Participant 5]

Ease of Use

Through the interviews, it appeared that the participants had above-average technological knowledge. They had advanced wheelchair controls, smart house functions, and different technical aids. None of the participants expressed any worries about being able to control the robot. All agreed that voice control was preferred. Some stated that a combination of voice and gestures and lights would be fine. All agreed that the robot would need to express some kind of confirmation on having received and understood a command, preferably through sound as the robot could be out of its user's sight at the time:

> *But you never know if the robot has confirmed or not...you need to know that it has received...if it repeats what it is supposed to do...that it confirms that it has received, for example when I ask for a glass of water, it should say "yes, it has been received, I will fetch a glass of water.*" [Participant 2]

One participant also commented that the robot's eyes and face should follow its users for more normalized communication. The participants expressed that the speakers and microphone for EVE would need to be of a better quality. All wanted a humanlike voice for the robot and the ability to choose the voice of the robot. One participant expressed that, similarly to his smart home control, he expected the robot to learn his voice and that he would be able to extend commands to the robot and they would learn from each other.

Perceived Adaptiveness

The participants expressed that the robot would need to be adapted to their particular needs. As most of the participants had reduced ability to grip objects, they were concerned with the robot handing over objects and particularly waiting to release the grip until they had managed to get a grip around the item. They mentioned the need for the robot to adapt to be able to navigate around the users' homes. Some were concerned with the robot's ability to understand the different Norwegian dialects:

> *So if...you can go in...and teach it commands, that you can go in and type in commands and then it will execute it, I think in Norway where are so many dialects, you have to find a way that you can override that [the programming]...so that the robot can teach itself.* [Participant 2]

Another participant stated the following:

[About receiving an object from the robot]It worked out really well. I was very unsure about when it would release the grip, because I was unsure if the operators were watching...I would like to have it like...if I said "ok," then it would let go, that it was sort of an agreement. [Participant 3]

Personal Norms

Privacy and Trust

Seven participants stated that they were not concerned at all with any privacy issues regarding having the robot in their homes. Even though they had been informed about how the robots used cameras for navigation and that remote operators would be able to connect through the robot, they did not find this disturbing. However, they did appreciate the idea of a sound or light announcing that someone was connecting from the operating central. Two participants were concerned about the idea that someone "looked" into their house without being informed. They suggested regulations that illegalized this and a log that could be checked for any distant use. One participant stated the following:

> *I haven't thought about privacy at all, because I would never communicate any details to such a machine anyway that I couldn't handle being exposed.* [Participant 1]

Another said the following:

> *It's kind of important that it [the robot] manages to do things automatically in relation to privacy...and so that no one sits looking into your house all the time, yes, because then you're alone, then you know that, this is my place and there's no one else lurking around.* [Participant 4]

All of the participants stated that they would trust the robot. One mentioned that he would trust it if he had a log to check for distant on-logging. They related this both to privacy issues and also physical safety. One participant said the following:

> *It will be the same as an alarm company...I have an alarm here...they can connect to the cameras at any time in theory, but you have to have confidence in it...and if someone abuses this, it must be prosecuted, so it's about trust and that you have legislation if something illegal was going to happen.* [Participant 2]

Autonomy and Independence

The participants had varying views on whether such a robot would increase their independence or autonomy. Most (n=7) believed that the robot could enhance their sense of freedom by assisting with necessary tasks, allowing them to do what they wanted, whenever they wanted, without waiting for assistants, home nurses, or family members. Two participants felt that the absence of a human caregiver and reduced need for constant human interaction would be advantages of robotic assistance. In addition, 2 participants mentioned that having robotic support during times without human assistance would make them feel safer rather than providing a feeling of autonomy:

> *Yes exactly, I think it's very fascinating and it's also a bit...because I get a little tired in my head from having people here all the time because...I cannot help but feel like being at "work" in a way, that I feel I have to be in such a nice positive mode and do some nice things [for and with the assistants]. Because even though I know that it is not in the job role of personal*

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> *assistants, it is my life that should be lived the way I want to live it, but I have to practice that extremely much, to completely relax when there are other people in the house. Yeah, I wish I could zero out my head and I think I would have done that easier with a robot than a human in a way.* [Participant 9]

Social Norms

Social Influence

Within this subcategory participants shared how others' opinions on whether they had a robot as an assistant mattered to them. Four participants stated that others' opinions would not affect their decision to have robotic assistants as they did not care about others' opinions. Two participants were concerned about others' opinions, especially on the robot's physical appearance in the room when having visitors:

> *...it matters a little to me if they [guests] feel alright in room.* [Participant 9]

Three participants stated that, somehow, they were often affected by others' opinions, but this was not particularly connected to robotic assistance. They cared about whether others had opinions on having assistance in general and on using technical aids:

> *Yes, it matters to me what people think, whether it's robots or assistants or the wheelchair, so of course you have that in the back of your mind, but from experience, so...knowledge and exposure tend to solve a lot of it.* [Participant 2]

Another participant stated something similar:

> *I've actually thought the same about having assistants...yes that "he's in such a poor condition that he must have assistants," they'd probably think that it was very strange [to have robotic assistance].* [Participant 7]

However, most participants believed that opinions about robotic assistance would not be negative, whereas one participant was concerned that health care employees might worry about losing their jobs.

Societal Impact

In addition to discussing the robot as a potential assistant for themselves, the participants also talked about how the robot could be useful for others. Several of the participants were concerned about the challenges in health care and how this might affect access to help for people in need of assistance and saw robots as a natural part of future health care services. One stated that the home nurses were so busy all the time and it would be good if robots could take some pressure off them, acknowledging that robotic assistance might not involve direct care but could instead focus on meeting practical assistance needs:

> *I am very positive to the idea that health professionals should be relieved of all the running...not necessarily the care...like wound care, but ask if you're okay and so on...and serving breakfast or taking a breakfast order.* [Participant 3]

Sociability

The participants discussed the robot's communication abilities and whether these abilities were important to them. For instance, several of the participants stated that they felt that it was natural to be polite to the robot and thank it for its services. They attributed this to its human likeness. As mentioned previously, one participant expressed dissatisfaction with the robot's inability to make eye contact during communication, suggesting that eye contact would make the interactions feel more natural. Most participants indicated that they did not prefer or need to engage in extensive communication with the robot beyond issuing commands as they preferred to fulfill their social needs with other humans. However, some noted that social interaction with the robot could be beneficial for individuals who live alone or feel isolated.

Control Beliefs

Anxiety

None of the participants reported feeling general anxiety or fear during the interactions. At one point, the robot moved behind the participants to lower a curtain, which they could hear but not see. Despite this, none of the participants expressed feeling uneasy. However, some participants described the robot's appearance and movements as "somewhat frightening," "a little creepy," or "not particularly nice looking." One stated the following:

> *Yes, but it was really only when it came in there and did that stuff, when it took that blanket and bent down it was almost like a snake person...and it doesn't say anything...just completely silent, just some ventilators running that's what was a bit creepy.* [Participant 7]

Another participant said the following:

> *No, it wasn't uncomfortable at all, but I wondered what he was going to do, but then I looked to the side, and I saw the blind coming down, then he pulled it all the way down.* [Participant 6]

Safety

The participants reported feeling safe in the robot's presence, and it was suggested that the robot should be able to alert health services in case of an emergency. The participants who had children in the house did not feel particularly concerned about the robot causing any harm; they simply stated that they expected the robot to be safe before implementation. One participant stated the following:

> *No, not at all [felt unsafe] and it was because I saw that it was so steady on the wheels, I analyzed it before it started driving. Another thing is that if something were to happen that there could have been a connection so that he [the robot] could have notified someone, to call someone at the home-services station: "now you have to come."* [Participant 1]

Facilitating Conditions

Regarding physical facilitating conditions, all participants stated that their home was already wheelchair accessible, so both

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placing the robot and the robot moving around was not seen as a problem:

...if people have a wheelchair, then it is very adapted for people who are on wheels, so in that sense, it is almost better that the robot is on wheels than if it should walk. [Participant 2]

This was supported by another participant:

> *Yes, it's good to have houses and apartments for wheelchair users because there are few thresholds, there are open solutions and things are kind of in such a way that it's easily accessible...I have my technical room around the corner there [I would have placed it there], but then it's a bit far away, so then it would take 20 seconds before he came into place, but if there are some automatic tasks, then it's ok.* [Participant 3]

Three participants expressed that they would prefer to have the robot placed in a separate room—to keep it out of sight—just as they did with other technical aids. Some participants were curious about the organization of a robot service. They expressed concerns that, if each robot required a separate remote operator, it would affect the possible societal impact.

Intention to Use

Although the participants were impressed by the robot's functions and its ability to perform tasks aligned to their needs, they did not see the robot as ready for implementation. However, they were willing to test the robot in their own home and were positive to using it when the technical readiness had progressed to a point at which the robot could perform most assistance tasks they needed autonomously. All participants saw the robot as a service to be combined with other assistance, and they would accept someone operating the robot from a distance if it was necessary. The mistakes that the robot made during the interactions, such as dropping an object or the fan being very loud at times, did not affect their willingness to have the robot at home. Some participants said the following:

> *...as long as it correct its mistakes.* [Participants 3, 4, and 6]

Another stated the following:

> *I can do that, I would be willing to try [the robot as a home service]...but of course I wouldn't have it instead of the care that the home care service comes with, I wouldn't replace that, no. So, care in the bathroom and care with inserts and things like that, I wouldn't have wanted to use a robot for those kind of tasks.* [Participant 6]

Discussion

Principal Findings

The aim of this study was to investigate the usefulness, ease of use, and acceptance of the prototype humanoid assistive robot EVE among users with physical disabilities, framed around key concepts from the Almere model and the model of DSRA: hedonic attitudes, utilitarian attitudes, personal norms, social norms, control beliefs, and facilitating conditions [27,28].

Our methodology used directed content analysis, initially applying a deductive approach to analyzing statements from participant interactions with the robot EVE. Subsequently, we adopted an inductive strategy, anticipating the discovery of statements misaligned with concepts from the Almere and DSRA models given their focus on assistive and domestic social robots for users without disabilities. Contrary to our expectations, the frameworks by Heerink et al [27] and de Graaf et al [28] aligned quite well with participant feedback, underscoring the relevance of these models even in contexts involving assistive robots for individuals with physical disabilities. However, we modified the subcategory Attractiveness to encompass the subcategories Appearance and Animacy. Participants were less concerned with the robot's attractiveness but more with its appearance, discussing issues such as size, speed, design, and anthropomorphism. Opinions on the robot's size varied among participants. Some felt that the robot was too large and appeared masculine, whereas others appreciated its ability to reach objects at higher levels. Most of the participants emphasized its humanlike appearance without it being unsettling. They preferred functional aspects over a fully humanlike appearance to avoid a "creepy" effect. This sense of discomfort has been termed the "uncanny valley" by Mori et al [55]. They noted that robots with humanlike features are generally more appealing to people but only to a certain extent. Beyond the uncanny valley, people's attraction turns into unease and a propensity to feel frightened.

While participants primarily valued the robot's assistive capabilities over its potential for entertainment, several noted that interacting with the robot was enjoyable and anticipated that having it at home would be fun. Hedonic factors such as appearance and enjoyment are crucial for acceptance and have been shown to directly influence the intention to use a robot [27,56]. Although robots designed for physical assistance are primarily utilitarian, they also incorporate hedonic aspects. Even if these hedonic elements are only partial, enjoyment remains a critical construct in any acceptance model for robotic technology.

The functionality of the robot impressed nearly all participants, especially its ability to perform precise tasks such as picking up and handling objects without spillage. Participants valued the robot's potential to assist with personalized tasks, although they recognized that it could not replace their human caregivers for more sensitive tasks. Participants also expressed ideas about how others might use the robot and noted that its deployment could potentially alleviate the burden on health care staff, highlighting its societal impact. Most participants in this interaction study had previously participated in a focus group that explored user needs and requirements after viewing videos of the robot EVE [15]. Although their identified tasks that would make the robot useful were similar to those mentioned in the focus group study and fell within the "Activity and Participation" category of the ICF framework [15,53,54], we observed that their expectations of the robot significantly increased after seeing it in real life. Studies on this issue present mixed results, revealing that users' expectations can either differ or remain consistent across virtual and real-life encounters with robots [57-59]. Real interaction may demystify a technology,

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making it more approachable and less intimidating. Once participants witnessed firsthand what the robot could do, their comfort with the technology may have grown, consequently raising their expectations. Direct interaction exposes users to the robot's practical applications and capabilities, potentially surpassing their initial assumptions based on mere descriptions or videos. This exposure could shift their expectations as they begin to envision more ways in which the robot could be beneficial in their daily lives. Moreover, after experiencing the robot's assistance, participants might recognize that it can perform tasks more effectively or efficiently than anticipated. This realization leads them to expect more from future interactions, seeing the robot's potential more clearly and imagining broader or more sophisticated applications for its use. In addition, the fact that the tasks performed by the robot were personalized specifically to meet their needs and executed exactly as the participants had described may have enhanced the overall experience.

Participants familiar with various technologies expressed confidence in their ability to operate (ease of use) the robot, favoring voice control as the primary mode of interaction. Although the robot made some mistakes, such as freezing for some seconds or dropping an object, the participants did not react negatively to this, stating that this would be expected of novel technology. This finding is different from those of other studies whose participants became frustrated with the robots' errors [60,61]. It is likely that this could be related to age or previous experiences with technology. This highlights the importance of designing robots with effective error management and recovery strategies to minimize frustration and enhance user interaction.

The consensus on the necessity for robots to adapt to specific user needs highlights a critical area of development in assistive robotics [22]. This adaptation is particularly crucial in tasks such as handling objects with care and effectively navigating home environments. Traditionally, the capacity for robots to adapt to the unique needs of individual users has been seen as overly complex and cost prohibitive. The challenges stemmed from the need for sophisticated sensing technologies and algorithms capable of understanding and responding to a diverse range of human behaviors and environmental contexts. However, recent advances in AI have begun to shift this perspective. AI technologies, particularly those involving machine learning and deep learning, have made significant strides in enabling robots to learn from interactions and adapt their behaviors over time. It will now be possible to analyze vast amounts of data generated from user interactions to continually refine and improve robot performance according to specific user preferences and needs. The integration of AI allows for greater personalization in robotic systems, which has been highlighted as crucial for adoption in several studies [22]. This can include adjusting the grip strength when handling objects or enhancing the robot's ability to operate in complex environments, such as typical home settings where every space is unique.

To our surprise, privacy concerns were minimal among most participants despite their awareness of the robot's data collection capabilities. They expressed a prominent level of trust in the robot, equating its use to that of other everyday technologies such as smartphones and home alarm systems. Participants also indicated that they were accustomed to the frequent presence of visitors in their homes, which may have contributed to their relaxed attitude toward privacy. During discussions about remote operation, participants preferred the robot to handle tasks autonomously. However, they acknowledged the necessity for remote intervention in situations in which the robot had not yet learned a specific task or during emergencies. de Graaf et al [28] discovered that lower levels of privacy concerns were associated with a higher likelihood of using a robot.

Although robots may be a means to solve some of the future health care challenges, we believe that the primary goal of using a physically assistive robot is to support the user's sense of autonomy and independence. Therefore, we included questions on this topic in our interviews despite its absence as an influential factor in existing literature on the acceptance of social robots. Previous studies have emphasized the importance of being able to act independently, doing what one wants, when one wants [15]. Participants have also highlighted the significance of not feeling like a burden to caregivers and the value of experiencing freedom from human carers occasionally [15]. We suggest including concepts on independence and autonomy when investigating the acceptance of robots assisting with daily activities.

Participants expressed varied opinions on the significance of others' perceptions regarding their use of robots as home assistants. Some were indifferent, whereas others cared to a degree similar to the degree to which they cared about others' reactions to other forms of assistance or technical aids. When interacting with the robot, participants were polite, stating that this behavior came naturally; however, they emphasized that their primary expectation of the robot was for physical assistance, not for engaging in conversation. Social norms play a crucial role in shaping individuals' attitudes toward robots by setting expectations for their behavior and societal acceptance [28]. These norms both directly and indirectly affect one's willingness to adopt and integrate robots into daily life. In addition, the degree to which robot use is viewed as normal or endorsed by one's social circle significantly influences an individual's decision to use robots [28].

Although participants noted that the robot appeared large and masculine, they felt safe around it and experienced no anxiety during their interactions. They also expressed no concern about the facilitating conditions as their living facilities were already adapted for wheelchair use.

Methodological Strengths and Limitations

The acceptance models developed by Heerink et al [27] and de Graaf et al [28] have predominantly been applied to quantitatively assess the acceptance of robots, particularly among older populations. In our study, we adapted concepts from these models to guide a qualitative investigation. We contend that using qualitative methods is particularly advantageous when seeking deeper, more nuanced insights into the reception of novel technologies, such as the humanoid robot EVE used in this research. This approach allows us to capture the rich, detailed user experiences and perceptions that quantitative methods might overlook, providing a comprehensive

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understanding of how individuals interact with and react to advanced robotic technologies in real-world settings.

The use of purposive sampling in this study might have introduced bias by including participants particularly interested in robotic assistance, which could have influenced their generally positive attitudes toward the technology [15]. We recognize that the small sample size of 9 participants may be seen as a limitation. However, we believe that the information power was sufficient, as defined by Malterud et al [62], who suggest that such power is achieved when participants actively share their experiences, thereby fulfilling the study's objectives. Our participants, all of whom had physical disabilities and varied levels of dependency on assistance, were engaged and provided rich, insightful discussions about the potential of the robot as a novel health care service. This depth of qualitative data bolstered the study's information power. In addition, our findings were rigorously analyzed through a 16-step process described by Assarroudi et al [41], resulting in categories that align with existing theories on robotic acceptance, directly addressing the research questions and aims of the study [27,28,41].

A significant number of participants had experienced an SCI, which could have introduced a specific bias in our results. Despite this, the needs expressed were strikingly consistent across different disabilities, focusing on functionality over the nature of the disability, such as impaired upper-limb function. Moreover, the sample included more male participants, mirroring the demographic trends observed in stroke and SCIs. Despite this gender imbalance, there were no notable differences in the needs or acceptance between male and female participants [63,64].

Using the Wizard of Oz approach raises an ethical concern due to the element of deception as participants are often unaware that a human operator is controlling the robot. This lack of transparency can raise issues related to trust and honesty in human-robot interactions. However, a study by Nasir et al [65] explored the impact of revealing the "wizard" behind the robot and found that participants' perceptions of the robot's autonomy remained largely unchanged even after the deception was disclosed. While the Wizard of Oz method remains a valuable tool for simulating and testing robot behavior, managing deception carefully is crucial, particularly in long-term human-robot interaction studies.

Conclusions

The results of our study reveal a complex interplay of functional expectations, technological readiness, and personal and societal norms influencing the acceptance and intended use of a physically assistive robot among individuals with physical disabilities. Participants were generally positive about the potential of robotic assistance to enhance their independence and reduce reliance on human caregivers for certain tasks, albeit recognizing the robot's current limitations and future potential. While the robot was not deemed ready for immediate full-scale implementation, participants were open to further testing in their homes, with the condition that the robot could perform most tasks autonomously in the future.

For developers, this study underscores the importance of a human-centered, iterative design process. The feedback collected has already informed improvements, leading to the development of a smaller, more functional robot with humanlike fingers and enhanced automation, better tailored to individual user needs. Health care managers, on the other hand, should recognize that, while robotic assistance is progressing, its integration into care settings will require significant adjustments to existing services. This includes rethinking care delivery models, staff training, and the balance between human and robotic caregivers.

As we move closer to successfully integrating robotic assistance into users' homes, both developers and health care managers should prepare for future implementation. This preparation includes addressing system maintenance, remote operation, and service delivery. The next steps should involve larger-scale studies to evaluate these aspects in real-world care environments.

Overall, the application of AI in robotics opens up new possibilities for creating more adaptable and personalized assistive technologies. This progress could reduce the costs associated with personalized adaptations but also enhance the effectiveness of assistive robots, making them a more viable and helpful option for individuals with disabilities.

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Authors' Contributions

LS, DTSJ, HM, and HMJ all participated in the planning and design of the study and the analysis and interpretation of the data. LS performed the data collection assisted by DTSJ. All authors contributed to writing, reviewing, and approval of the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

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Demonstration of 5 tasks for participant 9—shortened.
[MP4 File (MP4 Video), 151440 KB - rehab_v12i1e63641_app1.mp4]

Multimedia Appendix 2
Semistructured interview.
[PDF File (Adobe PDF File), 97 KB - rehab_v12i1e63641_app2.pdf]

Multimedia Appendix 3
Concepts with definitions.
[PDF File (Adobe PDF File), 292 KB - rehab_v12i1e63641_app3.pdf]

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Abbreviations

AI: artificial intelligence
DSRA: domestic social robot acceptance
HCD: human-centered design
ICF: International Classification of Functioning, Disability, and Health
PAI: physical artificial intelligence
SCI: spinal cord injury

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Original Paper

Physiotherapists' User Acceptance of a Lower Limb Robotic Exoskeleton in Specialized Rehabilitation: Qualitative Exploratory Study

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Abstract

Background: Robotic lower limb exoskeletons have emerged as promising tools in the clinical rehabilitation of patients with lower limb paralysis due to neurological disease, stroke, or spinal cord injury. Identified benefits in gait function rehabilitation include improved gait function, cardiovascular effects, enhanced training quality, patient motivation, and reduced physical and psychological workload for therapists. Despite the identified benefits, the successful adoption of this technology largely depends on therapists' user acceptance.

Objective: This study aims to explore physiotherapists' perceptions of using robot-assisted lower-limb gait training in specialized neurological rehabilitation using the unified theory of acceptance and use of technology framework.

Methods: A qualitative, exploratory research design with a deductive approach was used. Semistructured interviews were conducted with 7 expert physiotherapists in a Norwegian specialized rehabilitation hospital. Data collection and analysis were guided by the unified theory of acceptance and use of technology framework.

Results: The physiotherapists' use of lower limb exoskeletons was greatly influenced by perceived benefits for patients or challenges, such as usability issues, the time required for adjustment to each patient, and the lack of personnel resources to facilitate their use. Thus, perceived usefulness and facilitating conditions (or lack thereof) had a great influence on the physiotherapists' intentions to use and the actual use of the exoskeleton.

Conclusions: This study identified several factors influencing the physiotherapists' acceptance and integration of the lower limb exoskeleton. Available resources, such as time and personnel, were emphasized as important factors to increase the use of the exoskeleton in specialized rehabilitation. Our findings may inform service providers and engineers in specialized neurological rehabilitation settings.

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KEYWORDS

assistive technology; clinical implementation; deductive analysis; robot-assisted gait training therapy; RAGT; user experiences; unified theory of acceptance and use of technology; UTAUT; rehabilitation

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Introduction

Background

The use of robot-assisted gait training (RAGT) for patients with lower-limb paralysis due to neurological disease, stroke, or spinal cord injury has seen a global increase over the past 15 years [1-3]. The appeal of this technology in gait function rehabilitation is manifold, including improved gait function, cardiovascular benefits, enhanced training quality, objective measurements, patient motivation, and reduced physical and psychological workload for therapists [2,4-6].

Traditionally, treatment aimed at improving gait function requires frequent and meticulous follow-up several times a day by at least 1 physiotherapist to have a significant impact [7,8], which imposes significant resource burdens. To mitigate these challenges, lower limb exoskeletons have emerged as promising tools in clinical rehabilitation to allow intensive, high repetition of the gait cycle in individuals with locomotor disability, with reduced therapist effort [9]. Among health care professionals who interact directly with this technology, physiotherapists are expected to play a crucial role due to their specialized expertise. Their experiences and perceptions are likely to significantly impact the integration of exoskeletons into clinical practice because of both their academic competencies and hands-on experience in the rehabilitation of gait function. Physiotherapists are also proficient in the application of different modalities and new technology in clinical practice. Therefore, physiotherapists' perspectives are likely to be fundamental in the successful implementation of this technology.

The literature provides valuable insights into the experiences of physiotherapists regarding benefits, disadvantages, and practical considerations with RAGT [2,3,10-14]. Studies have explored physiotherapists' experiences with a diverse array of robotic exoskeletons in different treatment settings. Most studies have revealed a complex interplay of benefits and disadvantages. For example, using RAGT compared to traditional rehabilitation, physiotherapists have observed similar benefits to those experienced by patients, including increased training volume within a single session, improved gait, and better balance [2,12]. They also report that benefits include reduced physical strain and fatigue, improved gait patterns, the ability to stand upright, experiencing greater control and safety, and expansion of where rehabilitation can take place [2,10]. Studies have also reported challenges related to the use of robotic exoskeletons, such as the time required to calibrate the equipment, the time needed for training in its use, user-friendliness, adaptability to patients with various physical adaptations, and ensuring patient comfort and safety [3,10,13]. Physiotherapists have also expressed concerns about the technology's clinical integration, addressing resource requirements, overcoming equipment-specific challenges, and managing expectations of the technology [10,11,14].

While physiotherapists remain optimistic about the technology's ongoing evolution, the existing literature lacks a focus on the end user's perspective. Studies stress that this viewpoint is vital in the development and deployment of robot-assisted training tools [3]. They also assert that the successful implementation of these tools largely depends on therapists' perceived usefulness and user acceptance [15,16].

Knowing that the successful adoption of robot assistive technology largely depends on therapists' user acceptance, there are still gaps in fully comprehending the nuances of physiotherapists' perspectives. Therefore, this study aims to explore physiotherapists' perceptions of using robot-assisted lower-limb gait training in specialized neurological rehabilitation, using the unified theory of acceptance and use of technology (UTAUT) framework [17]. UTAUT is among the most used frameworks in explaining which determinants affect the acceptance of various health care technologies through different user groups, settings, and countries [18]. UTAUT has also proven to be valid for assessing technology acceptance among therapists in rehabilitation [19,20]. We foresee that the findings could potentially inform exoskeleton engineering, clinicians, researchers, and service providers while also contributing to the body of knowledge on RAGT in specialized neurological rehabilitation settings in Norway and beyond.

The Rehabilitative Robotic Exoskeleton

Robotic technology for gait training can be divided into 2 main categories: end effector and exoskeleton, with lower limb robotic exoskeletons further classified as "static" or "overground," where movement around the environment is possible [1]. This paper focuses on overground exoskeletons, which are of 2 main types: assistive and rehabilitative [21]. Assistive robotic exoskeletons aim to serve as aids in daily life, while rehabilitative robotic exoskeletons aim to restore gait function in patients, particularly those with neurological conditions. There are several manufacturers of this type, but this paper refers to the Ekso GT model (Ekso Bionics Holdings Inc) [5], which is shown in Figure 1.

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Figure 1. Overground exoskeleton, Ekso GT (Ekso Bionics Holdings Inc).



Gait rehabilitation robots commonly feature an external motorized exoskeleton that follows the legs on both sides. Movements are triggered by the physiotherapist with hand control or by the patient herself or himself using leg movement or upper body momentum. An actuator in the knee and hip joint then initiates movement. Gait robots require support from the upper body or a therapist to maintain balance [1]. Furthermore, we will refer to the Ekso GT by the term “exoskeleton” in this paper.

Methods

Study Design and Method

A qualitative exploratory research design with a deductive approach was used along with individual semistructured interviews [22].

Participants and Recruitment

A purposive sampling of physiotherapists was undertaken at a Norwegian specialized rehabilitation hospital based on the following inclusion criteria: physiotherapists with clinical experience using the exoskeleton, holding a minimum of 50% position, and having ≥2 years of experience in traditional gait rehabilitation. The head of the technological intervention center at the hospital assisted in disseminating invitations to physiotherapists who met the inclusion criteria. Initially, all 9 eligible physiotherapists responded with interest and were given a study information letter emphasizing confidentiality and voluntary participation. A total of 2 of the recruited participants chose to withdraw before the interview. Thus, our final sample consisted of 7 physiotherapists.

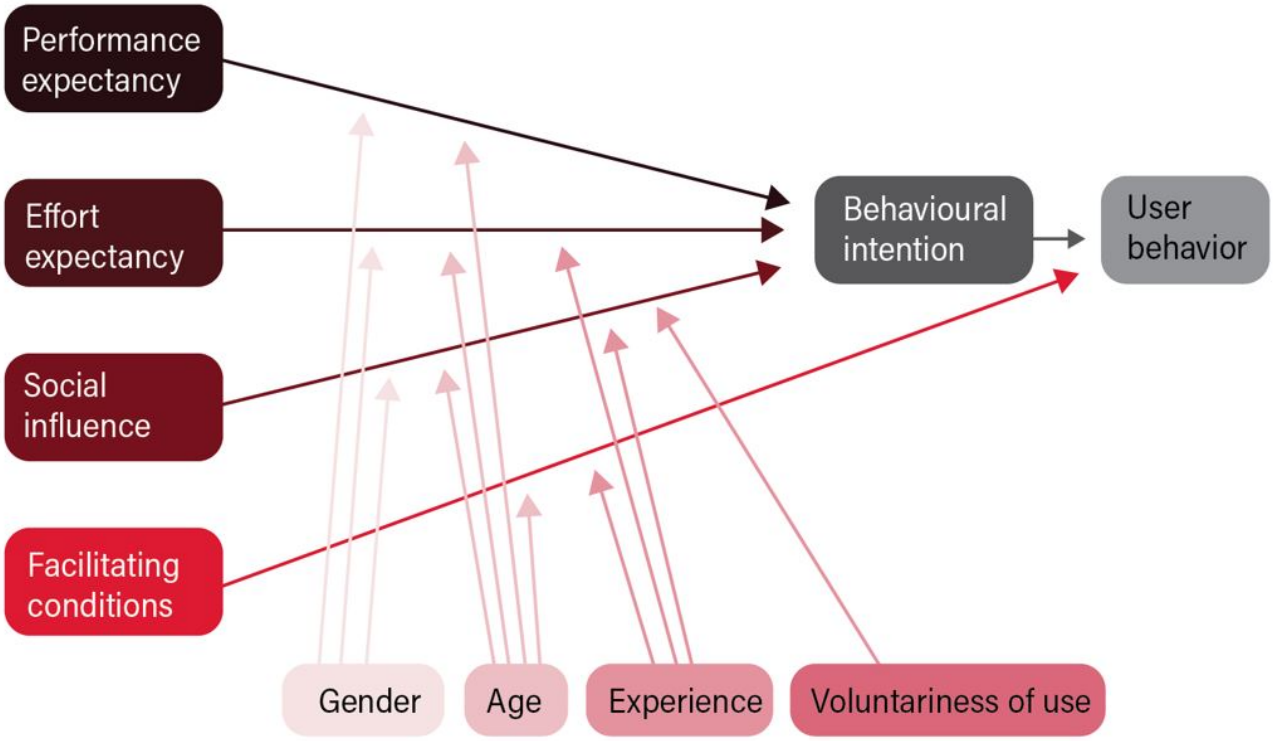
All included informants worked at Norway’s largest and most advanced rehabilitation hospital for individuals who have experienced severe illness or injury. The institution undertakes nationwide tasks and responsibilities and functions as a university-affiliated institution. The hospital is accredited according to the international standards of the Commission on Accreditation of Rehabilitation Facilities.

Data Collection

Individual interviews were chosen as they are suitable for capturing diverse experiences and subjective perceptions while preserving unbiased responses from the informants [22]. A semistructured interview guide was developed by the first author (AOH) and was based on the UTAUT framework (Figure 2 [17]).

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Figure 2. The unified theory of acceptance and use of technology framework.



UTAUT posits 3 determinants directly influencing behavioral intention (performance expectancy, effort expectancy, and social influence) and 2 determinants directly impacting use behavior (facilitating conditions and behavioral intention). Together, these 5 determinants, along with use behavior itself, comprise the 6 main constructs of user acceptance according to the UTAUT. In addition, the framework includes 4 moderators (gender, age, technology experience, and voluntariness of use). Table 1 shows how the main constructs of the UTAUT framework were applied in the development of the interview guide.

Table 1. Interview questions guided by the unified theory of acceptance and use of technology (UTAUT) framework.

Main constructs of the UTAUT framework	Interview questions
Performance expectancy	• How do you perceive the usefulness of the exoskeleton in treatment? • How does its usefulness compare to other or traditional gait training methods?
Effort expectancy	• How do you experience the user-friendliness of the exoskeleton? • What do you think are important factors for the technology to be perceived as more user-friendly in gait training?
Social influence	• In what ways are your use of the exoskeleton influenced by colleagues' or the management's attitude towards the exoskeleton? • In what way do you feel that having knowledge and skills in using this technology provides any benefits for you as an employee?
Facilitating conditions	• How is use of the exoskeleton organized in the department? (time, resources, etc) • What type of training have you received in using the exoskeleton?
Use behavior	• How often do you use the exoskeleton? • Do you choose the exoskeleton over other treatment methods?
Behavioral intention	• What are your intentions for future use of the exoskeleton? • What possibly promotes or hinders your use of the exoskeleton?

The interview guide was pilot-tested by a physiotherapy researcher at the specialized rehabilitation hospital who was familiar with RAGT and qualitative research. The pilot testing led to changes to a couple of questions; one of the questions proved to be leading, and the other was a yes or no type of question.

In the semistructured interview setting, the open-ended questions were based on the main constructs of the UTAUT framework (Table 1). These questions were followed up with probing

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questions to further explore responses and the topic of interest [22]. The first author (AOH) conducted all the interviews. Due to the COVID-19 pandemic and physical distancing requirements, all the interviews were conducted digitally using Microsoft Teams (version 1.5.00.9163) or Zoom (version 5.10.1; Zoom Communications Inc). The interviews lasted from 35 to 70 minutes, with a mean of 60 minutes. The interviews were audio recorded for transcription purposes using a digital recorder (web form) with approval from the data protection officer at the University of Agder.

Data Analysis

The first author (AOH) transcribed all the interviews and conducted the initial analysis combining deductive and inductive approaches [23]. First, the transcripts were read through to identify units of meaning that were relevant to the research question. Second, the units of meaning were placed under appropriate main categories aligned with the UTAUT constructs in an analysis matrix, representing the deductive part of the content analysis. Five of the 6 main constructs of the UTAUT were viewed as predetermined main categories and served as the deductive framework as follows: performance expectancy, effort expectancy, social influence, facilitating conditions, and behavioral intention (Table 1). Data concerning use behavior were not included in the content analysis but were considered demographic data regarding the actual use of the exoskeleton. Thus, the deductive analysis was used based on 5 of the 6 predetermined main categories of the UTAUT framework.

Next, all meaning units sorted under each category were reread inductively to identify possible subcategories. Furthermore, the units of meaning were condensed, coded, abstracted, and grouped into subcategories. The final part of the analysis process, as described in Table 2, represented the inductive part of the content analysis, and it allowed for the emergence of unanticipated subcategories. The first author (AOH) discussed all the findings of the deductive and inductive analyses with the last author (HMJ) until a consensus was achieved. Furthermore, the identified subcategories were discussed, and a consensus was reached among the 3 authors. The analysis was partly conducted with NVivo Pro 12 software (Lumivero).

In alignment with reporting qualitative research, the prevalence of participants' responses is generally presented using descriptors, such as "most," "many," and other equivalent terms. The manuscript preparation adhered to the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.

Table 2. Example of the inductive part of the content analysis.

Main category	Subcategory	Code	Meaning unit (participant statement)
Performance expectancy	Advantages of using the exoskeleton	The exoskeleton contributes to controlled and focused working conditions.	"What can be nice is that it's [the exoskeleton] slow and you can correct and have more focus on quality in gait training. I worked with stroke patients who don't use the affected side much without the robot. When using the robot, you can work on focusing on not letting them compensate with a shorter stance phase on the affected side."

Ethical Considerations

Ethics approval for this study was granted from the Norwegian Agency for Shared Services in Education and Research (578944) and the ethics committee at the faculty of health and sport sciences at the University of Agder. All participants received written and oral information about the project, and written informed consent was secured from all participants via email before the scheduled interviews. The first author (AOH), who conducted the interviews, had not physically met the participants before the actual interviews. The participants did not receive any compensation for their contribution in the study.

To secure confidentiality, study IDs were assigned to each participant that replaced their names in transcripts. Names and participant numbers were stored separately in a secure location. In addition, direct personally identifiable data, such as age, gender, and experience, were not directly reported in this paper but summarized under demographic data in the Results section because all the participants resided in the same unit at an identified hospital. Furthermore, participant numbers were not displayed in presenting direct quotations (translated from Norwegian into English by AOH) from the interviews in order to ensure the anonymity of the participants.

Results

Participants

A total of 7 physiotherapists participated in this study, 1 man and 6 women between the age of 38 and 71 (mean 39) years. They had worked in rehabilitation between 8 and 37 (median 15) years. The participants were physiotherapists with advanced expertise in rehabilitation. Education levels varied from bachelor's and master's to doctoral degrees in physiotherapy; however, all had completed courses and further education within the field to be titled specialist physiotherapist. In total, 5 physiotherapists had been certified to either level 1 or level 2 of the supplier's required training, which involves using the robot with more advanced settings. Each had between 8 and 37 years of clinical experience, with several serving in senior or leadership positions within specialized rehabilitation centers. This level of expertise provided an in-depth understanding of the factors influencing user acceptance of technology in a clinical setting. The level of experience using the exoskeleton varied from weekly use to almost no use in the past year. All the participants had started using the exoskeleton in the hospital's implementation project 3 years before data collection.

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Results From Content Analysis

Overview

Table 3 presents the findings based on the main categories of the UTAUT framework. Findings related to subcategories are described in the text, illustrated with citations representing all informants.

Table 3. Summary of the study findings. Main categories and subcategories aligned with the constructs of the unified theory of acceptance and use of technology framework.

Main category	Subcategories
Performance expectancy	• Perceived benefits of using the robot • Perceived disadvantages of using the robot
Effort expectancy	• Robot design and functionality • Customization and personalization of the robot
Social influence	• Managers' influence on use behavior • Peers' influence on use behavior
Facilitating conditions	• Available resources • Training and expertise
Behavioral intention	• Intentions to adopt the robot • Intentions not to adopt the robot

Performance Expectancy

Perceived Benefits of Using the Robot

The exoskeleton was described as a good supplement to existing walking training and its usefulness lay in the possibilities it added. All the participants described the benefits of using the robot, such as the ability for a patient to stand up, facilitating an increased number of steps, or symmetrical loading of the body in treatment. The usefulness for patients varied depending on the individual's functional abilities and diagnosis. For example, the exoskeleton offered new opportunities, especially for patients with complete spinal cord injuries:

> *If you have a complete spinal cord injury, you don't have the ability to walk. For these patients, it's been a great opportunity to be able to stand up straight and walk. Using the exoskeleton may also facilitate secondary treatment benefits such has cardiovascular effects which are also achieved by mobilization.*

Furthermore, the increased number of steps was considered particularly beneficial in spinal cord injury training that focused on neuroplasticity:

> *The patients can focus more on performing an increased number of steps. It [the robot] is stable, I control the balance. The patients can work on weight transfer. The steps come on their own or on impulse from the patients. So, they get a lot more repetitions by using the robot, because it's automatically possible to do more repetitions. That's clearly an advantage in using a walking robot.*

Participants who described benefits, such as symmetrical loading, mostly worked with patients who had experienced a stroke. One of the benefits they described was related to the possibility of "disconnecting" one of the exoskeleton's legs to allow the good leg to move freely. Other benefits described were related to the fact that the exoskeleton stabilized the patient quite well, and this simplified the work of the physiotherapists and freed up their hands so they could focus on other aspects of the treatment.

Furthermore, several participants stated that it was an advantage that the speed of the exoskeleton was slow, which made it easier to focus on the execution of movements and thus increased the quality of the treatment. It was also considered an advantage that the robot did not let patients compensate with a shorter stance phase on the affected side; rather, it supported the full weight transfer of their whole body.

Several participants also talked about the benefit of being able to help patients feel safer by creating safe and stable frameworks, which meant that patients dared to challenge themselves more. Furthermore, the experience of standing upright also seemed very motivating for the patients and, in that way, contributed to something beyond traditional walking training for certain patient groups.

Perceived Disadvantages of Using the Robot

Using the exoskeleton was quite time consuming, which was described by all the participants as a significant disadvantage. The initial treatment was perceived as particularly time consuming due to all the preparations, adjustments, and measurements that needed to be made. When the exoskeleton was used on different patients, the disadvantage related to time consumption was amplified. The time required for adjustments both before and after the training session made the disadvantages outweigh the benefits, as the time that could have been saved in terms of quantity and quality of treatment was consumed by preparation and adjustments. Some participants described it as taking time away from effective treatment time. However, participants reported reduced time consumption during subsequent training sessions in comparison to the first one.

Several participants mentioned that the exoskeleton could negatively affect patients' self-effort and expectations. For example, some participants described how the patient was

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confined within the "skeleton" of the exoskeleton, which made it difficult to assess the patient's own effort. This resulted in uncertainty about the effectiveness of treatment for several patients. Some participants explained this by describing how the exoskeleton could function as a crutch. One informant stated the following:

> *When they [patients] started getting better, it became apparent that they relied more on the robot's support to a greater extent than I had hoped...because something unconscious happens when you are so encapsulated that you automatically rely a bit more on the robot, and then it becomes difficult to challenge yourselves enough.*

Similarly, some physiotherapists described a downside to the benefits of the technology that dealt with the challenge of managing patient expectations, for example, for patients with spinal cord injury who could have high hopes or hopes of regaining function beyond what was realistic. Finally, it was mentioned that sometimes, patients used the robot for such a brief period that it was not effectively used. As a result, the physiotherapists did not experience any of the mentioned benefits of its use.

Effort Expectancy

Robot Design and Functionality

Certain physiotherapists said that the exoskeleton was large and heavy to handle. One suggested that it could have been made from completely different materials. The size and weight of the exoskeleton were perceived as particularly challenging when mobilizing patients from a chair and onto the exoskeleton and when supporting activity during walking training itself. Due to its weight, moving the equipment to other locations was out of the question. Few participants said that a ceiling rail had been installed to assist with this problem.

Most of the participants perceived that it was easy to learn how to use the exoskeleton. One described it as follows:

> *It [the robot] is easy to use in the sense that it can be learned by reading an instruction manual.*

At the same time, most of the participants thought the robot was very comprehensive and time consuming to use. This was partly explained by the fact that the physiotherapists had to conduct manual adjustments and programming of the robotics before using it. Some said that they had some kind of checklist they went through, which made it easy to get the basic settings right. Furthermore, many experienced the user interface on the exoskeleton as "old-fashioned" and not very user-friendly. It was pointed out that the menu system had many setting options, but there were few buttons for selecting settings. Finding the setting they wanted to use required several operations, which was exacerbated when using the technology's most advanced settings. As a result, most of the participants did not use the advanced settings. One of the informants summarized this as follows:

> *It's not user-friendly at all, I feel, because there are far too many possibilities on too few buttons, I think, so you have to scroll forever to find what you're looking for, even then you have to kind of learn by heart which functions are under which in the menu—so in relation to using a smartphone, it was in a way so far back in relation to those systems, you felt in a way that you were using an old personal computer.*

Some participants also mentioned that the technology felt "unnecessarily complex." One of the informants described it as follows:

> *We have a lot of technical aids here in the facility, but the Ekso is clearly the most comprehensive of them all.*

Customization and Personalization of the Robot

Some participants experienced that the robot device had physical limitations, which meant that some patients were too tall, too short, too wide, or too narrow to fit it. There was no solution to this, and several participants described this as a major limitation. One of the informants said the following:

> *It was a big limitation, especially on this issue of hip width, we were often adamant about it. There were several patients where we thought it would fit, but then they were too wide over their bum, it also happened that they were too small for it to fit. Or too tall or short.*

The physiotherapists described that if the exoskeleton was used frequently with different patients, there was no quick way to use the settings that had been used on the patient during a previous treatment. All settings had to be replotted. Challenges surrounding the need for manual adjustments to the device, such as adaptation and adjustment of the ankles, knees, and hips, were described by several of the participants. Some expressed that this was a matter of training and that one got better at adjustments when one had done it enough times. Some of the participants also described a fear of tightening the straps too tightly or making incorrect settings that could make it uncomfortable or create fear in the patients.

The participants were asked what could make the robot easier to use. Several said that ease of use for them in relation to the robot concerned whether it was quick to prepare for use, that it required few work operations, and that the user interface was clear and intuitive.

Social Influence

Managers' Influence on Use Behavior

The participants experienced that the management's commitment to and willingness in the implementation of the exoskeleton influenced their use of it to a large extent. The management's wish and plans to adopt the exoskeleton were communicated clearly, and this was followed by resources and goodwill to facilitate its implementation. The participants said that the management encouraged the inclusion of patients whose treatment could fit the use of the exoskeleton. These calls were followed up by the physiotherapists in many different treatment settings, which led to frequent use of the exoskeleton.

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Some participants suggested that the hospital management's aim and vision of being at the forefront of new technology and innovation played a role in why they chose to adopt the technology. They had also experienced that when other, and sometimes conflicting, innovation projects related to gait training came along, the enthusiasm and follow-up had somewhat decreased. One of the informants said the following:

> *We're supposed to do a lot of cool projects, but there's perhaps too little holistic thinking around walk training.*

Some participants also proposed that when the need for certain technology has not come "from the therapists," it may be difficult to follow calls that come from the management. One participant said the following:

> *You could say that the desire to use [the exoskeleton] did not come from the therapists. It has come from the top management, and it's a slightly unnatural way to approach a product—a bit like: Now you have it, so now you have to figure it out.*

Because the implementation of the exoskeleton had not been triggered by the needs of the therapists, some participants felt it was a form of forced use.

Peers' Influence on Use Behavior

Most participants said that the attitudes of their colleagues toward the exoskeleton did not matter much in relation to their own choice to use it. One stated that they had not experienced any negative attitudes toward using such a robot. Some participants shared that one could be influenced to use it if colleagues brought it up in plenary meetings, that is, asking for possible candidates for using the exoskeleton. Other participants proposed that professional discussions about the exoskeleton influenced their choice to adopt the technology. One participant said the following:

> *We had colleagues who were quite positive about it. At the same time, people wondered a little whether it would work for the patients we were going to use it for.*

Facilitating Conditions

Available Resources

Many participants described organization-related challenges in using the exoskeleton. Several mentioned that its use was perceived as resource intensive, as it required 2 people to be involved in the treatment and its use and thus needed to be coordinated with other staff. One explained it as follows:

> *It's a problem in the healthcare system in general that we don't have an abundance of staff. So, it became quite cumbersome to arrange it, to schedule the use of the exoskeleton, and to find someone to assist during the same time slot and manage the logistics so that it could work.*

Due to this, the use of the robot was perceived as vulnerable in case one of the therapists was absent from work. One participant stated the following:

> *I think the resources are not there in terms of personnel.*

Several participants mentioned that the use of the exoskeleton worked better during certain periods when they had a porter available to prepare the equipment before use. At the same time, some noted that if staff had to be reassigned to other tasks, they had to cancel the exoskeleton treatment due to staffing needs. Furthermore, most participants mentioned that when they needed to use the exoskeleton, they sometimes had to deprioritize something else that was already scheduled. This affected not only their own time allocation but also that of the other therapists who had to participate. Because the use of the exoskeleton was so time consuming, several of the participants who worked with patients with spinal cord injuries perceived that the exoskeleton was not suitable for the interdisciplinary program that patients went through during their stay.

The location of the exoskeleton in the gym was considered appropriate and well suited to its use. This was partly explained by the fact that it felt safe that there were more people available in the room. In addition, a rail with suspension from the ceiling had been added, which reduced the need for personnel. Other participants felt that the location in the gym made the exoskeleton less relevant for some patients because some patients had challenges that made it difficult if there were too many other people in the same room.

Several of the physiotherapists said that a large part of the resource needs would be solved if it were organized as a "lab" and that this could solve several of the challenges related to time and personnel resources. One participant said the following:

> *There should be a separate laboratory where one uses such technology, where there are staff who do this job. If we had such lab, [the exoskeleton] would probably have been used more because people would then be able to try it out, while they received other training and treatment, which they needed in addition. That more patients could be offered to try the Ekso.*

Regarding technology support, participants knew whom to ask if they were unsure about something regarding the device. They had superusers for support if needed.

Training and Expertise

All the participants perceived the training on using the exoskeleton as very useful. Some said that the training provided the skills needed to put it into use, and several described the training as having a good balance between theoretical and practical exercises. Some of the participants stated that the training was "very extensive," especially in order to be certified to level 2, which was required for being responsible for treatment with the use of the robot. The extensive part of the treatment was described as time consuming due to the need for an instructor from the robot supplier to be there for 1 week, in addition to several hours required afterward to be certified. Others described it as extensive due to the fact that their daily schedule was very tight, and they had to be replaced by other therapists.

The participants were satisfied with the training they had received, but, at the same time, they asserted that one had to

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practice a lot to become really good at using the exoskeleton and its advanced settings. One participant proposed the following:

> *Like with all new things, time must be set aside for someone to become very good at it.*

It was suggested by several participants that it could be an advantage to organize the use of the robot within a laboratory and engage certain physiotherapists to gain and maintain good competence in using the robot.

Behavioral Intention

Intentions to Not Adopt the Robot

The physiotherapists' biggest reasons for choosing not to use the exoskeleton referred to the time consumption and disadvantages of use, as described in the Performance Expectancy section, and to overly extensive planning, as described in the Facilitating Conditions section. Other reasons were their own professional judgment and the lack of evidence-based knowledge about the effects of using such a robot. One of the informants described some of this as follows:

> *For me, it's important that there's a professional foundation. It's not enough that it's technological and cool, or that we have to show off. The most important thing for me is what benefits the patient or not.*

Furthermore, several of the physiotherapists described how the acquisition of a walking robot was not triggered by a need from the therapists in the clinic. Some also found it difficult to know when and what to use it for. One of the informants said the following:

> *It must be said that this is also where a bit of our opposition lies—without having any good professional arguments for using it—the managers overlook our professional judgements on what is reasonable treatment and use of resources.*

All the participants expressed that the possible benefits that could be achieved in one treatment session using the exoskeleton were eaten up by the time spent on rigging it and the several operations related to its use. Several said that the need for 2 physiotherapists when using it was one big reason for choosing not to use the exoskeleton. It could be challenging to coordinate with another physiotherapist's timetable, or this could result in a second physiotherapist prioritizing to assist before conducting other valuable treatments. Both the planning and the logistics related to the exoskeleton treatment session were so time consuming and difficult to achieve that it could be perceived as easier to choose not to use the exoskeleton.

Intentions to Adopt the Robot

What the physiotherapists described as the biggest reason for choosing to use the exoskeleton was that it offered advantages for some patients, such as new opportunities to be able to stand up straight and walk. These benefits were related to those patients who had some gait function but could not yet practice traditional walking training. Others chose to use the exoskeleton to get people with spinal cord injuries, who otherwise would not be able to do so, to stand. The exoskeleton could provide a safe environment for insecure patients, and it could be used with patients who were motivated by using new technology. Furthermore, several participants described certain criteria for using the exoskeleton, such as consulting the responsible therapist and investigating whether there were contraindications due to specific medical conditions and whether it fitted the patient's physical goals.

Some participants said that the decision to use the exoskeleton initially was made because it was necessary to log hours for certification during the implementation project. Several of the participants who described this used it most frequently in that period. Other participants described that a priority on new technology being used was the reason for choosing to use it.

When asked what would be needed for the technology to be used more frequently in the future, the participants described how more resources and time were needed. Several said that it must "require less energy" for it to be used more frequently. Among other things, some participants pointed out that it will be important to start treatment early as a supplement in order to choose to use it. In addition, it must fit in with the way they work and their needs. For example, several of the participants highlighted the need to gather expertise and resources in a "lab." Here, the exoskeleton could be organized in such a way that one could book an appointment with one's patient, and it would not come at the expense of other treatment for one's other patients.

Several participants called for more evidence-based knowledge about the treatment effects before one could professionally defend using the time and resources needed to use the exoskeleton:

> *It becomes a dilemma in relation to what to invest in using it, when you don't know the actual effects. What we've seen from articles and such has not been very encouraging.*

Other improvement points that the participants described dealt with the development of the exoskeleton technology itself. Some argued that the weight and size of the device should be reduced to expand the range of use and that the control panel should be more intuitive and user-friendly.

Discussion

Principal Findings

Overview

To the best of our knowledge, this study is among the first to investigate the use of a lower limb exoskeleton in specialized neurological rehabilitation using the UTAUT framework, based on the experiences of expert physiotherapists. The physiotherapists predominantly perceived the disadvantages of using the exoskeleton as outweighing the benefits. The use of the exoskeleton was significantly influenced by the perceived benefits for patients, its time and personnel demands, the adequacy of training and support, clinical evidence, and accessibility. A cost-benefit perspective on its use and perceived advantages was decisive in determining how frequently they chose to use the exoskeleton in clinical practice.

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The exoskeleton was perceived as beneficial for rehabilitating patients with limited mobility, especially those with spinal cord injuries, by enabling them to stand and walk. It increased the number of steps in training, enhanced neuroplasticity, and promoted symmetrical weight distribution. Its stability allowed physiotherapists to focus on other treatment aspects, and patients felt safer and more motivated.

However, significant drawbacks included the time-consuming setup, especially during initial sessions, which reduced treatment efficiency. The exoskeleton's bulk and outdated user interface also posed challenges, making it cumbersome to handle and adjust. Physiotherapists expressed concerns that patients might rely too heavily on the device, undermining their own efforts. In addition, staffing constraints further limited its use, as 2 physiotherapists were required per session.

The findings are further discussed in accordance with the main categories of the UTAUT framework.

Performance Expectancy

The findings showed that the physiotherapists' perceived usefulness (performance expectancy) of the exoskeleton was primarily related to the possibilities and benefits it offered in treating their patients. They highlighted advantages, such as enabling patients to stand up straight, increasing the number of steps taken, and promoting symmetrical body loading. The experiences described by our participants regarding physical and diagnosis-dependent benefits align with previous studies by Vaughan-Graham et al [3] and Mortenson et al [13].

However, despite the aforementioned advantages, most physiotherapists identified the time required to prepare the exoskeleton for initial treatment as a significant disadvantage, which is consistent with findings from Read et al [2]. Additional perceived disadvantages revolved around the narrow scope of the exoskeleton's utility. The technology was perceived as effective only within a specific clinic area, depending on the diagnosis, and for a limited duration during rehabilitation. As patients' functions significantly improved, conventional gait training was preferred. Conversely, if patients' conditions were poor, adaptations were time consuming and deemed inefficient. This may be related to what several physiotherapists described as a "free ride," where patients were essentially passive, without significant therapeutic effect. This aligns with Turchetti et al [24], who identified this potential downside of robot technology in rehabilitation. One possible explanation for this issue is the difficulty physiotherapists face in assessing patients' exertion and contribution when they are confined within the exoskeleton. Another explanation could be related to the level at which physiotherapists use the exoskeleton. Few reported using it at a "high level" fully exploiting all the device's functionalities.

The physiotherapists predominantly perceived the disadvantages of using the exoskeleton as outweighing the benefits. This cost-benefit perspective is elucidated by Mortenson et al [13], who raised questions regarding the exoskeleton's efficacy and cost-effectiveness relative to other approaches. However, our findings are consistent with those of Liu et al [19], indicating that physiotherapists are likely to adopt new technology if they perceive it as beneficial for their patient-related work. For example, our participants found that the benefit of using the exoskeleton for certain patients was a key motivation for their intention to use it. Thus, our findings are in line with the UTAUT framework [17], showing that performance expectancy, herein perceived usefulness (or lack thereof), is the strongest predictor of user acceptance and intention to use technology.

Similar to participants in other studies [3,11,25], the physiotherapists expressed disappointment regarding their expectations of the potential benefits of using the technology. This may suggest a discrepancy between user needs and the acquired product, a known issue with acquisitions of commercial off-the-shelf solutions, as described by Turchetti et al [24]. Challenges associated with such acquisitions include products not being developed to address the needs they are meant to solve. Physiotherapists find it difficult to understand which requirement the exoskeleton is intended to fulfill. This can be explained, on the one hand, by the nature of the product but also by the absence of user engagement during the implementation process, a phenomenon commonly referred to as the "top-down" approach in the literature [26,27].

Effort Expectancy

The physiotherapists' effort expectancy was related to the design, functionality, customization, and personalization of the exoskeleton for each patient. For example, the exoskeleton was challenging to use due to its size and weight, and its outdated control panel (user interface) with limited options made adjustments unnecessarily complex. However, despite its perceived lack of user-friendliness, most participants found learning how to use it easy.

Effort expectancy in terms of usability is expected to significantly influence the degree of use during the initial phase of implementation when users have not yet learned how to use the technology [17]. Previous studies have demonstrated that the impact on the intention to use decreases the longer the technology has been in use regardless of how difficult it is to learn [17,19]. On the one hand, the findings of this study align with this notion, as the physiotherapists have been using the technology for >3 years, and perceived usability had less influence on their intention to use it. Some participants expressed that "it was a matter of training" and that proficiency improved with practice. On the other hand, several physiotherapists used the technology sparingly over these 3 years, suggesting that perceived usability might be more significant than the results indicate. A possible explanation is that all physiotherapists in this study found the gait robot easy to learn initially.

In this study, perceived usability has been shown to have little influence on physiotherapists' intention to use the gait robot, consistent with the findings of Liu et al [19]. For the exoskeleton to be perceived as more user-friendly, the participants suggested that such technology should be quick to prepare for use, requiring few operational steps, and having an interface that is clear and intuitive.

Social Influence

According to Venkatesh et al [17], social influence from others may directly influence behavioral intention. In addition, a

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moderating factor on social influence is the voluntariness of use. The physiotherapists in this study perceived they were influenced by their management, particularly at the onset of the implementation project when it was necessary to log hours to achieve certification. Some also indicated that the exoskeleton was a "top-down" investment not triggered by the physiotherapists' needs. In contrast to Venkatesh et al [17], our findings indicate minimal influence from colleagues on their behavioral intention.

Upon reviewing the literature on the use of rehabilitation robots, no other studies were found that described findings related to social influence.

Facilitating Conditions

According to Venkatesh et al [17], facilitating conditions have a direct impact on user acceptance. This was supported in our findings, as physiotherapists described shortcomings related to available resources, organization, training, and competence related to using the exoskeleton.

The findings of our study largely revolved around the disadvantages that physiotherapists experienced related to organization and resources. This affected physiotherapists' behavioral intention in such a way that they demanded more resources in terms of personnel and time to further use the exoskeleton. This aligns with the challenges described by Read et al [2], Mortenson et al [13], and Reicherzer et al [16]. Furthermore, our findings indicated that facilitating conditions, such as a lack of organization and resources, affected behavioral intention to a greater extent than their use behavior. This is in accordance with the findings of Liu et al [19] who found that physiotherapists who perceive good utility value use the technology regardless but more frequently if facilitating conditions were in place. Liu et al [19] referred to how facilitating conditions are the strongest factor influencing physiotherapists' use of new technology in the rehabilitation setting.

The finding that physiotherapists experience challenges related to planning and providing treatment on a hectic weekday aligns with the experiences of physiotherapists in the study by Mortenson et al [13]. Physiotherapists in our study emphasized the significant resource demands associated with coordinating appointments involving multiple physiotherapists for treatment, particularly in terms of personnel allocation. This was also found in the study by Mortenson et al [13]. Multiple physiotherapists described untapped potential in the current implementation of the technology, a recognized concern based on research in health technology and implementation [26,28].

It is important to note that the implementation of RAGT requires a large investment in training and equipment for most services.

Behavioral Intention

According to Venkatesh et al [17], behavioral intention captures the individual's motivation and intention to use the technology. They also described behavioral intention as a key predictor of actual use behavior when interacting with technology.

Physiotherapists in our study cited the exoskeleton's potential to benefit patients, particularly those with limited function or spinal cord injuries, as a key motivation for adoption. The technology provides new opportunities for patients to stand and walk and fosters a safe, motivating environment. In addition, participants identified specific criteria for use, including consultation with responsible therapists and consideration of patient goals. However, the lack of available resources within the organization, including time and personnel, emerged as a central barrier to adoption. Physiotherapists expressed concerns about the time-consuming nature of using the exoskeleton and the logistical challenges associated with coordinating sessions. In addition, uncertainty surrounding the technology's effectiveness and the need for evidence-based knowledge were highlighted as deterrents to adoption.

Our findings align with previous research by Liu et al [19], which identified performance expectancy and intention to use as key predictors for actual use. Similarly, Heinemann et al [11] and Mortenson et al [13] emphasized the importance of expanding the scope of use scenarios to promote future adoption. This aligns well with our findings in that physiotherapists experienced that for particular patients and particular rehabilitation phases, the robot simply could not be used. This was related to patients who had not obtained enough function to take advantage of the robot yet, but the time frame, between being ready to use the robot and when they were more likely to walk without it, was fairly short, limiting the "window of opportunity" for those particular patients and rehabilitation phases.

Our study uniquely highlights the potential barrier posed by the lack of available resources within the organization, a factor not extensively explored in previous literature. This underscores the need for a comprehensive examination of user acceptance among physiotherapists to guide the implementation of robot-assisted training in clinical practice, as highlighted by Venkatesh et al [17] and our own study.

Strengths and Limitations of This Study

The data and findings in our study are unique, as we applied the validated UTAUT framework in exploring physiotherapists' acceptance of a robotic lower limb exoskeleton in specialized neurological rehabilitation. To increase the validity and reliability of the findings, the main categories of the deductive analysis were based on the dimensions of the UTAUT framework. Knowing that using a deductive or directed content analysis approach may bias the identification of other possible main categories or subcategories in the text [29], the authors remained open minded during the analysis to allow for the emergence of additional themes or subthemes from the data.

The trustworthiness of the study was ensured using the criteria of credibility, dependability, and transferability [30]. Credibility can be understood as maintaining a careful focus on the project. This criterion was met by choosing participants who were most relevant to the aim of this study. Dependability was ensured through rigorous and well-documented data collection techniques and procedures. The interview guide was pretested, and the same questions were used for all the participants. Moreover, all interviews were conducted by the first author, who is a physiotherapist with extensive expertise in the use of technology in health care. The other authors have extensive

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expertise in specialized rehabilitation, pedagogics, and qualitative research, which influenced the study design, data collection, and data interpretation throughout the research process.

Although the generalization of findings is not a goal of qualitative research, qualitative researchers strive for the transferability of findings. To address this, we provided a thorough description of the context, participants, and research process. Furthermore, we attempted to present the findings in as much detail as possible while ensuring the deidentification of the informants. Thus, we argue that the qualitative part of the study meets the criteria for trustworthiness.

There are some limitations to this study. Due to the scarcity of physiotherapists certified in the use of the lower limb robotic exoskeleton in a specialized rehabilitation unit, the eligible sample was limited. Even so, despite the small sample size, it can be argued that information power was achieved, as the cohort of expert physiotherapists provided substantial insights relevant to the actual study [31]. The findings reflect the perspectives of physiotherapists at a specialized rehabilitation hospital in Norway. However, we think the findings may be transferable to comparable contexts.

Conclusions

Our findings showed that the participants' intention to use and their actual use of a lower limb exoskeleton in a specialized rehabilitation setting were influenced by perceived benefits (performance expectancy) for patients; challenges, such as usability issues and the time required for adjustment to each patient (effort expectancy); the lack of personnel resources to facilitate its use (facilitating conditions); and deficient evidence-based knowledge about its treatment effects. A cost-benefit perspective was adopted where the perceived advantages were a decisive factor in determining how frequently they chose to use the exoskeleton. The expert physiotherapists predominantly perceived the disadvantages of using the exoskeleton as outweighing the benefits.

This study advances understanding of the factors affecting the user acceptance of lower limb RAGT in specialized rehabilitation from the perspective of physiotherapists. Although the findings are limited by the sample size and the exploratory nature of the study, they provide directions for possible decisive factors for the acceptance and integration of lower limb exoskeletons in specialized rehabilitation. With a growing demand for technology in rehabilitation, our insights on acceptance and integration of the lower limb exoskeleton may inform others who are considering or in the process of integrating exoskeletons into clinical practice. The findings may inform exoskeleton engineering, researchers, and service providers in Norway and beyond.

Further research should focus on gathering evidence on the rehabilitation effectiveness and cost-effectiveness of lower limb exoskeletons. Such evidence can justify their integration into specialized rehabilitation by demonstrating clinical benefits and economic viability.

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Conflicts of Interest

None declared.

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
RAGT: robot-assisted gait training
UTAUT: unified theory of acceptance and use of technology

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Development of a Mobile App Game for Practicing Lung Exercises: Feasibility Study

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Abstract

Background: Chest injuries are a leading cause of death and disability, accounting for 10% of hospital admissions and 25% of injury-related deaths. About two-thirds of patients with thoracic injuries experience complications such as blood or air in the pleural space, causing lung deflation and poor gas exchange. Proper breathing management, using tools like incentive spirometers, improves lung function and recovery. However, there is a gap in mobile-based gaming apps designed for lung exercise, which could benefit both the general population and patients recovering from lung injuries.

Objective: This research aimed to develop and evaluate a mobile app game for practicing lung exercises, accompanied by a prototype device called the Pulmo device.

Methods: The study involved a sample group of 110 participants from the general public. It followed a research and development methodology comprising 4 steps. The research instruments included a mobile app game, a prototype lung exercise device, and questionnaires to assess users' satisfaction and the feasibility of both the app and the device.

Results: The findings revealed that the participants demonstrated a high level of overall satisfaction with both the mobile app game and the prototype lung exercise device (mean 4.4, SD 0.4). The feasibility for the mobile app game and the prototype lung exercise device connected to the game was evaluated. The results indicated that the sample group perceived the overall feasibility to be at a high level (mean 4.4, SD 0.5).

Conclusions: The research results reflected that the sample group believed the mobile app game for practicing lung exercises and the prototype device developed in this project have a high potential for practical application in promoting lung rehabilitation through gameplay. The mobile app game and the Pulmo device prototype received positive user feedback, indicating potential practical use; however, further validation is required among patients in need of pulmonary rehabilitation.

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KEYWORDS

mobile app game; practice lung exercises; feasibility study; mobile phone; pulmo device; app

Introduction

Chest injury is considered a leading cause of death and morbidity worldwide and is the second most common cause of death after head injuries. It is also one of the leading causes of long-term disability and hospital admissions, accounting for 10% of hospital admissions and 25% of injury-related deaths [1]. Approximately two-thirds of patients have thoracic injuries. These vary in severity from broken ribs to injuries that penetrate the heart or a torn trachea (tracheobronchial disruption). In addition, injuries resulting from concussion are the most common, with an incidence of 90% [2].

Furthermore, up to 70% of patients with thoracic injuries develop blood or air in the pleural space, preventing the lungs from fully expanding. This loss of negative pressure in the pleural space results in lung deflation and inefficient gas

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exchange. If correct, appropriate, and timely treatment is not received, it may cause oxygen depletion and can be life threatening [3].

Breathing exercises help improve lung function and increase quality of life. Practical breathing management often involves the use of a device known as an incentive spirometer, which helps to increase lung volume. This tool, designed for simple usage, allows patients to independently practice and improve their respiratory function. Nurses should have knowledge in breathing management. Breathing management is different from exercise. The breathing management will focus on every part of the respiratory tract, both in normal parts and in parts with pathology and should have knowledge in using the equipments in breathing management, which are used in many different types, even in the same hospital. This depends on objectives according to the doctor's treatment plan [4].

While existing research demonstrates the effectiveness of mobile games and technology-based interventions in various rehabilitation contexts from neurological rehabilitation showing improvements in cognitive skills, motor functionality, and balance, to successful applications in pulmonary rehabilitation for chronic obstructive pulmonary disease patients with enhanced quality of life and exercise capacity, there appears to be a significant gap in developing comprehensive mobile-based gaming apps specifically designed for practicing lung exercise in the general population that could be adapted for patients recovering from lung injuries. Current studies primarily focus on either specific medical conditions like chronic obstructive pulmonary disease and stroke, or on mobile-based apps, but don't address the potential of mobile-based gaming platforms that could serve both preventive purposes for the general population and therapeutic apps for post-lung–injury rehabilitation [5-9].

This research aimed to develop and evaluate a lung rehabilitation innovation combining a mobile-based gaming app with a prototype assessment device. The study had 2 primary objectives: first, to create an integrated system comprising a mobile application game for lung exercises paired with a prototype device for lung function assessment; and second, to evaluate this system's potential for practical implementation by assessing both user satisfaction among the general public and its feasibility as a tool for promoting lung rehabilitation through gamified exercise.

Methods

Study Design

Research and development consisted of 4 steps, details are as follows:

Step 1 research established the fundamental groundwork for developing our mobile app game for practicing lung exercise. We conducted a comprehensive literature review that examined both the clinical and educational aspects of our intervention. We systematically investigated existing innovations promoting lung exercise, focusing on both traditional approaches and technological interventions. In addition, we focused on game-based learning principles and their application in health care education.

Step 2 development encompassed the systematic design and development of our mobile app game for lung exercise practice, building directly on the insights gained from our literature review in step 1.

Step 3 research marked our transition from development to real-world implementation through testing of the mobile app game with 110 healthy participants. During this testing phase, we observed how users engaged with the lung exercise game and collected valuable data regarding both user satisfaction and the application's feasibility as a practical tool for lung exercise.

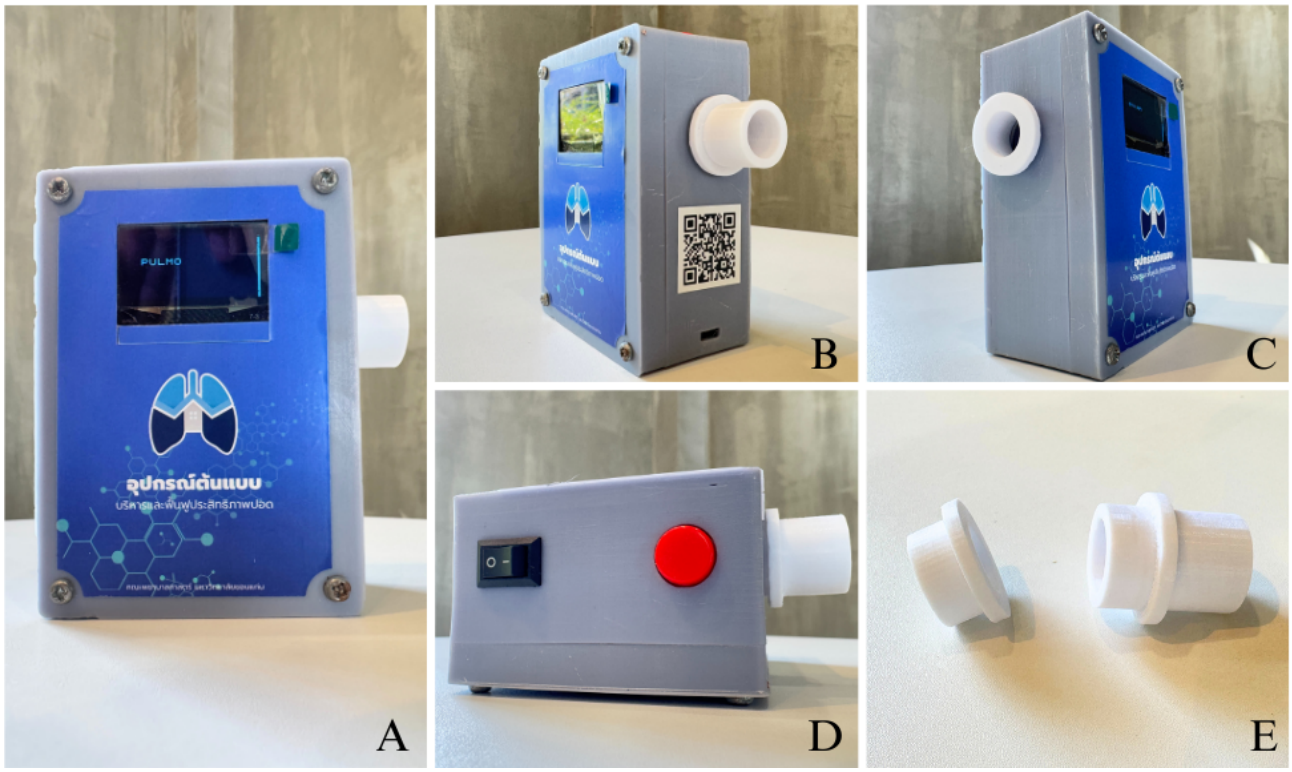
Step 4 development focused on refining both the device and app based on user feedback collected during the R2 testing phase. These improvements ensured our final product effectively addressed user needs identified during implementation.

Development Process

Developing an app with equipment to manage and restore efficiency is done when the air is blown, called the Pulmo device (Figure 1). The Hall effect describes the behavior of charge carriers in a material under a magnetic field. It is widely used in Hall effect sensors for accurate, noncontact detection in various fields. In the proposed lung exercise device, the sensor enables precise, real-time airflow or pressure measurements for effective monitoring [10].

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Figure 1. Pulmo device: (A) front view (B) lateral view (left side) (C) lateral view (right side) (D) top view (E) blowing plug (right), air outlet plug (left).



The sensor receives Hall effect values, used to measure the size of the magnetic field intensity. When a magnetic field is detected in the circuit, voltage will be generated. This voltage is called Hall voltage. This voltage is responsible for detecting the magnetic flux density. These sensors basically function as linear transducers. This flow rate sensor will be connected to nodemicrocontroller unit, a board that uses ESP8266 as a processing unit.

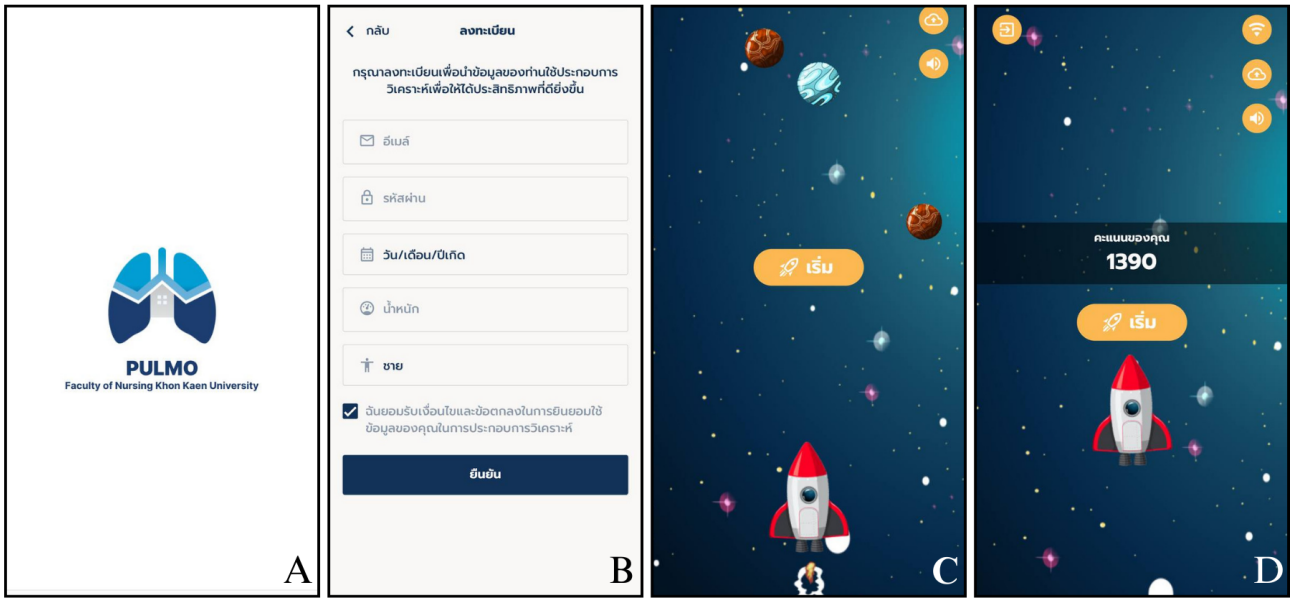
For processing, the device will be set up as a hotspot in order to connect in a computer network manner. It is a network linking system for 2 or more devices including other types of electronic equipment that can communicate, connect, and send data between each other within the transmission control rules according to the IP, where communication protocols are used by assigning addresses. The rules for controlling transmission are determined according to the transmission control protocol or IP of each device so that receiving and sending data can easily connect to each other. After receiving the speed of the air blowing through the sensor, the data and operating status will be displayed on a 1.8-inch thin-film liquid crystal display and will prepare to send fees through the internet communication protocols used to send and receive data between the client and the server (hypertext transfer protocol) only when requesting information. The device is powered by a 3.7 volt, 800 mAh battery. The battery can be charged by a USB port and has an on or off switch for the device's power supply circuit.

For the velocity values received from the sensors, the internal flow is analyzed. Smooth flow pattern a flow pattern in which fluid particles move in an orderly manner. There is no mixing between the fluid layers. This type of flow this generally occurs with fluids that have high viscosity and flow at low speeds or where the diameter of the pipe through which the fluid flows is very large compared with the volume of fluid flowing within the pipe. The flow characteristics of the fluid are important for its selection.

The mobile app game for practicing lung exercises (Figure 2) has a total of 10 game levels, in which the number of blows to be counted as passing must be greater than or equal to 1200 L/s. There is also a chat bot function where there will be questions to choose from, and when the user selects a question, an automatic answer will pop up for the user of the device to read.

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Figure 2. Application: (A) home page, (B) registration form, (C) game start page, (D) game end page.



The key elements of game-based learning (rule, objective, feedback, interaction, challenge, and narrative) [11] were implemented in the Pulmo device game app. The game provides clear instructions and descriptions regarding Pulmo device connectivity and proper usage procedures (rule) and defines gamification purposes to help users practice their lung exercise (objective). The system provides real-time performance metrics during breathing exercises and immediately responds to each breath (feedback and narrative). User interaction occurs through single-player engagement with the device-connected game environment (interaction). Furthermore, this application records exercise history tracking, allowing users to benchmark against their personal bests (challenge).

Recruitment

The study population comprised residents in Mueang Khon Kaen District, Khon Kaen Province, Thailand. The total population of 104,037 people, obtained from the Civil Registration Population Database for fiscal year 2023, was used to calculate the sample size [12]. The calculation incorporated a 95% CI, a 0.05 margin of error, and a population proportion of 0.07, based on the reported 7% prevalence of chronic obstructive pulmonary disease among Thai adults aged 40 years and above [13]. This calculation indicated a minimum required sample size of 100 participants. To account for potential incomplete data, we added a 10% buffer, resulting in a final sample size of 110 participants. Participants were selected through convenience sampling according to eligibility inclusion criteria.

Participants were recruited according to inclusion criteria. All participants were required to be healthy adults aged 18 years or older with no self-reported history of respiratory diseases, chronic lung conditions, or acute respiratory symptoms at the time of enrollment. In addition, participants needed to own a smartphone and provide informed consent for voluntary participation in the study. The study excluded individuals with pre-existing conditions that could be affected by respiratory gaming exercises, specifically those with cardiovascular disease, hypertension, hypotension, or diabetes, to ensure participant safety during the respiratory exercise protocol.

The data collection in phase R2 used 3 research instruments:

1. Demographic questionnaire collected participants' basic information including gender, age, highest level of education, and occupation to characterize the study population.
2. Satisfaction assessment form used a researcher-developed questionnaire based on literature review and previous research [14]. This instrument comprised eight items rated on a 5-point Likert scale (5=very satisfied and 1=less satisfied). The questionnaire underwent content validity assessment by three experts, yielding a content validity index of 0.85. Internal consistency reliability testing during this study demonstrated Cronbach α coefficient of .89.
3. Feasibility assessment form evaluated users' perspectives on implementing the mobile app games and prototype lung exercise equipment. This researcher-developed instrument, grounded in literature review and related research, contained 4 items rated on a 5-point Likert scale (5=most likely and 1=least possibility). Content validity assessment by 3 experts produced a content validity index of 0.82, and reliability testing during the study was Cronbach α coefficient of .86.

Ethical Considerations

The researcher protected the rights of the sample subjects and received approval from the Human Research Ethics Committee, Khon Kaen University, Thailand, number HE664028, approved on February 12, 2024. After receiving approval for data collection, an experiment was conducted and data were collected, taking into account the ethics of researchers, the principle of benefit, the principle of justice, and respect for people. All participants provided written informed consent before study enrollment. The consent process included a detailed explanation of the study objectives, procedures, potential risks and benefits, data collection methods, and confidentiality measures. Participants were explicitly informed of their right

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to withdraw from the study at any time without any negative consequences. They were given adequate time to read the consent form, ask questions, and discuss any concerns before signing. The sample group could terminate their participation without giving reasons to the researcher, and they would not lose any benefits. All information was kept confidential and was not disclosed. The researcher analyzed the data as a whole, using it solely for educational purposes.

Statistical Analysis

Data analysis was conducted using SPSS (version 28, IBMCorp). Demographic data were analyzed using descriptive statistics, specifically frequency and percentage distributions. Both satisfaction and feasibility scores were analyzed using means and SDs. The interpretation of satisfaction scores followed a 5-point scale: 4.51 - 5 (very satisfied), 3.51 - 4.5 (quite satisfied), 2.51 - 3.5 (moderately satisfied), 1.51 - 2.5 (less satisfied), 1.00 - 1.5 (least satisfied). Similarly, feasibility scores were interpreted using the following scale: 4.51 - 5 (most likely feasible), 3.51 - 4.5 (highly feasible), 2.51 - 3.5 (moderately feasible), 1.51 - 2.5 (less feasible), 1 - 1.5 (least feasible).

Results

The study was conducted from April 25, 2024, to July 31, 2024. As shown in Table 1, 84 out of 110 participants (76.4%) were female, and 71 out of 110 participants (64.5%) were aged between 18 - 39 years. In total, 56 out of 110 participants (50.9%) had a bachelor's degree or higher education and 82 out of 110 participants (74.5%) were civil servants, government employees, or state enterprise employees.

From Table 1, this study included 84 out of 110 participants (76.4%) were female, and 71 out of 110 participants (64.5%) were aged between 18 - 39 years. 56 out of 110 participants (50.9%) had a bachelor's degree or higher education and 82 out of 110 participants (74.5%) were civil servants, government employees/state enterprise employees.

Table . Number and percentage of the sample classified by personal information (n=110).

Demographic characteristics		Participants
Gender, n (%)		
	Male	26 (23.6)
	Female	84 (76.4)
Age (years), n (%)		
	18 - 39	71 (64.5)
	40 - 59	36 (32.7)
	>59	3 (2.7)
Education, n (%)		
	Elementary school	3 (2.7)
	High school or vocational certificate	51 (46.4)
	Bachelor's degree or higher education	56 (50.9)
Occupation, n (%)		
	Civil servants, government employees, or state enterprise employees	82 (74.5)
	Private employees	7 (6.4)
	Farmer	5 (4.5)
	General employee	2 (1.8)
	Student	12 (10.9)
	Unemployed or did not work	2 (1.8)

The satisfaction of users of mobile app games and prototype lung exercise equipment connected to the game is presented in Table 2. It was found that the sample group was satisfied overall at a high level (mean 4.4, SD 0.4). When consider each item. It was found that the sample group was satisfied at a high level in all items. When categorizing each item, it was found that the sample had interesting games on mobile app (mean 4.5, SD 0.6), and the strength and durability of the prototype lung exercise device is connected to the game (mean 4.5, SD 0.5). Followed by the appropriateness of the shape and size of the prototype lung exercise device is connected to the game (mean 4.4, SD 0.5).

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Table . Satisfaction of users of mobile application games and prototype lung exercise equipment connected to the game.

Satisfaction topics	Mean (SD)	Result
Interesting games on mobile application.	4.5 (0.6)	High
Suitability of the game display screen on the mobile application.	4.3 (0.6)	High
Ease of use of mobile application games.	4.3 (0.5)	High
Convenience in recording basic information for using games on mobile applications.	4.3 (0.5)	High
The appropriateness of the shape and size of the prototype lung exercise device is connected to the game.	4.4 (0.5)	High
The appropriateness of the selection of materials for the prototype lung exercise device connected to the game.	4.4 (0.6)	High
The strength and durability of the prototype lung exercise device is connected to the game.	4.5 (0.5)	High
Details and clarity of the user manual.	4.4 (0.5)	High
Overall satisfaction	4.4 (0.4)	High

The feasibility of mobile app games and prototype devices that use lung exercises connected to games is shown in Table 3. It was found that the sample group was of the opinion that the overall feasibility was at a high level, (mean 4.4, SD 0.5). When considering each item, it was found that mobile app games and prototype devices that use lung exercises connected to games are useful at the highest level, (mean 4.5, SD 0.5), followed by the response of the game on the mobile app and the prototype lung exercise device connected to the game (mean 4.4, SD 0.5).

Table . Feasibility of mobile app games and prototype devices that use lung exercises connected to games.

Feasibility topics	Mean (SD)	Result
Feasibility of games on mobile applications and prototype devices that use lung exercises connected to games.	4.4 (0.5)	High
Putting a game on a mobile application and a prototype device that uses lung exercises connected to the game into practice.	4.4 (0.6)	High
Mobile application games and prototype devices that use lung exercises connected to games are useful.	4.5 (0.5)	Highest
The response of the game on the mobile application and the prototype lung exercise device connected to the game.	4.4 (0.5)	High
Overall feasibility	4.4 (0.5)	High

Discussion

Principal Findings

In addressing our first objective of developing an integrated lung rehabilitation innovation, our results demonstrated successful creation of a mobile-based gaming app paired with a prototype assessment device. The user satisfaction scores (mean 4.4, SD 0.4) indicate strong user acceptance of the integrated system, particularly in terms of interesting mobile app games and the strength and durability of the prototype lung exercise device connected to the game. These findings align with previous research [15] in which the researchers similarly found that gamified respiratory interventions achieved high user acceptance rates in their 2021 study.

Analysis of satisfaction data revealed important insights about our integrated system's design and functionality. Participants expressed high satisfaction with 2 key aspects including the mobile app game's visual appeal and the durability of the prototype lung exercise device. The physical design elements, specifically the shape and size of the prototype device, also received favorable ratings. These findings align with research emphasizing the importance of aesthetic appeal and ergonomic design in health care devices, particularly for maintaining user engagement in rehabilitation tools. However, our assessment also identified an area requiring improvement such as the process of recording basic information within the mobile app. Similar challenges in user data management have been noted in other digital health interventions, such as in the study by Ezeonu et al [16].

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Regarding our second objective of evaluating implementation potential, the feasibility assessment results (mean 4.4, SD 0.5) suggest that our system shows promise for practical application in lung rehabilitation. This finding particularly resonates with Rung et al's [17] work, which demonstrated that game-based mindfulness interventions can effectively promote consistent practice adherence. User feedback analysis revealed high satisfaction ratings for the "Headspace app," with participants reporting positive acceptance and engagement with the meditation platform.

The feasibility assessment revealed strong potential for practical implementation of our integrated system. Participants rated the utility of the mobile app game and connected prototype device at the highest level of feasibility, suggesting robust practical value for lung rehabilitation purposes. The system's responsiveness, a critical factor in gaming interventions, also received high feasibility ratings. These positive evaluations of both use and responsiveness indicate that our integrated approach successfully addresses key requirements for real-world implementation in lung rehabilitation practice. These findings align with current trends in digital health interventions, where responsive, user-friendly systems have been shown to enhance engagement with therapeutic exercises [16].

The high feasibility ratings for both use and responsiveness support previous research indicating that gamified approaches can effectively bridge the gap between traditional rehabilitation exercises and patient engagement. Our results particularly complement studies [18], in which researchers found, in their 2024 systematic review, that interactive digital platforms incorporating augmented reality for physical exercise show significant promise for widespread adoption, with demonstrated improvements in both physical activity levels and mental health outcomes across diverse populations [18]. A previous study [19] demonstrated that mobile apps with visual elements significantly outperform traditional audio-only approaches for breathing training. Their study proved that wave-based visualizations led to both measurably deeper breathing and higher user satisfaction, establishing that well-designed visual interfaces enhance respiratory exercise outcomes [19].

The positive satisfaction ratings for both physical and digital components validate our integrated approach to lung rehabilitation, while the identified area for improvement offers a clear pathway for system enhancement. The strong feasibility scores across both technical performance and practical use suggest that our integrated system has significant potential for further development and implementation in clinical settings.

Limitations and Future Research

This study developed a mobile app game for practicing lung exercises, but it was tested only on healthy volunteers, limiting its applicability to patients requiring lung rehabilitation. The short testing period also restricted the assessment of long-term effectiveness. Future research should involve clinical trials with patients, such as postoperative or chest trauma patients, to evaluate the application's impact on lung function and its role in pulmonary rehabilitation.

Conclusions

This study developed a mobile app game for practicing lung exercises, accompanied by a prototype device called the Pulmo device, which connects to the app. The innovation was used by the general public and user feedback indicated high levels of satisfaction and suggested the potential for practical app. However, future studies should evaluate the effectiveness of this innovation in patients requiring pulmonary rehabilitation to further validate its clinical benefits.

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Author PP is not affiliated with any institution but is a freelance engineer and developer based in Bangkok, Thailand.

Authors' Contributions

CP, KA, LW, and PN conceptualized the project. CP, LW, AJ, SH, PN, and PP designed the device and app. CP managed funding and administration, while CP, KA, LW, and WP developed the methodology. Data collection was conducted by LW, WP, and AJ, with analysis by CP, LW, WP, AJ, SH. Visualization was done by CP, KA, LW, WP, and PP. CP, LW, and WP drafted, reviewed, and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

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Assessment of Pelvic Motion During Single-Leg Weight-Bearing Tasks Using Smartphone Sensors: Validity Study

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Abstract

Background: Clinicians and athletic training specialists often assess the performance of single-leg, weight-bearing tasks to monitor rehabilitation progress and guide exercise progression. Some of the key metrics assessed are excessive pelvic motion, balance, and duration of each repetition of the exercise. Motion can be objectively characterized using motion capture (MOCAP); however, MOCAP is often not available in clinics due to the high costs and complexity of the analyses. Smartphones have built-in sensors that can be used to measure changes in body segment orientation and acceleration, which may make them a more feasible and affordable technology to use in practice.

Objective: This study aimed to determine if, compared to gold-standard MOCAP, smartphone sensors can provide valid measures of pelvic orientation, acceleration, and repetition duration during single-leg tasks in healthy individuals.

Methods: Overall, 52 healthy participants performed single-leg squats and step-down tasks from heights of 15 and 20 cm. Pelvic motion was assessed using MOCAP and a smartphone placed over the sacrum. The MATLAB (MathWorks) mobile app was used to collect smartphone acceleration and orientation data. Individual repetitions of each exercise were manually identified, and the following outcomes were extracted: duration of the repetition, mediolateral acceleration, and 3D pelvic orientation at peak squat. Validity was assessed by comparing metrics assessed with a smartphone and MOCAP using intraclass correlation coefficients (ICCs) and paired Wilcoxon tests. Differences between tasks were compared using 1-way ANOVA or the Friedman test.

Results: Across the 3 single-leg tasks, smartphone estimates demonstrated consistently high agreement with the MOCAP for all metrics (ICC point estimates: >0.8 for mediolateral acceleration and frontal plane orientation; >0.9 for squat duration and orientation on the sagittal and transverse plane). Bias was identified for most outcomes (multiple $P<.001$). Both smartphone and MOCAP recordings identified clear differences between tasks, with step-down tasks usually requiring larger changes in pelvic orientation and larger mediolateral sways. Duration did not differ between tasks.

Conclusions: Despite a consistent bias, the smartphone demonstrated good to excellent validity relative to gold-standard MOCAP for most outcomes. This demonstrates that smartphones offer an accessible and affordable tool to objectively characterize pelvic motion during different single-leg weight-bearing tasks in healthy participants. Together with earlier reports of good between-day reliability of similar measures during single-leg squats, our results suggest that smartphone sensors can be used to assess and monitor single-leg task performance. Future studies should investigate whether smartphone sensors can aid in the assessment and treatment of people with musculoskeletal disorders. More user-friendly interfaces and data analysis procedures may also facilitate the implementation of this technology in practice.

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KEYWORDS

smartphone; kinematics; acceleration; exercise; squat

Introduction

The single-leg squat (SLS) and the step-down are 2 functional performance tests often used to identify abnormal movement of the trunk, pelvis, and lower limbs [1,2] and to assess single-leg balance in dynamic tasks [3]. Minimal pelvic tilt and rotation, and small postural sways, are factors required to rate squat performance as “good” [4], whereas excessive motion has been associated with various musculoskeletal conditions. For example, individuals with patellofemoral pain often exhibit increased contralateral pelvic drop during SLS in comparison to healthy participants [1]. People with hip pathologies may present greater anterior pelvic tilt during step-down [5] and larger mediolateral sways than healthy participants during SLS [6]. Gender-specific variations in pelvic kinematics have also been described. Compared to males, females demonstrate larger

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anterior pelvic tilt and pelvic drop during step-down [5] and greater pelvic rotation toward the weight-bearing limb during SLS [7]. These gender-specific movement patterns have been hypothesized to contribute to an increased incidence of anterior cruciate ligament injuries [8] and patellofemoral pain [9] in females. Assessing and monitoring pelvic orientation and acceleration during functional tasks may assist health care providers to identify injury risk factors, design individualized rehabilitation programs, and track rehabilitation progress over time.

SLS performance has traditionally been assessed visually [4,10,11] or in the laboratory [12-14]. Assessment in the clinic is often performed visually [15], although systematic reviews suggest that the validity of most of the procedures used to score squat performance is insufficient [16], and reliability is only moderate [10]. Additionally, research on a number of different tasks and joints shows that it is challenging for clinicians to visually identify single-plane movement changes smaller than 12 degrees [17], suggesting that small alterations in pelvic movement may not be detected visually. Motion can be assessed objectively by using laboratory techniques. Motion capture (MOCAP) is considered the gold standard to assess joint angles, but it is unsuitable to use in practice due to high costs and the time needed to collect and analyze the data. Inertial measurement units (IMUs) have been demonstrated to be valid and reliable in measuring lower limb kinematics [18,19] but still require equipment often not available outside specialized centers [20]. This lack of availability of sensors outside research laboratories is one of the key barriers to the implementation of objective motion measures in practice.

Contemporary smartphones have sensors that are similar to those embedded in laboratory-grade IMUs and may therefore offer a simple solution to assess body kinematics in practice. Compared to dedicated laboratory equipment, which can be expensive and is often not available in clinical practices, smartphones are readily available to the wider population and therefore have the potential to be used as an inexpensive tool to assess motion objectively. Smartphone sensors are valid and reliable when measuring static joint range of motion [21-23] and when assessing balance [24-26]. In the past, smartphones have been used to assess pelvic orientation in clinical tests [27,28] and during walking [29], as well as acceleration during SLS [30] and sit-to-stand [31]. While smartphone measures of pelvic acceleration and orientation during SLS demonstrated good to excellent reliability between days [32], whether these measures are valid compared to gold-standard MOCAP is yet to be determined.

The objective of this study was to investigate whether smartphone sensors provide valid estimates of pelvic motion during single-leg weight-bearing tasks compared to MOCAP. Specifically, we assessed whether smartphone sensors provide valid estimates of pelvic orientation in the frontal, sagittal, and transverse planes; pelvic mediolateral acceleration; and exercise duration. We further investigated whether smartphone sensors can objectively characterize pelvic motion differences between different single-leg weight-bearing tasks.

Methods

Participants

Overall, 52 participants from the University of Birmingham student population (26 females and 26 males, with a mean age of 24.9, SD 4.4 years; weight of 68.1, SD 12.3 kg; and height of 170.7, SD 9.5 cm) were enrolled in the study. The inclusion criteria were a population (1) aged 18 - 50 years, (2) with no present lower limb or lower back pain or injuries, (3) with no history of lower limb or lower back surgery, (4) with no conditions that may impair balance or movement, and (5) who are able to communicate in English.

Ethical Considerations

Ethical approval was obtained from the School of Sport, Exercise Science and Rehabilitation of the University of Birmingham (MCR2223_23). All participants signed an informed consent form before participating in the study and could request to opt out of the study. All data were deidentified before the analysis. The participants did not receive any remuneration but could request that the time spent in the laboratory be counted as research credits.

Procedures

After a 5-minute, self-directed warm-up, participants performed 3 weight-bearing single-leg tasks (SLS, step-down tasks from 15 cm [SD15], and step-down tasks from 20 cm [SD20]) in a random order using a computer-generated sequence. Since neither pelvic orientation [32] nor balance [33] are affected by leg dominance, tasks were performed on the right leg, which was the preferred leg for kicking a ball in 47 of 52 participants. To better simulate clinical practice, participants wore exercise shoes for the test. Participants performed all tasks with their arms crossed in front of the chests. Participants performed 5 repetitions for each task following a digital metronome set to maintain a tempo of 60 beats per minute; they were instructed to squat down and up in 4 seconds, with a minimum rest interval of 2 seconds between repetitions. Prior to recording, a practice trial was conducted to ensure proper pace and technique. Repetitions where a participant lost balance and placed their foot on the ground were repeated. To easily identify the start and end of each set of squats in the recordings, participants stood quietly for 5 seconds before the task.

SLSs were performed as follows. To standardize the squat depth, a white T-shaped tape measuring 3×10 cm horizontally and 2×10 cm vertically was applied to the floor [34]. Participants positioned their right foot along the T-shaped marker's long axis, with the tip of their toe just before the marker's short axis. The participants' left thigh was vertical, with the knee bent to 90 degrees [34]. Participants were asked to squat down, bringing the knee of the supporting leg forward until the tape in front of their toes disappeared from view. This procedure was followed to aim for a knee flexion of approximately 60 degrees, which is a knee flexion angle usually considered appropriate when performing SLSs [4,13].

Participants performed the step-down from 2 block heights: 15 and 20 cm. The block heights were selected to align with the step height typically used in clinical practice [35]. For each

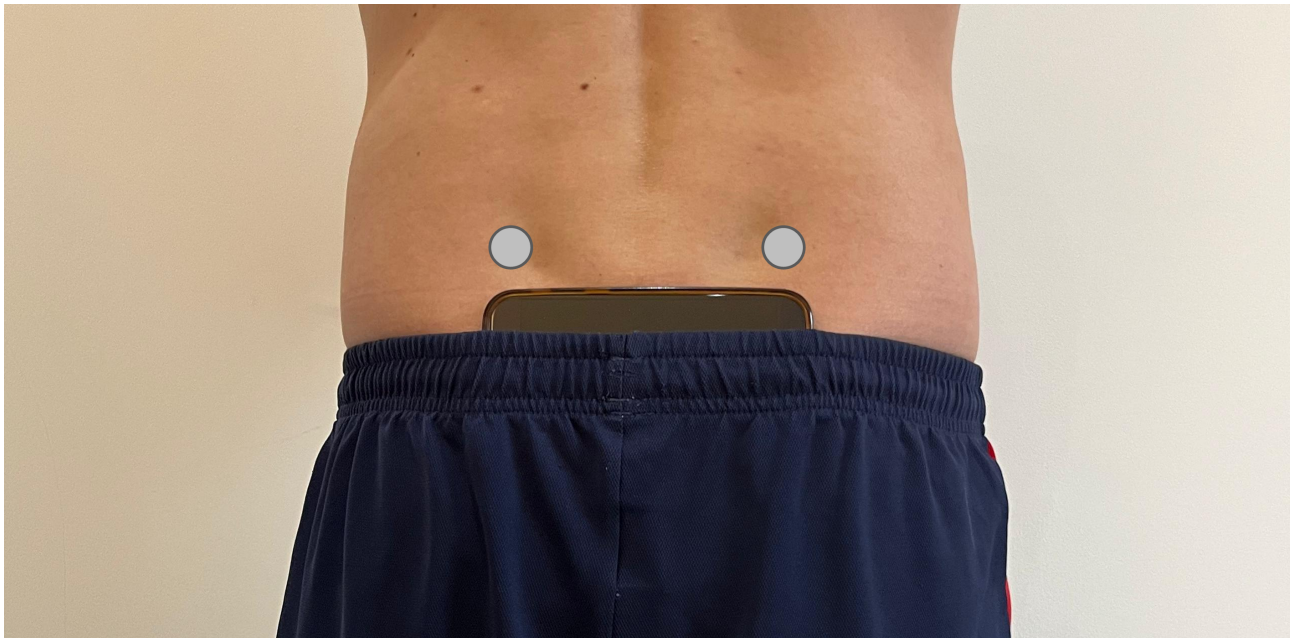
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step-down exercise, participants positioned both feet on a block. From the beginning position, participants shifted their weight onto their right leg, extended their left leg anteriorly, and squatted down until their heel lightly touched the floor [36]. Participants who could not reach the floor were instructed to squat down as much as possible while maintaining balance. A researcher took note of when this happened.

Data Collection

Before starting data collection, the maximal knee flexion angle during SLS, SD15, and SD20 was measured using a goniometer while participants held a static squat position for each task. During all tasks, pelvic kinematics was simultaneously collected using MOCAP and a smartphone. The MOCAP (8 cameras, Gaitlab, BTS Bioengineering; sampling rate 250 Hz) tracked the position of 4 reflective markers (12 mm diameter) placed on the participants' bilateral anterior superior iliac spines and posterior superior iliac spines (Figure 1). A smartphone (Android, Samsung A5) was placed in landscape orientation on the participants' sacrum, with the screen oriented outward and the camera to the left. We chose to place the smartphone over the sacrum in accordance with a prior study that demonstrated good or excellent between-day reliability [32]. The MATLAB (MathWorks) mobile app was used to collect smartphone orientation and acceleration at 100 Hz; smartphone orientation data were estimated from rotation vectors collected by the smartphone's virtual orientation sensor, which integrates accelerometer, gyroscope, and magnetometer data. To ensure consistent placement throughout the tasks without the need for additional equipment, the smartphone was secured in place using the elastic band of the participant's trousers at the waist.

Figure 1. Placement of the smartphone and of the motion capture markers on the posterior superior iliac spines (grey circles).



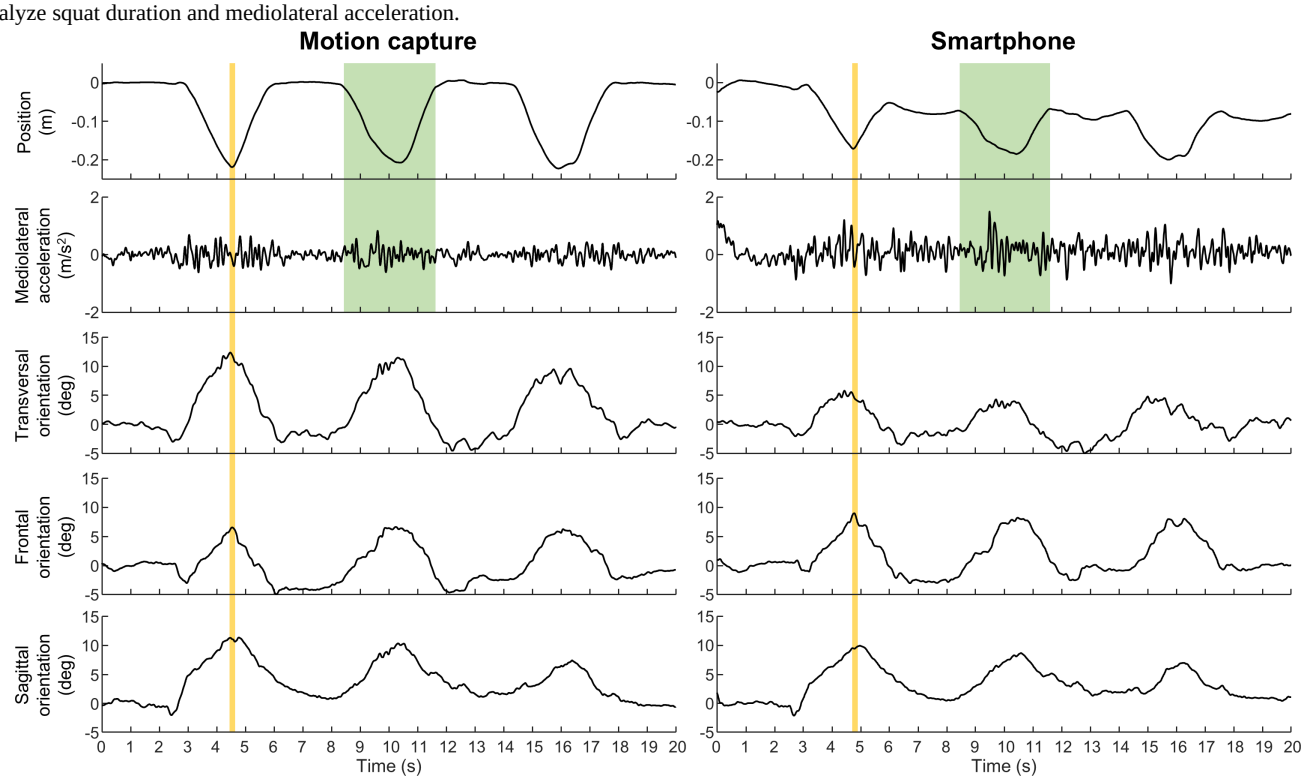
Data Analysis

The data were analyzed using MATLAB and Microsoft Excel. For the MOCAP data, pelvic orientation was calculated from the marker position using trigonometry; the average position of the 4 markers was used to calculate vertical pelvic displacement and mediolateral pelvic displacement, which was double-differentiated to obtain mediolateral pelvic acceleration. The smartphone orientation was collected as roll (sagittal plane), pitch (frontal plane), and azimuth (transverse plane). Both MOCAP and smartphone orientation data were adjusted so that larger values indicate greater anterior pelvic tilt, contralateral pelvic drop, and forward contralateral pelvic rotation. The smartphone acceleration includes data in the X, Y, and Z axes, representing vertical, mediolateral, and anteroposterior directions, respectively. An approximation of the vertical displacement of the smartphone was calculated by double integration of the vertical acceleration signal, applying a high-pass filter (2nd order Butterworth, 0.1 Hz) at each step to reduce the drift. All data were filtered before analysis (4th order Butterworth; 10 Hz low-pass filter for orientation data; 1 Hz high-pass filter for acceleration data). These data were exported to Microsoft Excel to manually identify the start, end, and peak of each squat, as well as a stable baseline value. These time indices were identified visually from plots, separately for the MOCAP and smartphone vertical displacement. The baseline was identified as a time instant in 5 seconds before the start of the first repetition with stable pelvic orientation. The start and end of the movement were identified as the points where the pelvic vertical displacement deviated from the baseline. Peak squat was identified as the lowest pelvic vertical displacement, or the middle point of the pelvic vertical displacement plateau if the participant paused when they reached the maximal squat depth. Visual identification of these values was determined to be more appropriate than a programmatic approach because of distortions of the smartphone vertical displacement data due to the double integration of acceleration data and differences in how participants performed the task. Pelvic orientation at peak squat was calculated as the average orientation in the frontal, sagittal, and transversal planes in a 200-millisecond window centered on the identified peak squat (Figure 2). For each task and repetition, the pelvic orientation in the 3 planes was

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calculated by subtracting the baseline from the pelvic orientation measurements at the peak squat. The squat duration was determined as the difference between the start and end of the movement. The mediolateral acceleration was quantified as the standard deviation of the mediolateral acceleration signal between the start and end of each repetition. For each outcome and task, the median value across the 5 repetitions was used for the analysis.

Figure 2. Example of the vertical position waveform, mediolateral acceleration, and pelvic orientation in the transverse, frontal, and sagittal planes during 3 cycles of a step-down task (20 cm) measured with motion capture (left) and smartphone (right). Positive values indicate forward contralateral pelvic rotation, contralateral pelvic drop, and anterior pelvic tilt, respectively. The yellow shaded areas indicate the 200-millisecond window centered on the peak squat, used to analyze pelvic orientation. The green shaded areas depict the window from the start to the end of the second squat, used to analyze squat duration and mediolateral acceleration.



Statistics

SPSS (version 27, IBM) was used for statistical analyses. The presence of systematic bias between MOCAP and smartphone measures was calculated using a 2-tailed, paired sample *t* test for each outcome measure. When the Shapiro-Wilk test identified significant deviations from normal distributions, the Wilcoxon signed-rank test was used instead. The level of agreement between the 2 measurements was evaluated using the intraclass correlation coefficient (ICC) and Bland-Altman plots. ICC estimates and 95% CI were calculated using 2-way mixed-effects models for average measures; consistency or absolute agreement models were used depending on whether there was a significant difference between MOCAP and smartphone data or not. The ICC levels were categorized as follows based on the lower bound of the confidence interval of the ICC: ＜0.5 (poor), 0.5 - 0.75 (moderate), 0.75 - 0.9 (good), and＞0.9 (excellent) [37].

Repeated measured ANOVA (or Friedman tests for variables not normally distributed) were used to identify differences in maximum knee flexion (analog goniometer data), pelvic orientation, mediolateral acceleration, and squat duration across tasks, both on smartphone and MOCAP data. When significant differences were identified, pairwise post hoc tests with Bonferroni correction were conducted to decompose the main effects. Gender differences were investigated on the smartphone data using a 2-tailed, independent sample *t* test (or Wilcoxon rank-sum test when not normally distributed).

The significance level was set at $P<.05$, and P values are reported after Bonferroni correction when applied. Since most variables exhibited nonnormal distributions, data are generally reported as median (IQR).

Results

During SD15 and SD20, 11 and 19 participants, respectively, were unable to reach the floor. Smartphone data from one participant demonstrated visible drift when measuring orientation in the transverse plane during SD20; this participant was excluded from analyses of this task.

Group values, bias analysis, ICCs, and between-gender comparisons are presented in Table 1. Bland-Altman plots comparing measurements by MOCAP and the smartphone are shown in Figure 3. Kinematic differences between tasks are presented in Table 2 and graphically as boxplots in Figure 4.

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Table . Validity of smartphone data compared to motion capture. This table presents estimates (median and IQR) of pelvic orientation, mediolateral acceleration, and squat duration. Smartphone data are also presented by gender. Results of the validity analysis are presented as intraclass correlation coefficient (ICC) with 95% CIs to describe agreement and *P* values for the bias analysis. Statistics of the between-group analyses are also presented. Significant comparisons (*P*<.05) are highlighted in italics.

	Motion capture, median (IQR)	Smartphone, median (IQR)	ICC[a] (95% CI)	Bias (*P* value)	Gender differences		
					Smartphone, median (IQR)		*P* value
					Females	Males	
Pelvic orientation (deg)							
SLS[b] transversal	–6.2 (–8.9 to –3.1)	–6.4 (–9.5 to –3.3)	0.92 (0.86 - 0.95)	.13	–7.5 (–11.0 to –4.0)	–5.6 (–8.3 to –2.5)	.05
SLS frontal	–0.6 (–3.9 to 2.4)	–0.9 (–2.6 to 1.2)	0.81 (0.66 - 0.89)	.32	–1.5 (–2.9 to 0.9)	–0.3 (–1.6 to 1.4)	.31
SLS sagittal	5.2 (2.3 to 8.9)	0.9 (–3.0 to 6.5)	0.90 (0.82 - 0.94)	<.001	1.2 (–3.0 to 6.7)	0.9 (–3.0 to 6.2)	.39
SD15[c] transversal	0.8 (–4.6 to 3.9)	–1.2 (–6.5 to 1.5)	0.93 (0.88 - 0.96)	<.001	–3.7 (–7.5 to 0.6)	0.2 (–3.5 to 1.9)	.07
SD15 frontal	3.8 (0.2 to 6.2)	3.4 (0.9 to 5.3)	0.83 (0.70 - 0.90)	.24	3.5 (1.4 to 5.4)	3.3 (0.5 to 5.2)	.86
SD15 sagittal	1.8 (–2.2 to 7.3)	–3.2 (–7.6 to 2.0)	0.92 (0.87 - 0.96)	<.001	–0.2 (–4.5 to 5.1)	–4.5 (–7.8 to –0.2)	.05
SD20[d] transversal	1.5 (–2.3 to 6.5)	–0.2 (–4.9 to 2.9)	0.96 (0.93 - 0.98)	<.001	–0.3 (–4.0 to 5.5)	2.9 (–0.7 to 7.1)	.08
SD20 frontal	3.8 (0.3 to 6.9)	4.5 (0.5 to 6.4)	0.91 (0.84 - 0.95)	.68	4.4 (–0.3 to 6.1)	4.9 (2.2 to 7.2)	.28
SD20 sagittal	4.1 (–0.7 to 9.3)	–1.3 (–5.7 to 5.7)	0.91 (0.84 - 0.95)	<.001	–1.7 (–5.0 to 8.2)	–1.2 (–5.7 to 3.9)	.39
Mediolateral acceleration (m/s^2)							
SLS	0.15 (0.12 to 0.18)	0.22 (0.19 to 0.28)	0.84 (0.72 - 0.91)	<.001	0.22 (0.19 to 0.29)	0.24 (0.19 to 0.28)	.85
SD15	0.17 (0.14 to 0.21)	0.26 (0.22 to 0.30)	0.80 (0.65 - 0.88)	<.001	0.26 (0.22 to 0.29)	0.26 (0.23 to 0.33)	.38
SD20	0.19 (0.16 to 0.22)	0.29 (0.25 to 0.36)	0.82 (0.68 - 0.89)	<.001	0.26 (0.23 to 0.36)	0.30 (0.28 to 0.35)	.14
Duration (seconds)							
SLS	3.4 (3.0 to 3.7)	3.1 (2.8 to 3.5)	0.95 (0.91 - 0.97)	<.001	2.9 (2.5 to 3.2)	3.1 (3.1 to 3.7)	.01
SD15	3.3 (3.0 to 3.7)	3.1 (2.8 to 3.5)	0.96 (0.93 - 0.98)	<.001	3.0 (2.8 to 3.3)	3.2 (2.9 to 3.6)	.11
SD20	3.3 (3.0 to 3.6)	3.2 (2.9 to 3.5)	0.98 (0.96 - 0.99)	<.001	3.0 (2.7 to 3.4)	3.3 (3.0 to 3.7)	.04

[a]ICC: intraclass correlation coefficient.

[b]SLS: single-leg squat.

[c]SD15: step-down tasks from 15 cm.

[d]SD20: step-down tasks from 20 cm.

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Figure 3. Bland-Altman plots comparing variables measured using motion capture and smartphone during single-leg squat (SLS) and step-down tasks from 15 cm (SD15) or 20 cm (SD20). The thick black line represents the mean difference between motion capture and smartphone. The dashed lines illustrate the 95% limits of agreement.

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Table . Comparison of pelvic orientation, mediolateral acceleration, and duration between tasks. Significant comparisons (P<.05) are highlighted in italics.

	Motion capture (P value)		Smartphone (P value)	
Outcome	Overall test	Post hoc	Overall test	Post hoc
Pelvic orientation				
Transverse (deg)	<.001		<.001	
SLS[a]<SD15[b]		<.001		<.001
SLS<SD20[c]		<.001		<.001
SD15<SD20		.003		—[d]
SD15=SD20		—		.055
Frontal (deg)	<.001		<.001	
SLS<SD15		<.001		<.001
SLS<SD20		<.001		<.001
SD15=SD20		.44		—
SD15<SD20		—		.003
Sagittal (deg)	.002		.001	
SLS>SD15		<.001		<.001
SLS=SD20		.09		.10
SD15<SD20		<.001		<.001
Mediolateral acceleration (m/s^2)	<.001		<.001	
SLS<SD15		<.001		.02
SLS<SD20		<.001		<.001
SD15<SD20		.02		<.001
Duration (seconds)	.63	—	.76	—

[a]SLS: single-leg squat.

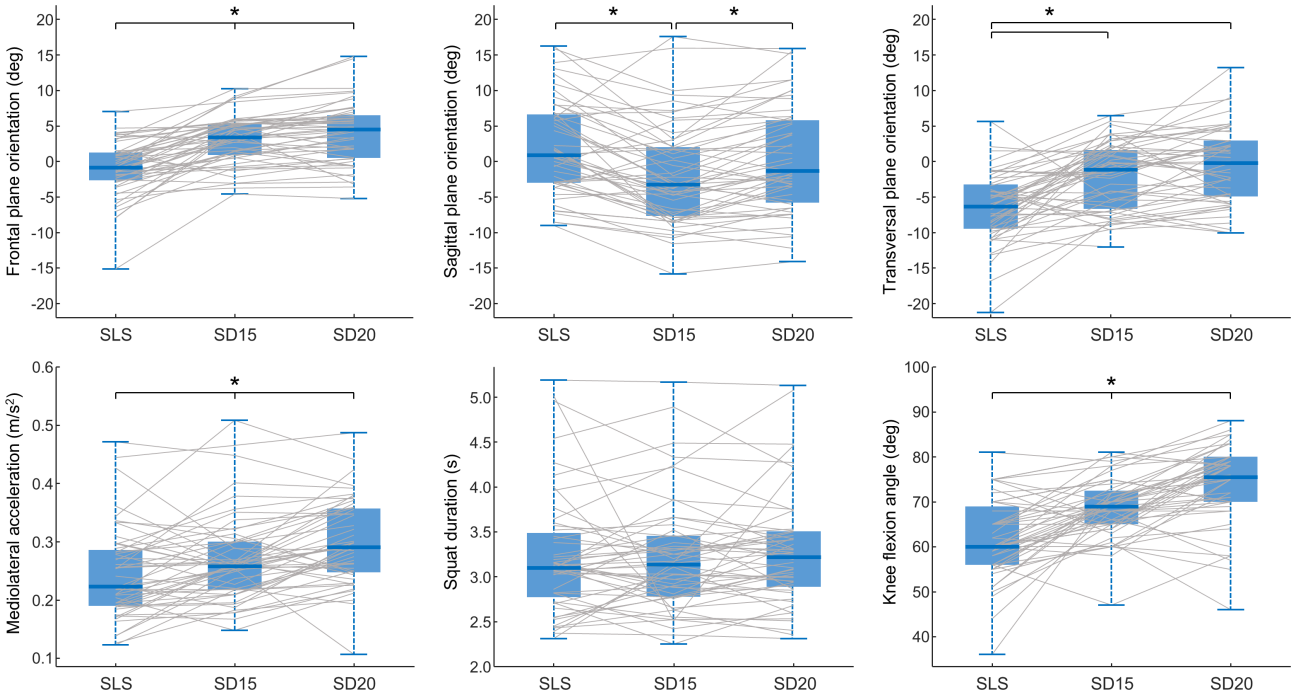
[b]SD15: step-down tasks from 15 cm.

[c]SD20: step-down tasks from 20 cm.

[d]Not applicable.

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Figure 4. Boxplots comparing pelvic orientation, mediolateral acceleration, squat duration, and knee flexion angle. In the transverse, frontal, and sagittal orientations, positive values indicate forward contralateral pelvic rotation, contralateral pelvic drop, and anterior pelvic tilt. Each boxplot represents data during single-leg squat (SLS) and step-down tasks from 15 cm (SD15) and 20 cm (SD20) steps, and the grey lines are individual participant data. *P<.05.



A systematic bias between MOCAP and smartphone data was observed in 5 pelvic orientation variables (SLS sagittal, SD15 sagittal, SD15 transverse, SD20 sagittal, and SD20 transverse), all acceleration variables, and all duration variables. In comparison to MOCAP, the smartphone tended to measure consistently lower anterior pelvic tilt across all tasks (SLS: median 4.1 [IQR 1.8-7] deg, z=−5.71, P<.001; SD15: median 4.5 [IQR 2.2-7.3] deg, t_{51}=9.51, P<.001; SD20: median 4.3 [IQR 2-7.3] deg, z=−5.53, P<.001). In the transverse plane, the smartphone measured less contralateral pelvic anterior rotation than MOCAP during SD15 (median 1.9 [IQR 0.4-3.8] deg, z=−4.85, P<.001) and SD20 (median 2.4 [IQR 1.1-3.7] deg, t_{50}=8.27, P<.001). For mediolateral acceleration, the smartphone accelerometer recorded approximately 0.1 m/s^2 larger acceleration than MOCAP for all tasks (SLS: median −0.09 [IQR −0.11 to −0.06] m/s^2, z=6.21, P<.001; SD15: median −0.09 [IQR −0.11 to −0.06] m/s^2, z=6.22, P<.001; SD20: median −0.1 [IQR −0.14 to −0.07] m/s^2, z=6.25, P<.001); the Bland-Altman plots demonstrate a proportional bias, with larger bias present for higher accelerations recorded. The smartphone-identified squat durations were approximately 150 milliseconds shorter than those recorded by MOCAP across all tasks (SLS: median 0.17 [IQR 0.08-0.34] seconds, z=−4.7, P<.001; SD15: median 0.12 [IQR 0.04-0.23] seconds, z=−4.48, P<.001; SD20: median 0.12 [IQR 0.05-0.32] seconds, z=−5.05, P<.001).

Regarding the agreement of the measurements obtained from the smartphone and MOCAP, the lower bound of the CI was higher than 0.75 for 7 out of 9 orientation outcomes, which indicates at least “good” agreement between the 2 devices in assessing pelvic orientation during SLS, SD15, and SD20. Agreement of mediolateral acceleration demonstrated ICCs with point estimates higher than 0.8, but the lower bound of the CI was between 0.65 and 0.72, and therefore in the “moderate” agreement range. For squat duration, the smartphone demonstrated a high correlation with the MOCAP measurement, with the lower bound of the ICC confidence interval ranging from 0.91 to 0.99, indicating “excellent” agreement between the smartphone and MOCAP.

There were trends for females to demonstrate less contralateral pelvic anterior rotation during SLS (t_{50}=2.02, P=.05) and greater anterior pelvic tilt during SD15 (t_{50}=−2.01, P=.05) compared to males. Squat duration was longer for males than females during both SLS (z=−2.48, P=.01) and SD20 (z=−2.08, P=.04), while no such difference was noted for SD15 (z=−1.62, P=.11).

Knee flexion measured with the goniometer differed between tasks (χ^2_2=48.5, P<.001), with increasing knee flexion angles from SLS to SD20 (all comparisons P<.001; SLS: median 60 [IQR 56-68.5] deg; SD15: median 69 [IQR 65-72.25] deg; SD20: median 75.5 [IQR 70-80] deg). Smartphone sensors detected significant differences in pelvic kinematics between tasks. In the transverse plane (χ^2_2=31.8, P<.001), participants demonstrated less contralateral anterior rotation during SLS compared to SD20 (median 6.3 [IQR 3.5-9.2] deg, P<.001) and SD15 (median 5 [IQR −0.2 to 8.2] deg, P<.001). In the frontal plane (χ^2_2=61.2, P<.001), participants demonstrated more contralateral pelvic drop during SD20 than both SLS (median 4.7 [IQR 2.5-7.1] deg, P<.001) and SD15 (median 0.9 [IQR 0-2.2] deg, P=.003), and during SD15 compared to SLS (median 3.9 [IQR 1.6-6.3] deg, P<.001). In the sagittal plane ($F_{1.66,84.86}$=15.77, P<.001), the pelvis was in less anterior pelvic tilt during SD15 than both SLS (median −4.3 [IQR −6.3 to −0.4] deg, P<.001) and SD20 (median −1.7 [IQR −4.4 to 0.6] deg, P<.001). Mediolateral acceleration differed between tasks

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(χ^2_2=30.7, *P*<.001), with lower values during SLS than both SD15 (median −0.02 [IQR −0.06 to 0.01] m/s^2, *P*=.015) and SD20 (median −0.06 [IQR −0.10 to −0.03] m/s^2, *P*<.001), and during SD15 compared to SD20 (median −0.03 [IQR −0.06 to 0] m/s^2, *P*<.001). Squat duration did not differ across tasks (χ^2_2=0.5, *P*=.76). Overall, MOCAP revealed differences between tasks comparable to those observed using smartphones (Table 2), the main notable exception being a lack of differences in pelvic orientation in the frontal plane when comparing SD15 and SD20 (*P*=.44).

Discussion

Main Findings

We observed a high level of agreement between pelvic kinematics measured with a smartphone and MOCAP across tasks, especially for task duration, and orientation on the sagittal and transverse planes. Significant bias was identified for most outcomes. Smartphone sensors detected differences in pelvic motion between weight-bearing tasks, and these differences were generally consistent with those identified using MOCAP. Our findings suggest that smartphone sensors can effectively characterize pelvic kinematics, pelvic acceleration, and exercise duration during single-leg weight-bearing tasks in healthy individuals, which demonstrates their potential to be used as a low-cost technology to assess motion objectively in rehabilitation without the need for specialized equipment.

Validity of Smartphone Compared to MOCAP

The good validity of smartphone measurement is consistent with previous studies. Several studies have proved the validity of smartphones in assessing body segment orientation during static tasks [21,22]. Jung et al [28] validated a smartphone-based app for measuring pelvic rotation in the transverse plane during single-leg lifting and reported an excellent correlation (ICC=0.99) between the smartphone and MOCAP. However, the pelvic range of motion was assessed in the supine position, which was a task less functional than those assessed in our study. Mizuno et al [29] explored the validity of smartphones in measuring dynamic pelvic orientation in frontal and sagittal planes during walking and found that smartphones provide accurate measurement of pelvic orientation, especially at slower walking speeds, although the error between the smartphone and MOCAP measurements tended to increase with walking speed [29], suggesting an effect of movement speed on the validity of smartphone-recorded data. Compared to the sagittal and transverse planes, orientation in the frontal plane demonstrated lower validity across tasks. This could be possibly explained by a lower variance across participants, which may have made measures on the frontal plane more susceptible to small movements of the smartphone relative to the skin. A good validity of smartphones in assessing balance-related parameters has also been proved in prior studies [24]. Marshall et al [30] observed significant large correlations between smartphone-recorded acceleration data and corresponding force plate measurements (*r*=0.56 and *r*=0.71) when assessing postural sway during squat movements in individuals with and without hip pain. The higher correlation we observed could be explained by the use of pelvic acceleration derived from the MOCAP, as opposed to force plates. The duration of each squat detected from the smartphone waveform in our study showed good agreement with the MOCAP measurement, with ICCs ranging from 0.91 to 0.99. This was consistent with previous studies that found smartphones to provide valid measurement of step duration during walking [38,39]. It should be noted that measurement validity is highly dependent on the specific characteristics of the task. Our data suggest that smartphone sensors provide valid pelvic orientation and exercise duration data during single-leg weight-bearing exercises; whether the estimates are similarly valid in other conditions, such as highly multiplanar motion or high-speed movements, remains to be determined.

Smartphone sensors measured consistently less anterior pelvic tilt and forward contralateral pelvic rotation, larger acceleration, and shorter squat duration than MOCAP. For pelvic orientation measurements, a consistent bias was identified in the sagittal and transverse planes. Our study observed higher biases and wider limits of agreement in the sagittal plane, but similar biases and limits of agreement in the transverse plane, when compared to IMU used to measure lower-limb joint kinematics during SLS [40]. Smartphone sensors also tended to systematically overestimate the mediolateral acceleration by approximately 0.1 m/s^2 on average; trends in the Bland-Altman plots show that this difference is minimal when acceleration is low, and especially pronounced at higher accelerations. A systematic overestimation was also observed in a previous study [41], which found that trunk-mounted accelerometers overestimated peak accelerations by 0.85 g compared to MOCAP during locomotion. One possible reason for the overestimation might be that the smartphone records additional linear acceleration besides mediolateral motion, for instance, due to incomplete removal of acceleration due to gravity, leading to higher smartphone acceleration estimates. Bland-Altman analyses indicated that smartphones consistently underestimated squat duration by approximately 150 milliseconds, differently from previous research reporting negligible bias when smartphone accelerometers are used to quantify gait temporal parameters [38,39]. Sources of bias could include hardware and software differences, imprecise smartphone sampling rates, or position and attachment of the smartphone compared to MOCAP; however, we are unable to clearly identify the source of bias from our dataset. Overall, our data demonstrate good agreement and significant, small bias between orientation and acceleration measures collected using smartphone sensors and MOCAP, demonstrating good validity when estimating pelvic kinematics during single-leg weight-bearing tasks.

Kinematic Differences Between Tasks

We observed consistent differences in pelvic kinematics and acceleration between the single-leg weight-bearing tasks, and these differences were usually comparable when assessed with MOCAP or a smartphone. As expected, the amount of knee flexion was lower for SLS than for the step-down tasks, and for SD15 compared to SD20. Compared to quiet standing, the pelvis remained horizontal and rotated posteriorly during SLS, while during step-down tasks a consistent contralateral pelvic drop

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and negligible rotation were observed. Similar movement patterns were also described previously when comparing similar tasks [36]. Kinematics during SLS differed from our previous work using smartphones, where we identified minimal pelvic drop and rotation, and larger anterior pelvic tilt [32]. These different movement patterns are likely influenced by different requirements of the tasks. In the SLS performed in this study, the goal was to bring the supporting knee forward to cover the tape while keeping the nonsupporting leg off the floor, whereas SLS performed at home [32] were standardized by asking participants to lightly touch an object placed behind them. The aim of the step-down tasks was to lightly touch the ground with the heel, which could be achieved by increasing contralateral pelvic drop and forward rotation. Pelvic kinematics in the sagittal plane is variable across studies, likely because of differences in the position of the nonsupporting leg [13].

Increasing the step height resulted in greater contralateral pelvic drop and anterior tilt, although differences were small (approximately 2 degrees in the sagittal plane and 1 degree in the frontal plane). Our result agreed with a previous study [36]. However, it is noteworthy that alterations in pelvic kinematics may be related to specific phases of movement. In Lewis et al [36] study, significant differences in pelvic kinematics were only observed at peak knee flexion, with no significant differences at 60 deg of knee flexion. In our study, participants exhibited a maximal knee flexion higher than the 60 deg threshold in 83.3% (130/156) of the tasks. The pronounced changes in pelvic orientation observed during the terminal phase of the step-down tasks suggest that changes in pelvic orientation during the terminal phase of the step-down test may play a crucial role in maintaining balance and biomechanical efficiency.

Mediolateral pelvic acceleration was lower during SLS compared to the step-down tasks and during SD15 compared to SD20. A larger acceleration suggests that step-down tasks challenge balance and smoothness of movement more than SLS, more so for larger step-down heights. This finding aligns with previous research that investigated the biomechanical differences between tasks, since step-down tasks were found to require greater knee flexion, hip flexion, and adduction compared to SLS [36], and therefore likely more challenging for balance.

No significant differences between tasks were observed for squat duration; however, it is notable that the vast majority of the participants completed the task in less than the 4-second duration prescribed by the metronome. Since we only monitored pelvic displacement, it is possible that other joints may have initiated motion before the pelvis, or stopped after the pelvis, leading to an underestimation of the squat duration. However, since one of the main aims of these exercises is to activate the leg muscles, whose activation increases proportionally with squat depth [42-44], monitoring exercise duration as pelvic displacement is likely more relevant than monitoring other joints. Overall, the shorter squat duration suggests that the time under tension of the leg muscles was less than that prescribed (4 seconds). Our results are similar to what was observed using other sensors to measure time under tension during knee exercises [45] and highlight the need to objectively measure exercise dosage in clinical trials and in practice. Given the good validity observed in this study, smartphone sensors may be a possible solution to provide accurate estimates of exercise duration remotely.

Gender Differences

Minimal gender differences in pelvic orientation were observed across the transverse and sagittal planes during SLS and SD15, while no significant gender differences were identified in the frontal plane. Our results are inconsistent with previous studies that reported significant gender differences in transverse [7,46], sagittal, and frontal planes [5,47]. Specifically, we found females to exhibit less forward contralateral pelvic rotation compared to males during SLS. This contrasts with the findings of Weeks et al [46] and Graci et al [7], who reported females demonstrating greater forward contralateral pelvic rotation, and Zawadka et al [47], who found females to have greater anterior pelvic tilt and contralateral pelvic drop. Moreover, in our study, a significant gender difference was noted in the anterior pelvic tilt during SD15, whereas Lewis et al [5] also found females to demonstrate greater contralateral pelvic drop during the step-down test. Additionally, we found no significant gender differences in mediolateral acceleration across all tasks, which also contrasts with a previous study [48]. The differences in results may be due to variations in task requirements. It has been found that greater squat depth is linked with greater pelvic motion [49], and previous studies that identified differences between genders required a knee flexion of 75 - 85 degrees [46] or maximal squat depth [7,47]. In contrast, this study targeted a squat depth of 60 degrees, which is in line with clinical recommendations [4] but is less than previous studies. Our study observed a significant gender difference in squat duration during SLS and SD20, indicating that females had a shorter squat duration than males. The result was similar to a previous study [7], which also found that females performed SLS in less time than males. Since slower squats generate greater muscle tension on lower limb joints than fast squats [50], our results suggest that monitoring exercise dosage may be especially important for females.

Practical Applications

Our findings support the validity of smartphone sensors to measure pelvic kinematics during single-leg weight-bearing tasks. This adds to evidence that smartphone measures of pelvic kinematics during SLSs are reliable between days when people test themselves at home [32]. Taken together, this evidence suggests that smartphone sensors may be useful to characterize and monitor pelvic kinematics, pelvic acceleration, and squat duration during single-leg weight-bearing tasks over time, which has potential implications for the assessment [4] and treatment [51] of people at risk of lower limb disorders or with musculoskeletal disorders (if validated on that population). This motion analysis could be performed in clinical settings, reducing the reliance on specialized equipment, or remotely, making health care more accessible, particularly in remote areas. Future work may include the simplification of the data analysis process (see Limitations), the definition of a standardized protocol that includes smartphone positioning, patient instructions, and data collection and analysis procedures to ensure consistent data quality.

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The kinematic differences observed between different single-leg weight-bearing tasks may be helpful to guide exercise prescription. The specific kinematic and kinetic differences between SLS, SD15, and SD20 observed in this study may help practitioners guide their exercise prescription, depending on the specific target of their treatment. Future studies may investigate if smartphone sensors can assist in identifying kinematic criteria for progression between exercises.

Limitations

Our study has several limitations. First, due to variations in waistband elasticity among trousers, in some participants the smartphone might have shifted position during the performance of the exercise. While our placement was simple, did not require additional equipment, and resulted in ICC point estimates higher than 0.8, the use of a dedicated elastic band may further increase the validity of smartphone measurements. This may be especially necessary if faster movements are required. Second, the smartphone app we used requires to export the data and analyze it offline; while most of the analysis was performed on Microsoft Excel, which is widely available and requires no coding knowledge, some parts of the process (eg, estimation of displacement from smartphone acceleration) were implemented using a proprietary coding software because they are difficult to implement in spreadsheet editors. A more user-friendly function that displays data waveforms and allows to analyze data on the screen would facilitate implementation in practice. We chose to let participants perform a self-directed warm-up; while this was intended to reflect the variety of settings the procedure may be used in, interindividual differences in warm-up exercises may have contributed to the wide range of kinematic values observed in the study. Lastly, our study only investigated healthy participants who were university students in a rather narrow age range. To generalize our findings, further research should encompass a more diverse range of populations, such as athletes, older people, or people with lower limb pathologies.

Conclusions

Compared to MOCAP, smartphone sensors provide valid measurements of pelvic motion (orientation, acceleration, and task duration) during single-leg weight-bearing tasks in healthy adults. This can assist health care and sport practitioners in characterizing pelvic motion, balance, and exercise duration in practice, which could be helpful to guide assessment and exercise prescription.

Data Availability

The datasets generated or analyzed during this study are available in the University of Birmingham repository [52].

Conflicts of Interest

None declared.

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Abbreviations

ICC: intraclass correlation coefficient
IMU: inertial measurement unit
MOCAP: motion capture
SD15: step-down tasks from 15 cm
SD20: step-down tasks from 20 cm
SLS: single-leg squat

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Investigating Challenges in Implementing a Digital Play Intervention in a Complex Organization Across Pediatric Departments: Non-Randomized Controlled Feasibility Trial

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Abstract

Background: Patients and health care providers can use playful digital games in a hospital setting to increase motivation and distract patients during painful procedures. Future digital interventions for pediatric hospitalization must do more than distract; they must also encourage socialization and promote physical activity, for example, by exploring novel interactive approaches to boost motivation.

Objective: The pilot study investigated the feasibility of a non-randomized controlled trial (non-RCT) assessing a new digital play intervention, Monster Gardener, that aims to motivate and increase physical activity for children and adolescents in a hospital.

Methods: This feasibility study was a non-RCT conducted from October to December 2023. We recruited hospitalized children, 7 - 17 years of age, and health care professionals from 4 pediatric departments at Copenhagen University Hospital – Rigshospitalet, Denmark. The children were allocated to intervention and control groups. Data collection included physical activity data measured with accelerometers, data on app use, and usability questionnaires completed by participants and health care professionals. The control group received usual care and accelerometer measurements, while the intervention group received accelerometer measurements and was invited to play Monster Gardener. We applied the 8 focus areas by Bowen et al to describe and evaluate the app's feasibility.

Results: A total of 22 children and adolescents from 3 pediatric departments agreed to participate. Our main findings, based on the framework by Bowen et al, were (1) acceptability: prolonged recruitment due to fewer hospital stays more than 24 hours than expected; (2) demand: software coding error in the app prevented data registration, causing a potentially major risk of data loss; (3) practicality: Monster Gardener was incompatible with certain mobile phones, and discomfort from the adhesive plasters used to attach the accelerometer led to early removal by one-third of participants; (4) implementation: technical problems and perceived complexity hindered successful app deployment; (5) adaptation: the app demonstrated adaptability across different departments; (6) integration: enhanced information sessions with the health care professionals were needed prior to data collection, and participants were too exhausted and overwhelmed by consultations, blood tests, examinations, and pain and nausea from surgical procedures to use the app; (7) expansion: app facilitation requires additional resources, posing a challenge given limited availability of staff; and (8) limited-efficacy testing: participants were inactive 22 hours a day and data loss limited efficacy testing.

Conclusions: The digital play intervention showed that Monster Gardener could potentially motivate children to be physically active during pediatric hospitalization; however, when using the framework by Bowen et al, the current version was deemed infeasible for implementation in an RCT. Various organizational, technological, and practical issues must be addressed to improve the intervention prior to effectiveness testing. Future studies should use simpler digital play interventions and invite end users' active involvement in developing the intervention.

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KEYWORDS

hospital; pediatric; toddler; child; youth; adolescent; teenager; physical activity; feasibility; mHealth; mobile health; mobile app; digital health; digital technology; digital intervention; digital play; smartphone; exergame; digital game

Introduction

Emerging technologies can be used to create playful digital interventions for children and adolescents. Patients and health care providers can use digital games in a hospital setting to increase motivation, distract patients during painful procedures, and encourage social interaction [1]. Game technologies can improve children's psychosocial health [1,2]; however, a lack of knowledge exists regarding the types of games that should be used. A recent review of game technologies for pediatric patients showed that the most common approach is mono-user games on ordinary computers or video consoles, for example, PlayStation and Nintendo Wii, that often serve to distract children undergoing procedures such as venipuncture or who experience chronic, neurological, or traumatic diseases or injuries [1]. The review recommends that future digital interventions for pediatric hospitalization should do more than distract; they must also promote socialization and mobility and exploit new technologies, such as robots and interactive features that encourage intrinsic motivation [1].

During hospitalization, children and adolescents often exhibit excessive sedentary behavior, primarily engaging in low-intensity activities [3]. While studies on adults indicate that immobilization during hospitalization can lead to heightened deconditioning, clinical complications (eg, pneumonia, venous thromboembolism, and constipation), and prolonged recovery [4-7], similar research on children is minimal. Reduced physical activity can lead to reduced functional capacity in musculoskeletal and cardiovascular systems, jeopardizing functional independence, which is a crucial factor for hospital discharge and the foundation for postinjury or illness recovery [4,8,9]. Early mobilization has repeatedly been proven safe and feasible for critically ill children and adults with stable cardiorespiratory function [10-13].

Increasing physical activity in sedentary hospitalized children and adolescents is considered beneficial [14]. Play can facilitate increased physical activity. A recent scoping review on play interventions in hospitals finds that play involving physical activity improves coping with hospitalization, disease, and sequelae [15] and could potentially benefit children's health during hospitalization. Another scoping review finds that various clinical settings have used digital play in rehabilitation but emphasizes the need to investigate further digital play interventions for early rehabilitation of hospitalized children [16]. Mobile apps combining games with physical activity, such as Pokémon Go, can facilitate substantial short-term increases in physical activity [2,17]. Pokémon Go, however, is not designed to accommodate children with functional limitations, such as casts, IV lines, catheters, and walking aids.

This study investigated the feasibility of a customized digital play intervention via a mobile application for hospitalized children and adolescents using the framework by Bowen et al [18], including these 8 focus areas of acceptability, demand, practicality, implementation, adaptation, integration, expansion, and limited efficacy testing. The study preceded a comprehensive randomized controlled trial (RCT) aimed at exploring the impact of the application.

Methods

Design

This small-scale feasibility study is a non-RCT conducted from October to December 2023. As noted, we applied the 8 focus areas by Bowen et al [18] to describe and evaluate the feasibility of a digital play intervention called Monster Gardener. The data from this feasibility study were reported using the CONSORT (Consolidated Standards of Reporting Trials) statement extension to pilot and feasibility trials [19].

Setting and Subjects

Prior to recruitment, we proactively contacted all chief nurses across pertinent departments to secure their approval before proceeding. We then sought endorsement and permission from departmental head nurses, chief pediatric surgeons, and chief pediatricians. To ensure awareness among the clinical nurses, we personally visited all the departments to provide information about the project. Standardized information was disseminated in departmental newsletters, and informative posters were strategically placed in, for example, staff break rooms and offices. Two health care professionals from each department volunteered to be project ambassadors, fostering a collaborative and informed environment.

Initially, we recruited hospitalized children 7 - 12 years of age but expanded the criteria to 7 - 17 years of age due to a poor recruitment rate. Convenience sampling was used to recruit participants from the department for children with surgical diseases of the abdomen, intestines, or urinary tract; the department for surgical diseases of the face, bones, and joints; the department for children with heart disease; and the department for neuropediatric diseases and children with liver or kidney diseases in a semi-intensive care unit at Rigshospitalet, which is a national tertiary hospital. Children who were in isolation could also participate if they met the eligibility criteria (Textbox 1), which were defined in collaboration with a highly specialized neuropediatrician. The health care professionals treating the patients assessed the eligibility criterion of cognition around 7 - 17 years of age, which was chosen to ensure that participants had the mental capacity to understand the intervention and associated questionnaire. We recruited health care professionals who actively engaged in facilitating the digital play intervention in their departments to examine their perspectives on using the app to encourage patients to be more mobile.

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Textbox 1. Eligibility criteria for the children and adolescent study population.

Inclusion criteria:

- Expected hospitalization >24 hours.
- Able to speak Danish.
- Cognition around 7 - 17 years of age.
- Able to use a mobile phone with one hand.
- Wheelchairs and isolation acceptable.

Exclusion criteria:

- Severe uncorrectable visual impairment.
- Neurological or psychiatric disorders that prevent participation.
- Continuous electroencephalogram monitoring.
- Participation in other physical activity studies.

Intervention

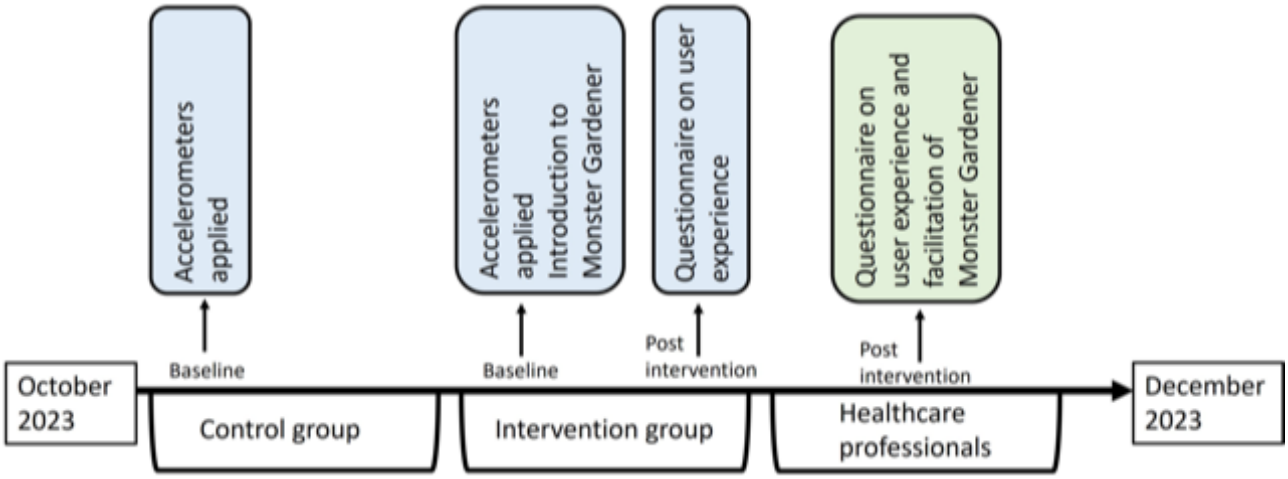
The first 10 participants were allocated to the control group and the next 10 to the intervention group (Figure 1). Participants in the control group received usual care, which consisted of daily mobilization encouragement and sometimes activities supervised by health care professionals.

The intervention group was invited to play Monster Gardener during their hospitalization. Monster Gardener aimed to motivate and increase physical activity for hospitalized children. Hospitalized children and adolescents, health care professionals, researchers, and external game designers co-designed Monster Gardener in a public-private partnership. The app's development, which was outsourced to 4 software development and game design companies between 2018 and 2022, underwent continuous testing and evaluation by hospitalized children in an oncology ward, and health care professionals. The companies were responsible for all technical aspects of the app, while the project manager for the app's design was responsible for clinical testing and providing feedback to the developers.

Augmented reality (AR) technology in the app merges the real world with digital elements, encouraging physical activities like walking and boxing, and the camera lens in users' phones captures the real world combined with digital elements integrated into the surroundings. Designed to be playful and engaging in countering the negative impacts of hospitalization on children's health, Monster Gardener invites children to act as gardeners for animated monster plants. The app comprises 6 mini-games: 3 for adaptation (feeding, decorating, and social activities) and 3 five-minute mini-games that encourage physical activity. These games, including 2 walking activities and an activity for the upper extremities, were disguised and embedded in the digital play to encourage movement in an entertaining digital context. AR codes strategically placed in the children's hospital rooms, around the hospital wards, and on staff uniforms contained food and decorative items for the monster plants that would appear on the children's phones, nudging them to get out of bed to find the codes. The AR codes, which were color-coded red, yellow, and blue, were positioned in the middle and on either end of the ward. Each quest required scanning at least 2 AR codes to ensure that participants walked from the middle to the end of the ward at a minimum. Upon completing a quest, a new one appeared with an additional AR code to allow participants to advance further. Multimedia Appendix 1 provides additional details. The participants were asked to play the game as frequently as they wished, and the health care professionals and parents were asked to encourage them to play. If a participant did not have a smartphone, they could borrow one from the research team.

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Figure 1. Timeline of the feasibility study. Physical activity in the control group was measured with accelerometers in October 2023. Physical activity in the Monster Gardener group was measured with accelerometers in November 2023. Health care professionals' user experience was assessed in December 2023.



Technology and Data Collection

Overview

The children were invited to participate in the study as soon as possible following admission. Data collection continued until discharge or 7 days after inclusion, whichever was the shortest. We aimed for a sample size of at least 10 per arm, referencing Whitehead et al [20].

Accelerometers

LW conducted the data collection, which included data on physical activity during hospitalization measured with accelerometers (SENS Motion) embedded in waterproof medical adhesive plasters. Three tri-axial sensors were fitted to each participant's sternum, lateral aspect of the distal femur, and proximal on the humerus of the dominant arm [21]. The participants were able to engage in usual activities (eg, showering, playing, and sleeping), but the sensors were removed for x-rays, magnetic resonance imaging, and computed tomography scans.

The accelerometers, which continuously sampled accelerations at 12.5 Hz during hospitalization, were connected via Bluetooth to a dedicated app installed on a tablet that uploaded data to a secure server. The device contained onboard memory capacity for approximately 2 weeks to prevent data loss due to occasional lack of connectivity. In the dedicated app, a built-in algorithm detected the accelerometer's orientation and movements, classifying activities into lying in bed, sitting, standing (including short bouts of shuffling), walking, and the number of steps taken, summarized every 5 seconds. A previous study validating the sensors contains additional technical specifications on the accelerometers [21].

Physical activity was measured in minutes as time in bed (lying down), time spent inactive (sitting or lying down), and time spent out of bed (standing or walking) based on accelerometer wear time, which was reported as the average daily time in or out of bed and being inactive (minutes/day) [22]. Secondary measures included the average daily time spent sitting, standing, and walking, and the average daily number of sit-to-stands and steps per day.

Research Electronic Data Capture (REDCap)

To collect data on app use, we used the REDCap (Research Electronic Data Capture; Vanderbilt University) application programming interface (API) feature to automatically import data into the REDCap software [23] using an API key to authenticate requests to ensure security and legitimacy [23]. We also used REDCap to distribute and collect questionnaires.

Intrinsic Motivation Inventory (IMI)

When discharged, the participants were asked to complete a questionnaire based on a short version of the Intrinsic Motivation Inventory (IMI) [24] that was translated into Danish using forward-backward translation in a previous study [25] and modified to target children and adolescents. We selected 4 of 7 subscales (interest or enjoyment (motivation), perceived competence, pressure or tension, and perceived choice (autonomy) for our short version, including 12 statements, and modified the scale from 7 to 4 points to make it easier for the youngest participants to respond. To score the IMI, we modified the score for the reversed items by subtracting the response from 5, averaging all item responses on each subscale, where 1=very true and 4=not at all true.

Technology Acceptance Model (TAM)

After the last participant in the intervention group was discharged, health care professionals were asked to complete a web-based questionnaire distributed via an iPad on their experience with implementing the intervention in their departments. The questionnaire was based on the Technology Acceptance Model (TAM) [26] and was previously translated into Danish [27]. TAM includes 4 subscales: perceived usefulness, perceived ease of use, attitude, and behavioral intention. We added more study-specific questions on Monster Gardener's influence on workflow and the use of the accelerometers. All TAM items and additional questions used a 5-point Likert scale, with scores ranging from 1 (strongly agree) to 5 (strongly disagree).

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Feasibility

To assess the challenges involved in implementing an early-stage digital play intervention, we assessed feasibility using the framework by Bowen et al [18] , including 8 focus areas and used the Consolidated Framework for Implementation Research (CFIR) to analyze implementation potential [28]. Table 1 shows how we organized data collection and outcome measures to investigate the feasibility of the Monster Gardener intervention.

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Table . The 8 focus areas by Bowen et al [18], feasibility considerations, data collection, and data analysis methods.

Eight focus areas and feasibility considerations	Population	Data collection methods	Time of evaluation
Acceptability			
Participant acceptance of the new technology	Children	IMI[a] (motivation)	Post intervention
Participant acceptance rate to participate	Children	Percentage acceptance	Enrollment
Management's support, health care professionals' acceptance of the new technology	Health care professionals	TAM[b] (attitude)	Post intervention
Demand			
Interest in the app	Children	IMI (autonomy)	Post intervention
Use of the app	Children	Monster Gardener data	Post intervention
Interest in the app	Health care professionals	TAM (behavioral intention)	Post intervention
Implementation			
Degree of likelihood of implementation	Children	CFIR[c]	Post intervention
Degree of likelihood of implementation	Health care professionals	CFIR	Post intervention
Practicality			
Technological aspects of the app	N/A[d]	Fieldnotes, observation	Post intervention
Technological aspects of data collection	N/A	Fieldnotes, observation	Post intervention
Accelerometers	N/A	Fieldnotes, observation	Post intervention
Adaptation			
Degree of similar outcomes in a new format	Children	SENS[e] activity data	Post intervention
Degree of similar outcomes in a new format	Health care professionals	Study-specific questionnaire (workflow modifications)	Post intervention
Integration			
Perceived fit with infrastructure	Children	Fieldnotes, observation	Post intervention
Perceived fit with infrastructure	Health care professionals	Study-specific questionnaire, fieldnotes, observation	Post intervention
Expansion			
Fit with organizational goals and culture	Children	SENS and use	Post intervention
Fit with organizational goals and culture	Health care professionals	Study-specific questionnaire	Post intervention
Limited efficacy testing[f]			
Intended effect on key intermediate variables	Children	SENS activity data	Post intervention

[a]IMI: Intrinsic Motivation Inventory.

[b]TAM: Technology Acceptance Model.

[c]CFIR: Consolidated Framework for Implementation Research.

[d]N/A: not applicable.

[e]SENS: SENS Motion.

[f]Not applicable to health care professionals.

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Ethical Considerations

This study conforms to the Declaration of Helsinki, was approved by the Danish Data Protection Agency (P-2020 - 121), and did not require ethical approval from the National Committee on Health Ethics Research (FSP 21054778). Participants' parents received an introductory letter accompanied by an information sheet and a consent form. The children provided verbal assent prior to inclusion in the study, and parents provided written informed consent [29]. All data were pseudoanonymized by removing identifiable information and assigning each record a code. The key linking the codes to individual identities was stored securely and separately, in accordance with data protection guidelines.

Data Analysis

Data analysis was performed using SPSS Statistics (version 29; IBM). All nonnormally distributed data were reported with medians and ranges, and intergroup differences were tested with the Mann-Whitney *U*-Test. Determining reliability was not considered meaningful due to the small sample sizes in IMI and TAM [30].

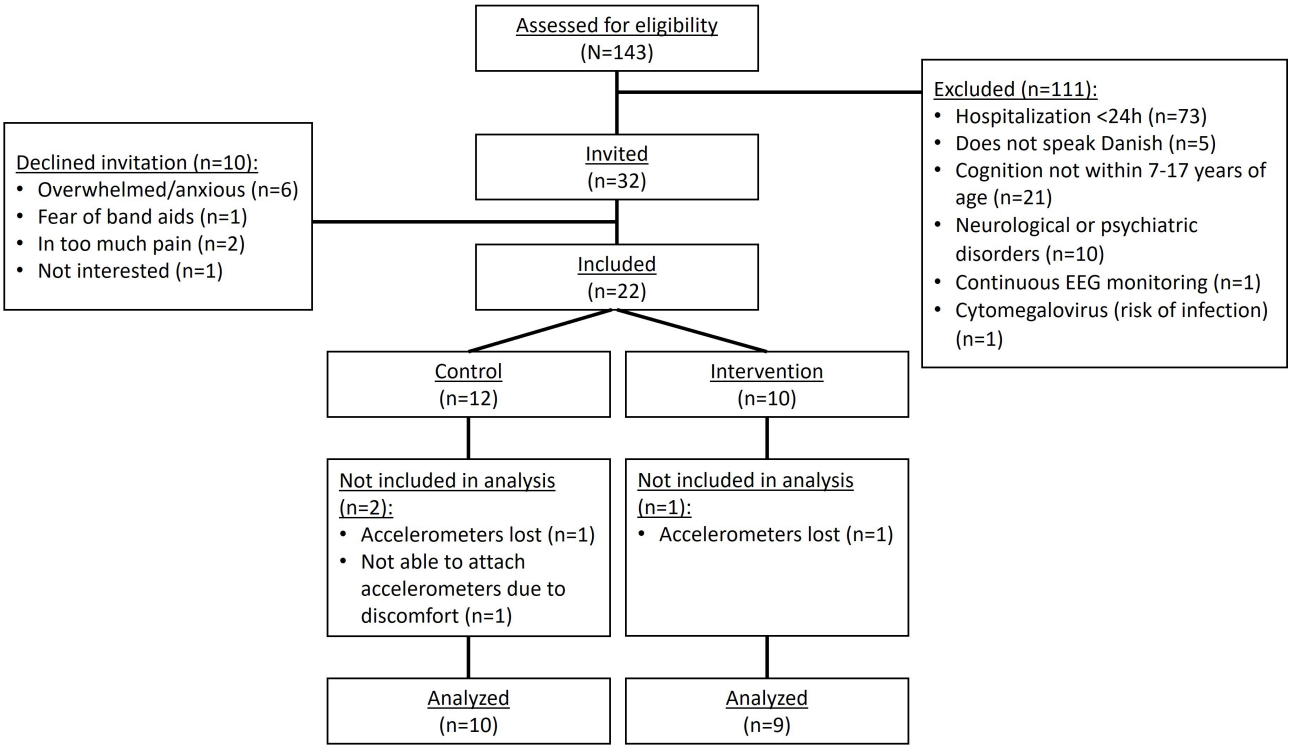
Results

Overview

There were 143 children from 7 to 17 years of age hospitalized in the 4 pediatric departments from October to December 2023. We excluded 111 patients (Figure 2) and invited 32 to participate, 22 of whom agreed.

The number of participants was 22, with 12 participants in the control group and 10 participants in the intervention group. The median age range was 12 years (7-17 years) for the total, 11 years (7-17 years) for the control group, and 13 years (10-17 years) for the intervention group. Females represented 59% (13 individuals) of the total, of which 67% (8 individuals) were in the control group and 50% (5 individuals) were in the intervention group. Regarding specific medical conditions, 18 participants had surgical diseases affecting bones, joints, or facial structures, with 9 each in the control and intervention groups. Additionally, 3 participants had heart diseases, comprising 2 in the control group and 1 in the intervention group. Last, 1 participant required semi-intensive care, present solely in the control group.

Figure 2. Flowchart of participants in the feasibility study. EEG: electroencephalogram.



Acceptability

Management's Support

A total of 10 out of 10 managers (chief pediatric surgeons, chief pediatricians, head pediatric nurses, and head physiotherapists of all departments) approved and supported the project.

Acceptance to Participate

We recruited participants from October 3, 2023, to December 8, 2023. Three children per week met the inclusion criteria, but we included 2 a week, yielding a moderate to high participation rate (22/32, 69%). It was difficult to recruit preoperatively as the children were anxious about their imminent medical procedures. Postoperative recruitment was also a challenge due to pain, nausea, and fatigue but it was better tolerated than preoperative recruitment.

Participant Acceptance of the New Technology

The children's motivation to play Monster Gardener and the perceived competence and autonomy while playing were neither positive nor negative, and the children did not feel pressure or anxiety while playing (Table 2).

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Table . Results from the Intrinsic Motivation Inventory (IMI) and the Technology Acceptance Model (TAM).

Questionnaire and subscale	Value, median (range)
IMI (4-point Likert scale), subscale scores (children; n=9)	
Interest or enjoyment (motivation)	2 (1-3)
Perceived competence	2 (1-3)
Tension	4 (3-4)
Perceived choice (autonomy)	2 (1-3)
TAM (5-point Likert scale), subscale scores (health care professionals; n=5)	
Perceived usefulness	1 (1-1)
Perceived ease of use	2 (1-5)
Attitude	2 (1-2)
Behavioral intention	2 (1-2)

Health Care Professionals' Acceptance of the New Technology

When asked about the perceived usefulness, attitude, behavioral intention and perceived ease of use of Monster Gardener, the health care professionals were overall positive (Table 2).

Demand

Use of the App

We integrated the automatic transfer of usage data into REDCap, but it did not function as anticipated. The user account with the API token was unintentionally suspended due to inactivity within REDCap's given timeframe; therefore, usage data were not registered. An error log to detect this event had mistakenly not been integrated into the software coding. Most of the children told the investigator that they did not play the game very much. Some found it difficult to understand or lost interest due to lagging but most were too exhausted to engage. One family felt it was too soon after general anesthesia. Only 1 adolescent played it enthusiastically while hospitalized.

Interest in the App

A total of 7 in the control group and 3 in the intervention group declined to participate, the latter indicating that an appealing intervention creates greater interest in participating. Two from the intervention group who declined to participate reported too much discomfort, and one (girl, 16 y) said it did not appeal to her. The remaining participants found it interesting to participate and were curious about the app.

Implementation

Authors LW, JLS, DJC, and MS discussed the data and identified the facilitators and barriers shown in Table 3 to implementation based on CFIR [28].

Table . Barriers and facilitators to implementation based on Consolidated Framework for Implementation Research (CFIR) [28].

	Facilitators to implementation	Barriers to implementation
Innovation (Monster Gardener)	• Co-designed with hospitalized children • Applied in various clinical settings	• Complex, 6 different mini-games and augmented-reality code scan to open new mini-game • Incompatible with Android and Motorola phones
Outer setting	• Outsourcing to professional game designers and software developers ensured quality of Monster Gardener app	• Absence of overall project plan causes lack of overview on competing projects • Unintentional outsourcing of operational app data use to software developers
Inner setting	• Did not require a specific room or take up space	• Wall stickers may not be clearly visible
Individuals	• Participants welcomed distraction from waiting time • Supportive management and clinicians who emphasized the need for mobilization efforts	• Participants too exhausted to play or lacked cognitive capacity to comprehend the app • Lack of resources (time, staff shortage) hinders app facilitation
Implementation process	• The app's design allows for easy adaptation across departments due to uniform layouts	• Variations in hospitalization characteristics probably make the app most suitable for patients, who have longer stays and are less anxious than first-time patients

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Practicality

Technological Aspects of the App

Monster Gardener supports a wide range of mobile phones, but not all (eg, 2 types of Motorola phones were incompatible) and was available in iOS and Android; however, the Android operating system does not support the games with upper extremity activities, thereby hindering the intended levels of physical activity in the app for Android users.

Technological Aspects of Data Collection

We used REDCap to gauge participants' app use and assess the perspectives of participants and health care professionals. Unfortunately, REDCap malfunctioned before data collection commenced, delaying the initiation of the intervention by a week also failed to record actual app use despite direct integration.

We used iPads to collect data on perceived feasibility from participants and health care professionals. If the children were discharged (n=2) or the nurses were too busy (n=1) the questionnaires were distributed by e-mail. The overall response rate was 90% for participants (n=9) and 83% for health care professionals (n=5).

Accelerometers

Data were unavailable for 3 participants and limited to 7. Two accelerometer sets were lost—one accidentally taken home and another mistakenly discarded. The third set of missing data was attributed to a participant declining to wear the accelerometers due to discomfort.

A total of 7 of 22 participants removed accelerometers early due to discomfort from the Conformité Europèenne–approved adhesive plasters, for example, itchiness and overall discomfort. One participant, burdened by multiple medical devices, felt overwhelmed, while another declined because they were afraid of the adhesive plasters.

Accelerometers were also removed for computed tomography or magnetic resonance imaging scans, and due to time constraints, reattaching them was not possible, shortening the data collection period. Children who had heart surgery wore the accelerometer on their backs due to surgical wounds on the sternum, resulting in data misclassification with time spent lying down classified in the software as time spent sitting up.

Adaptation

The app could be adapted to accommodate different needs and situations, although no one in the intervention group was in isolation.

Integration: Perceived Fit With Infrastructure

Pain, nausea, examinations, and ward rounds left 90% of the children too exhausted to use the app. The study-specific questionnaire based on a 5-point Likert scale asked health care professionals whether the intervention disturbed their usual workflow, with a mean score of 3.2 (SD 0.8) indicating that they neither agreed nor disagreed. When asked if the intervention was unnecessarily time-consuming, they neither agreed nor disagreed (mean 2.6, SD 0.6). They felt that the children were more active when using the app (mean 1.2, SD 0.5).

Several nurses said they had not been told about the study despite our systematic efforts. A lack of a project coordinator across departments posed challenges concerning competing projects. For example, the investigator accidentally discovered an ongoing competing project at the department during data collection for the control group. How many children participated in the competing project or whether it influenced the data in the control group is unknown as it was not a research project, and no data were collected.

Expansion: Perceived Fit With Organizational Structure

The app's design makes it appropriate for different departments and hospitals but it requires instruction and facilitation. These resources were limited due to departmental staff shortages that affected all included departments. Management and clinical staff from all departments supported the project; however, the clinical staff did not have the time or capacity to engage further, for example, fix adhesive plasters or facilitate the game. We included no children from one department since it treated primarily infants and toddlers (<4 y).

Limited Efficacy Testing

The accelerometer data for 19 participants showed that they were inactive (sitting or lying down) for 22 hours a day (lying down 17 h per day). On average the cohort walked 2339 steps daily (Table 4). Between-group differences in accelerometer wear time and sit to stands were statistically significant, but there were no significant between-group differences for other measures.

Table 5 summarizes the main findings for the 8 feasibility areas on levels of concern. No concerns indicate that there is no need for adjustments to the feasibility area; some concerns indicate the need for some adjustments to the area prior to efficacy testing; and serious concerns indicate a strong need for changes.

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Table . Limited efficacy testing of device-based physical activity during hospitalization.

	Total (n=19)	Control group (n=10)	Intervention group (n=9)	*P* value[a]
Hospitalization duration (days), median (range)	4 (1-9)	4 (1-7)	3 (1-9)	.81
Time between hospitalization and recruitment (days), median (range)	1 (0 - 6)	1 (0 - 5)	2 (0 - 6)	.40
Accelerometer wear time (hours), median (range)	42 (2 - 126)	62 (26 - 126)	26 (2 - 48)	.005
Time in bed (minutes per day), median (range)	1082 (68 - 1394)	1119 (68 - 1366)	961 (455 - 1394)	.17
Time inactive (minutes per day), median (range)	1368 (1059 - 1423)	1369 (1293 - 1423)	1353 (1059 - 1415)	.22
Time out of bed (minutes per day), median (range)	58 (1 - 141)	52 (1 - 134)	58 (5 - 141)	.51
Sitting time (minutes per day), median (range)	289 (5 - 1233)	264 (5 - 1233)	336 (21 - 898)	.19
Standing time (minutes per day), median (range)	17 (0 - 58)	16 (0 - 48)	17 (0 - 58)	.84
Walking time (minutes per day), median (range)	33 (0 - 119)	21 (0 - 119)	41 (5 - 101)	.37
Sit to stand (number of times), median (range)	26 (8 - 160)	19 (8 - 160)	48 (17 - 94)	.04
Steps (number), median (range)	1635 (0 - 9017)	1062 (10 - 9017)	2103 (0 - 5443)	.33

[a]Mann-Whitney *U* test significance. Statistical significance set at <.05.

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Table . Levels of concern regarding the intervention's feasibility.

Levels of concern in the 8 focus areas by Bowen et al [18]	Degree of concern	Main findings	Proposed actions required before conducting a randomized controlled trial
Acceptability	Some concerns	• Prolonged recruitment due to fewer hospitalizations >24h	• Use a sample size power calculation from similar studies to determine required number of participants for statistical significance • Consider multi-hospital recruitment to meet recommended number of participants
Demand	Serious concerns	• Significant risk of data loss due to a lack of awareness of REDCap API regulations and lack of software coding of error log • Children too exhausted to play due to overwhelming medical routines	• Mitigate risk of operational data loss at hospital or regional level by implementing measures such as dedicated REDCap software service accounts • Simplify game intervention and enhance motivational aspects, eg incorporating rewards
Practicality	Serious concerns	• Monster Gardener was incompatible with some Motorola phones, 50% of app unavailable on Android phones • One-third of the children removed accelerometer adhesive plasters early due to discomfort	• Develop Monster Gardener further to address challenges or provide iPhones to test the app further (both costly measures) • Explore and test alternative solutions to adhesive plasters or attachment methods like Velcro bands
Implementation	Some concerns	• Technical glitches and perceived complexity hindered successful app deployment	• Improve internet connection by encouraging participants to use free hospital guest WiFi • Introduce app during presurgery conversations for home exploration the day before admission • Simplify the app by having fewer features (incurs additional costs)
Adaptation	No concerns	• App demonstrated adaptability across different departments	—[a]
Integration	Some concerns	• Enhanced information sessions with the health care professionals needed prior to data collection	• Conduct information meetings on different days to ensure that all shifts are covered • Appoint ambassadors to disseminate project details among colleagues
Expansion	Some concerns	• App facilitation requires additional resources, posing a challenge given limited availability of health care professionals	• A possible action could be to hire a student or research assistant to facilitate use of the app
Limited efficacy testing	Some concerns	• Children inactive for 22 hours a day; however, data loss and a small sample size limited the efficacy testing	• Examine alternative ways to attach accelerometers even though the accelerometer technology performed well

[a]Not applicable.

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Discussion

Principal Findings

We assessed the feasibility of implementing the customized Monster Gardener app in pediatric departments in a highly specialized tertiary hospital in Denmark. We found that the implementation of the app was not feasible without substantial amendments and identified several areas of concern when implementing digital interventions in a complex organization.

According to the World Health Organization's guide for monitoring and evaluating digital interventions [31] identifying a digital intervention's stage of maturity is a critical first step in defining the appropriate evaluation approach. On a continuum from preprototype, prototype, and pilot (early stage) to scaling up (middle) and eventually integrated implementation (advanced), we estimated that Monster Gardener was in the early stage. World Health Organization maintains that the appropriate evaluation approach for interventions in early-stage maturity is testing feasibility, usability, and efficacy. Our feasibility study findings indicate that we correctly estimated the maturity stage and evaluation approach, avoiding premature assessment.

Underreporting of negative results from feasibility studies is estimated to be high [32]. Failure to publish negative results causes publication bias and is unethical, leading to unnecessarily investing resources in interventions already proven to be infeasible [33]. As a result, publishing our negative findings is imperative so that others can learn from them [34].

Overall, this study showed that the acceptability of Monster Gardener differed between management, health care professionals, and hospitalized children. Acceptability was high among management and health care professionals, but the children did not find the app motivating, nor did playing it give them a sense of competence and autonomy, which can contribute to the intrinsic motivation to play [35]. The app's design or hospitalization may have deterred this motivation as indicated by some children's statements that it was too complex, or they were too exhausted to play. The recruitment rate also indicated that hospitalization may be overwhelming. In the case of pediatric burn rehabilitation, one study [36] found that a virtual reality intervention was more fun during pediatric burn rehabilitation than standard therapy, while another [37] found no difference between video games and standard therapy. An intervention's digital nature alone does not guarantee that it will have a motivational impact [16], and the Monster Gardener app is possibly an example of an unmotivating design in this sample of children.

A key finding of this study was identifying the major risk of data loss when using REDCap API to track usage data directly from the app. Using REDCap API for data import from other technologies has great potential for automating data import and controlling data input [38]; however, we were not aware that inactivity in the account holding the API key would lead to suspension of the key. We were unable to identify other researchers with a similar experience, but we believe that awareness of this issue when using the REDCap API feature is particularly relevant.

A similar study on the feasibility of video games to enhance physical activity in children in a pediatric critical care unit found that the video games were not feasible as the children needed to be cognitively alert and able to comply with the intervention [39]. Correspondingly, we found that the children were too exhausted and did not have the capacity to interact with the app.

A recent scoping review finds that studies on digital play and rehabilitation rarely examine implementation options [16]. Using CFIR, we analyzed the barriers and facilitators for implementing our intervention since we aimed to conduct a subsequent RCT. Implementing interventions in complex organizations poses multifaceted challenges [40], and one barrier to implementation was that the nurses were too busy to facilitate the intervention. Another feasibility study comparing using videogames for exercise to standard physical therapy in a pediatric burn unit emphasized that having physical or occupational therapists facilitate the exercises in the videogames ensured safe and appropriate use of the technology with maximum benefit [37]. A recent scoping review on digital play and rehabilitation indicated that interventions that do not occupy physical space facilitate the intervention [16]. During our intervention, the wall stickers with AR codes were occasionally covered by beds, hindering implementation. To address these challenges, intervention development should be considered a dynamic iterative process to be executed in close collaboration with the health care professionals who will ultimately use the intervention, while simultaneously drawing on existing evidence, undertaking primary data collection to understand the context and thoroughly analyzing facilitators and barriers for future implementation [40].

Another significant finding was that certain app features were not compatible with Android phones, causing them to operate differently than expected. Hence, researchers and health care professionals must be aware that the software's engineering may function in unforeseeable ways.

The adhesive plasters used to attach the accelerometers, which had been used previously for children in settings other than hospitals [21,41,42], caused skin reactions in one-third of the children. One of the various reasons for their discomfort may be that they were often lying down under covers in bed for many hours a day, possibly leading to increased sweating and itchy, irritated skin under the adhesive plasters. Perforated adhesive plasters that improve ventilation are a possible solution just as removable Velcro bands could be tested, which would also allow staff to reattach accelerometers more easily.

Accelerometer data showed that the children were inactive for 22 hours a day. Due to the small sample size, their inactivity reflects individual diseases and treatments more than a general issue. The low level of activity means a few extra daily steps would be beneficial and that 1, not 3, accelerometers are likely sufficient to provide a detailed activity profile. The level of inactivity, however, resembles that of hospitalized adults [22] and calls for further investigation.

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Strengths and Limitations

We followed all relevant guidelines when planning and conducting this feasibility study. Some of the strengths include asking the children about their motivation and attitude towards the intervention rather than assuming it would be fun and motivating just because the app is playful. One limitation is that we only surveyed the children, adolescents, and health care professionals about their opinions, experiences, and attitudes concerning the intervention instead of using more in-depth interviews to gain greater insights.

Perspectives

If the objective is to go further by testing the efficacy of this intervention in a full-scale RCT, we propose adjusting the intervention by (1) recruiting from several hospitals, (2) adding measures to reduce the risk of data loss, (3) further developing the app to support all types of mobile phones and operating systems, or providing devices for the duration of the intervention, (4) encouraging participants to use the free Wi-Fi to ensure a proper internet connection, and (5) using a more comfortable method to attach the accelerometer. In addition, future digital interventions should be simplified to minimize cognitive distress. Another suggestion is to hold informational meetings with health care professionals and recruit nurse ambassadors familiar with the intervention to publicize it. Including end users in intervention development would also be useful. To lighten the nurses' workload, a student assistant could also be employed to facilitate the intervention. Last, the level of physical inactivity reported in this feasibility study is alarming. Moreover, there is currently no known scientific literature evaluating the level of physical activity among hospitalized children, and no reference material exists for this population. We highly encourage future studies to evaluate the activity level of hospitalized children across various health conditions.

Conclusions

The digital play intervention Monster Gardener demonstrated potential in terms of fostering motivation for physical activity during pediatric hospitalization; however, the current version was deemed infeasible for implementation in this setting, based on the 8 feasibility focus areas by Bowen et al [18]. Our findings indicated that various organizational, technological, and practical issues must be addressed to adjust and improve the intervention prior to conducting effectiveness testing. Finally, future studies should focus on simple digital play interventions and the dynamic involvement of end users in development.

Acknowledgments

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Authors' Contributions

LW, DJC, MS, CHD, and JLS conceptualized and designed the study. All authors provided critical input during the data analysis and interpretation. LW collected data and drafted the initial manuscript. All authors revised the manuscript for intellectual content and read and approved the final manuscript. This research project involved collaboration with 2 external partners: Trifork A/S, which developed Monster Gardener, and SENS Motion, which provided the accelerometers. None of the external partners engaged in the planning, design, execution, or presentation of the research project.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Description of the app, Monster Gardener.
[PDF File, 370 KB - rehab_v12i1e58019_app1.pdf]

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Abbreviations

API: application programming interface
AR: augmented reality
CFIR: Consolidated Framework for Implementation Research
CONSORT: Consolidated Standards of Reporting Trials
IMI: Intrinsic Motivation Inventory
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
TAM: Technology Acceptance Model

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Usability of Videoconferencing for Physical Exercise Interventions in Older Adults: Scoping Review

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Abstract

Background: Videoconference combines the convenience of home-based physical exercise (PE) with group interaction and supervision of exercise in the community and could be useful for facilitating PE practice among older adults.

Objective: This scoping review aims to assess the evidence regarding the usability of videoconferencing technologies. Specifically, it explores whether tele-exercise solutions based on videoconferencing are usable for older adults and professionals, and how the heterogeneity of evaluation tools influences the generalization of results.

Methods: Electronic searches were conducted in databases Pubmed-Ovid Medline, Science Direct, Scopus, and CINAHL from January 2000 to March 2025 for identifying articles on measures of usability (ie, effectiveness, efficiency, and satisfaction of technology).

Results: A total of 14 studies out of 2506 unique records were included. The results showed that videoconferencing strategies can effectively deliver synchronous exercise interventions. However, their effectiveness, efficiency, and user satisfaction vary depending on the technological medium used. Despite widespread use among older adults, there is a notable gap in studies evaluating usability, particularly regarding remote PE interventions.

Conclusions: The review highlights that videoconferencing can be an effective tool for delivering synchronous exercise interventions to older adults. However, the effectiveness and user satisfaction depend on the technology used and the individual's characteristics. Further studies using standardized evaluation tools are needed to better assess usability. These findings underscore the importance of continued research to evaluate the effectiveness and acceptability of videoconferencing technologies for exercise interventions and to develop customized solutions to optimize the efficacy of these interventions for this population.

(JMIR Rehabil Assist Technol 2025;12:e65552) doi:10.2196/65552

KEYWORDS

usability; videoconferencing; tele-exercise; older adult; physical exercise; older adults

Introduction

The practice of physical exercise (PE) is defined as planned, structured, and repeated physical activity performed to improve or maintain regular physical fitness [1]. It limits some of the detrimental effects of aging and helps preserve the quality of life and independence of older adults [2], defined as individuals aged 65 years and older [3].

In particular, multimodal exercises (eg, pilates [4], the Otago exercise program [5], or the Vivifrail program [6]) have become popular for targeting balance impairments in older adults [7]. However, older adults' commitment to physical exercise is low [8]. It may be influenced by individual factors, such as physical limitations [9,10], motivation, and personal beliefs [8,11], or environmental factors [12], such as the difficulty of accessing the infrastructure where these programs are delivered [13].

Recently, the COVID-19 pandemic has reduced opportunities for activities among older adults and similarly limited their access to physical activity programs and exercise [14]. In this context, tele-exercise refers to the practice of physical exercises conducted remotely, guided by health care professionals or trainers, aiming to improve participants' overall physical fitness and well-being [15]. Information and communication technologies, particularly videoconferencing, allow clinicians to offer synchronous physical activities tailored to individuals' needs. These technologies offer the potential for new strategies such as feedback, social support, coaching, and appear to be particularly useful for increasing PE engagement [16]. To be

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used effectively, it appears essential that the technology matches the user's needs (clients and physical activity professional) [17].

This consideration refers to the concept of usability. The International Organization for Standardization (ISO) described usability as "the degree to which a product can be used, by identified users, to achieve defined goals with effectiveness, efficiency, and satisfaction, within a specified context of use" [18]. According to this definition, effectiveness refers to a tool's ability to achieve its intended objective, while efficiency corresponds to the ratio of resources to results. Satisfaction corresponds to the comfort felt by the user when using a tool [18]. Usability is therefore not a fixed property of a technology but rather depends on the characteristics, needs, and experiences of its users. As previously reported by Broekhuis et al [19], usability studies are crucial for understanding the reasons behind older adults' acceptance or rejection of technologies, considering factors such as complexity, lack of experience, and fear of reducing human interaction.

Despite the increasing use of tele-exercise strategies over the past decade, no review has specifically addressed the usability of videoconferencing technologies used in PE interventions for older adults. While there is significant research on general barriers to telehealth adherence, few studies focus on the usability of remote PE interventions for older adults, especially in terms of their effectiveness, efficiency, and user satisfaction. Therefore, it seems essential to appraise existing evidence on the usability of videoconferencing solutions for delivering PE interventions to older adults, as the effectiveness of these interventions partly depends on the usability of the technologies used. This research area is still developing, with various types of studies and methodologies being used [20], including usability tests such as the System Usability Scale, user feedback, post-use interviews, and questionnaires, resulting in a heterogeneous body of knowledge. Based on a scoping review approach [21], we aimed to assess the evidence regarding the usability of videoconferencing technologies. Specifically, it explores whether tele-exercise solutions based on videoconferencing are usable for older adults and professionals and how the heterogeneity of evaluation tools influences the generalization of results. The following two main hypotheses will be explored: (1) Tele-exercise devices are usable in terms of effectiveness, efficiency, and user satisfaction. (2) The heterogeneity of assessment tools limits the comparability of studies, making it difficult to establish standardized recommendations for integrating these technologies into clinical practice.

Methods

Search Strategy

This scoping review was structured according to the PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) guidelines [22] (see Checklist 1). The review was conducted by 2 independent reviewers (LR and BB) using the following 4 leading databases: Pubmed-Ovid Medline, Science Direct, Scopus, and CINAHL, which are among the main databases in health and physical activity field. These 4 databases cover the different dimensions of our topic, namely biomedical, paramedical, and interdisciplinary. The following keywords were identified and combined to address the research questions: (1) The target population was older adults living in the community. The population studied in the articles did not have to present any specific health characteristic (osteoarthritis, postfall, motor, or cognitive disorders), (2) videoconference should have been used as support of intervention, (3) program of PE as a type of intervention, and (4) usability as the main purpose. Synonyms were used to maximize inclusion. Keywords and related subject headings were searched using Boolean operators. The selected studies were limited to those published between January 2000 and February 2025. No language restrictions were applied to the selected studies. The MeSH (Medical Subject Headings) terms and combinations used are listed in Table 1.

Table . Research terms.

Parameter	MeSH[a] terms used in Pubmed-Ovid Medline, Scopus, and CINAHL	MeSH terms used in ScienceDirect
Population	(Aged people) OR (Aged adult*) OR (Aging) OR (older adult*) OR ("Older people") OR (Elder*) OR (Seniors)	(Aged people) OR (older adult)
Method of intervention	(eHealth) OR (web-based) OR (e-Health) OR (MHealth) OR (teleconferenc*) OR (Videoconferenc*) OR (Telehealth) OR (Telerehabilitation) OR (Tele-rehabilitation) OR (Teleexercise) OR (Tele-exercise)	(Videoconferencing) OR (Teleexercise)
Type of intervention	(Physical exercise*) OR (Physical activit*) OR (Fitness exercise*) OR (Physical fitness) OR (physical exercises program)	(Physical exercise) OR (Physical activity)
Outcomes	(Usability) OR (Acceptability) OR (feasibility)	(Usability) OR (Acceptability) OR (feasibility)

[a]MeSH: Medical Subject Headings.

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Eligibility Criteria

The selection of studies was conducted based on prespecified PICOS (Participants, Intervention, Comparison, Outcomes, and Study design) criteria [23] (see Textbox 1):

Non–peer-reviewed conference and journal publications, review articles, and publications that took place in hospitals, rehabilitation centers, or care settings were excluded.

Textbox 1. Eligibility criteria.

- Participants: Older adults (aged 65 years and older) living in the community.
- Intervention: Physical exercises delivered via videoconferencing technologies. The tele-exercise should have been delivered at home or in the context of the local community.
- Comparison: A control group was not necessary for this research.
- Outcomes: Information on usability as defined by the International Organization for Standardization (ISO) criteria (even if it was not the main outcome)—different criteria such as (1) efficiency (ease of use, reliability, and cost), (2) effectiveness (retention rate, rate of sessions completed, and adherence rate) of videoconferencing technologies, or (3) level of satisfaction (feeling about technology) or acceptance of the older adults—testified to the usability of the technology as a means of remote intervention.
- Study design: We included randomized controlled trials (RCTs), nonrandomized controlled trials (NRCTs), noncontrolled trials (NCTs), crossover, and pilot studies without a control group (qualitative or quantitative design).

Data Collection and Analysis

Selection of Studies

Using Covidence software (Veritas Health Innovation), 2 authors (LR and BB) reviewed and prescreened all titles and abstracts of studies identified by the search strategy for possible inclusion according to the PICOS eligibility criteria. The full text of the preselected articles was checked for eligibility.

Data Extraction

When articles met the eligibility criteria, we extracted, from the full text, authors' names, year of study, country, objectives, study design, population (ie, sample size, age, and place of residence), intervention modalities (eg, technological support, group, or individual sessions) and, when available, comparator (eg, face-to-face intervention or simply counseling), results, and conclusions on usability (effectiveness, efficiency, and satisfaction) of the proposed technologies. A narrative synthesis of the data was produced [24].

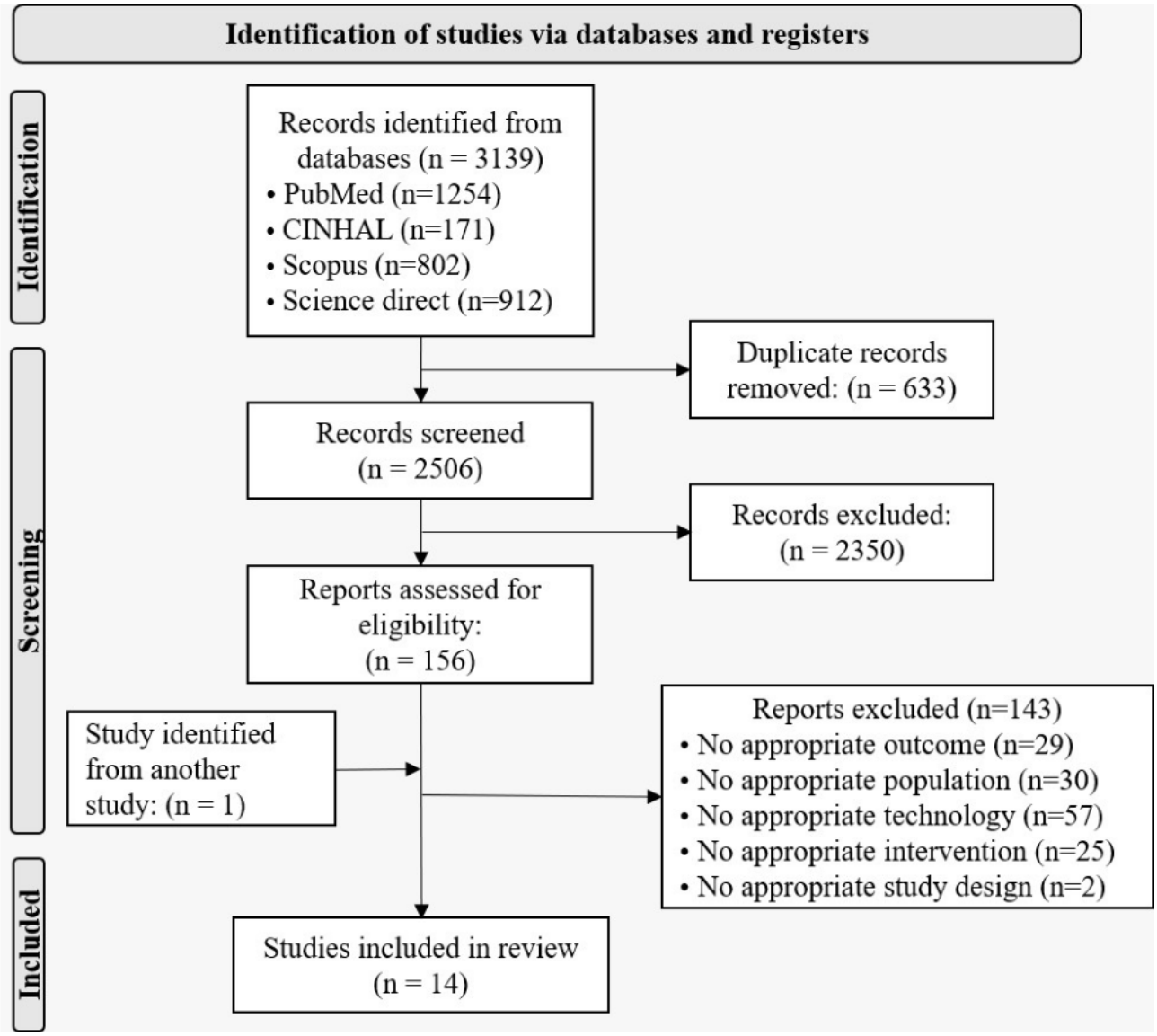
Results

Overview

The search strategy yielded 3139 records, from which 2506 abstracts were selected after eliminating duplicates. After title and abstract selection, 156 articles were retained for full-text screening. After reading each publication, 1 article was found and added after reading an included article, and 143 publications were excluded. Figure 1 shows the reasons for article exclusion. Finally, 14 full-text publications were included (see Figure 1).

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Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) flow diagram.



Included Studies

The main characteristics of the studies are summarized in Table 2. The studies were published in English and came from various countries: England [25], the United States [26-32], Brazil [33], Canada [34,35], Singapore [36], Japan [37], and Israel [38].

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Table . Main characteristics of the included studies.

Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
Granet et al [35], 2021	RCT[a] to examine and compare the acceptability, feasibility, and potential benefits of 2 modalities of web-based PA[b] interventions in older adults.	Nonphysically active community-dwelling older adults (>60 y) from the CRIUGM's[c] volunteer database. EG[d]: 70.7 years (SD 5.2), n=38 (81% of women); CG[e] (recorded group): 69.6 years (SD 5.1), n=45 (83% of women).	• Exercise protocol: Muscle function, flexibility, and cardiovascular exercises. • A total of 55 minutes, 3 days/week for 12 weeks. Program delivered by 2 certified instructors (kinesiologists). • Participant-to-professional ratio=10-14:1. Online via Zoom videoconferencing interfaces.	• Initial ability to use technology in both groups: >78% used technologies for more than 1 y, >82% considered themselves "tech savvy," and >59% used touchpad. • Feasibility: • Adherence rate: 85%; EG: 89%, CG: 81% • Retention Rate EG: 16% drop out versus CG: 46% -> lack of interest • Acceptability of intervention (4-Likert scale): • Satisfaction: EG: 77% vs CG: 64% • Enjoyment: 100% • Perceived difficulty (easy): EG: 69% vs CG: 82% • Perceived exertion (a little easy - a little difficult): EG: 42 - 42% vs CG: 48 - 37%. • Satisfaction precautions: ie, phone close by, remove objects or carpets from path, levels of progression. No adverse events. • No model or analysis grid reported.
Gell et al [30], 2022	RCT to determine the feasibility of remotely delivered exercise (tele-exercise) for older, rural cancer survivors.	Cancer survivors (>60 y), 2/3 are classified as obese. EG: 70.1 years (SD 5.3), n=20 (80% of women); CG (waiting list): 70.6 years (SD 6.2), n=19 (78% of women).	• EnhanceFitness (tele-EF) exercise program, inclusive of aerobic, strength, and balance training. • For 1 h, 3 days/week for 16 weeks. • American Council on Exercise certified instructors. • Participant-to-professional ratio: 10-12:1 online via Zoom videoconferencing interfaces.	• Feasibility: • Enrollment: 64% consented to participate, higher than 50% expected. • Adherence rate: median 86.9% (IQR 79 - 94%) • Attrition: 95% completing the study. • Safety: • Precaution: assistant joined each class to monitor for safety • No serious adverse events. • No model or analysis grid reported.

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
Gell et al [28], 2021	Exploratory mixed methods study: (1) examine the needs of older adults previously enrolled in community-based exercise for transition to tele-exercise, (2) identify barriers to and facilitators of tele-exercise uptake and continued participation, and (3) describe technology support challenges and successes encountered by older adults starting tele-exercise.	Community-dwelling older adult with symptomatic knee osteoarthritis (>65 y). EG: 74 years (SD 6.3), n=44 (86% of women).	• EnhanceFitness (tele-EF) exercise program, inclusive of aerobic, strength, and balance training. • For 1 h, 3 days/week. • Participant-to-professional ratio: Not reported, session available for all participants. • Online via Zoom videoconferencing interfaces.	• Material: 91% owned a smartphone and had broadband access, but 1/3 did not own a tablet and 1/3 did not own a computer with a webcam. • Acceptability (senior Technology Acceptance Model [TAM]): • Attitudinal beliefs: 8.7 (SD 3) out of 10. • Control beliefs: 8.9 (SD 2.5) out of 10. • Gerontechnology anxiety: 3.5 (SD 4) out of 10. • Challenge during setup phase: no device camera or microphone (n=1). • Challenge during classes: internet connectivity issues (n=5); Zoom audio (n=11), joining or staying on the meeting (n=15). • Facilitating conditions: 48% required a single call to address the technology challenges. • Adherence: median 93% (IQR 88%-98%).
Hawley-Hague et al [25], 2021	Feasibility study: Usability, acceptability, and feasibility of smartphone-based teleconferencing for health professionals and older adults.	Community-dwelling older adults. EG: 77 (range 64 - 92), n=7. Health professionals: n=11.		

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
			• Virtual intervention: Otagot program + balance exercises from the FaME[f] program (evidence-based falls management exercise). • For 2 wks: classic intervention before usability test. • Program delivered by a health professional, 1 x/week during 2 weeks in individual and 1x in a single group session. Researchers present with participants and help to use technology if difficult. • Participant-to-professional ratio: 1:1 for the individual session and 2-3:1 for the group sessions. • Samsung Galaxy S4 with 4G network connected to TV or screen provided by HDMI cable or Chrome Cast. Broadband (if not available) has been set up and paid for by the research team (as a smartphone) Wireless headset. Software: Skype.	• Issue log or field notes: Acceptability and Usability (TAM): • Setting up and connecting the technology and accessing Skype requirement for internet or 4G. • Poor connectivity -->limited reliability of teleconferencing. • Positioning of the technology for delivery exercise. • Anxiety and safety concerns: the patients were not as concerned as the health professionals. • Cost: Broadband installation met with resistance, even when it was proposed to provide it, due to the cost that would be incurred once the study was completed. • Experiences of using the technology: issues with the positioning of technology and with view and contrast. • Feasibility: Ideal size of group, types of exercise that could be delivered through the smartphone.
Ho and Merchant [36], 2022	Cross-sectional study to study the acceptability of technology and perceived self-reported benefit of tele-exercise in our community-dwelling older adults.	Older adult (>60y) in community-dwelling. EG: 69.1 years (SD 4.7), n=42 (93% of women)?		

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
			• Healthy Aging Promotion Program for You (HAPPY): multicomponent exercise focusing on cognition and physical function. • Minimal length of 8 sessions. 3 sessions of theoretical training and cocreation of dual-task exercise and 8 hours of on-site training as assistant instructor and assessment. Program was conducted by health coaches and peer leaders who were trained to perform dual-task exercises by physiotherapists. Participant-to-professional ratio: No reported, session available for all participants. Online via Zoom videoconferencing interfaces.	• Online questionnaire regarding technology • Acceptability of digital technology: • Utility: 91% agreed that technology is a good idea and 79% agreed that technology would allow them to be independent for longer. • Ease of use: 79% thought they had the necessary knowledge and 86% thought they could use the technology if someone showed them or provided an instruction manual. A total of 41% disagreed or were neutral that technology is easy to use and that technology is easy to learn. • Facilitating condition (knowledge, external assistance): Someone was available for technological assistance for 91% of participants. • Technology apprehension: 7% (n=24) were apprehensive about using technology. • No model or analysis grid reported.
Hyodo et al [37], 2023	Pilot study to examine the feasibility, safety, and enjoyment of a web-based aerobic dance exercise program and the usability of a web-based exercise delivery system using a videoconferencing platform for older adults.	Older adult (>65y) in community-dwelling. EG: 77.6 years (SD 4.5), n=16 (75% of women).	• Slow aerobic dance exercise (SADE). • Duration of 20 min, every weekday for 8 weeks. • Participant-to-professional ratio: 16:1. • Online via Zoom videoconferencing tablet interfaces.	• Feasibility • Retention rate=93.8% • Adherence rate=97.40% • Security: No adverse event. • Enjoyment, 11-point Likert scale: improvement throughout sessions. • Usability (interview) Ease of use: • 27% had no problem. • 73% had some challenges at the beginning. • No model or analysis grid reported.
Jennings et al [26], 2020	Pilot study to describe the preliminary results and lessons learned from the rapid implementation of a telehealth-supported group exercise intervention.			

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
		Veterans (>65 y), with authorization of Durham Veterans Affairs (VA) Medical Center (offered at 17 medical centers in the United States). EG: 74.0 years (SD 6.7), n=308.	• "Gerofit program": (cardiovascular exercises, strengthening on individual machines + classes, such as Tai Chi, yoga, chair, or floor. • Total of 3x/wks. For at least 8 weeks for some centers. • Program delivered by 2 instructors. • Participant-to-professional ratio: variable group sizes. • Online via Zoom videoconferencing tablet, smartphone, or computer interfaces, or Veteran Affairs (VA) supported platforms (The VA supports telehealth using VA Video Connect (VVC) within the VA Virtual Care Manager (VCM) platform).	• Feasibility • Adherence rate: 6.4% attended fewer than 25% of the total available number of GTH[g] classes, and the majority (93.6%) attended classes regularly, with 53% attending more than 75% of the time. • Satisfaction and safety: 94% are likely to recommend GTH to another veteran, and 95% said they felt safe exercising at home. • No model or analysis grid reported.
Patel et al [29], 2022	Pilot study to evaluate the feasibility and acceptability of remotely delivered EF (tele-EF).	Older adults (>65 y) residents of Lewis County, with symptomatic knee osteoarthritis. EG: 71.8 years (SD 5.8), n=15 (93.3% of women).	• EnhanceFitness (EF): Strength training involved progressive resistance exercises using adjustable 1- to 10-pound ankle and wrist weights. • EF-certified instructor 60 min, 3 days/week for 12 weeks. • Participant-to-professional ratio: 10-12:1. Online via Zoom videoconferencing interfaces.	• Feasibility • Retention rate: 55.6% enrolled. • Adherence rate: 86.7%. • Acceptability of program (satisfaction): Median 91.4% (IQR 84.5 - 94.3%; n=15) • Material: 5 participants were loaned a cellular enabled tablet • Technology acceptance (TAM scale) • Ease of use: 6.4/7 • Usefulness: 6.6/7 • Financial cost: 2.8/7 • Intention to use: 6.3/7 • No model or analysis grid reported.
Pinto et al [33], 2023	Feasibility study to compare the barriers and facilitators of telerehabilitation between groups of people with and without Parkinson disease.	Older adults with and without Parkinson disease (PD). EG: 69.00 (IQR 64.68-73.32), n=14; CG with PD: 69.00 (IQR 65.17- 72.83), n=12.	• Dance for PD. • Total of 60 min, 2 days/weeks for 8 weeks. • Professional dancer and physiotherapist sequence of movements. • The participant-to-professional ratio was not reported. • Online via Zoom videoconferencing tablet, smartphone, or computer interfaces.	

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
				• Feasibility • Retention rate: 100% • Adherence rate: 91.7% to 87.5% with PD and without PD, respectively. • Usability • Connection: 5.8 reported poor connection. • Sound problem: <2.4% in both groups. • Difficulty accessing or managing between 9.6% and 10.4%. • Security: • Precaution: Check of environment (enough and clear space to move). • No adverse event. • No model or analysis grid reported.
Robin et al [34], 2024	Feasibility and pilot study. Explore the feasibility, acceptance, and usability of a PA program offered synchronously via a mobile robotic telepresence (MRP).	Older adult: EG: 83.5 years (SD 4.5), n=21.	• Exercise program inspired and based on the Otago exercise program. • Total of 60 min, 2 days/weeks for 4 - 6 wk. • Occupational therapist. • Participant-to-professional ratio: 3:1. • Online via the MRP.	• Feasibility: • Retention rate: 17/21 • Adherence rate: 58% • Usability: • French version of system of usability scale (F-SUS): 55.0, SD 18.7, out of 100, reflecting low usability. • Clinicians' observations and semi-directive interview (UTAUT[h] model): • Effectiveness: A total of 61 sessions were offered to older adults • Efficiency: (1) A total of 3 cancelations: 2 instances of impossible simultaneous connections (participants or therapist), 1 abnormal noise (possible power surge). (2) Internet connection issues (shortened or interrupted sessions). (3) A total of 3 sessions with no visibility between participants. • Satisfaction: Hedonic motivation score: 4.7 (SD 1.6) out of 7.
Schwartz et al [38], 2021				

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
	Pilot study to explore the feasibility of an 8-week intervention in a group of older adults.	Older adults (>60 y old) living in the community. EG: 71.5 (SD 4), n=31 (67% of women).	• Exercise protocol. • Resistance and aerobic exercises; individualized program according to perceived exertion (Borg scale). 45 min, 2 x/week for 8 weeks. • Search teams=2 physiotherapists +2 personal trainers, 2 instructors, and 1 technical assistant. • Participant-to-professional ratio: 15:1. • Online via Zoom videoconferencing interfaces. • WhatsApp group chat or reminders.	• Online questionnaire: Satisfaction levels with the technological aspects (final survey): • Ease of use: 7 (5-7) out of 7. • Quality of video and audio: 7 (5-7) and 7 (5-6) out of 7. • Future intentions: 97% would like to continue. • Enjoy training: 7 (5-7) out of 7. • Perceived exertion: 6 (3–7) out of 10. • No model or analysis grid reported.
Tomita et al [31], 2016	RCT to explore attrition rate and effectiveness to the intervention on falls, balance, and depression.	Older adults (60-90) living in the community. N=51; EG: 72.3 years (SD 7.7), n=25 (92% of women). CG: 74 years (SD 7.8), n=26 (87% of women).	• EG=Virtual-Group Exercise at Home (V-GEAH). The exercise program inspired by Tai-Chi and the Otago program. • CG=encouragedto walk. • 25 to 40 min, 3 x/week for 24 weeks. • Certified fitness trainer. • Participant-to-professional ratio: 25:1. • Intervention is possible on a desktop or laptop computer. • Video communication software called ooVoo (ooVoo LLC) and a free program called ManyCam (ManyCam, IPM).	• Feasibility: • Adherence rate: 84.4%. • Satisfaction: 5% of participants thought the 6-month duration was very long while 77% said they would miss the V-GEAH session. • Security: Participants felt safe. • No model or analysis grid reported.
VanRavenstein et al [32], 2020	Controlled study to examine the feasibility of tele-intervention to a small group of low-income older adults living independently in the community.	Older adults (>55 y), relatively autonomous (able to stand for 15 minutes, able to move 150 feet, follow instructions, charge, wear and use a Fitbit tracker). EG: 74 (60-84), n=6 (100% of women); CG: 69 (57-74), n=6 (83% of women).		• Qualitative interviews (Constructivist grounded theory): Feeling on the participation in an exercise program over the technology. • Ease of use: difficult to the touch screen (n=2). • Satisfaction: Participants appreciated the telehealth sessions.

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Study	Study design and objectives	Population	Intervention, supervision, duration, and frequency of intervention technology and equipment	Outcomes
			• Modified Otago exercise program: strength and balance exercises. EG=distance session; TG=face-to-face session; 2 x/week, 12 weeks Program physical therapist (PT), and PT student. • Participant-to-professional ratio: 6:1. • Instructor: desktop computer with a 32-inch screen, speakers, and the Vidyo telehealth platform. • Participants could view the instructor using a second computer. • Fitbit (recorded walking activity).	
Wu et al [27], 2006	Pilot study to assess the feasibility of a group intervention designed for balance-impaired older adults to improve their balance and reduce their fear of falling.	Older adults (>65 y) community-dwelling. EG: 81 (IQR 72-93), n=17 (76% of women).	• Yang style Tai Chi Quan movements emphasizing flexibility, strength, and balance coordination. • 1 h 3 x/week for 15 weeks with a Certified tai-chi teacher. • Participant-to-professional ratio: 6-11:1. • Video camera and ordinary TVs, displaying all participants for the instructor, and displaying either the instructor alone or with other participants.	• Feasibility • Adherence rate: 78 ± 15% (ranging from 51 to 98%) • Drop out: n=3 Interview questionnaire and logbook • Level of acceptance and satisfaction: All subjects reported favorably about the program via videoconference. • Ease of use: • Most subjects (n=15) reported no concerns. • A total of 2 participants required assistance until the third week. • Efficiency: • Participants were satisfied with image and voice quality. • Technical support mainly concerned connection problems, audio problems (microphone volume), or hardware problems (camera, microphone, or audio circuit failure). Most problems were solved by telephone. Hardware problems required 1-hour home visits. • No model or analysis grid reported.

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[a]RCT: randomized controlled trial.

[b]PA: physical activity.

[c]CRIUGM: Centre de Recherche de l'Institut Universitaire de Gériatrie de Montréal.

[d]EG: experiment group.

[e]CG: control group.

[f]FaME: Fitness and Mobility Exercise.

[g]GTH: Gerofit-to-Home.

[h]UTAUT: Unified Theory of Acceptance and Use of Technology.

Publication Year and Study Participants

Most of the identified articles were relatively recent as none of the included articles were published before 2006; 1 study was published in 2006 [27] and 12 between 2016 and 2023 [25-33,35-38]. Sample sizes varied across the studies, ranging from 7 to 302 participants. Participants were, on average, aged 73.1 years, with an average age range from 69.6 to 81 years, according to the sources reviewed.

Intervention

The interventions consisted of the adaptation of a PE program inspired by preexisting home-based activity programs, eg, Gerofit [26], Otago [25,32,34], or yoga and tai chi techniques [27] or designed by physiotherapists [38]. Except for 1 study [25], which lasted only 3 weeks, PE interventions duration ranged between 8 and 24 weeks. The interventions were supervised by health professionals (ie, kinesiologists, physical therapists, physiotherapists, and occupational therapists) or certified trainers. Furthermore, 2 studies compared the group receiving a live remote intervention with a group receiving a recorded intervention [35] or a control group receiving a traditional intervention [32]. The participant-to-professional ratio varied across studies, ranging from 1 to 25 participants, and could also fluctuate within the same study depending on the number of available participants.

Videoconferencing Systems

Authors used different terms to describe the intervention: teleconferencing [25], videoconferencing [27,38], tele-exercise [28,30,34,36], telehealth [26,32], web-based intervention [35,37], and virtual-group exercise [31]. Similarly, various technological supports were used: computer [31,32], tablet [37], smartphone [25], TV screen [27], and telepresence robot [34], allowing access to various videoconferencing software such as Zoom (Zoom Communications) [26,28,30,33,35-38], Skype (Microsoft) [25], WhatsApp (Meta Platforms) [38], or other undetermined applications [27,31,32,34]. Despite the different terms and configurations used, all these studies proposed a synchronous intervention with direct interaction.

Usability of Technological Support

Overview

In this synthesis, various methods were identified in the included articles for assessing the usability of videoconferencing technology for delivering PE programs to older adults. This included qualitative interviews [27,32,38], self-administered questionnaires [29,34-36], and observations [25,26,30,31,33-35,37]. In addition, some studies applied theoretical frameworks such as the constructivist grounded theory [32], the Technology Acceptance Model [25,28,29], or the Unified Theory of Acceptance and Use of Technology (UTAUT) model, and system usability scale [34]. These tools and frameworks allowed for the evaluation of different aspects of the usability of videoconferencing technology, including its effectiveness, efficiency, and user satisfaction with the technological support in delivering tele-exercise programs.

Effectiveness of Technological Support for Videoconferencing

All studies indicate that it is possible to deliver PE interventions synchronously via videoconferencing technology. Mean adherence rate of intervention was 87.8% (range 78%-97%) [27-35,37,38]. Reasons given for continuing or not continuing exercise during studies were independent of the technology used. There were individual characteristics, like lack of interest in the intervention or health problems [35]. The instructions and progression of the exercise were the same as face-to-face [31]. All the technological supports have been effective in delivering video conferencing intervention programs.

Efficiency of Technological Support for Videoconferencing

A total of 12 studies evaluated the efficiency of the interventions offered by videoconferencing [25-30,33-38]. These studies report the correct efficiency of the technologies used, but certain points of concern concerning technological anxiety, ease of use and learning, technological reliability, safety, and cost are highlighted.

Ease of Use and Learn

Hyodo et al [37] reported that 73% of participants had some problems using technology at the beginning. VanRavenstein et al [32] highlighted that 2 participants had difficulty using the touch screen. In the study led by Granet et al [35], 69% of participants found the technology easy to use. Ho and Merchant [36] highlighted that, while 79% of respondents reported knowing to use the system, 57% (n=24) were apprehensive about using the technology. In addition, 41% (n=17) disagreed or were neutral that technology is easy to use. However, a majority (n=25, 60%) of respondents agreed with the affirmation “technology is easy to learn.” Furthermore, 86% (n=36) agreed that they could accomplish the task if someone showed them or through an instruction manual [36]. Similarly, Robin et al [34] reported that participants assessed the expected effort to use a telepresence robot at 4/7. If the technology was easy to use, the presence of technical support was appreciated.

Finally, Patel et al [29,38] and Schwartz et al [38] reported that participants rated ease of use at 6/7 and 7/7, respectively. For some participants, the proper use of the tool required a learning

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period from the intervention sessions in 2 studies [25,27]. These sessions were either 2 face-to-face sessions to learn about the technology and software [25] or a short 2.5 hours of training session [27]. In addition, to deal with problems arising during the course (staying on the meeting), telephone assistance was also necessary [28].

Reliability of Technology

In case of technology-related issues, the authors report that support services can assist with various aspects, including connectivity and audio adjustments (such as modifying microphone volume). They also help with troubleshooting hardware issues (eg, malfunctioning camera, microphone, or audio circuit in the videoconferencing device) that could compromise the interaction between the clinician and the participant, as well as the execution of the intervention [25,27-30,33,34,38]. The technology support chosen to be more or less effective depends on the group. Jennings et al [26] indicated that the group size was influenced by the platform used. The Veteran Affairs platform had limitations on the number of people observed simultaneously, while the Zoom platform did not.

In terms of cost, the economic situation of older adults was considered in 2 studies. For 35% of the participants in the study of Ho and Merchant [36], this aspect limited technology use. Similarly, participants (n=7) were resistant to broadband installation because of the cost that would have to be borne once the study was completed [25].

Satisfaction of Technological Support for Videoconferencing

Some people were afraid to have the technology installed in their homes, finding it too intrusive. Gell et al [30] reported that participants were not anxious about using the technology (mean score 3.5, SD 4; out of 10). According to Hawley-Hague et al [25], the initial concerns of the older adults were about installing the equipment and using it (sometimes large screens in small spaces). Nevertheless, most of the participants managed to use the technology without major difficulties. Where difficulties arose, the use of the technology was facilitated by the existence of associated services [25,27].

However, as reported in many other studies, people were satisfied with the overall intervention, the proposed program and the technology [25-27,29,31,32,34-38]. They were willing to continue the interventions by videoconference if possible [29,31,38].

Hawley-Hague et al [25] reported that for health professionals, a display issue emerged: difficulty in seeing contrasts when the older person was dressed in black or if the room light was low. This was exacerbated in group sessions as the individual image was smaller. While these difficulties were not a concern for the patients who felt safe performing the exercises, they raised increased safety concerns according to the professionals [25]. However, no adverse events were reported by different authors [30,33,35]. Jennings et al [26] also reported that 95% of participants had reported feeling safe during exercise sessions.

Various advantages of videoconferencing technologies were noted, enhancing user satisfaction. These technologies made it possible to limit external risks such as frozen roads [27] and were more interesting than telephone follow-up, particularly during the follow-up phase [25]. The group sessions enabled by technology provided considerable added value through possible interaction between participants and the instructor. Schwartz et al [38] reported that for one person, the group activity allowed by videoconferencing helped alleviate feelings of loneliness and created a positive atmosphere. The instructor's remote presence via videoconferencing and professionalism were appreciated and reassuring [31,34,38]. A total of 3 studies reported that the technology delivered an intervention in which participants perceived benefits on physical and mental well-being [34,36,38].

Discussion

Principal Findings

The use of videoconferencing allows professionals to offer PE interventions to older adults. Nevertheless, it seemed important to evaluate the usability of the technological support used to propose these interventions while encouraging the adherence of the older adults. To our knowledge, this is the first scoping review to evaluate the usability of various technological supports (ie, laptop, tablet, smartphone, or telepresence robot) for delivering tele-exercise programs to older adults via videoconferencing. Our results indicate that the usability of tele-exercise programs may vary according to the technological support used for their delivery via videoconferencing.

Usability of Videoconferencing Technologies

All the studies included in this review demonstrated the effectiveness of technological videoconferencing media in the implementation of live and remote PE interventions. Adherence rates were variable, ranging from 57% to 100%, and were sometimes higher than adherence rates for exercise programs offered without videoconferencing [39]. The high adherence of participants in the studies testifies to the effectiveness of the technologies used. It appears possible for participants to join the interventions conducted remotely. These technologies (ie, laptop, tablet, smartphone, or telepresence robot) offer great accessibility for remote communication, thus facilitating exchanges without the need for physical presence. This accessibility is likely a key factor in the high adherence rates observed, allowing participants to engage in PE interventions from the comfort of their own home, while overcoming geographical and logistical barriers.

While videoconferencing is effective in providing a live remote PE intervention, our results indicate various points of caution. First, variations in participants' adherence to the program could be influenced by user characteristics. It may be more difficult to use technology for adults inexperienced with technology [35]. The results of this scoping review showed that older adults may need external assistance to use the technology [25,27,30,36]. Some factors hold back the use of technology by older adult users, namely the cost of the technology, followed by the complexity to use it [40,41]. This may justify the importance for obtaining environmental supports, that is, financial support

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and training opportunities, as it appears essential to help older users to overcome technological barriers (ie, connection issues, audio issues) [42]. Second, variations in technology effectiveness could be influenced by device characteristics and user satisfaction with the technology. According to our results, clinicians and older adults may encounter reliability issues with the technology that compromised the intervention and thus hindered users' satisfaction and safety of older adults [27,32]. Some platforms appear to be less usable than others for large group interventions (ie, Zoom platform on smartphone) [25,26]. For videoconferencing systems, the required bandwidth, the security of the transmitted images and the reliability of technology are important factors to consider [43]. In the event of difficulties with technology, some solutions exist, for example, Granet et al [35], who suggested that recorded sessions may be appropriate for participants who are temporarily unable to attend live, online group sessions.

Assessment of Usability

Qualitative interviews, self-administered questionnaires, and observations were the preferred approaches for evaluating the efficiency of technological support and user satisfaction with the system and the proposed interventions. These self-reported methods provide valuable insights into users' perceptions: when users report positive experiences with technology, they are more likely to adopt or continue using it [44]. Some studies have also based their measures on theories like constructivist grounded theory [32] or the Technology Acceptance Model [25]. However, while a study did use existing usability scales such as the System Usability Scale [45] or the Quebec User Evaluation of Satisfaction with Assistive Technology [46], the lack of widespread use of these standardized tools makes it difficult to draw general conclusions. While qualitative methods are essential for providing specific details that quantitative measures sometimes cannot capture, both qualitative and quantitative approaches should be applied to the design or improvement of technologies. Albert and Tullis [44] emphasized the importance of using standardized tools to ensure measurement quality because these tools are valid, reliable, and available for comparison purposes.

We also noted that just 1 study had assessed all the usability attributes defined by the ISO [18]. Most studies assessed elements covering only part of the theoretical concept, with satisfaction and effectiveness being the most common attributes, while other important aspects such as ease of use or safety are left out. This observation is also shared by Sousa and Dunn Lopez [47]. The results of their review indicated that the questionnaires constructed and used to assess usability in studies only assessed part of the usability construct. However, it is possible that some effectiveness studies did not include the assessment of efficiency and satisfaction, as these data could be assessed earlier in the intervention design process.

Limitations

Although the use of technology in health and exercise has gained widespread popularity in recent years, particularly with the rise of remote interventions, high-quality studies specifically evaluating the usability of these technologies remain limited. This gap raises concerns about the reliability and generalizability of the information currently available and highlights the need for rigorous scientific research focused on usability aspects.

As our review suggests, a reason for the limited number of studies included is that usability testing is often overlooked or insufficiently addressed in research involving older adults. This observation is consistent with the findings of Meiland et al [48], who reported that usability issues related to technologies designed for people with dementia are rarely studied. More broadly, the field of usability testing for remote interventions in aging populations appears to be still emerging, with its relevance becoming more visible during events such as the COVID-19 pandemic [20].

To reflect the current state of the literature, we included pilot studies, which are particularly useful in areas where large-scale evaluations are still lacking. These studies often serve as precursors to broader investigations and provide valuable insights into the feasibility and usability of technological interventions. Pilot studies can assess (1) participant recruitment processes, (2) the reliability and adaptability of technological tools, and (3) potential adverse events—whether related to the technology, the exercise intervention, or user safety [49,50].

In this sense, even preliminary data contributes meaningfully to understanding usability and helps inform the development of future interventions.

Perspectives

The findings of this review highlight the potential of videoconferencing technologies to support access and continuity of remote physical exercise programs for older adults in home-based settings. This approach is especially useful for individuals who have difficulty traveling, such as those with mobility limitations or who live in remote areas. Beyond healthy older adults, it would be relevant to assess the usability of these technologies in rehabilitation settings, where individuals with troubles often have specific needs. Future studies could explore how cognitive, sensory, or motor impairments may affect interaction with digital tools, and how these technologies may need to be adjusted in terms of usability and support.

To provide a more complete understanding of usability, future research could combine qualitative and quantitative approaches, using mixed methods and standardized tools. This would allow for more consistent and comparable results, reflecting both user and professional perspectives. As remote interventions become more common—especially following the acceleration brought by the COVID-19 pandemic—it is important to continue research on how these technologies are integrated into care practices, making sure they remain acceptable, effective, and safe for all types of users.

Conclusion

The results of this exploratory study highlight the ease of use of videoconferencing support technologies to deliver remote exercise programs, highlighting positive aspects such as usability, user satisfaction, efficiency, and effectiveness. However, our findings also highlight the importance of environmental support, such as financial assistance and training opportunities, which are essential in helping older people to use

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information and communication technologies. In the future, it is imperative to conduct research, using standardized tools, to enhance the usability of technologies tailored to the specific needs and characteristics of older adults, thereby ensuring the clinical effectiveness of these interventions.

Conflicts of Interest

None declared.

Checklist 1
PRISMA-ScR checklist.
[PDF File, 103 KB - rehab_v12i1e65552_app1.pdf]

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Abbreviations

ISO: International Organization for Standardization
PE: physical exercise

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Action Observation Combined With Motor Imagery Training to Improve Motor Function in People With Stroke: Systematic Review and Meta-Analysis

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Abstract

Background: Action observation combined with motor imagery (AO+MI) training is considered a potentially effective approach for improving motor function in patients after stroke. Therefore, it is important to review and analyze the existing research evidence of its effectiveness.

Objective: This study aims to evaluate the effectiveness of AO+MI training on the limb motor function of patients with stroke.

Methods: A systematic search was conducted in PubMed, Cochrane Library, Web of Science, Embase, Proquest, Physiotherapy Evidence Database, ClinicalTrials.gov, and ChiCTR. The last search was performed in June 2025. Three reviewers independently screened the articles, and 2 reviewers extracted data. Quality assessments of randomized controlled trials were done using the Cochrane Risk-of-Bias Tool. The certainty of evidence was evaluated with GRADEpro GDT (Evidence Prime, Inc). A meta-analysis was performed using RevMan 5.3 (The Cochrane Collaboration) software and Stata software.

Results: A total of 13 articles were included with 399 patients with stroke. The results of the meta-analysis showed that compared with routine rehabilitation, AO+MI could improve the upper extremity function (standard mean difference [SMD]=1.02, 95% CI 0.28 - 1.75; *P*=.007) and the lower extremity function (SMD=6.31, 95% CI 4.75 - 7.87; *P*<.001) of patients with stroke. There was no significant difference between AO+MI and routine rehabilitation for improving activities of daily living (SMD=0.06, 95% Cl –0.35 to 0.47; *P*=.06). AO+MI could promote the recovery of upper extremity function in patients compared with MI independently (SMD=0.97, 95% Cl 0.13 - 1.80; *P*=.02). There was no significant difference between synchronous combination and asynchronous combination in upper extremity function rehabilitation of patients after stroke (SMD=−1.04, 95% Cl –2.56 to 0.48).

Conclusions: AO+MI can improve the motor function of limbs and can be considered an effective limb rehabilitation therapy for patients after a stroke.

Trial Registration: PROSPERO CRD42023488270; https://www.crd.york.ac.uk/PROSPERO/view/CRD42023488270

(JMIR Rehabil Assist Technol 2025;12:e75705) doi:10.2196/75705

KEYWORDS

action observation; motor imagery; limb motor function; systematic review; meta-analysis; stroke

Introduction

Stroke represents a major cause of long-term adult disability worldwide [1]. About 60% of patients with stroke will have different degrees of limb dysfunction [2], which will not only have a significant impact on the quality of life of patients and caregivers but also increase the additional economic burden [3,4].

Action observation (AO) refers to watching human movement either via a prerecorded video or a live demonstration [5]. Motor imagery (MI) is defined as the mental simulation of a given movement that is internally reproduced in the brain without any actual motor output [6]. Both AO and MI can activate the neurons in the motor area [7-9], improve brain structure, and positively affect the motor behavior and performance of the patients [10-12], which are considered effective interventions to promote motor learning and rehabilitation [13,14]. In recent years, systematic reviews have been conducted to analyze the effectiveness of AO or MI on limb function rehabilitation of patients with stroke. Silva et al [6] synthesized data from 6

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randomized controlled trials and found that, compared to other therapies, MI is more beneficial for improving poststroke gait (walking speed) at the end of treatment (standardized mean difference [SMD]=0.44). Barclay et al [15] systematic review revealed moderate-quality evidence indicating that MI combined with other treatments improves upper extremity activity (SMD=0.66) and reduces upper extremity impairment (SMD=0.59) in adult survivors of stroke with deficits in upper extremity activity. Borges et al [16] meta-analysis demonstrated that AO improved arm function (SMD=0.39) and enhanced hand function (mean difference=2.76). Peng et al [17] meta-analysis results indicated that, compared to control treatments, AO had a moderate-to-large effect size on walking outcomes (Hedges *g*=0.779), a large effect size on gait velocity (Hedges *g*=0.990), and a moderate-to-large effect size on activities of daily function (Hedges *g*=0.728). When patients with hemiplegia after stroke cannot complete rehabilitation training, AO or MI can replace or supplement traditional rehabilitation training and become a feasible therapy.

The combined intervention of AO and MI (AO+MI) is typically defined as observing an action while simultaneously imagining the feelings associated with performing it [18]. More recently, it has been found that the brain regions involved in MI and AO overlap extensively with each other and with the regions involved in motor execution, so combined use may promote cortical activation in the premotor, rostral parietal, and somatosensory areas [19,20]. A population-independent meta-analysis revealed that AO+MI increased corticospinal excitability compared to AO and control interventions [21]. The training measures of AO+MI have been applied to healthy participants [22], Parkinson disease [23], and limb injuries [24]. A systematic review study on populations with Parkinson disease found that AO+MI can improve individuals' freezing of gait, speed, physical function, and balance [25]. Some studies [26,27] have applied AO+MI to rehabilitating limb function in patients with stroke. However, most of these studies are small sample trials, and there is heterogeneity among the results of the studies, so the validity is unclear.

The combination of AO and MI has 2 modes: synchronous and asynchronous. In synchronous mode, participants observe human movement, and at the same time, imagine themselves executing either the same or a different action. In asynchronous mode, AO happens at a different time than MI [28]. Some scholars believe synchronous AO+MI has unique advantages [5], but others argue that it is unclear whether synchronous indeed improves performance beyond asynchronous [29-31].

Therefore, our systematic review and meta-analysis aim to explore (1) whether AO+MI has more advantages in limb function rehabilitation of patients with stroke compared with routine rehabilitation, (2) whether AO+MI has an advantage in limb function rehabilitation of patients with stroke compared with their independent use, and (3) whether there are differences in limb function rehabilitation of patients with stroke between synchronous AO+MI and asynchronous AO+MI. Through this review, we discuss the feasibility and effectiveness of applying AO+MI in the rehabilitation of limb function in patients with stroke to provide evidence-based evidence for clinical practice. We hope that this systematic review can provide clinical rehabilitation therapists with some implications for alternative therapy in poststroke limb rehabilitation.

Methods

Overview

The systematic review was registered a priori to PROSPERO (CRD42023488270) and reported following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; checklist provided in Checklist 1).

Search Strategy

We systematically searched publications in the following databases in June 2025: PubMed, Cochrane Library, Web of Science, Embase, Proquest, Physiotherapy Evidence Database, and clinical trial registries: ClinicalTrials.gov and ChiCTR. Two researchers (PS and CN) developed and performed the search strategy together. The following keywords were used for the search: "Stroke," "Motor Imagery," "Action Observation," "MI," "AO," etc. The search method uses the combination of Medical Subject Headings (MeSH) and free terms, and the search strategy is shown in Table 1.

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Table . Search strategy.

Database	Search strategy
PubMed	1=(((Strokes[MeSH Terms]) OR (Cerebrovascular Accident*[MeSH Terms])) OR (CVA*[MeSH Terms])) OR (Apoplexy[MeSH Terms]) 2=(((((stroke*[Title/Abstract]) OR (post stroke[Title/Abstract])) OR (post - stroke[Title/Abstract])) OR (apoplex*[Title/Abstract])) OR (Cerebrovascular Accident*[Title/Abstract])) OR (CVA*[Title/Abstract]) 3=(((((((brain[Title/Abstract]) OR (cerebr*[Title/Abstract])) OR (cerebell*[Title/Abstract])) OR (intracerebr*[Title/Abstract])) OR (intracran*[Title/Abstract])) OR (cerebral vasc*[Title/Abstract])) OR (brain vasc*[Title/Abstract])) AND ((((((((((ischemi*[Title/Abstract]) OR (infarct*[Title/Abstract])) OR (thrombo*[Title/Abstract])) OR (emboli*[Title/Abstract])) OR (occlus*[Title/Abstract])) OR (hemorrhag*[Title/Abstract])) OR (hematoma*[Title/Abstract])) OR (bleed*[Title/Abstract])) OR (accident*[Title/Abstract])) OR (disorder*[Title/Abstract])) OR (disease*[Title/Abstract])) OR (apoplexy[Title/Abstract])) 4=((((Action observation[Title/Abstract]) OR (AO[Title/Abstract])) OR (AOT[Title/Abstract])) OR (action images[Title/Abstract])) OR (video therapy[Title/Abstract]) 5=((observ*[Title/Abstract]) OR (watch*[Title/Abstract])) AND ((((((((((action*[Title/Abstract]) OR (movement*[Title/Abstract])) OR (reach*[Title/Abstract])) OR (activit*[Title/Abstract])) OR (task*[Title/Abstract])) OR (motion*[Title/Abstract])) OR (motor[Title/Abstract])) OR (train*[Title/Abstract])) OR (perform*[Title/Abstract])) OR (gestur*[Title/Abstract])) OR (demonstrat*[Title/Abstract])) 6=(((mental[Title/Abstract]) OR (cognitive*[Title/Abstract])) OR (covert*[Title/Abstract])) AND (((((((image*[Title/Abstract]) OR (imagination[Title/Abstract])) OR (imagining[Title/Abstract])) OR (rehears*[Title/Abstract])) OR (practic*[Title/Abstract])) OR (train*[Title/Abstract])) OR (represent*[Title/Abstract])) 7=(((((motor[Title/Abstract]) OR (locomot*[Title/Abstract])) OR (visual*[Title/Abstract])) OR (motion[Title/Abstract])) OR (movement[Title/Abstract])) AND ((((image*[Title/Abstract]) OR (imagination[Title/Abstract])) OR (imagining[Title/Abstract])) OR (ideation[Title/Abstract])) 8=((((Imagery[Title/Abstract]) OR (imagination[Title/Abstract])) OR (kinesthetic imagery[Title/Abstract])) OR (Movement representation techniques[Title/Abstract])) OR (mental simulation practice[Title/Abstract]) 9=(Randomized Controlled Trial[MeSH Terms]) OR (Randomized Controlled Trials[MeSH Major Topic]) 10=((((randomized controlled trials[Title/Abstract]) OR (randomized controlled trial[Title/Abstract])) OR (RCT[Title/Abstract])) OR (RCTs[Title/Abstract])) OR (Random allocation[Title/Abstract]) 11=((control*[Title/Abstract]) OR (clinical[Title/Abstract])) AND (((trial*[Title/Abstract]) OR (stud*[Title/Abstract])) OR (experiment*[Title/Abstract])) 12=1 OR 2 OR 3 13=4 OR 5 14=6 OR 7 OR 8 15=9 OR 10 OR 11 16=12 AND 13 AND 14 AND 15

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Database	Search strategy
Cochrane Library	#1 (Strokes or Cerebrovascular Accident* or CVA* or Apoplexy): ti,ab,kw
	#2 ((brain or cerebr* or cerebell* or intracerebr* or intracran* or cerebral vasc* or brain vasc*) AND (ischemi* or infarct* or thrombo* or emboli* or occlus* or hemorrhag* or hematoma* or bleed* or accident* or disorder* or disease* or apoplexy)):ab
	#3 (Action observation or AO or AOT or action images or video therapy):ab,ti,kw
	#4 ((observ* or watch*) and (action* or movement* or reach* or activit* or task* or motion* or motor or train* or perform* or gestur* or demonstrat*)):ab
	#5 ((mental or cognitive* or covert*) and (image* or imagination or imagining or rehears* or practic* or train* or represent*)):ab,ti,kw
	#6 ((motor or locomot* or visual*or Motion or movement) and (image* or imagination or imagining or ideation)):ab
	#7 (Imagery or imagination or kinesthetic imagery or Movement representation techniques or mental simulation practice):ab,ti,kw
	#8 (randomized controlled trials or randomized controlled trial or RCT or RCTs or Random allocation):ab,ti,kw
	#9 ((control* or clinical) and (trial* or stud* or experiment*)):ab,ti,kw
	#10 #1 or #2
	#11 #3 or #4
	#12 #5 or #6 or #7
	#13 #11 and #12
	#14 #8 or #9
	#15 #10 and #13 and #14
Web of Science	#1 (TS=(stroke* or post stroke or post - stroke or apoplex* or Cerebrovascular Accident*or CVA*)) NOT (SILOID==(“PPRN”))
	#2 (TS=((brain or cerebr* or cerebell* or intracerebr* or intracran* or cerebral vasc* or brain vasc*) AND (ischemi* or infarct* or thrombo* or emboli* or occlus* or hemorrhag* or hematoma* or bleed* or accident* or disorder* or disease* or apoplexy)) and Preprint Citation Index (Exclude – Database)
	#3 (TS=(Action observation or AO or AOT or action images or video therapy)) NOT (SILOID==(“PPRN”))
	#4 (TI=((observ* or watch*) and (action* or movement* or reach* or activit* or task* or motion* or motor or train* or perform* or gestur* or demonstrat*))) NOT (SILOID==(“PPRN”))
	#5 TS=((mental or cognitive* or covert*) and (image* or imagination or imagining or rehears* or practic* or train* or represent*)) and Preprint Citation Index (Exclude – Database)
	#6 (TI=((motor or locomot* or visual*or Motion or movement)and (image* or imagination or imagining or ideation))) NOT (SILOID==(“PPRN”))
	#7 (TI=(Imagery or imagination or kinesthetic imagery or Movement representation techniques or mental simulation practice)) NOT (SILOID==(“PPRN”))
	#8 TS=(randomized controlled trials or randomized controlled trial or RCT or RCTs or Random allocation) and Preprint Citation Index (Exclude – Database)
	#9 TS=((control* or clinical) and (trial* or stud* or experiment*)) and Preprint Citation Index (Exclude – Database)
	#10 #1 or #2 and Preprint Citation Index (Exclude – Database)
	#11 #3 or #4 and Preprint Citation Index (Exclude – Database)
	#12 #5 or #6 or #7 and Preprint Citation Index (Exclude – Database)
	#13 #8 or #9 and Preprint Citation Index (Exclude – Database)
	#14 #11 and #12 and Preprint Citation Index (Exclude – Database)
	#15 #10 and #13 and #14 and Preprint Citation Index (Exclude – Database)

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Inclusion Criteria and Exclusion Criteria

The studies were selected based on the PICOS verification method (P-participants; I-intervention; C-comparison; O-outcome; and S-study design), as shown in Table 2.

Table . Selection criteria for meta-analysis.

Category	Inclusion criteria
Participants	• Adult patients with stroke (age >18 years), conscious, with motor impairment. Selection of studies was not influenced by the chronicity, severity, or type of the stroke
Intervention	• A combination of action observation and motor imagery intervention with or without routine rehabilitation. Studies were included even if the AO[a]+MI[b] intervention group was contaminated with other concurrent treatment effects, such as mirror box therapy or graded motor imagery
Comparison	• Routine physical therapy or occupational therapy. • AO or MI independently, with or without routine rehabilitation • Placebo or no therapy
Outcome	• Primary outcome: limb function. Assessment tools include but are not limited to FMA-tUE[c], ARAT[d], WMFT[e], WAQ[f], and MAL[g] • Secondary outcomes: dependence on ADL[h], measured tools include but are not limited to the Barthel Index and FIM[i]
Study design	• Clinical randomized controlled trial
Exclusion criteria	• Conference articles • The full text cannot be obtained • Non-English literature • Inability to extract outcome index data

[a]AO: action observation.

[b]MI: motor imagery.

[c]FMA-UE: Fugl-Meyer assessment.

[d]ARAT: Action Research Arm Test.

[e]WMFT: Wolf Motor Function Test.

[f]WAQ: Walking Ability Questionnaire.

[g]MAL: Motor Activity Log.

[h]ADL: activities of daily living.

[i]FIM: Functional Independence Measure.

Study Selection and Data Extraction

Two reviewers (XL and XZ) carried out the study selection independently in accordance with the eligibility criteria, and in case of disagreement, a third reviewer (PS) was asked to resolve this. Initially, all potential articles were screened according to the title, abstract, and keywords. Then the full text of all selected articles was checked, and the final selection was made based on the predefined selection criteria.

Three reviewers (PS, XL, and XZ) independently extracted data from the included studies using a predefined form. Data abstraction included study characteristics, participant characteristics, sample size, intervention measures and intervention content, duration of experiments, assessment instrument, and outcomes. Pre-post differences data were extracted directly. For studies that did not report the mean and SD of the pre-post differences, we used the Follmann et al [32] method to convert the means and SDs of the baseline and final values into the mean and SD of the pre-post differences, as described in version 3.0.2 of the Cochrane Collaboration Handbook (page 213). In case of missing or unclear data, we tried to obtain additional information from the study authors.

Risk of Bias and Certainty of the Evidence

Methodological quality assessment will be conducted independently by 2 researchers, following the Cochrane Risk of Bias tool (RoB 2.0; The Cochrane Collaboration) for assessing the risk of bias in randomized trials [33] recommended in the Cochrane Handbook [34]. If 2 reviewers (XL and XZ) cannot determine the evaluation results in the quality evaluation, a third independent reviewer (PS) makes the decision.

Two independent reviewers (XZ and XL) used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the certainty for each meta-analysis outcome. There are 4 classification levels to assess the quality of evidence: high, moderate, low, and very low. We used the GRADEpro GDT (GRADEpro GDT; Evidence Prime, Inc) to create the “Summary of findings” tables.

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Data Analysis

Statistical analysis was performed using Review Manager software (RevMan 5.3; The Cochrane Collaboration). Measurement data with the same outcome index unit were calculated using mean difference and 95% CI. SMD and 95% CI were used for different outcome index units. The difference was statistically significant at $P<.05$. For studies reporting median, we converted these values to mean and SD using the method proposed by Hozo et al [35].

Heterogeneity was tested using the chi-square test and I^2 statistic [36]. The heterogeneity was considered low when $P>.1$ and $I^2<50\%$, and the fixed-effects model estimated the combined effect size. The heterogeneity was considered significant when $P<.1$ and $I^2>50\%$, and the random effects model was adopted. When it was impossible to combine effect sizes, we performed only a descriptive analysis of the results. Subgroup analyses were conducted to explore potential sources of heterogeneity through subgroup analysis.

For interventions that could not be directly compared, a mesh meta-analysis was performed using Stata 14.1 software (StataCorp LLC). SMD and 95% CI were used to calculate the effect size of this study. The surface under the cumulative ranking curve (SUCRA) was used to predict and rank the efficacy of rehabilitation measures [37]. When there was a closed loop in the network map, the inconsistency model was used for testing. If $P>.05$, the consistency model was used for analysis. If $P\leq.05$, the source of heterogeneity should be identified and eliminated.

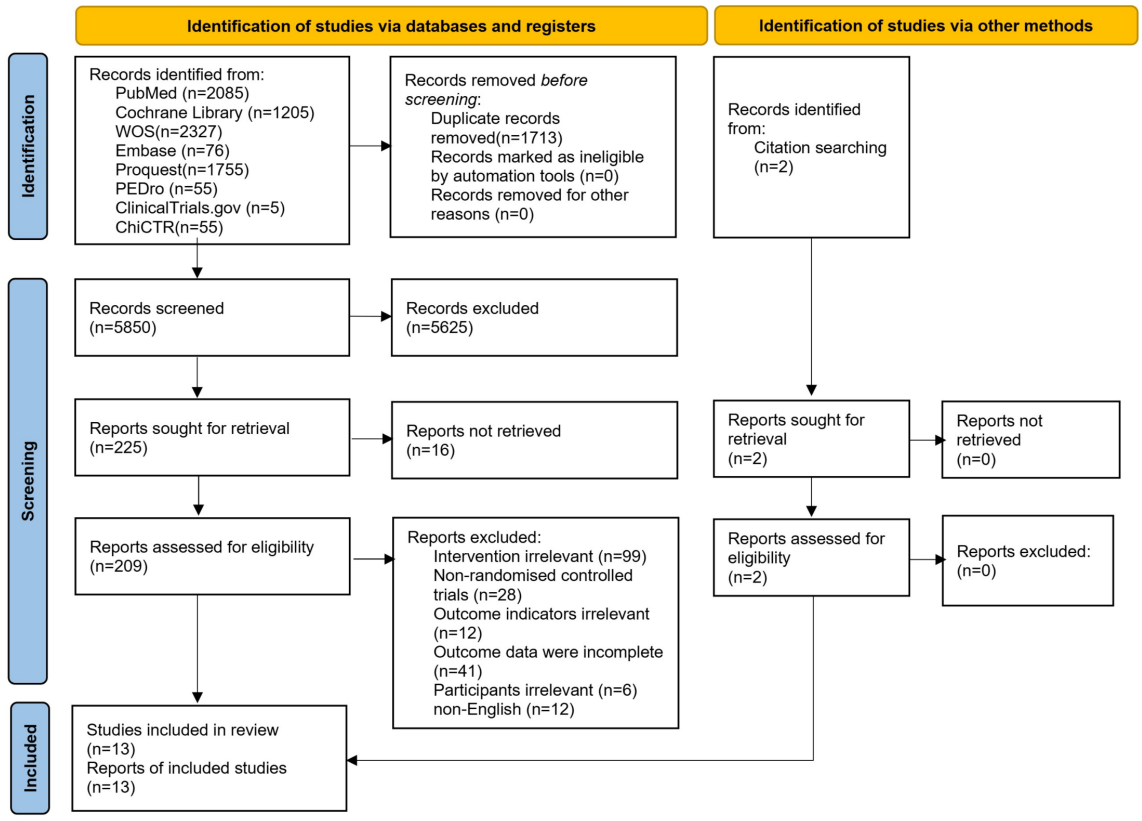
We conducted the sensitivity analysis using the one-by-one elimination method and changing the combined model. If more than 10 studies were included, the funnel plot was used to analyze publication bias.

Results

Study Selection and Characteristics

A total of 7563 results were retrieved from 8 databases, and 5850 results remained after removing duplicates. After the preliminary screening, 219 articles remained. After reading the full text and rescreening, 13 articles [38-50] were finally included, and the flowchart is shown in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of literature screening (source: adapted from Page and Levine [47], which is published under Creative Commons Attribution 4.0 International License [51]).



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

The 13 included studies [38-50] involved a total of 399 participants, and most of them were small sample trials. The participants were mainly patients with stroke with upper limb paralysis. A total of 12 studies compared AO+MI with their independent use or conventional rehabilitation [38-49]. In addition, one [50] compared synchronous and asynchronous combination models. Most of these studies had an intervention duration of about 4 weeks. Most of the primary outcome indicators were upper extremity function, while only 2 studies [39,45] assessed the lower extremity function and 1 study [49] assessed the overall motor function. The features of literature inclusion are shown in Table 3. In this table, age and stroke course were expressed as mean (SD) or median (IQR) or median (maximum, minimum).

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Table . Characteristics of included studies.

Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
Green et al 2023 [41]	United States	• ≤1 month after stroke onset paralysis of one upper limb	• EG: G1: 5; G2: 4 • CG: G3: 4; G4: 5	• EG: G1: 71.4±7.1; G2: 58.5±8.8 • CG: G3: 59.0±11.5; G4: 60.8±11.2	• EG: G1: MI[a]+audio and repetitive task practice; G2: asynchronous AO (video)+MI[b] and repetitive task practice; CG: G3: repetitive task practice; G4: conventional rehabilitation. • The intervention tasks for group 1, group 2, and group 3 included (a) wiping a table, (b) picking up a cup, (c) brushing hair, and (d) turning the page of a book. • The intervention tasks for group 4 included range of motion, weight-bearing, massage, modalities, and task-oriented training.	• During hospitalization • 20 rounds of mental practice and 10 body exercises per session, 3 times a week • 20 rounds of mental practice only, 2 times a week	• WMFT[c] • FMA-UE[d]	A significant change in FMA-UE scores and WMFT time scores in the G1 and G4, but no significant change in the G2 and G3 groups. Among all groups, no statistically significant change was found between pretest and posttest scores for the WMFT functional ability score.

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
Rungsirisilp et al 2023 [48]	Thailand	• ≥6 months after stroke onset • Upper limb paralysis	• EG: 9 • CG: 8	• EG: 61.11±7.16 • CG: 61.63±7.83	• EG: Synchronous AO+MI-based BCI[e] and physical therapy. • CG:MI-based BCI and physical therapy. • The AO+MI or MI tasks included wrist and hand extensions.	• AO+MI/MI: 40 trials per session, 3 times a week, for 4 weeks • Physical therapy: 1 to 2 days a week	• FMA-UE	Both AO+MI and MI-based BCI training improved upper limb function in patients with chronic stroke. However, the EG showed significantly greater motor gain than the CG.
Sui et al 2023 [49]	China	• 2 weeks to 3 months after stroke onset • With motor dysfunction	• EG: 50 • CG: 50	• EG: 59.50±4.80 • CG: 58.90±4.78		• AO+MI: 30 minutes per session, 5 times a week, for 4 weeks • Conventional rehabilitation: 5 hours per day, 5 days a week for 4 weeks	• FMA	After treatment, FMA in the 2 groups was significantly higher than those before treatment, with the EG showing higher scores than the CG.

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
					• EG: asynchronous AO+MI and conventional rehabilitation. • CG: conventional rehabilitation. • The AO+MI tasks included (a) steady trunk movement with a Bobath ball and (b) balance movements while sitting, standing, and reaching out to move a water cup. • The conventional rehabilitation training included good limb positioning, neuromuscular promotion techniques, such as the proprioceptive neuromuscular facilitation (PNF) technique, Rood approach, motor relearning, occupational			

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
					therapy, daily living ability training, and traditional therapy.			
Choi et al 2022 [40]	Korea	• 2 - 8 months after stroke onset • Upper limb paralysis	• EG: 22 • CG: 23	• EG: 62.68±8.54 • CG: 63.43±9.57	• EG: synchronous AO+MI and physical therapy. • CG:AO and physical therapy. • The AO+MI or MI tasks included 10 ADLs[f] (eg, using chopsticks, pen, and hand washing). • Participants selected and completed 5 meaningful activities.	• AO+MI/AO: 25 minutes per session, 5 times a week, for 8 weeks • Physical therapy: 30 minutes each day	• FMA-UE • WMFT • MAL[g]	The EG showed significant improvements in FMA-UE, WMFT, and MAL scores after the intervention compared to preintervention and the CG.
Page et al 2021 [47]	United States	• ≥3 months after stroke onset • Hand dyskinesia	• EG: 9 • CG: 9	• EG: 57.4±10 • CG: 57.8±9.8	• EG: asynchronous AO+MI and repetitive task practice. • CG: repetitive task practice. • The repetitive task practice and AO+MI tasks included 5 upper extremity activities.	• 3 times a week for 10 weeks • EG: 30 minutes of AO+MI and 15 minutes of occupational therapy • CG: 45 minutes of occupational therapy	• FMA-UE • ARAT[h] • SIS-H[i]	The EG exhibited significantly larger increases on all 3 outcome measures compared with the CG and surpassed minimal clinically important difference standards for all 3 UE outcome measures.
Nam et al 2019 [46]	Korea		• EG: 10 • CG: 10					

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
		• 1 - 6 months after stroke onset • Wrist extensor below grade 2		• EG: 61.8±14.0 • CG: 59.6±15.0	• EG: synchronous AO+MI and conventional rehabilitation. • CG: conventional rehabilitation. • The AO+MI tasks included grasping, carrying a cube, pegboard, pinching, sliding an object across a table, and holding a cup. • The conventional rehabilitation therapy included proprioceptive exercises, muscle strengthening, gait training, and paretic hand and wrist mobilization, among others.	• 5 times a week for 4 weeks • EG: 20 minutes of AO+MI and 30 minutes of conventional rehabilitation per session • CG: 50 minutes of conventional rehabilitation per session	• FMA-UE • MFT[j] • FIM[k]	Significant differences were found from baseline to postintervention assessments within both groups on FMA-UE and FIM scores, whereas there were no statistically significant differences in mean FMA-UE, MFT, and FIM scores between groups.
Kim et al 2018 [43]	Korea	• ≥3 months after stroke onset • Brunnstrom stage ≥3	• EG: 7 • CG: 7	• EG: 52 (49–74) • CG: 66 (49–72)			• JTHFT[l] • MAL	

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
					• EG: asynchronous AO+MI. • Modified constraint-induced motion. • CG: listen to music. • Modified constraint-induced motion. • The AO+MI task was to visualize the use of a spoon to eat soup with the affected hand. • Modified constraint-induced motion included 5 to 6 tasks, repetitive ADL tasks (eg, brushing teeth, drinking from a cup, making a phone call).	• AO+MI: listen to music: 10 minutes per session, 5 times a week for 2 weeks • Modified restraint-induced movement for more than 6 hours every day		Both groups showed significant improvement in the MAL scores. The EG also showed significant improvement in the JTHFT scores. The improvements in the JTHFT and MAL scores were significantly greater in the EG compared to the CG.
Sun et al 2016 [50]	China	• ≤2 months after stroke onset • Hemiplegia of the right upper limb	• EG: 5 • CG: 5	• 59.8±4.94		• 15 rounds AO+MI each time, 6 times a day, 7 days a week for 4 weeks	• FMA-UE • PST[m]	The FMA and PST scores achieved with the synchronous AO+MI group were also significantly higher than those achieved with the asynchronous group.

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
					• EG: synchronous AO+MI and conventional rehabilitation. • CG: asynchronous AO+MI and conventional rehabilitation. • The AO+MI task was having the participant use his (or her) right arm to insert a peg into the hole on a wooden board and then to remove it from the board.			
Assis et al 2016 [38]	Brazil	• ≥12 months after stroke onset • Grade 2 spasm at most	• EG: 4 • CG: 4	• EG: 50.5 • CG: 59.5	• EG: asynchronous AO+MI based on augmented reality and conventional rehabilitation. • CG: conventional rehabilitation. • The AO+MI tasks included shoulder abduction, shoulder flexion, and shoulder horizontal flexion.	• 60 minutes per session, once a week, for 4 weeks	• FMA-UE	At a significance level of 5%, Fugl-Meyer scores suggested a trend for greater upper-limb motor improvement in the EG than in the CG.
Lee et al 2013 [44]	Korea		• EG: 8 • CG: 7					

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
		• ≥6 months after stroke onset • Brunnstrom stage 5		• EG: 63±3.7 • CG: 60±5.9	• EG: synchronous AO+MI. • CG: sham control. • The AO+MI task was the action of stretching out the right hand to pick up a cup, bringing the cup to the mouth in order to touch the mouth, and then returning the cup to its initial position.	• 10 minutes per session, 5 times a week, for 3 weeks	• Number of drinking motions in each period	The drinking behavior functions for the EG showed a significant difference before and after the intervention, and the postintervention performance of the EG was superior to that of the CG.
Cho et al 2013 [39]	Korea	• ≥6 months after stroke onset • Ability to walk >10 m independently	• EG: 15 • CG: 13	• EG: 53.93±12.60 • CG: 53.85±12.44	• EG: synchronous AO+MI and gait training. • CG: gait training. • The AO+MI task was the normal gait movement.	• 3 times a week, for 6 weeks • EG:15 minutes of AO+MI and 30 minutes of gait training • CG: 30 minutes of gait training	• FMA-LE[n] • TUG[o] • FRT[p]	All measurements improved significantly compared with baseline values in the EG. In the CG, there were significant improvements in all parameters except the Fugl-Meyer assessment.
Lee et al 2011 [45]	Korea	• ≥6 months after stroke onset • Ability to walk >10 m independently	• EG: 13 • CG: 11	• EG: 60.7±7.35 • CG: 61.9±11.26	• EG: asynchronous AO+MI and gait training. • CG: gait training. • The AO+MI task was the normal gait movement.	• 3 times a week, for 6 weeks • EG: 30 minutes of AO+MI and 30 minutes of gait training • CG: 30 minutes of gait training	• Gait speed	The gait speed among the temporal parameters had significantly increased in the EG, compared to preintervention.
Ietswaart et al 2011 [42]	United Kingdom							

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Study	Country	Participants	Sample size (n)	Age (years)	Intervention	Duration of experiment	Outcomes measure	Summary of results
		• 1 - 6 months after stroke onset • Persistent arm movement weakness	• EG: 39 • CG: G1:31; G2: 32	• EG: 69.3±10.8 • CG: G1: 68.6±16.3; G2: 64.4±15.9	• EG: asynchronous AO+MI. • CG: G2: attention-placebo control intervention. • G2: sham control. • The AO+MI tasks included a variety of elementary movements (eg, opening and closing of the hand), goal-directed movements (eg, reaching), and activities of daily living (eg, doing buttons on a shirt). • Attention-placebo refers to cognitive training that does not involve motor imagery, including sustained attention, visualization, memory demands, visual illusions, and inhibition.	• EG: 30 minutes of AO+MI, 10 minutes of active MI, and 5 minutes of a certain implicit form of MI per session, 3 times a week, for 4 weeks • G2: 25 minutes of active visual and sensory imagery, 10 minutes of controlling for cognitive inhibition, 5 minutes of watching optical illusions of motion, and 5 minutes of a visual imagery activity per session, 3 times a week, for 4 weeks	• ARAT • Grip strength Barthel Index	Recovery between baseline and outcome assessment was evident on all outcome variables. However, no differences between the 3 groups were found on the ARAT scores, grip strength, and Barthel Index.

[a]MI: motor imagery.

[b]AO+MI: action observation combined with motor imagery.

[c]WMFT: Wolf Motor Function Test.

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[d]FMA-UE: Fugl-Meyer assessment of upper extremity.
[e]BCI: brain–computer interface.
[f]ADL: activities of daily living.
[g]MAL: Motor Activity Log.
[h]ARAT: Action Research Arm Test.
[i]SIS-H: hand subscale of the Stroke Impact Scale.
[j]MFT: manual function test.
[k]FIM: Functional Independence Measure.
[l]JTHFT: Jebsen-Taylor hand function test.
[m]PST: pinch strength test.
[n]FMA-LE: Fugl-Meyer assessment lower extremity.
[o]TUG: Timed Up and Go Test.
[p]FRT: Functional Reaching Test.

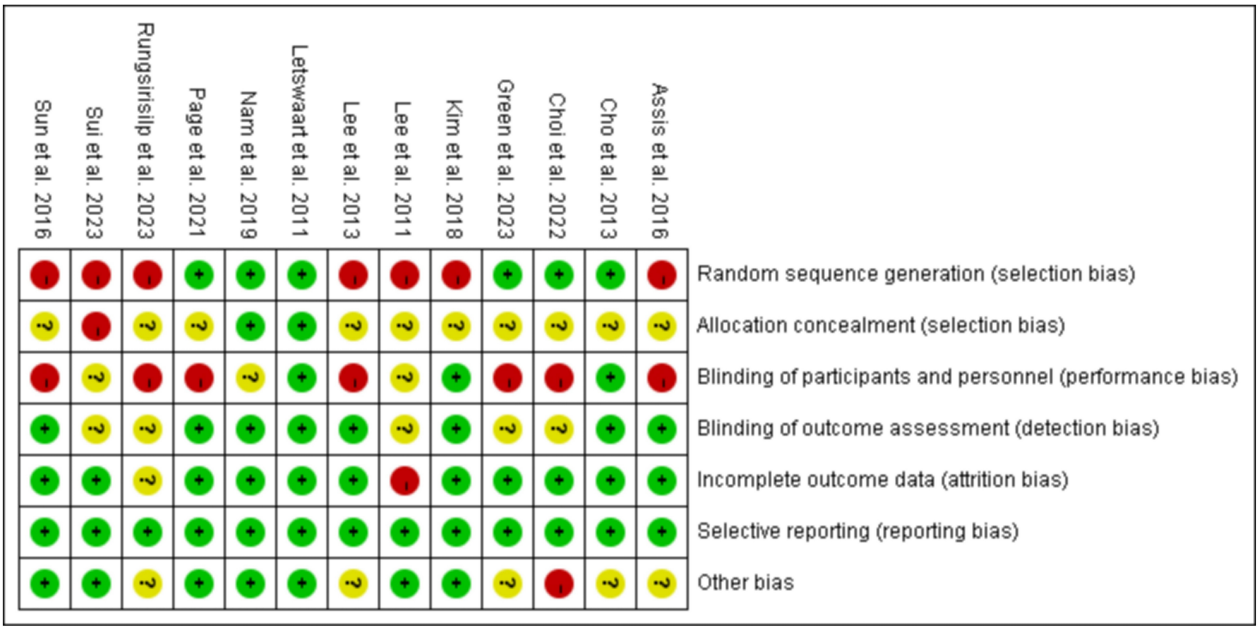
Risk of Bias and Certainty of the Evidence

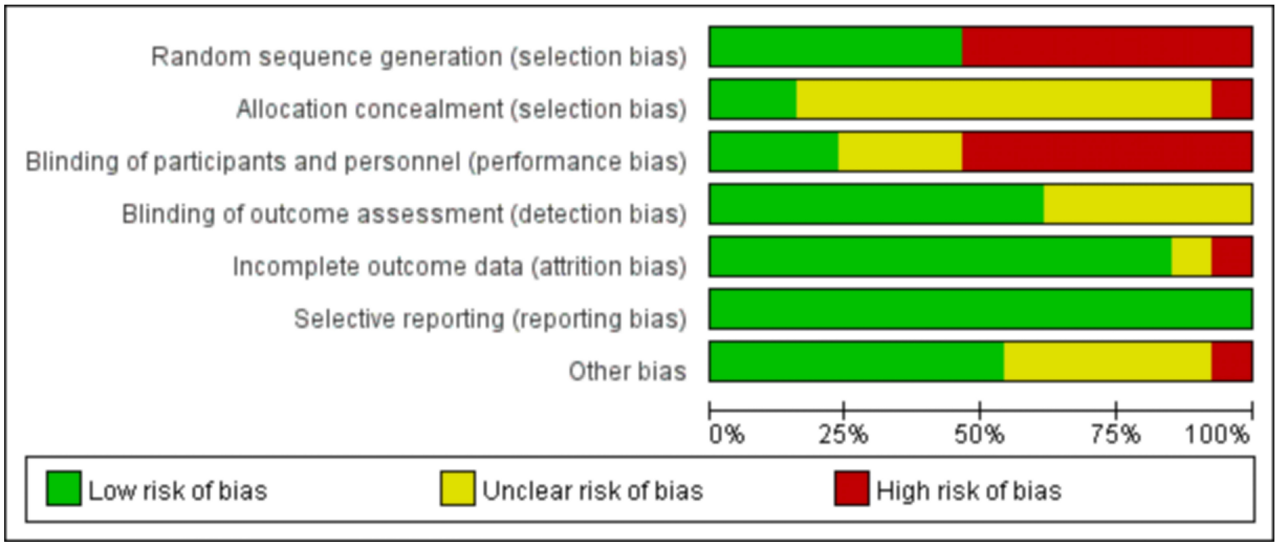
The RoB 2.0 tool was used to evaluate literature quality. All 13 randomized controlled studies were included, of which 6 [39-42,46,47] had a low risk of selection bias, 2 [42,46] used assignment concealment, 3 [39,42,43] blinded participants and implementors, 8 [38,39,42-44,46,47,50] blinded outcome evaluators, only one [48] outcome measure was incomplete, all studies reported full results, and 7 [42,43,45-47,49,50] had a low risk of other bias. The final evaluation results are shown in Figure 2.

We assessed the certainty of evidence for the 7 outcomes in the meta-analysis. The overall certainty of evidence was rated as low to very low. The GRADE results are shown in Table 4.

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Figure 2. Risk of bias graph [38-50].





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Table . Summary of findings.

Certainly assessment							No. of patients		Effect	
No. of studies	Study design	Risk of bias	Inconsistency	Indirect evidence	Imprecision	Others	Experimental	Control	Absolute (95% CI)	Certainty
Overall motor function (AO+MI[a] vs routine)										
1	RCTs[b]	Serious[c]	Not serious	Not serious	Serious[d]	None	50	50	SMD[e] 3.22 higher (1.55 to 4.89 higher)	⊕⊕ Low
Upper extremity function (AO+MI vs routine)										
7	RCTs	Not serious	Serious[f]	Serious[g]	Serious[d]	None	81	76	SMD 1.02 higher (0.28 to 1.75 higher)	⊕ Very low
Self-care ability (AO+MI vs routine)										
2	RCTs	Not serious	Not serious	Not serious	Very Serious[h]	None	49	42	SMD 0.06 higher (0.35 lower to 0.47 higher)	⊕⊕ Low
Lower extremity function (AO+MI vs routine)										
2	RCTs	Serious[c]	Not serious	Not serious	Serious[d]	None	28	24	SMD 6.31 higher (4.75 to 7.87 higher)	⊕⊕ Low
Upper extremity function (AO+MI vs MI)										
2	RCTs	Serious[c]	Not serious	Not serious	Serious[d]	None	13	13	SMD 0.97 higher (0.13 to 1.80 higher)	⊕⊕ Low
Upper extremity function (AO+MI vs AO)										
1	RCTs	Serious[c]	Not serious	Not serious	Serious[d]	None	22	23	SMD 1.92 higher (0.66 to 3.18 higher)	⊕⊕ Low
Upper extremity function (asynchronous vs synchronous)										
9	RCTs	Serious[c]	Not serious	Serious[i]	Very Serious[h]	None	93	22	SMD 1.00 higher (1.33 lower to 3.33 higher)	⊕ Very low

[a]AO+MI: AO combined with MI.

[b]RCT: randomized controlled trial.

[c]$50\% < I^2 < 75\%$.

[d]One study used surrogate endpoint measures to replace the patient's important outcome of interest.

[e]SMD: standard mean difference.

[f]The sample size was less than 100.

[g]The 95% CI crosses the equivalence line and the sample size is less than 100.

[h]Most of the information (two-thirds) came from moderate bias.

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[i]Network meta-analysis.

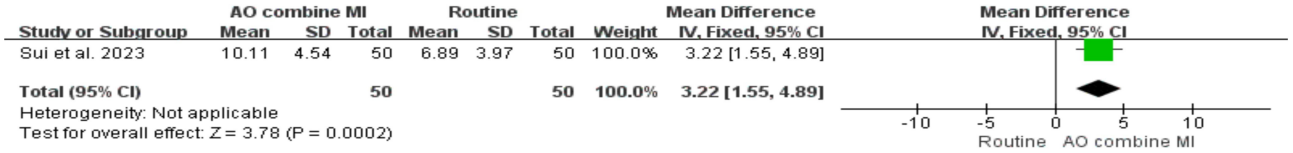
Outcomes

Comparison of AO+MI and Routine Rehabilitation

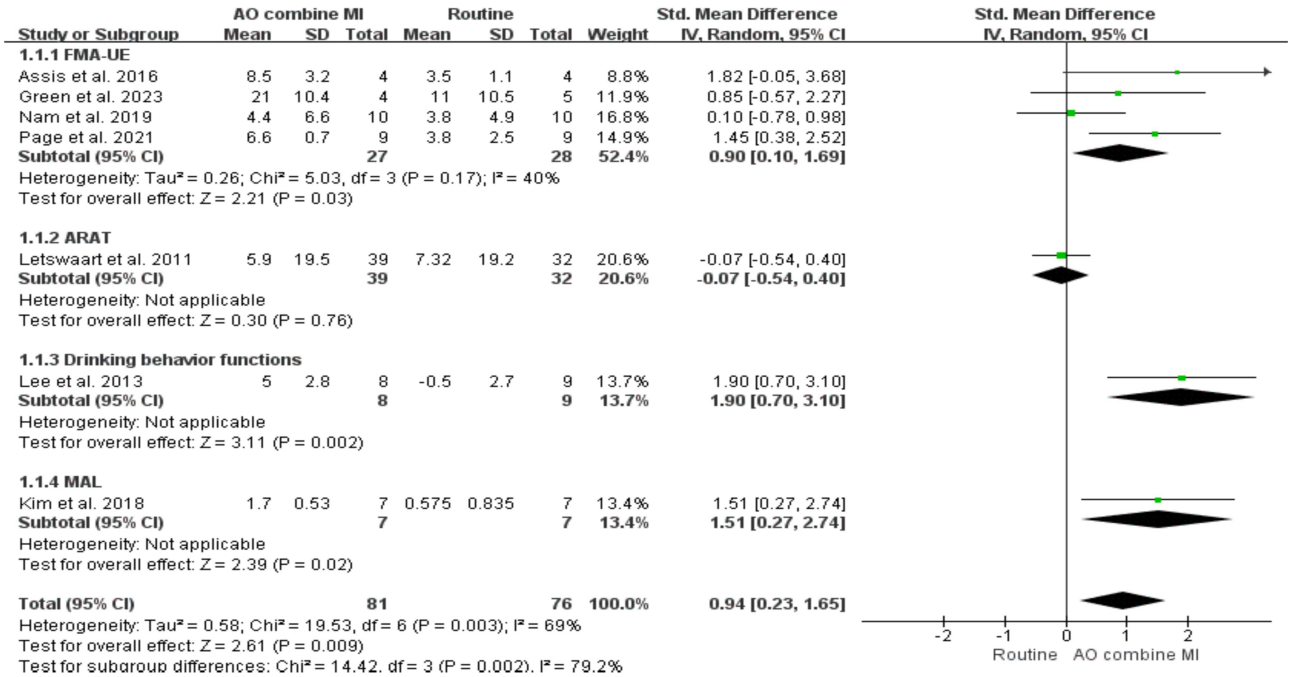
A total of 10 studies compared the effects of AO+MI and routine rehabilitation on patients' motor function [38,39,41,42,44-47,49,50]. One study [49] evaluated the impact of AO+MI on overall motor function, demonstrating that AO+MI enhanced Fugl-Meyer assessment (FMA) scores versus routine rehabilitation (SMD=3.22, 95% CI 1.55 - 4.89; *P*<.001), as shown in Figure 3A.

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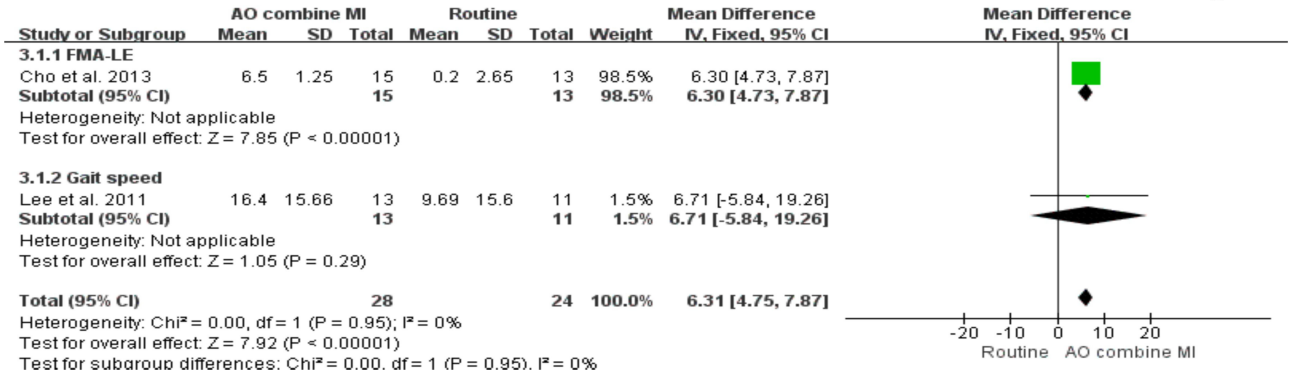
Figure 3. The action observation combined with motor imagery therapy versus conventional physical therapy for (A) overall motor function, (B) upper extremity motor function, (C) lower extremity motor function, and (D) activities of daily living [38,39,41-47,49].



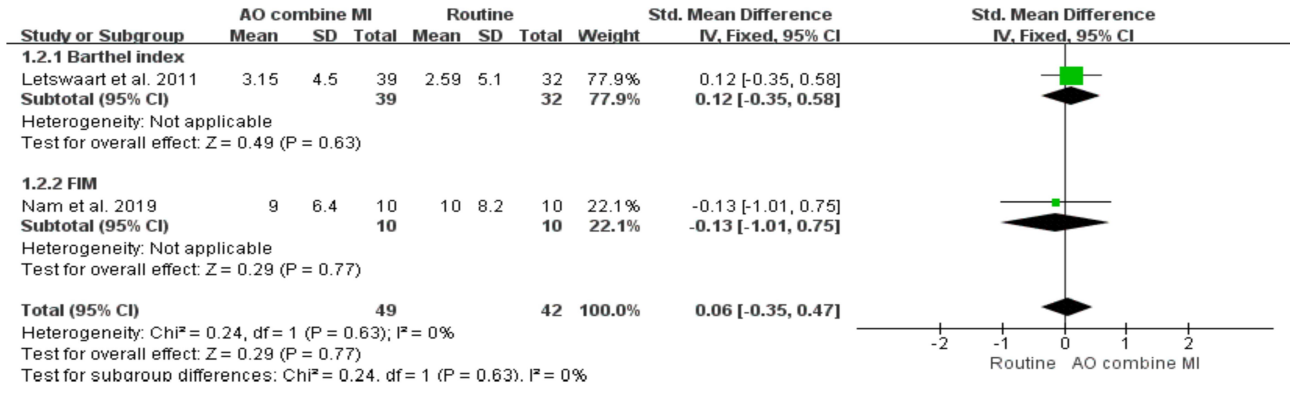
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A total of 7 studies [38,40,41,46-48,50] assessed the effect of AO+MI on upper extremity motor function and were included in the meta-analysis. Among these 7 studies, 4 studies [38,41,46,47] used Fugl-Meyer assessment of upper extremity (FMA-UE) as the main evaluation index to evaluate the upper extremity motor function of patients, one study [42] used Action Research Arm Test (ARAT), one study [43] used Motor Activity Log (MAL), and one study [44] used the data of 1-minute drinking movements of patients. A random effects model was used as the studies had high heterogeneity (P=.002, I^2=71%). The results showed a significant difference between the 2 groups (SMD=1.02, 95% CI 0.28 - 1.75; P=.007), as shown in Figure 3B.

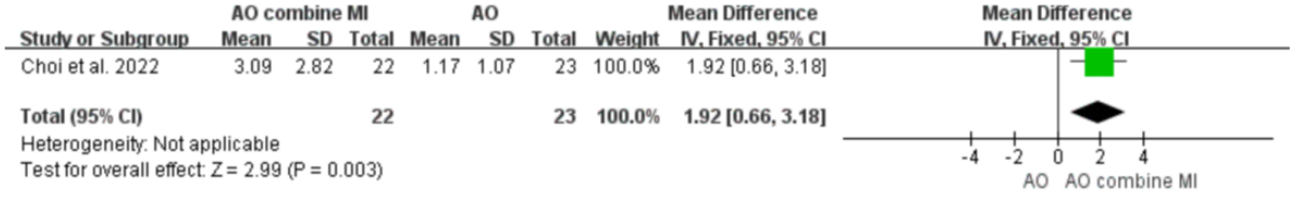
A total of 2 studies [39,45] evaluated the effects on lower extremity motor function, with one study [39] using the Fugl-Meyer assessment lower extremity (FMA-LE) as the evaluation index and one study [45] using gait speed. Analysis using a fixed-effects model (P=0.95, I^2=0%) and meta-analysis results showed a significant difference between the 2 groups (SMD=6.31, 95% CI 4.75 - 7.87; P<.001), as shown in Figure 3C.

A total of 2 studies [42,46] evaluated the effects on activities of daily living (ADL), with one study [42] using the Barthel index as the evaluation index and one study [46] using the Functional Independence Measure (FIM). Analysis using a fixed-effects model (P=0.63, I^2=0%) and meta-analysis results showed no statistically significant difference in ADL between the 2 groups (SMD=0.06, 95% Cl −0.35 to 0.47; P=.77), as shown in Figure 3D.

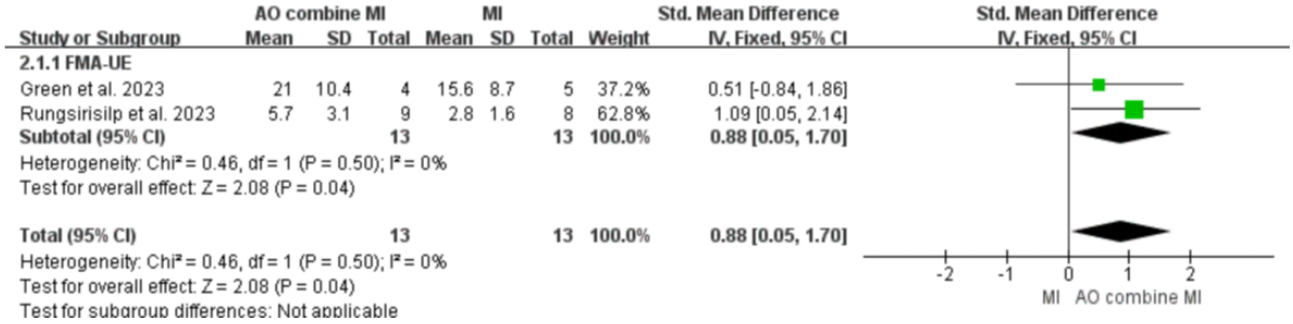
Comparison of AO+MI and Their Independent Use

A total of 3 studies [40,41,48] compared the effects of AO+MI and their independent use on patients' motor function. One study [40] compared the effects of AO+MI and AO on patients' upper extremity function. The results demonstrated a statistically significant improvement in FMA-UE scores with AO+MI relative to AO alone (SMD=1.92, 95% CI 0.66 - 3.81; P=.003), as shown in Figure 4A. Two studies [41,48] compared the effects of AO+MI and MI independently on patients' upper extremity function; both used FMA-UE as an evaluation index. A meta-analysis was performed using a fixed-effects model (P=.69, I^2=0%), and results showed that AO+MI could promote the recovery of upper extremity function in patients compared with MI independently (SMD=0.97, 95% Cl 0.13 - 1.80; P=.02), as shown in Figure 4B.

Figure 4. A, Action observation combined with motor imagery versus action observation independently for upper extremity function and B, AO+MI versus motor imagery independently for upper extremity function [40,41,48]. AO: action observation, AO+MI: Action observation combined with motor imagery, FMA-UE: Fugl-Meyer assessment of upper extremity, MI: motor imagery.



A



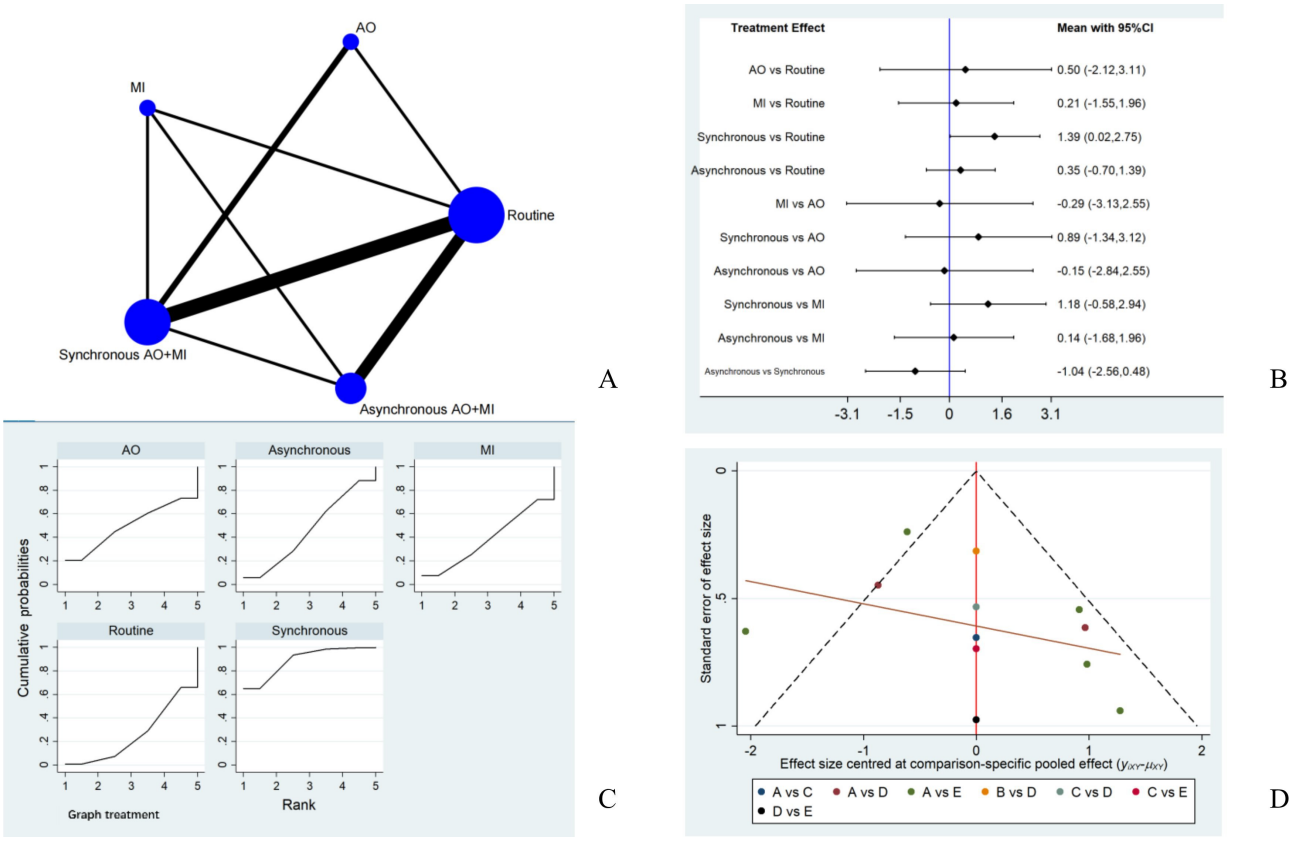
B

Comparison of Synchronous Mode and Asynchronous Mode

Of the studies included in this review, 7 studies [38,41-43,45,47,49] used the asynchronous AO+MI mode, 5 studies [39,40,44,46,48] used synchronous mode, and one study [50] directly compared the therapeutic effects of synchronous and asynchronous combined mode. A total of 10 studies [38,40-44,46-48,50] were included in the network meta-analysis to compare the effects of the 2 combination interventions on upper extremity motor function across 5 rehabilitation measures: routine rehabilitation, AO, MI, synchronous AO+MI and asynchronous AO+MI; the network diagram is shown in Figure 5A. FMA-UE, ARAT, MAL, and 1-minute drinking movements of patients were used as indices to evaluate extremity function rehabilitation.

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Figure 5. (A) The network diagram. (B) Forest plot of the network meta-analysis for upper extremity function. (C) Surface under the cumulative ranking curve analyzes the sort diagram. (D) The comparison-correction funnel plot. AO: action observation; AO+MI: action observation combined with motor imagery; MI: motor imagery.



The global inconsistency test revealed no inconsistency between the studies (χ^2df=1.53, *P*=.67). The results of the node-splitting analysis demonstrated local inconsistency between synchronous mode and asynchronous mode (*P*=.02). The forest map results showed no statistically significant difference between synchronous mode and asynchronous mode effects on upper extremity function rehabilitation of patients after stroke (SMD=−1.04, 95% Cl −2.56 to 0.48), as shown in Figure 5B. The results of the SUCRA analysis showed that the interventions most likely to promote the rehabilitation of patients' upper extremity function were asynchronous (89.3), synchronous (46.4), AO (49.9), MI (38.6), and routine rehabilitation (25.8), as shown in Figure 5C.

Publication Bias

The analysis of the effect index for limb motor function was conducted, generating a funnel plot. The results showed good symmetry, indicating that publication bias was not noticeable. The comparison-correction funnel plot is shown in Figure 5D.

Discussion

Principal Findings

This study review aimed to synthesize the evidence on the effects of AO+MI on limb functional rehabilitation in patients after stroke through a systematic review and meta-analysis. We included 13 trials with 399 participants in this review.

The meta-analysis showed that compared with routine rehabilitation therapy, AO+MI could improve limb motor function in patients with stroke. And compared with their independent use, AO+MI could improve upper extremity motor function in patients with stroke. These findings are consistent with the results of a meta-analysis by Chye et al [21] that included all populations (encompassing patients with Parkinson disease, older individuals, children, and healthy adults et al). Relevant and experience-dependent practice encourages the brain to create and reorganize functionally appropriate neural connections, which is pivotal for neurorehabilitation following stroke [52]. A related functional magnetic resonance imaging study [53] has revealed that when individuals engage in AO+MI, blood oxygen level-dependent (BOLD) signals increase and become more widespread in brain regions involved in motor execution. Electroencephalography investigation demonstrates that during AO+MI, individuals exhibit significantly decreased power spectral densities in the alpha and beta bands, indicating heightened activity in the primary sensorimotor cortices [54]. For patients with stroke who have difficulty performing actual movements, the increased neural activity during AO+MI may support repeated Hebbian modulation of intracortical and subcortical excitatory mechanisms through synaptic plasticity, producing effects similar to those of physical practice [21]. This may be the reason why AO+MI improves motor function in patients with stroke. However, our meta-analysis showed that AO+MI did not improve ADL in patients after stroke compared with routine rehabilitation. A potential explanation is that poststroke ADL improvement requires a longer intervention duration, while the 2 studies [42,46] included in this meta-analysis featured relatively short intervention periods (2 - 4 weeks).

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Although the only direct evidence suggests that synchronous may enhance motor function in patients with stroke compared to asynchronous [50], the network meta-analysis results in this review indicate no significant difference between synchronous and asynchronous AO+MI in improving upper extremity function in patients with stroke. The potential reason for the inconsistency between direct evidence and meta-analysis results may stem from differences among participants. As Eaves and colleagues point out [5], synchronous AO+MI may impose greater cognitive load compared to asynchronous AO+MI. This could result in the synchronous mode being overly demanding for certain patient populations or rehabilitation stages. In such cases, asynchronous intervention might be more advantageous. Consequently, variations in key characteristics among participants across included studies—such as severity of neurological deficits and baseline cognitive levels—may modulate the boundaries of effectiveness between synchronous and asynchronous intervention modalities. Therefore, future studies with more direct evidence are needed to compare the effects of these 2 modalities on poststroke recovery. In addition, asynchronous AO+MI does not rule out the possibility of participants spontaneously performing MI during the AO component of AO then MI. This may result in some studies using asynchronous mode inadvertently including elements of synchronous mode, which might also explain why no significant difference in effectiveness has been observed between the 2 combined approaches.

This review evaluated the included studies strictly according to the relevant measures in the Cochrane 5.1.0 manual for randomized controlled trial quality assessment. Among the 13 studies [38-50] included, only one study [42] had a low risk of bias in all 7 aspects of bias analysis, while the risk of bias in the other studies mainly focused on selection bias and implementation bias. Although most studies claim randomization, only half clearly state the correct way to generate random sequences. In addition, most studies did not report how the randomization scheme was assigned to hide, which led to high-risk outcomes in both evaluations. Most of the studies included in this review were not blinded, which may be due to the changes in rehabilitation measures and the limitations of human resources, material resources, and venues, making it challenging to perform double blindness. The overall quality of the evidence presented in this review, as assessed by the GRADE approach, was low or very low for all comparisons. The main limitations were imprecision due to very small sample sizes, risk of bias, and inconsistency.

In addition to the low quality of the included articles, this review has several limitations. First, the studies we included may exhibit a certain degree of heterogeneity in terms of interventions. In some studies, the effects of AO +MI might be influenced by other concurrent therapeutic approaches, such as mirror therapy or graded motor imagery. For instance, in the study by Ietswaart et al [42], in addition to the 30-minute AO+MI intervention, each session also included an additional 10 minutes of active motor imagery and 5 minutes of a certain implicit form of motor imagery activity. This multicomponent intervention approach may mean that the observed therapeutic effects cannot be entirely attributed to pure AO+MI, potentially affecting the results of this study in the overall analysis. Second, there are a few included articles, and most are small sample studies, thus limiting the reliability of the research conclusions. Third, we only searched and reviewed articles in English; publications in other languages may have been missed. Fourth, the absence of standardized intervention protocols and variation in outcome assessment tools across the included studies complicates direct comparisons and meaningful synthesis of the findings. In addition, significant heterogeneity was observed in the meta-analysis results. Consequently, the results should be interpreted cautiously.

Dorsch et al 2024 [55] meta-analysis explored the effect of adding nonstimulation-based priming prior to task-specific practice on activity and motor impairment outcomes compared with task-specific practice alone in stroke rehabilitation, searching for manuscripts up to March 2019. This review included 2 trials investigating the impact of AO+MI on activity outcomes in patients after stroke, and the results did not show a significant improvement effect of AO+MI. The reason for the inconsistency with our findings might be that Dorsch et al [55] compared the postintervention scores between the conventional group and the AO+MI group, whereas our study compared the pre-post differences of the 2 groups.

Lin et al [56] systematic review included 9 studies investigating the effects of AO+MI on upper limb function in patients with stroke, and the results demonstrated that AO+MI significantly improves upper limb function in participants. Our study differs from Lin et al [56] review in several key aspects. First, our study adopted broader inclusion criteria, examining not only upper extremity function but also lower extremity function, overall motor function, and activities of daily living, thereby addressing a wider range of clinical outcomes. As a result, the set of included studies differs somewhat from that in Lin et al [56] review. Second, this study conducted separate meta-analyses according to the type of control group (conventional intervention, MI alone, or AO alone), thereby minimizing heterogeneity introduced by differences in control conditions, enhancing the precision of the findings, and offering more specific guidance for clinical practice. In addition, this study incorporated a network meta-analysis to compare the effectiveness of 2 AO+MI integration modes—synchronous versus asynchronous—on upper extremity function after stroke. Therefore, although there are overlapping findings, this study and Lin et al [56] review can complement each other and reinforce key conclusions, serving the valuable purpose of replication and strengthening the evidence base.

Conclusions

This systematic review and meta-analysis examined the effects of AO+MI on motor function in patients with stroke. Our results found that AO+MI can improve the motor function compared to routine rehabilitation, AO, or MI. Furthermore, no conclusive evidence supports AO+MI's efficacy for improving ADL, nor demonstrates differential effects between synchronous and asynchronous application modes on poststroke limb function. The quality of GRADE - based evidence in this review varied from low to very low, due to the high risk of bias and small sample sizes. Consequently, large-scale randomized controlled

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trials with rigorous methodology are imperative to establish definitive clinical recommendations.

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Authors' Contributions

NC and SP conceived the study and developed the protocol. SP and NC developed and performed the search strategy together. SP, LX, and ZX carried out the study selection, data extraction, and quality assessment. HM, LX, and ZX performed data analysis. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Checklist 1
PRISMA checklist.
[DOCX File, 30 KB - rehab_v12i1e75705_app1.docx]

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Abbreviations

ADL: activities of daily living
AO: action observation
AO+MI: action observation combined with motor imagery
ARAT: Action Research Arm Test
BOLD: blood oxygen level dependent
FIM: Functional Independence Measure
FMA: Fugl-Meyer assessment
FMA-LE: Fugl-Meyer assessment lower extremity

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FMA-UE: Fugl-Meyer assessment of upper extremity
GRADE: Grading of Recommendations Assessment, Development and Evaluation
MAL: Motor Activity Log
MeSH: Medical Subject Headings
MI: motor imagery
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RoB: Cochrane Risk of Bias tool
SMD: standardized mean difference
SUCRA: surface under the cumulative ranking curve

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Essential Requirements and Relevant Technologies for Load-Bearing 3D-Printed Transtibial Prosthetic Sockets and Their Components: State-of-the-Art Review

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Abstract

Background: The manufacture of load-bearing prosthetic lower limb sockets is traditionally reliant on skilled technicians working with qualified clinicians to create bespoke solutions. While this approach is effective and, in some situations, necessary, the appeal of a sustainable, efficient, and digitalized production solution cannot be ignored. The focus of additive manufacturing (AM) is typically on low-weight-bearing prostheses, which can be misleading for clinics attempting to adopt AM solutions for clientele with weight-bearing or activity-level needs.

Objective: This review aims to offer readers a way to approach AM for load-bearing requirements as opposed to non–load-bearing counterparts. The use cases of AM for the production of load-bearing transtibial prosthetic sockets and components are reviewed to highlight current trends, protocols, and standings.

Methods: By reviewing publications from the past 25 years, this state-of-the-art review highlights the key requirements and technologies relevant for load-bearing transtibial prosthetic sockets specifically.

Results: The most commonly used AM solutions for commercial use, such as selective laser sintering and binder jetting through Multi Jet Fusion, are outlined. As these solutions are most often paired with the structural testing standard International Organization for Standardization 10328, their relevance for evaluating the strength and durability of lower limb sockets is also discussed. Clinician and technician experiences of digitalized ways of working within the prosthetic industry for load-bearing applications are outlined.

Conclusions: Observations of adoption barriers of AM solutions are brought to light, focusing on clinician and technician education, skill set, exposure to innovative technologies, and trust in the regulation of digital processes in a clinical and technical environment.

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KEYWORDS

load-bearing; prosthesis; transtibial; additive manufacturing; digitalization; 3D printing; prosthetic socket

Introduction

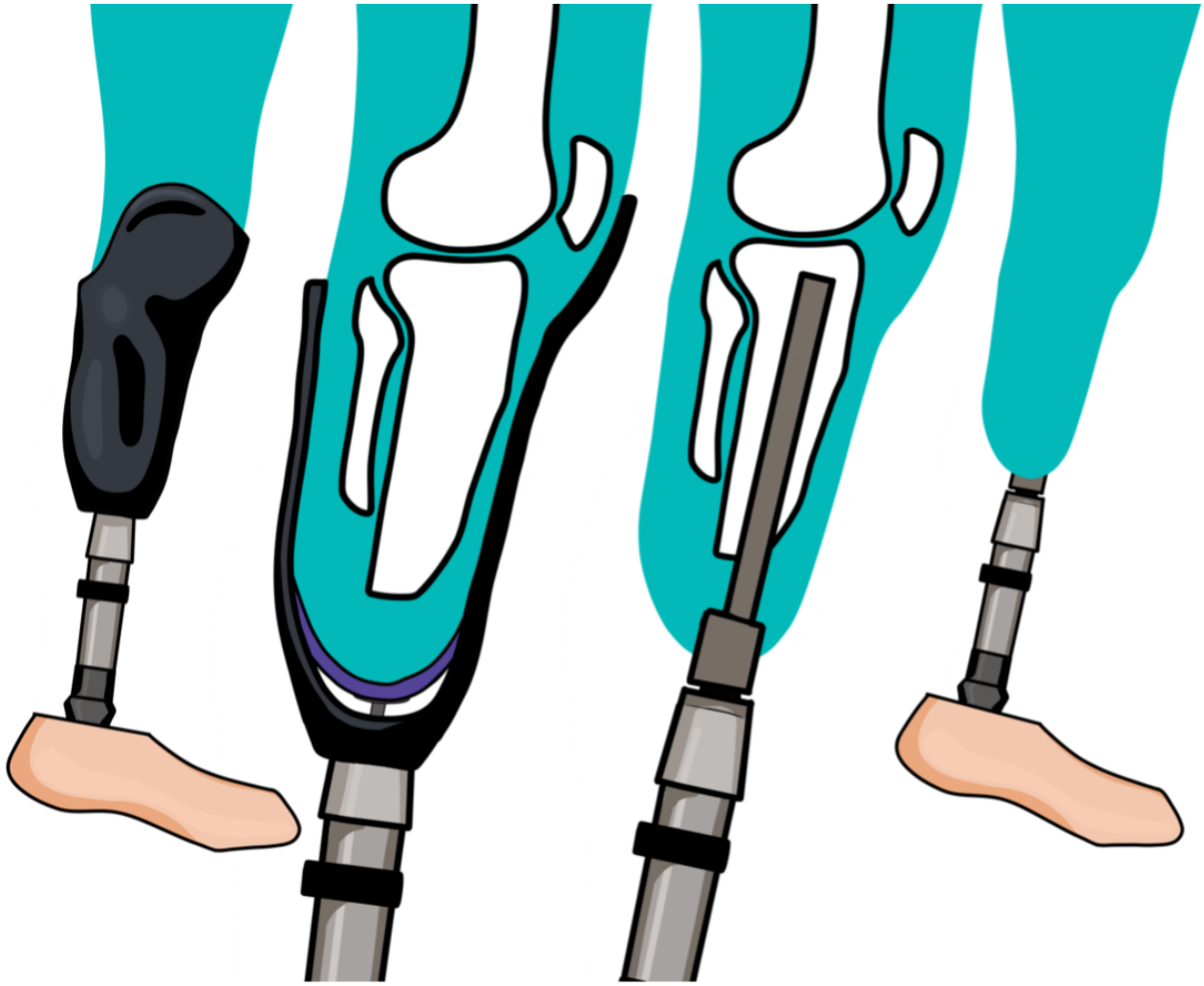
Background

A prosthesis, or prosthetic device, acts as a replacement for a lost or missing limb or body part, with functionality as a key added value [1]. The function of a prosthesis can range from basic motion to combined rotation and hinging. The device may contain technological parts, which can rotate, stabilize, and compress. These parts can be manipulated through the interpretation of electronic pulses in the body recorded from microprocessors [2,3]. With many components making up the assembly of a prosthesis, there must be a connection point between the existing limb and the artificial device to provide functionality. In the case of a lower limb prosthesis, this connection can be made through the implementation of an osseointegrated implant or using an external component known as a socket [4]. Depending on the degree of limb loss, the attachment of a prosthesis can be made above the knee (transfemoral) or below the knee (transtibial). The focus of this review is relevant to the implementation of transtibial external prosthetic sockets specifically. Figure 1 provides a visual

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comparison of an external transtibial prosthesis using a socket component and an implanted osseointegrated transtibial prosthesis.

Figure 1. Transtibial prosthetic devices, observing an external approach using a socket component (left) and an internal osseointegrated approach (right).



When manufacturing transtibial sockets, a traditional, skill-based workflow has determined shape, weight, function, and fit for the end user [5]. The procedure involves a hands-on approach, convenient for control and accuracy for the clinician and technician. However, this approach has been proven to be costly, wasteful, and time-consuming for both material and clinical time usage [6]. For these reasons, the manufacturing workflows have been evolving with digitalization and technological advances [7].

The exploration of additive manufacturing (AM) processes is currently showing success for non–load-bearing prosthetic devices. There are a variety of solutions available for the AM of upper limb prostheses, each using a variety of materials [8]. With the demand present in low-income countries, there have been volunteer assistive device designers actively contributing to the AM of prosthetic devices in the past few years [9].

For load-bearing devices, however, validating the efficacy of 3D-printed devices remains a challenge, compounded by the customized nature of each prosthesis. A variety of AM processes have been used to create load-bearing transtibial prosthetic sockets, with some methods bearing more strength and durability than others [10,11]. In Kim et al's [12] review of 1023 studies on this topic, the considerable amount of heterogeneity between studies (in terms of materials and alignment used) meant that the absolute values for failure could not be established for AM. As such, these values also could not be compared to traditionally made devices. Kim et al [12] highlight that the reviewed studies provide limited evidence for AM used in a clinical setting, and those that do so have only evaluated the durability of these prostheses for a period of 2-6 weeks [12].

As digitalization becomes more prevalent, positive effects, such as time efficiency, improved patient care, and sustainability have been noted [13]. Positive convergence between prosthetics and orthotics (P&O) and a variety of industries can develop and progress new and innovative technological solutions. This has the potential to evolve our society from a global cultural perspective and improve the quality of life for the end user [14]. However, with traditional methodologies still being at the forefront of education and day-to-day workflows, it is difficult for clinicians and technicians to value the benefits of 3D printing in their roles [15].

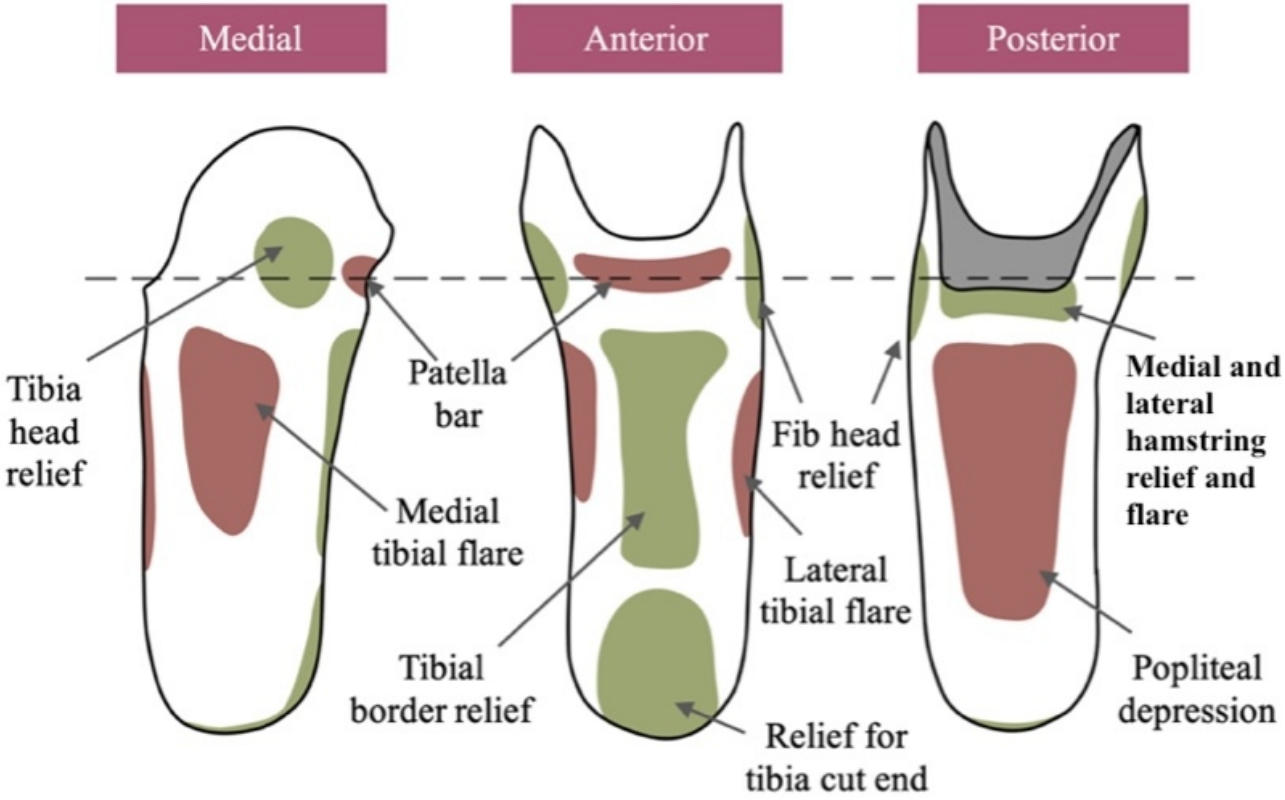
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Traditional Manufacturing of Transtibial Prosthetic Sockets

There are a variety of transtibial socket types varying for each patient, dependent on their weight class, bone structure or definition, and limb condition (scarring, skin vulnerable to breakdown, etc) [5]. Many transtibial sockets created are patellar tendon bearing. There are a variety of suspension and load-bearing conditions branching from this socket type to give the most comfortable and functional solutions for each patient.

In traditional manufacturing of clinical prostheses, it is the duty of a qualified clinician to carry out socket rectification (manipulation of the socket form to optimize distributed loading onto the limb) [16,17]. Traditionally, this rectification process is performed by hand on a plaster replica of the patient's residual limb by the clinician. When being worn, the socket is considered a total-contact device. However, loading should be avoided in areas, such as the fibula head, cut or distal ends of the tibia and fibula, and the anterior border of the tibia (shin) [18]. The rectification process involves shaping the socket form to alleviate pressure and load-bearing from these sites. The rectification process subsequently applies load-bearing areas to other appropriate and learned landmarks [5]. Figure 2 illustrates the basic landmarks and areas of a socket that may be altered during the rectification of a transtibial socket.

Figure 2. Relevant landmarks for transtibial socket rectification, where green areas are typically areas of pressure alleviation. Fib: fibula.



The material choice for traditionally made sockets for lower limb prostheses has evolved through the ages. Transitions from wooden and metal componentry to lightweight thermoplastics and reinforced composite polymers have occurred for sockets [19]. The use of carbon fiber as an incorporated material for sockets has enhanced device strength while maintaining its lightweight property. Each traditionally made socket can consist of varied materials, such as standard polyester and acrylic resin, laminates, and more complex composites with fabric inclusions [7].

With an understanding of the load-bearing characteristics of a transtibial prosthetic sockets in place, the following information aims to guide the reader into the process of digital processing and AM. The upcoming sections focus on relevant load-bearing testing, materials, and manufacturing requirements of load-bearing sockets that are applicable to traditionally made and AM sockets alike.

Clinical Applicability of AM for Prosthetic Sockets

AM is the process of creating 3D physical objects using machinery hardware and computer-aided design data from modeling software [20]. Also referred to by its original title "3D printing" in many instances, all these processes use a layer-by-layer method of fabrication in order to construct a physical 3D form [20].

Although AM technologies have been used effectively in cosmetics and small orthotic devices, industry adaptation for load-bearing componentry has been slow to occur. This raises questions as to why AM is not being used in more P&O clinics worldwide. Within P&O, there is not only an added opportunity to personalize the original devices when using AM but also to decrease material wastage, clinical, and labor time. AM can also improve data collection and production rates [21]. Slow industry adaptation can be seen with new technologies in the P&O industry due to trust and establishment requirements, ethical concerns, and educational barriers to the usage of such

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devices or workflows [22]. An example of slow adaptation in this industry can be seen through the introduction of microprocessor knees, which, although developed in the 1980s, were not commercially viable until 1999 [23].

Nevertheless, the solution of AM has been recorded as viable and advantageous for the production of transtibial load-bearing sockets, showing considerable benefits when combined with a digitalized workflow in industry.

Figure 3. A typical digitalized process for 3D printing prosthetic sockets.



To create a transtibial socket using AM, the process typically entails a new digitalized process of manufacturing. In this process, digital technologies such as 3D scanning and online or computerized rectification and fabrication systems take over the physical plaster mold form capture [24].

Figure 3 provides an overview of the typical steps involved in the digitalized process.

The need for physical storage space is significantly reduced as plaster casts become digitalized files. These files can be stored in secure computer storage systems, accessible to recognized employees of the company for 3D printing. However, without appropriate regulation, online data storage inevitably brings data protection issues and potential risks of personal data sharing to light [25].

A prosthetic team of clinicians, technicians, and administrative staff typically works together to decide on the appropriate AM solution and polymeric material, be it composite or noncomposite materials used. This typical production team is established for devices produced in-house or through external AM facilities. The implementation of this way of working has been found to be successful in improving business processes for prosthetic service providers and manufacturers [26-28].

In summary, with plaster limb casting translating to 3D scanning, companies have the opportunity to reduce the requirement of physical material and storage space for limb form capture. Digital rectification, used in place of traditional rectification, again offers the possibility to eliminate the use of plaster, as well as reduce the requirements of technician resources. Resin casting and thermoform fabrication, translating to AM technologies, lead to significantly fewer environmental and health hazards in the workplace if printed out-of-house. All of these innovative technologies have positive effects on the prosthetic manufacturing process, compared to their traditional counterparts [27].

Regulatory Challenges of Lower Limb Prostheses

In the realms of regulation, a lower limb prosthesis is identified as a custom-made device and does not require a Conformité Européenne (CE) marking as an assembly. As with all medical devices, the regulations and protocols surrounding the design, manufacture, and rollout of prosthetic devices are strictly adherent to various key regulations. Table 1 is a summary of the key regulations for load-bearing prosthetic lower limb sockets [29-33].

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Table . Regulations and standards relevant to load-bearing lower limb prosthetic sockets.

Standard/Regulation	Relevance	Requirements (nonexhaustive)
European Union Medical Device Regulations (EU MDR) 2017/745.	• Identifies prosthetic devices as custom-made devices. • Outlines the rules and requirements of manufacturers and the device itself.	• Manufacturer's statement. • General safety and performance requirements (GSPR) adherence. • Postmarket surveillance system. • Implementation of appropriate quality management and risk assessment systems.
International Organization for Standardization (ISO) 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.	• Outlines a quality management system for the manufacturing and distribution of prosthetic devices.	• Documentation of design, development, production, installation, and servicing of devices. • Risk management, compliance, and documentation for devices. • Traceability and documentation of materials, processes, and testing of devices.
ISO 22523:2006 - External limb prostheses and external orthoses (requirements and test methods).	• Outlines testing requirements for external prosthetic devices, referencing strength, and material considerations.	• Definition of terminology, performance, and safety requirements for devices. • Biocompatibility of materials for devices. • Labeling and device information requirements. Minimum structural and functional safety requirements of devices.
ISO 10328: Structural testing of lower limb prostheses.	• Outlines the mechanical testing requirements of assembled prosthetic devices for CE[a] marking and evaluation.	• Unique test rig aligned to toe-off and heel strike phases of gait. • Specified loading according to patient weight and activity level. • Number of tests and cycles required for proof, ultimate and fatigue, and torsion testing. • Alignment requirements for various assemblies and component inclusions.

[a]CE: Conformité Européenne.

It is the duty of the prosthetist or physician to determine the activity level (also known as "K level") of a patient. This is determined in the consultation and assessment periods prior to allocating the patient a prosthesis [34]. A patient's activity level can change over time through rehabilitation if deemed suitable by the prosthetist, during recurrent monitoring of the patient's rehabilitation process [35]. Table 2 shows each K level with a descriptor of the ability of each patient [35].

The level of loading applied to a lower limb prosthesis is determined by the variety and quantity of CE-marked components used, as well as the level of design complexity (for CE-marked components only). ISO (International Organization for Standardization) 10328 determines the weight limit of the prosthesis wearer for the device being tested [36]. This weight limit is calculated through the testing of mechanical load capacities to ensure the safety and durability of all devices with varying patient activity levels [36]. Transtibial prosthesis assembly will have different loading requirements than that of a transfemoral device with knee joint componentry, although the alignment requirements for testing remain consistent for both. By maintaining consistent limitations and alignment, device componentry can be accurately compared for its changes in material and form. It is not stated how the individual socket and residual limb alignments may affect the consistency of testing results.

The load capacities of a lower limb prosthesis are addressed as "P Levels" within the standard ISO 10328. Ranging from P3 to P8, each level determines a separate weight limit dependent on the loading that each prosthesis can withstand. The standard also notes how factors such as lifestyle and body mass must be taken into account when determining which P level is reflective of the prosthesis use case. Table 3 offers the reader a breakdown of weight limits for each P level [36].

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Table . K levels indicating the rehabilitation potential of amputees.

K Level	Descriptions
Level 0	• Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance their quality of life or mobility
Level 1	• Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence. • Typical of the limited and unlimited household ambulator.
Level 2	• Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers, such as curbs, stairs, or uneven surfaces. • Typical of the limited community ambulator.
Level 3	• Has the ability or potential for ambulation with variable cadence. • Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic usage beyond simple locomotion.
Level 4	• Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. • Typical of the prosthetic demands of the child, active adult, or athlete.

Table . Outlined loading levels with weight limits according to the ISO (International Organization for Standardization) standard 10328: Structural testing of lower limb prostheses.

Loading level	Weight limit (up to, kg)
P3	60
P4	80
P5	100
P6	125
P7	150
P8	175

Mechanical Performance Requirements of Load-Bearing Lower Limb Prostheses

The scope of ISO 10328 states that the standard is “suitable for the assessment of the conformity of lower limb prosthetic devices or structures, with the strength requirements specified in 4.4 of ISO 22523:2006” [36].

The alignment of loading in this standard can be set up in 2 separate test conditions (conditions 1 and 2). These alignments represent the heel strike and toe-off gait phases of walking, respectively. The alignments remain constant for all variations of loading levels. Early studies show Current et al [37] adhering to the testing procedures of ISO 10328 for transtibial prosthetic sockets in the 90s.

Alignment offsets to determine the condition’s loading line are marked at the heights of specific anatomical landmarks, such as the ankle and knee center. These alignment requirements, however, do not account for the complex alignment requirements of each individual patient limb and socket. A visual of the alignment requirements for a custom test rig for condition 2 of ISO 10328 can be seen in Figure 4.

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Figure 4. An example of a testing configuration for condition 2 of the test standard ISO (International Organization for Standardization) 10328: structural testing of lower limb prostheses (digital simulation render).



A breakdown of ISO 10328's structural tests includes the following [36]:

1. Proof test: The ability for a device to withstand a load capacity relevant to its determined loading level and device complexity, with no deformation above 5 mm for a total predetermined device length.
2. Ultimate strength test: The device is tested once until failure or until it has reached the maximum load capacity as determined by the standard.
3. Fatigue test: The device is tested cyclically using an outlined pulsating test force for a prescribed number of cycles, determined by the loading level and device complexity used.

The standard also outlines requirements for torsional testing, which is a common cause of lower limb prosthesis failure as investigated by Heitzmann et al [38] and Quinlan et al [39] in separate studies. Another common point of failure due to loading is observed at the socket's distal end. Failure here is typically due to the concentration of forces at connection points made between the custom-made socket and CE-marked componentry of adapters (leading to the pylon and foot of the device [40]. Throughout ISO 10328, there is no consideration for the prosthetic socket component wall thickness, alignment, or structural design complexity, regardless of their impact on mechanical and structural efficacy.

Other test requirements outlined in ISO 22523 include the following for lower limb prostheses [32]: (1) flammability, toxicity, and biocompatibility of materials; (2) infection and microbiological contamination; (3) corrosion and degradation resistance; and (4) protocol on design and mechanical requirements of the device.

ISO 22523 also states that safety factors corresponding to the particular use of a lower limb prosthesis are determined "by the ratio between the test loading conditions and/or test loading levels applied to the device and the corresponding loads expected to be exerted on the device during use" [32].

Device failure has a direct and immediate result on the quality of the life of the wearer, be it structural or chemical. If a device fails, it takes time and clinical capacity to replace the device, meaning a patient may not have an immediate solution. By performing these tests and forecasting the applications of new technologies in the industry, devices are provided to wearers in the most efficient and safe manner, with security and sustainability in mind.

While there are challenges surrounding the efficacy of test standards for transtibial sockets, the socket itself has evolved and continues to increase in strength, material, and form with technological advancements. The aim of this review is to highlight advances and advantages of innovative technology adaptations to the field by understanding both traditional and digitalized methods. The focus of the review is specifically for the manufacture of load-bearing transtibial prosthetic sockets. This review pertains to an equal focus on clinical applicability,

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regulatory challenges, and mechanical performance of these sockets.

Methods

This state-of-the-art review was conducted by using appropriate keywords across a multitude of reputable and peer-reviewed databases to identify relevant publications made over the last 25 years. In accordance with the Introduction section of this review, the focus of these keywords was equally divided between the topics of clinical applicability, regulatory challenges, and mechanical performance of load-bearing lower limb sockets. The key subheadings that were identified for the purposes of the communication of results were as follows:

1. Current relevant materials.
2. Current AM technologies for load-bearing socket production.
3. Current structural design and testing approaches for load-bearing sockets.
4. Clinician and technician experience in the 3D printing of load-bearing prosthetic sockets.

A collection of publications was compiled and separated according to their relevance to each of the aforementioned subheadings of the "Results" section. Knowledge and literature gaps were identified and stated in the "Discussion" section of this review upon analysis, with recommendations for future studies and consideration also offered.

Technical information and prices were referenced for specific AM solutions from relevant companies engaged in the AM of prosthetic load-bearing sockets from the years 2022 and 2023. This was carried out to provide further context to the current state of technology in an economic environment. These insights were compiled according to their technological solution and compared for their strengths, weaknesses, and clinical relevance for load-bearing prostheses.

Results

Current Relevant Materials for Load-Bearing Socket Production

Comparable material properties of traditionally laminated sockets are difficult to produce due to the nature of the socket itself. The customized design approach for each individual patient, combined with the nonstandardized use of specific ratios and material combinations, results in the lack of identifiable durability readings for a prosthesis. Activity levels and weight limits further complicate matters. For example, a socket without carbon fiber may support one person; however, if activity level increases, this socket may be considered redundant. As activity levels increase, there may be further requirements, such as material additions, overall mass, and thickness of the socket itself.

Current AM material solutions most commonly explored for load-bearing sockets consist of polypropylene, polylactic acid (PLA), polyamide 12, and carbon fiber reinforced composites [12,41]. The method of AM used to manufacture devices from these materials also has an impact on the structural and chemical integrity of the final device. As AM typically relies on the adhesion of layers of material to build a 3D form, there is an added risk of delamination dependent on preloaded process parameters. Print orientation will also add risk of delamination dependent on the loading applied to the printed socket. The problem of delamination is most commonly seen to arise when using fused filament fabrication (FFF) solutions, which are defined and discussed in the following section [42]. Other solutions, such as selective laser sintering (SLS) and Multi Jet Fusion (MJF), result in more efficient layer adhesion compared to FFF (also discussed in the following section) [43].

Current AM Technologies for Load-Bearing Socket Production

Overview

For the AM of prosthetic sockets, research has concentrated on polymer-based approaches due to cost, weight, and similarity of resins or postprocessing to existing applications. The following four forms of AM will be the focus of this review: (1) FFF, (2) stereolithography, (3) powder bed fusion, and (4) binder jetting.

Table 4 highlights the comparative insights of each, with the following relevant to further details and technical processes of each.

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Table . Comparative insights of fused filament fabrication, stereolithography, powder bed fusion (selective laser sintering), and binder jetting (Multi Jet Fusion) for prosthetic lower limb socket production.

Solution	Strengths	Weaknesses	Clinical relevance
FFF[a]	Highly accessible, cheaper option.	Inferior mechanical properties for more accessible material options.	Entry point to 3D printing, highly relevant for prototyping and concept ideation.
SLA[b]	High-resolution prints offer more detail in prints.	Postprocessing requirements are essential for biocompatibility and mechanical properties.	Most accurate printing solution but higher risk of technical and patient contact with harmful substances.
SLS[c]	Strong parts are more suitable for load-bearing applications.	Expensive, large machinery, and time-consuming.	More accessible option for load-bearing 3D printing than MJF[d].
MJF	Higher isotropic properties than SLS.	Limited material and color choices for finished print.	Reliable for load-bearing applications.

[a]FFF: fused filament fabrication.

[b]SLA: stereolithography.

[c]SLS: selective laser sintering.

[d]MJF: Multi Jet Fusion.

Fused Filament Fabrication

FFF is the most common method of commercial 3D printing and is one of the cheapest methods of AM. This process involves the melting of material extruded through a heated nozzle and layering these extrusions to form a 3D shape [44].

FFF printing has been used to create load-bearing transtibial sockets using materials, such as polypropylene, PLA, and carbon fiber–reinforced PLA [12]. This technology also has the ability to create accessory components to load-bearing prostheses, such as socket liners from thermoplastic polyurethane material [45].

Where FFF-printed sockets have been tested to compare with traditionally made load-bearing sockets, results concluded that an FFF-printed socket was at higher failure risk than traditionally made sockets at higher loading weights and activity levels [12]. The process involved with FFF production also leaves vulnerabilities in layer line adhesion and resolution in comparison to other processes. FFF layers can appear as visible weld lines, prone to delamination dependent on the stresses that are applied to the print [46]. As a high percentage of prosthesis wearers are those who experience symptoms of diabetes and are prone to infection, it is best practice to minimize bacteria growth on a prosthesis. Performing postprocessing can decrease the potential buildup of bacteria that may accumulate between the crevices of layer lines [47]. As a result, postprocessing practices are often implemented to obtain a more homogeneous surface on FFF-manufactured sockets.

Stereolithography

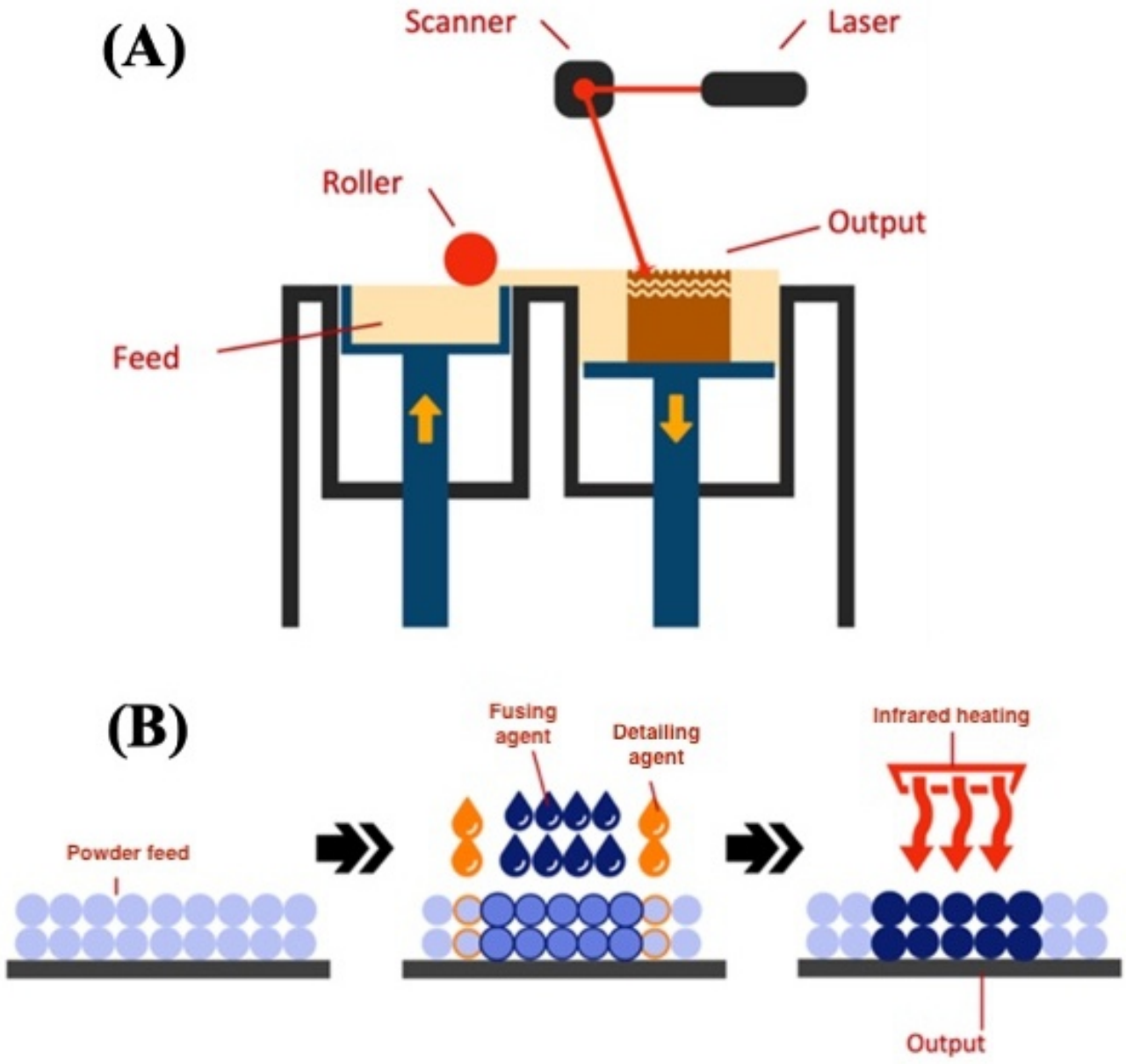
Kim et al [48] showed that stereolithography printers use lasers to cure resin one layer at a time to create a 3D structure, making it one of the most accurate printers on the market for socket production. If produced correctly, a stereolithography-manufactured device can display promising mechanical properties for load-bearing socket purposes that can often supersede FFF applications. However, the manufacturing and postprocessing procedure can result in a more brittle final component if not produced correctly [49]. Although there are biocompatible material solutions available for prosthetic socket production, improper stereolithography curing and postprocessing can still result in harmful material contact with human skin. This hazard has the potential to impact not only the operator of the technology but also the wearer of the prosthesis. As such, biocompatibility concerns are often brought to the forefront for stereolithography production [50]. Stereolithography printing is recognized in this paper as a commonly known and accessible AM process; however, the literature surrounding its use to produce load-bearing lower limb sockets is limited when compared to FFF, SLS, and MJF solutions in research. Improper postprocessing and curing also have a greater effect on device properties for stereolithography than that of other AM solutions. However, it is important to note that disparity or misalignment with processing requirements in any AM or traditional process can have a detrimental effect on the efficacy of the manufactured device without isolating the stereolithography solution.

Powder Bed Fusion

Powder bed fusion by laying and curing thin layers of powder material to create a 3D form. One method of using this powder approach lies in SLS, where Budinski et al [46] describe how a UV beam cures each layer in a predetermined path to create the 3D form (refer to Figure 5A) [51]. Postprocessing requirements for SLS involve cleaning the print from excess powder, tumbling the print for a smooth finish, and possibly applying finishing dyes or coatings.

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Figure 5. Breakdown of selective laser sintering: (**A**) Multi Jet Fusion and (**B**) polymer printing solutions.



The strength of SLS-printed parts exceeds those of FFF and stereolithography alternatives, making it an AM solution worthy of definitive use for a variety of applications [52]. These applications can be seen throughout the medical, automotive, and aerospace industries [53]. With the ability to recycle unused powder and the freedom of printing without supports accessed through this solution, SLS printing is an attractive solution when mechanical strength and sustainability are necessary for their application [54]. The disadvantages with SLS printing, however, come from the limitations of material choice, costs, and postprocessing [52,55]. Both material and color choices are limited, yet are currently being explored through composites that need extra attention in their application [56]. Postprocessing of parts can result in hours of work due to parts cooling and manual cleaning requirements [57].

SLS-printed sockets have been deemed to be an identifiable solution for the manufacture of patellar-bearing socket solutions for transtibial amputees due to their high strength [58]. Sockets for load-bearing solutions have been created and are commercially viable. However, initial research into the device design shows that there is work to be done on the distal end of the socket [59]. Time frame and conditions required for SLS printing may also be a challenge for P&O companies, as there are long and regulated cooldown requirements before the part can be postprocessed to avoid issues such as part warpage.

Multi Jet Fusion

Guo et al [52] outline binder jetting as similar to powder bed fusion; however, the final curing process involves the addition of a liquid binding agent to fuse each layer together [60]. Figure 5 (B) visually outlines the differences between the 2 solutions for further context, with MJF representing binder jetting technology through.

MJF's nylon materials are almost identical to those of SLS nylon, with the advantage of being up to 25% more ductile in the Z axis of prints [60]. MJF printing solutions are currently being used for load-bearing prostheses and have been tested to show similar strength to that of traditionally made sockets [10].

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The testing used to show this, however, is varied across the literature. In the case of Ráž et al [10], the sockets tested were laid horizontally, and an axial force was applied to an exterior wall. This is not reflective of everyday use, where a socket would be in an approximate vertical position as a user is walking, running, or jumping.

Current Structural Design and Testing Approaches for Load-Bearing Sockets

There have been several studies over the past few decades on AM of prosthetic sockets. However, fewer are available that report the success of load-bearing prostheses. Many initial studies focus on the software design optimization to improve the finished socket component by increasing wall thicknesses and adding reinforcements to the 3D-printed socket exterior [28,61,62]. Others, such as Hsu et al [63] would later go on to improve the strength of printed sockets by using resin coatings [52,63].

Kim et al [12] could conclude from data collected in their systematic review that "failure mainly occurred at the distal end of the socket or the pyramid attachment […] whether a laminated composite socket or a 3D printed socket". This is consistent with the ISO 10328 testing protocol. Although design modifications can improve socket strength in digitalized workflows, there are no clear limitations on maximum socket density, wall thickness, or viable mounting or assembly components and solutions for the socket.

When reviewing a variety of prosthetic socket testing papers and abstracts, it is apparent that the most logical approach to structural testing is to use the standard ISO 10328. However, there is a disparity in test setup approaches across the literature. This is apparent in the componentry used not only in the assembly of the prosthesis, but also in the attachment of the prosthesis to the test machine. The American Prosthetic and Orthotic Association recently published findings of key areas that are in need of attention when considering the creation of a standardized testing solution for prosthetic sockets [62]. The findings of this paper outline the need to represent patients who lie outside the "norm" for prosthetic socket shape and loading. They also highlight the need to determine appropriate loading conditions that will suitably reflect all socket types. Taking these findings into consideration, it would be suggested that more than one test setup would be required in order to capture a broader range of patient alignment, physical form, and loading parameters.

Assuming the requirements in ISO standards 10,328 and 22,523 are met during testing, the structural and physical makeup of a 3D-printed load-bearing transtibial prosthetic socket is valid and acceptable for use. However, including a socket in testing according to ISO 10328 presents complications in designing a test rig that ensures consistent alignment. Many studies have tested transtibial sockets with this standard, although each test rig used is custom-made and varies between studies [10-12,37,39-42,48]. As per the nature of socket loading in a real scenario, forces applied to the internal socket surface are transferred through the soft tissue of the residual limb. It is difficult to translate these loading conditions into a repeatable test rig. As such, rigid or foam structures are typically used in custom test rigs as a replacement for the residual limb during testing. This draws even more disparity between not only each study completed but also between testing and real-life scenarios [11,40]. Concerns are raised for the reliability of comparing or correlating results through systematic review, as each custom test rig uses different attachment components and applies different forces to the internal socket [39,48].

Numerous papers suggest the replacement of the prosthetic foot with custom-made fixtures made of metals from aluminum to steel, as a prosthetic foot alters the moments acting on the specimen. In the ISO standard 10328, the load line (or alignment offsets) for condition 1 (heel strike) passes through the distal end of the socket, whereas the load line for condition 2 (toe-off) passes anterior to the socket distal end. Condition 2 generates larger moments at the distal end of the sockets, representing the worst-case scenario load [36]. To lessen moments caused by fixed components, Owen and DesJardins [61] use ball joints in the upper and lower loading fixtures during ISO 10328 testing [42]. It is also seen in this paper that, although both conditions 1 and 2 were tested for proof strength, only ultimate strength tests performed with condition 2 were communicated to readers.

The use of finite element analysis (FEA) is prevalent in the studies involving the production and testing of load-bearing prosthetic sockets [10,54,64]. Using FEA modeling for prosthetic testing can reduce the requirement of clinical appointments for an end user, further promoting a hygienic and efficient workflow of manufacturing, fitting, and design [54]. Through FEA evaluation, detailed information on internal and external tissue loading (which can be responsible for discomfort and injury) is made available [65]. By incorporating FEA into the structural design and form of the socket, researchers have reduced the potential weight and material use required for creating a lower limb prosthesis, focusing on a monocoque design [66].

SLS-printed sockets have been observed to fail when socket design in the digitalization space is altered to improve efficiency. These alterations sacrifice material or design quality to optimize material usage. As such, it has been noted that parts produced with SLS technology must be produced at the highest density outcome to minimize failure [67].

Software solutions for the structural design of the prosthetic socket are constantly being explored, as there is a significant bridge to gap between engineering design approaches and clinical expertise. It is difficult to incorporate patient comfort, pressure relief, and the understanding of patient alignment when engineering a digital file [68]. Optimal design solutions would see a simple, step-by-step process wherein artificial intelligence would accommodate for patient landmarks and clinical expertise to automatically create an ideal socket form for a patient.

An important result from literature on structural testing for load-bearing sockets is that failure mode is commonly identified at the distal end of a socket for both traditionally made and 3D-printed sockets. In the cases of 3D-printed sockets, delamination of print layers is also identified as a primary failure mode [44,69]. Kermavnar et al [70] have noted that SLS-printed prosthetic sockets may also leave a grainy surface finish, which may be undesirable for sensitive skin contact or regular

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movement of the body. However, it is possible that this issue can be rectified with postprocessing the printed socket.

Clinician and Technician Experience in the 3D Printing of Load-Bearing Prosthetic Sockets

The practices of prosthetists and orthotists are accredited through 14 education standards outlined by the International Association of Prosthetists and Orthotists (ISPO) or through the university courses themselves [15]. Where a clinician is required to achieve a minimum level of 6 on the European Qualification Framework, a technician (who works outside the presence of the patient in the manufacturing process) only requires a minimum level of 4. Despite technological advancements, the current clinical and technical education system does not incorporate AM knowledge or experience into its learning outcomes. Educational systems have also not adopted 3D scanning or digital rectification processes as outputs to module learnings. Any experience of 3D printing, its materials, or the digital manufacturing process for P&O must be obtained through external training services provided by digital manufacturers. Other than this, typical clinician and technician experience with 3D printing will stem from hobbies outside of working hours. For the future of prosthetic education, Spaulding et al [71] call for "a more evidence-based approach to applying new technology and materials" in their considerations.

Although there has been an increase in the adoption of AM in the prosthetic industry, there are limited controls implemented for product quality. The World Health Organization has incorporated 3D printing into their regulations of lower limb prostheses and recommends the adherence to quality standard ISO 13485. However, little guidance is given for the validation and monitoring of AM sockets [33,72]. Despite these challenges, there have been successful rates of adoption for digitalization internationally. Low-income countries have seen benefits from the accessibility of 3D printing and scanning through voluntary organizations [73]. In a direct clinical setting, business process reengineering has been analyzed for the digitalization of the prosthetic socket industry by Mohamed et al [74]. It was found that "implementing digitalization in the fabrication process can significantly address the bottlenecks identified in the current business model" for prosthetic socket production. Another paper by Gutierrez [75] highlights the reduction in manufacturing time when switching to digitalized workflows and providing "clinicians with additional time to dedicate to patient care and improved outcomes."

Discussion

Principal Findings

Upon analyzing the findings in the current literature for load-bearing sockets manufactured using digitalization, the following discussion is outlined: (1) outlook on developing technologies for load-bearing prostheses; (2) recommended solutions for prosthetic socket additive manufacture; (3) recommendations for improving adoption rates of digitalized processes; (4) bias and limitations of the current literature; and (5) conclusions.

Outlook on Developing Technologies for Load-Bearing Prostheses

The clinical and manufacturing procedures for P&O have remained virtually the same for a number of decades, with excessive cost, waste, and physical data volumes produced [76]. The materials involved with production are reliable, consistent, and measurable through approved material standards and product requirements. This reliability increases difficulties in the deviation of current to digitalized processing methods. As a result, the manufacturing process had not developed from plaster molding, resin casting, and thermoforming up until the possibilities of AM were explored [76].

All physical data imperative to produce a traditionally manufactured prosthetic socket (such as the plaster molds of the patient) must be retained for a determined period [68]. This results in the need for large storage areas and physical records. The entire fitting and manufacturing process itself can take several days to weeks, including steps from fitting the socket, assembling componentry (such as the foot and other components), and refitting, to ensure correct alignment and comfort [68]. For initial patient plaster casting, the traditional process of obtaining data for socket rectification is a time-consuming and physically invasive process.

The introduction of innovative technology has the ability to address these discussed pain points and impact the design methodology of prostheses for the better [24]. Changing to 3D scanning for form capture, digitalizing rectifications, and 3D printing final sockets are just a few examples of beneficial innovative technology implementation for sockets [68]. These evolutions have the potential to reduce financial, time, and employee resource costs if effectively executed [26]. The integration of technologies from AM, 3D scanning, and computer-aided modeling will form innovative design and production workflows. This may bring an opportunity to create new products that can be more functionally pleasing and sustainable through human-centered and emotional design practices [70]. Practices can become less physically invasive for patients, particularly through 3D scanning, resulting in greater cases of positive experiences within a clinical setting.

Recommended Solutions for Prosthetic Socket Additive Manufacture

The manufacturing hardware mentioned in this review favors powder bed fusion and binder jetting in achieving the mechanical properties when prioritizing quality and high strength for weight-bearing devices. Out of both processes, Cai et al [60] highlight how MJF has higher ductility in the Z axis by up to 25% for nylon printed parts. They also highlight how surface finish and print accuracy were superior to SLS nylon printed parts.

With the above stated, it is important to note that although the cost of printers for SLS is more expensive than MJF, printers for MJF need a higher amount of maintenance. Parts replacement and material handling are highly demanding compared to those of SLS due to their additional use of fusing agents. The recommendations from this review are that SLS or MJF technologies accessible within a P&O company would

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promote adoption for new businesses investing in digitalized workflows, as their strength is comparable to traditional sockets. The possibilities of color printing are also becoming more accessible through MJF printing, and dyeing parts is possible through SLS technology.

For cheaper in-house prototyping, FFF is recommended over stereolithography due to the lack of postprocessing requirements and reduced health and safety hazards that come with stereolithography's liquid resin curing. By prototyping in FFF before committing to SLS or MJF costs, it is possible to achieve clarity in the final component form ahead of investing greater resources and expense. By using a prototyping FFF printer for prosthetic printing, it may also build user confidence and engagement with AM technologies for technicians and clinicians.

Recommendations for Improving Adoption Rates of Digitalized Processes

There is an increased demand for security in digitalized socket manufacturing processes through mechanical testing. To achieve reliable data on this subject, the importance of replication and repetition of a singular testing method for both traditional and 3D-printed prosthetic sockets should be realized. If a standardized method for socket testing was discovered, it may have the opportunity to increase the application of both functional and emotional design opportunities through 3D printing. These emotionally driven alterations may then be tested for impact on overall device strength. This would allow for the evaluation and inclusion of custom accessory components if deemed safe after passing relevant test standards. These additions would aid the cultural adoption of device wearers, improving the device sustainability at a decreased cost in comparison to traditional cosmetic inclusions.

In mechanical testing of orthopedic implants for the hips, components are often tested to last within set condition parameters from worst-case scenario to best-case scenario. A testing procedure similar to this approach may be most useful, with sockets tested from a worst-case to best-case scenarios in terms of alignment, form, and loading parameter. If the material or process used for socket creation passes both these setups, then it may be considered that all scenarios varying between these extremes can be considered safe for use.

It is recommended that the digitalization workflow should be treated as achievable and relevant to (but not altogether a substitute for) the traditional socket workflow. Although digitalized processes have the potential to streamline socket production, they cannot replace the traditional workflow entirely for more complex patient cases. Further study is required to prove the efficacy of digitalized workflows for various cases of extreme alignment, component inclusions, and individual patient considerations.

Finally, it is important to recognize that implementing a digitalized workflow, which works in a predominantly online space, is a significant change to the know-how, skill sets, and culture, learned and lived by current clinical and technical employees. This transition should be recognized as a challenge for clinicians and technicians. It is recommended that clinical language, taught landmarks, clinical experience, and employee work ethic should be incorporated into the digitalized workflow in order to minimize abandonment of this way of working.

New employee recruits may be better suited to the adoption of digitalization due to a lack of experience working traditionally, compared to established and experienced employees. However, by building on current innovation, engaging with educational exercises on digitalization, and increasing AM accessibility, the digitalized workflow can be adopted by all within the P&O industry regardless of experience. The transition from traditional workflows to digitalized ones takes time and must be provided with appropriate support and resources by company management and the industry.

Bias and Limitations of the Current Literature

As AM is a rapidly evolving field with gray literature and commercial data that may not be peer-reviewed, it is important to note a potential effect of bias in reviewed data sources. This review has taken care in referencing peer-reviewed literature through the exploration of case studies, AM implementation, and previous research. Some references are commercially biased for the purposes of exploring and expanding upon the current state of the art of the AM and prosthetic industry within this review.

Conclusions

When it comes to the manufacture of prosthetic and orthotic devices, both a standardized and customized way of working converge to return a final product. If AM is to aid in the customized manufacture of components, such as prosthetic sockets, the finished component must have high tensile strength and be relatively lightweight, with ductility for potential failure and some flexibility for everyday wear. The device must also be sufficiently resistant to wear over time and have the ability to withstand varied temperature, humidity, and UV exposure. These requests are not easy to accomplish in all outlined processes.

Upon literature review for essential requirements of prosthetic lower limb devices, it has been identified that there is a distinct lack of regulation of custom-made devices in comparison to the standardized componentry used alongside them. When reviewing the possibilities of testing these custom-made components, such as the prosthetic socket, there are many challenges to face in order to achieve a true representation of the broad range of prosthetic device wearers. While research is currently being conducted using test methods on prosthetic sockets that are designed for standardized componentry, there is a need to apply regulations of socket testing to reduce disparity in testing setups, parameters, and componentry inclusion. The choice of AM solution as well as material can also significantly impact the structural integrity of the socket, as processing times, volumes, cost, strength, and layer adhesion are among the top values to be considered for each method of printing.

It is suggested that an understanding of the culture of P&O companies be captured to evaluate the true potential of AM in the prosthetic space. It is also imperative to note that although AM technologies have the scope to greatly enhance and improve the manufacturing processes of load-bearing sockets, the

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technical skill set and decision-making of a clinician and technician cannot be replaced and left behind, both due to their clinical knowledge or expertise and the need for further work on the efficacy of AM for load-bearing prosthetic devices.

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Data Availability

All data generated or analyzed during this study are included in this published article.

Authors' Contributions

Conceptualization: ED (lead), DD (equal), B Casey (equal), GK (equal), B Clancy (equal).
Data curation: ED.
Formal analysis: ED (lead), DD (equal).
Methodology: ED.
Project administration: DD (lead), GK (supporting), B Casey (supporting), B Clancy (supporting).
Resources: ED.
Supervision: DD (lead), GK (supporting), B Casey (supporting), B Clancy (supporting).
Validation: DD (lead), GK (supporting), B Casey (supporting), B Clancy (supporting).
Visualization: ED.
Writing–original draft: ED.
Writing–review & editing: ED (lead), DD (supporting), GK (supporting), B Casey (supporting), B Clancy (supporting).

Conflicts of Interest

None declared.

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Abbreviations

AM: additive manufacturing
CE: Conformité Européenne
FEA: finite element analysis
FFF: fused filament fabrication
ISO: International Organization for Standardization
ISPO: International Association of Prosthetists and Orthotists
MJF: Multi Jet Fusion
P&O: prosthetics and orthotics
PLA: polylactic acid
PP: polypropylene
SLS: selective laser sintering

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Smart Wearable Technologies for Balance Rehabilitation in Older Adults at Risk of Falls: Scoping Review and Comparative Analysis

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Abstract

Background: Falls among older adults are a significant public health concern, often leading to severe injuries, decreased quality of life, and substantial health care costs. Smart wearable technologies for balance rehabilitation present a promising avenue for addressing the falls epidemic, capable of providing detailed objective movement data, engaging visuals, and real-time feedback. With the recent and rapid evolution of innovative technologies, including artificial intelligence (AI), augmented reality (AR) or virtual reality (VR), and motion tracking, there is a need to evaluate the market to identify the most effective and accessible smart balance systems currently available.

Objective: This study aims to evaluate the current landscape of smart wearable technology systems for balance rehabilitation in older adults at risk of falls. In addition, it aims to compare market-available systems to the telerehabilitation of balance clinical and economic decision support system (TeleRehab DSS), a recently developed smart balance system.

Methods: A scoping review and strengths, weaknesses, opportunities, and threats (SWOT) analysis was completed, exploring the landscape of smart balance systems in older adults at risk of falls. Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines, electronic databases PubMed, MEDLINE, and Cochrane were systematically searched for articles in English from July 1, 2014, to July 1, 2024. Gray literature searches of relevant institutions and web pages were also conducted. The database search and commercial systems were then compared against the TeleRehab DSS in a SWOT analysis.

Results: The scoping review yielded 17 systems that met the inclusion criteria; 10 investigational systems and 7 commercially available systems. Out of 10 studies, only 1 reported the use of intelligent learning or AI, 8 studies reported the use of motion tracking, and 9 studies used virtual reality. Of the studies incorporating motion tracking, 3 provided feedback as either visual or auditory. All but 2 studies reported the use of gamification, and 7 studies incorporated balance exercises. In total, 2 studies reported remote delivery, with 5 being clinician-supervised and 4 providing a clinician report. The SWOT analysis of TeleRehab DSS against the 7 market-available smart balance systems revealed several unique advantages, including personalized therapy with AI-DSS, AR for real-world interaction, enhanced clinician involvement, and comprehensive data analytics.

Conclusions: The findings from this scoping review highlight the rapid evolution of smart balance systems, yet significant gaps remain in AI integration, remote accessibility, and clinician-driven data analytics. Despite limitations such as cost, accessibility, and user training requirements, TeleRehab DSS emerges as a significant innovation, addressing many of these gaps through AI-driven personalization, AR for real-world interaction, and real-time clinician monitoring. These features position it as a next-generation solution that aligns closely with the evolving needs of patients and clinicians. The results of this review provide valuable insights for future research, supporting the need for further validation studies and the development of more intelligent and accessible balance rehabilitation technologies.

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KEYWORDS

falls; balance; telerehabilitation; technology; augmented reality; motion tracking; stroke; mild cognitive impairment; long COVID; vestibular

Introduction

Background

Falls among older adults are a significant public health concern, often leading to severe injuries, decreased quality of life, and substantial health care costs [1-4]. Globally, falls are the second leading cause of accidental or unintentional injury deaths, with adults over 65 years being the most affected group [1-4]. Each year, approximately 28% - 35% of people aged 65 years and over experience a fall, increasing to 32% - 42% for those over 70 years [1-3]. This rising trend underscores the urgent need to address balance disorders and implement effective fall prevention strategies.

The impact of falls and balance disorders extends beyond individual health, affecting families, communities, and health care systems. Individuals who experience falls often face prolonged recovery periods, reduced independence, and heightened fear of falling again, which can lead to social isolation and decreased physical activity [1,2,5,6]. Communities bear the emotional and financial burdens of caring for fall-prone older adults, while health care systems are strained by the high costs associated with emergency treatments, hospitalizations, and long-term care needs. Consequently, there is a critical need for effective interventions that can mitigate these negative effects, with health care services that are accessible and meet the needs of older adults.

Previous Work

Smart wearable technology for balance rehabilitation presents a promising avenue for addressing the falls epidemic among older adults [7-11]. These advanced systems, often prescribed by health care professionals have the potential to facilitate home-based balance exercises by leveraging motion tracking, virtual reality (VR) or augmented reality (AR), and real-time feedback [10-14], Emerging evidence suggests that these digital health technologies, when combined with personalized training and regular home-based practice, can improve balance and gait outcomes, thereby reducing the risk of falls among older adults [10-12,15]. The World Health Organization defined digital health as “the field of knowledge and practice associated with the development and use of digital technologies to improve health” [16-18]. These technologies include both assistive technologies designed to maintain or improve the independence, social participation, and functionality of older people at home, as well as health information technology for managing long-term conditions, including telehealth, wearable devices, and mobile health [16-18].

The adoption of wearable technology has increased significantly in recent years. In Germany, a 2016 survey found that 33% of adults use a wearable, with 57% - 63% reporting a willingness to use wearables with health monitoring sensors [19]. In the United States, it is estimated that 1 in 3 American adults uses a wearable device such as smart watch or band to track their health and fitness [20]. However, despite this growth, challenges remain in widespread adoption among older adults. A survey in the United Kingdom indicated that many seniors over 65 years are hesitant to adopt new technologies due to concerns about online privacy, high costs, and the rapid pace of technological advancements [21,22], with similar findings reported in Singapore [23]. These statistics highlight the need to evaluate the market and identify the most effective and accessible smart balance systems currently available for older adults.

These wearable technologies have the ability to enhance multisensory stimulation, a key component required for balance [24]. Multisensory integration, that is, the integration of visual, vestibular, and somatosensory inputs, is critical for bodily awareness and movement coordination [24]. Technologies such as AR- and VR-supported systems can enhance rehabilitation by delivering immersive, and multisensory experiences, offering a strong advantage over conventional balance interventions [24].

Despite the growing number of smart balance systems available, many have not been systematically compared in terms of suitability for older adults. Previous reviews have focused on general rehabilitation technologies [10,14,25,26], but no study has comprehensively evaluated these systems against predefined criteria such as AI integration, remote monitoring, and clinical usability. To address this gap we establish clear inclusion or exclusion criteria to assess the most clinically viable smart balance systems for older adults, enabling clinicians to make evidence-based decisions in the selection of rehabilitative technology.

Research Question and Aims

This scoping review aims to address this gap, by summarizing the current landscape of smart wearable technologies for balance rehabilitation in older adults at risk of falls. Throughout this study, smart wearable technologies refer to systems that incorporate motion tracking and some form of visual display (ie, computer interface, VR, or AR). The review seeks to provide clinicians with a comprehensive understanding of available resources, facilitating informed decision-making of rehabilitative technologies for balance.

In addition, we compare these existing systems to the TeleRehab Decision Support System (TeleRehab DSS) [27], a novel tool designed to reduce fall risk in individuals with balance problems or dizziness through: (1) AI analytics for personalized rehabilitation, (2) remote clinician monitoring for real-time assessment, and (3) multisensory balance rehabilitation with real-time patient feedback.

TeleRehab DSS is a next-generation AI-driven balance therapy platform that integrates depth-sensing body-worn motion trackers, heart-rate monitors, and AR interfaces to deliver highly personalized home-based rehabilitation (Figure 1). By conducting a strengths, weaknesses, opportunities, and threats

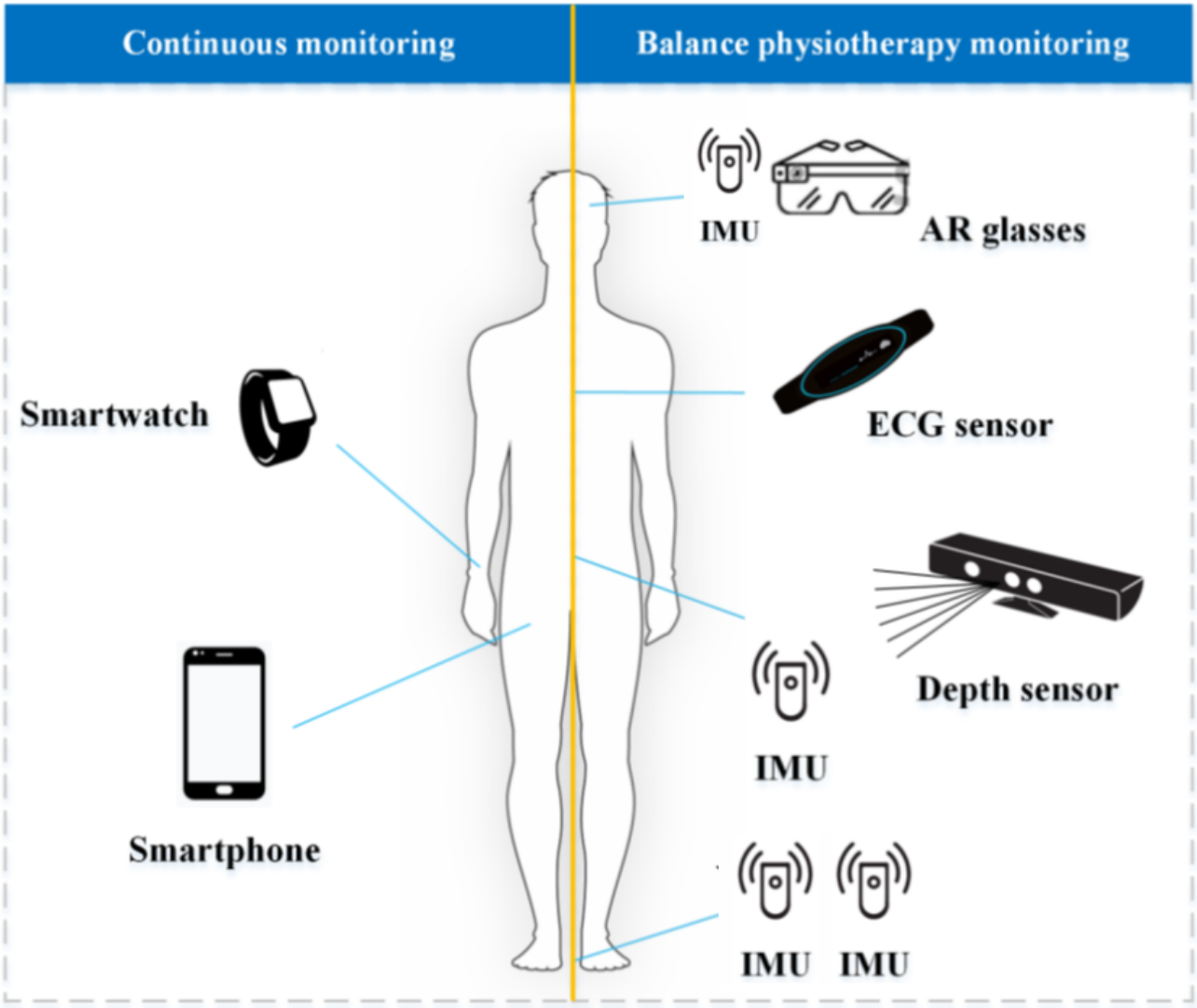
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(SWOT) analysis [28,29], this study compares TeleRehab DSS against other market solutions and investigation systems, identifying it is unique advantages and areas for improvement.

The primary research questions of this scoping review and SWOT analysis are: (1) to identify the current commercially available or investigational smart wearable technologies for balance rehabilitation that support clinicians in managing older adults with balance disorders or dizziness at risk of falls, and (2) to conduct a comparative analysis evaluating how these solutions compare to TeleRehab DSS.

This work aims to raise awareness of available technology-based rehabilitation solutions, guide clinicians in selecting appropriate interventions, and, thus, contribute to reducing fall risk and improving the quality of life for older adults.

Figure 1. TeleRehab Decision Support System (TeleRehab DSS) equipment configuration including an augmented reality head-mounted display, smartwatch, smartphone, 4 IMU (head, trunk, and ankles), a chest ECG monitor, and depth camera. ECG: electrocardiogram; IMU: inertial measurement unit.



Methods

Study Design

This study combines a scoping review and a SWOT analysis–based market analysis to explore the landscape of smart wearable technologies for balance rehabilitation in older adults at risk of falls. Scoping reviews have flexible study designs that allow authors to include any type of study that may be appropriate to answer their research questions [30,31]. The scoping review identifies existing solutions and research trends, while the SWOT analysis evaluates market opportunities and challenges.

Scoping Review

The scoping review was conducted to identify the current and emerging market landscape and for smart technology, including motion tracking, systems, or solutions for balance rehabilitation in older adults at risk of falls. The review follows the methodological approach proposed by Arksey and O'Malley [31], which consists of six stages: (1) identifying research questions; (2) identifying relevant studies; (3) study selection; (4) charting the data; and (5) collating, summarizing, and reporting the results; and (6) consultation with stakeholders. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines were followed (Checklist 1) [30].

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Search Strategy

Three main concepts were identified from the review question: (1) balance disorders, (2) remote rehabilitation, and (3) wearable technology solutions or systems. For each concept, subject headings were used, and when possible, keywords were searched using synonyms and related terms. A systematic search of PubMed, MEDLINE, and Cochrane databases for articles in the English language from July 1, 2014, to July 1, 2024, was conducted. This timeframe allowed the review to capture the early emergence of modern smart wearables until the more recent advancements, which are relevant to current practice, while excluding older, less relevant technologies. Articles were included if they described completed studies, ongoing studies, or protocols for interventions related to smart wearable technologies for balance rehabilitation in older adults at risk of falls. This criterion was selected in efforts to address this identified gap of smart wearable technology among older adults at risk of falls, specifically. Please refer to Multimedia Appendix 1 for details of the search strategy. The search strategies were developed through discussion (BN and BG) and with the aid of an experienced researcher (DEB).

A gray literature search was conducted using Google and targeted searches within company web pages, professional organizations, industry leaders, and clinical trial registries to identify relevant reports, guidelines, and nonpeer-reviewed sources. Search queries included terms related to smart wearable balance rehabilitation, AI, and remote monitoring, with results filtered based on targeted population group, publication date (July 1, 2014, to July 1, 2024), and relevance to remote balance rehabilitation. Only reports from reputable institutions, research organizations, and technology companies were included, while opinion pieces and promotional content were excluded.

Finally, consultation with a stakeholder (Health Innovation Network) was carried out to identify and discuss additional references and insights beyond those retrieved in the literature.

Eligibility Criteria

Studies were included if the system was a technological system or solution with wearables and motion tracking for balance rehabilitation to improve balance or gait outcomes or reduce falls in older adults at risk of falls. The population of interest included older adults (≥50 y) with potential balance impairments or falls deficits due to age-related physiological decline or specific health conditions. While an explicit fall risk assessment (eg, Timed Up and Go Test and Berg Balance Scale) was not a requirement for study inclusion, the selected studies targeted populations commonly identified in the literature as at risk of falls. These included individuals with neurological conditions (eg, stroke, Parkinson disease, and mild cognitive impairment), vestibular dysfunction, orthopedic conditions affecting mobility, or generalized age-related balance impairments. Studies had to be published after July 1, 2014, and in the English language. Protocols were included to capture ongoing developments and emerging trends in the field, as they provide insights into planned interventions and methodologies. Refer to Table 1 for inclusion and exclusion criteria.

Table . Inclusion and exclusion criteria of smart wearable technology systems for balance rehabilitation among older adults at risk of falls.

	Included	Excluded
Populations of interest	• Community dwelling adults (50 - 80 y) at risk of falls or dizziness	• <50 or >80 years of age • Without balance problems or not at risk of falls
Primary outcome	• Primary outcome to improve balance or reduce risk of falls	• Primary outcomes that did not assess balance and falls risk
System specification	• Technology solutions to facilitate home based balance exercise intervention with motion tracking	• Solutions which do not include motion tracking • Systems which only look at gait via exoskeletons or robot assisted walking • Systems involving only electrical stimulation or biofeedback • Only assessed falls detection without rehabilitation
Prescription	• Interventions prescribed by a health care professional	• Systems not prescribed by a health care professional
Study design	• Primary study design, such as RCTs[a] and nonrandomized controlled trials, case studies, protocols	• Systematic reviews and meta-analysis
Publication dates	• July 2014-July 2024	• Studies >10 years old
Publication language	• English	• Not English

[a]RCT: randomized controlled trial.

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Article Screening and Data Extraction

Database searching was completed by 2 authors (BN and BG). EndNote (Clarivate) was used to manage the literature retrieved, and after removing the duplicates using EndNote, the eligibility of papers was independently reviewed by 2 authors (BG and BN) at each key step, including abstract screening and full-text review. Lists of article selection by each author will be compared for agreement, and any controversial papers were further assessed by the third author (DEB) for the final decision.

One reviewer (BG) independently extracted data into a predesigned data extraction table, developed to systematically assess smart balance rehabilitation systems based on key technological, clinical, and research-based parameters. The table included: company or institution, system summary, population of use, current use of system, automated feedback or real-time monitoring, AI analytics, clinician report, motion tracking method, display features, gamification, balance exercises, user experience, and remote suitability. These categories were selected to capture essential features relevant to balance rehabilitation and to enable direct comparison with the TeleRehab DSS system. Study characteristics were also extracted, including authors, publication date, study design, country or region, to ensure standardization across included studies. For protocols, additional data on study objectives, planned interventions, target population, outcome measures, and projected timelines were recorded separately to identify trends in ongoing research. The structured table facilitated both the descriptive summary and the SWOT analysis, ensuring a comprehensive evaluation of available and investigational systems. Any disagreement in the data extracted from studies was resolved through discussion between reviewers.

A comparative analysis was then performed, focusing on key aspects of technological features (inclusion of AI, AR or VR, motion tracking, and remote monitoring), rehabilitation focus (types of balance exercises, gamification, and feedback mechanisms), and clinical integration (mode of clinical supervision, reporting, and remote accessibility).

Synthesis of Results

The reporting of key subsections and information throughout this manuscript follows the PRISMA-ScR guidelines. Given that no dedicated reporting guidelines exist for SWOT analyses within the Enhancing the Quality and Transparency of Health Research network, an adapted approach was taken to align with systematic review standards.

To provide a structured comparison, the Results section was organized into two primary classifications: (1) smart balance systems currently under investigation, further divided by study type (randomized controlled trials, quasi-experimental studies, feasibility and usability studies, and study protocols), and (2) commercially available smart balance systems, with an evaluation of their features, accessibility, and evidence base.

Comparative Analysis

A structured comparative analysis was conducted to evaluate the features and functionalities of smart balance rehabilitation systems in relation to the TeleRehab DSS. Systems were assessed based on key technological (motion tracking, AI integration, real-time feedback, display modality, and gamification), clinical (target population, rehabilitation exercises, clinician oversight, and report generation), and usability parameters (remote suitability and adaptability for home use, and patient engagement features).

Data for these comparisons were extracted systematically from published literature, company websites, and clinical trial protocols and summarized in a descriptive manner. Where full-text articles or system specifications did not explicitly mention certain features (eg, AI support and gamification), they were marked as “not reported” rather than assumed to be absent. The competitive features of each study are listed in Table 2 and Table 3 to enable a comparative assessment of the TeleRehab DSS with investigational and commercially available systems. The study characteristics of the investigational and commercially available systems are collated in the Multimedia Appendix 2.

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Table . Competitive features of the included studies.

Author (year)	AI[a] supported	Motion tracking	Real-time feedback	AR[b] or VR[c]	Gamification	Balance exercises	Remotely delivered	Clinician supervised	Clinician report
Liao et al [32]		✓	✓	✓	✓	✓		✓	✓
Proffitt et al [33]		✓		✓	✓		✓		
Rosiak et al [34]		✓	✓	✓	✓	✓			
Khushnood [35]		✓		✓	✓	✓		✓	
Ku et al [36]		✓		✓	✓	✓		✓	
Bessa [37]				✓		✓		✓	
da Silva Soares [38]				✓	✓	✓			
Yun et al [39]	✓	✓		✓					✓
Zeigelboim et al [40]		✓		✓	✓	✓		✓	✓
Guo et al [15]		✓	✓		✓		✓		✓

[a]AI: artificial intelligence.

[b]AR: augmented reality.

[c]VR: virtual reality.

Table . Competitive features of the included commercial systems.

Company	AI[a] supported	Motion tracking	Real-time feedback	AR[b] or VR[c]	Gamification	Balance exercises	Remotely delivered	Clinician supervised	Clinician report
TeleRehab DSS[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓
HoloBalance	✓	✓	✓	✓	✓	✓	✓	✓	✓
Reflexion Health VERA		✓	✓		✓	✓	✓	✓	✓
XRhealth		✓	✓	✓	✓	✓	✓	✓	✓
Evolv Rehab	✓	✓	✓		✓	✓	✓	✓	✓
Jintronix		✓	✓		✓	✓	✓	✓	✓
TRAK	✓	✓	✓			✓	✓	✓	✓
Homebalance		✓	✓		✓	✓	✓	✓	✓

[a]AI: artificial intelligence.

[b]AR: augmented reality.

[c]VR: virtual reality.

[d]TeleRehab DSS: TeleRehab Decision Support System.

SWOT Analysis

The SWOT analysis was performed to contextualize the competitive positioning of TeleRehab DSS in relation to the evaluated systems. Originally developed as a business strategy tool, SWOT analysis is widely used to compare an organization, product, or service against competitors by identifying internal (strengths and weaknesses) and external factors (opportunities and threats) [29]. Beyond business applications, SWOT analysis has been extensively applied in health research, including health care policy and health technology assessment [28,41,42].

For instance, in the United States, a SWOT analysis of the health care industry IT adoption identified key challenges in improving patient safety, data security, cost containment, and productivity

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[28]. This demonstrates the value of SWOT analysis in evaluating digital health innovations and their impact on health care systems.

In this study, a SWOT analysis was conducted to evaluate the positioning of TeleRehab DSS relative to investigational and commercial smart balance systems. The SWOT structured approach was applied (Textbox 1).

This SWOT analysis was structured based on established methodologies from previous digital health and medical technology SWOT frameworks [28,29,41,42]. The results are summarized in Textbox 2 and further contextualized in the discussion to provide key insights for clinicians, researchers, and stakeholders.

Textbox 1. SWOT (strengths, weaknesses, opportunities, and threats) summary criteria of TeleRehab Decision Support System (TeleRehab DSS).

- Strengths: unique features of TeleRehab DSS not present in the reviewed systems, such as AI-driven personalization, real-time monitoring, and augmented reality based balance exercises.
- Weaknesses: challenges impacting usability, accessibility, or scalability, including cost, technical proficiency requirements, and need for external validation.
- Opportunities: emerging trends in digital rehabilitation, such as the growing adoption of remote balance training and increasing demand for AI-driven clinical support.
- Threats: competing technologies with overlapping features, regulatory hurdles, and user adoption challenges.

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Textbox 2. SWOT (strengths, weaknesses, opportunities, and threats) analysis of TeleRehab Decision Support System (TeleRehab DSS): positioning in the smart balance technology landscape.

Strengths

- Integrated multisensory feedback: combines motion tracking, heart rate, and AR for a detailed and engaging rehabilitation experience, offering richer patient interaction than many single-feature systems.
- Evidence-based: as TeleRehab DSS is the next iteration of HOLOBalance, it is an evidence-based system with initial preliminary findings supporting its feasibility and acceptability in older adults at risk of falls.
- AI–powered personalization: customizes exercises and therapy progression based on individual patient data, making it more adaptive and individualized than traditional preset programs.
- Real-time clinician monitoring: allows clinicians to monitor patient performance remotely and in real-time, enhancing oversight and intervention capabilities.
- Comprehensive data analytics: enables in-depth tracking of patient progress, which can aid in refining treatment plans and provide valuable data for ongoing research.
- Enhanced accessibility: offers home-based therapy, reducing the need for in-person sessions, which is especially beneficial for patients with limited mobility or those in remote areas.

Weaknesses

- High initial cost: advanced sensors and AR interfaces increase upfront expenses, potentially limiting accessibility in low-resource settings.
- Complex setup and maintenance: multicomponent setup can be challenging for non-tech-savvy users or those with limited technical support.
- Potential for technological resistance: some older adults or less tech-savvy patients may struggle with advanced AR or sensor-based systems, leading to reluctance or inconsistent usage.
- Dependence on internet connectivity: real-time features require stable internet, limiting use in areas with poor or unreliable connections.

Opportunities

- Expansion into related rehabilitation areas: the system's adaptability makes it suitable for other types of rehabilitation (eg, poststroke or musculoskeletal recovery), expanding its market potential.
- Growing demand for telemedicine solutions: the increase in telemedicine adoption, driven by the need for remote health care solutions, offers a supportive environment for TeleRehab DSS's expansion.
- Collaboration with wearable technology companies: partnering with popular wearables (like Fitbit [Google] or Apple Watch) could expand monitoring capabilities and potentially reduce system costs.
- Inclusion in health care insurance plans: efforts to integrate such technology into insurance plans could drive affordability and adoption by reducing the cost burden on patients.

Threats

- Intense market competition: competing solutions like XRHealth, Jintronix, and Reflexion Health, each with specific strengths, may limit market share, especially if they are more affordable or easier to use.
- Regulatory and compliance challenges: adhering to health care regulations (eg, Health Insurance Portability and Accountability Act and General Data Protection Regulation) is complex and costly, potentially slowing down deployment in new regions.
- Privacy and security concerns: handling sensitive health data brings stringent privacy requirements, and any breach could impact the system's reputation and user trust.
- Adoption hurdles among clinicians and patients: clinicians may be skeptical of the efficacy of remote rehabilitation, and some patients may prefer traditional, in-person therapy over telemedicine solutions.

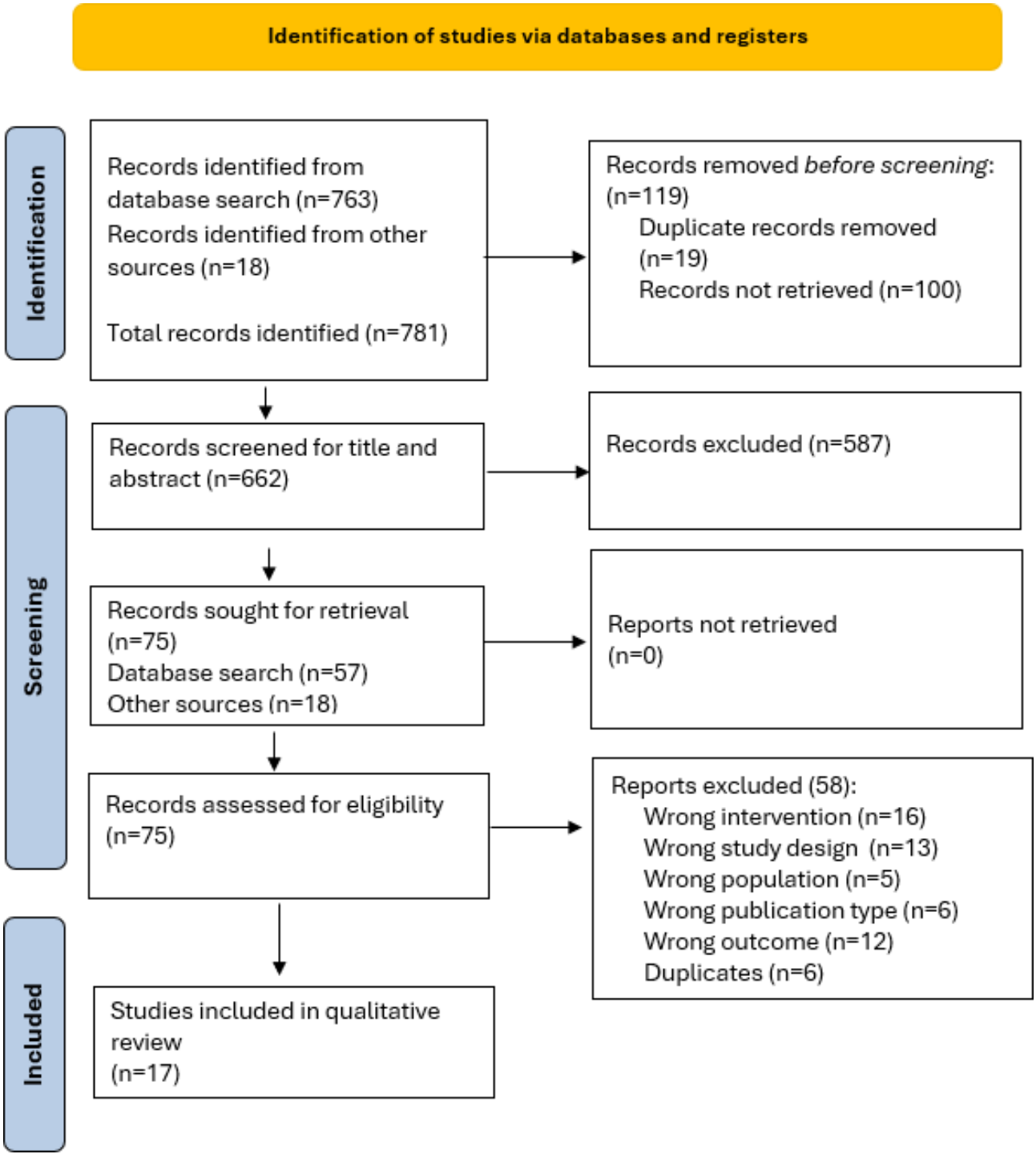
Results

Overview

The systematic search yielded 626 articles after removing duplicates (Figure 2). Of these, 57 were screened in full text, and subsequently, 10 studies met the inclusion criteria. In addition, manual retrieval of 18 market available systems was identified by searching the gray literature and institution web pages, with 7 included.

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Figure 2. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart of identification and selection of studies.



Included Study Characteristics

Overview

The characteristics of the included papers identified by database search that are described in the supplementary material. The 10 studies identified from the database search were published between 2015 - 2023, with 3 from Brazil, 2 from Korea, 1 from Pakistan, 1 from the United States, 1 from China, 1 from Taiwan, and 1 from Poland.

Data analysis revealed various smart balance rehabilitation systems currently being researched, that is, those using motion tracking and some form of visual display, with details found in the supplementary materials (Multimedia Appendix 1).

In total, 5 [15,33,35,37,38] of the included studies investigated the use of smart balance systems in stroke patients; 1 study [34] with peripheral vestibular dysfunction patients, 1 study [32] looked at patients with Parkinson disease, 1 [36] in independently mobile older adults, 1 [40] in adults with hereditary spastic paraplegia and 1 [39] with physiatrists, occupational therapists and older adults with mild cognitive impairment.

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Intervention Features

Multimedia Appendix 2 details the intervention features of the included studies. Only 1 study [39] reported the use of intelligent learning or AI. In total, 8 studies [15,32-36,39,40] reported use of motion tracking, with 2 protocols [37,38] not reporting the use of motion tracking. Of the studies incorporating motion tracking, 3 [15,32,34] made comments of feedback provided as either visual or auditory. A total of 9 [32-40] of the 10 included studies incorporated either AR or VR, with 1 study [15] using a computer interface. All [15,32-36,38,40] but 2 studies [37,39] reported use of gamification (the addition of game elements to nongame activities; ie, Apple picking game added to the activity of bending over), and 7 [32,34-38,40] studies incorporated balance exercises. In total, 2 studies [15,33] reported that it was remotely delivered, with 5 studies [32,35-37,40] being clinician supervised and 4 [15,32,39,40] providing a clinician report.

Comparative Analysis of TeleRehab DSS and Smart Balance Systems Under Investigation

Overview

The rapid advancement of AI, AR or VR, motion tracking, and remote monitoring has led to the development of multiple smart balance rehabilitation systems, necessitating an analysis of these systems from both a competitive viewpoint as well as to identify key factors for consideration in future work. This review identified 10 investigational systems, including 5 registered protocols, 3 randomized controlled trials, 1 quasi-experimental study, and 1 feasibility or usability study. The target populations of these studies ranged from stroke survivors [15,33], older adults with balance impairments [36], patients with Parkinson disease [32], individuals with mild cognitive impairment [39], to those with vestibular dysfunction [34].

Most of the investigational systems share common features, including motion tracking and gamification, with a strong emphasis on VR-based rehabilitation. However, none integrates all the key technological components present in TeleRehab DSS, particularly AI-driven personalization, AR-based balance training, real-time corrective feedback, and comprehensive clinician monitoring.

Motion Tracking and Gamification

While most investigational systems use motion sensors, their level of data granularity and clinical application varies. All but 2 studies [35,38] used motion tracking via inertial measurement units (IMUs), depth cameras, or gaming sensors (eg, Xbox Kinect and Nintendo Wii). Guo et al [15] used 3 IMUs for feedback on static and dynamic balance in stroke patients but lacked real-time corrective feedback. TeleRehab DSS differentiates and strengthens itself by using 4 IMUs and a depth camera, enabling a more detailed biomechanical analysis than existing systems.

Gamification was incorporated in 8 of the 10 studies, reinforcing its growing role in smart rehabilitation technologies. However, the extent of engagement and customization varied with limited details of the games provided. The consistent presence of gamification highlights its importance, which TeleRehab DSS acknowledges for enhancing engagement through customization and interactive exercises.

AR versus VR

VR was used by all studies (n=9) [32,33,35-40,43] delivered via a head-mounted display (HMD) or screen-based interfaces, with one study using AR [36]. Liao et al [32] explored VR rehabilitation for Parkinson disease, but primarily for upper limb motor function rather than balance and gait rehabilitation. Zeigelboim et al [40] combined VR and vestibular rehabilitation using Nintendo Wii Balance Board and hand-held IMUs, providing a promising but non–AI-enhanced system.

TeleRehab DSS is distinct in its use of AR rather than VR, facilitating real-world applicability for balance training and improved safety through an overlay of one's environment, unlike VR-based systems that require simulated environments that encompass the entire visual field.

AI and Real-Time Feedback

Few systems incorporate AI for adaptive rehabilitation. The one study that did report AI personalization [39] focused more on cognitive training rather than balance rehabilitation. Furthermore, only 3 [15,32,34] studies reported providing feedback, which was either visual or auditory, with no mention of real-time corrective feedback provided, such as the TeleRehab DSS.

The AI personalization stands out as a unique and key advantageous feature of TeleRehab DSS [39]. Providing tailored rehabilitation plans has always been recognized as a gold standard, and TeleRehab DSS has the potential to enhance this personalization with real-time corrective feedback and dynamic adjustments, predictive analytics, and objective data to optimize outcomes.

Remote Usability and Clinician Involvement

Many investigational systems are clinician-supervised in clinical settings, with limited capability for remote rehabilitation. Only 2 studies [33,35] explicitly support home-based rehabilitation, while others provided delayed reporting to clinicians rather than real-time oversight. TeleRehab DSS is fully designed for remote use, with real-time clinician monitoring, remote dashboards, and data-driven decision-making, reducing travel time and [33,39] costs for both patients and clinicians.

Comparative Analysis of TeleRehab DSS and Commercial Smart Balance Systems

Overview

The increasing prevalence of fall-related injuries among older adults has driven the rapid advancement of smart balance rehabilitation systems. TeleRehab DSS offers a multifaceted approach to telerehabilitation, integrating AI-driven adaptive therapy, AR-based exercises, gamification, and real-time clinician monitoring to enhance patient engagement and rehabilitation outcomes. This section compares TeleRehab DSS with commercially available systems, focusing on technology integration, monitoring capabilities, and user engagement strategies.

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AR-Based Rehabilitation Systems

HOLOBalance [44] integrates AR and wearable sensors to deliver balance rehabilitation exercises, supported by a decision-support system for clinicians. It offers personalized interventions based on real-time sensor data, focusing primarily on fall prevention in older adults. While HOLOBalance provides a robust, AR-driven approach to balance training, TeleRehab DSS extends these capabilities with enhanced AI-driven personalization and broader functionality with gamification, multisensory feedback, and a more comprehensive decision-support system beyond fall prevention. Furthermore, as TeleRehab DSS is the next iteration of HOLOBalance, it is an evidence-based system with initial preliminary findings supporting its feasibility and acceptability in older adults at risk of falls [45].

Reflexion Health's VERA [46] uses motion capture technology to guide patients through balance and rehabilitation exercises, offering real-time feedback to improve exercise accuracy and efficacy. Its remote monitoring capabilities allow clinicians to oversee patient progress without requiring frequent in-person visits, however, it lacks AR and AI-driven personalization, limiting adaptability for diverse rehabilitation needs. TeleRehab DSS leverages AR and AI-driven personalization for enhancing patient engagement, treatment adherence, and the overall rehabilitation experience.

VR-Based Rehabilitation Systems

XRHealth [47] and Evolv Rehab [48] use VR environments for immersive therapy and gamification with data analytics and clinician oversight. While VR is effective, TeleRehab DSS's AR integration offers the advantage of real-world applicability, improving the transferability of balance skills to daily life. Furthermore, TeleRehab DSS's AI-driven personalization provides more tailored interventions compared to XRHealth's reliance on preset VR experiences. [48]

Gamified and Motion-Tracked Rehabilitation Systems

Jintronix [49] integrates motion capture and gamification to create an interactive rehabilitation experience, using gamified exercises to boost patient adherence and enjoyment, particularly for long-term therapy. Its remote monitoring capabilities allow clinicians to oversee progress and adjust therapy as needed, offering flexibility for remote rehabilitation. However, Jintronix's approach relies on preset gamified content and lacks the AI-driven personalization of TeleRehab DSS. TeleRehab's emphasis on real-time data analytics and adaptive clinician monitoring enables more precise and tailored interventions, making it a more comprehensive solution for rehabilitation.

TRAK [50] is a telerehabilitation platform that provides tailored exercise plans with video guidance, offering a user-friendly interface suited for patients with minimal technical skills. It demonstrates exercises through videos to ensure proper form and tracks patient progress, generating reports for clinicians. However, it lacks real-time feedback and monitoring. In comparison, TeleRehab DSS offers a more comprehensive solution with multisensory feedback, real-time clinician oversight, and adaptive support, making it particularly effective for complex rehabilitation cases requiring continuous adjustments.

Home Balance [51] provides basic balance exercises supported by instructional videos or written guidelines, offering a cost-effective solution accessible to a wide range of users. However, it lacks the technological sophistication of TeleRehab DSS, which includes features like motion tracking, real-time feedback, and AI-driven customization. While Home Balance is affordable, it may not meet the needs of users requiring intensive or guided therapy, where TeleRehab DSS's advanced capabilities are more effective.

Strengths of TeleRehab DSS

Following a comparative evaluation of the above smart balance systems for balance rehabilitation, several unique advantages of TeleRehab DSS become apparent: (1) personalized therapy with AI-DSS, (2) AR for real-world interaction, (3) enhanced clinician involvement, and (4) comprehensive data analytics.

TeleRehab DSS's AI-based approach allows for highly personalized therapy, adapting to individual patient needs in real-time. This level of customization is not present in most other systems, which often rely on generic exercise plans and preset "level" progressions. Unlike VR-based systems that isolate patients in virtual environments, TeleRehab DSS's AR functionality enables patients to interact with their real surroundings, enhancing the practical applicability of their training, while also improving safety. TeleRehab DSS offers clinicians a comprehensive view of patient progress through real-time monitoring and detailed data analytics uploaded to a remote dashboard, promoting a collaborative and adaptable rehabilitation process with big data objective analytics. The advanced analytics in TeleRehab DSS enable continuous monitoring of patient progress, allowing clinicians to make data-driven adjustments to therapy plans and flag concerns requiring prompt action. This feature distinguishes it from systems that provide only summary data or lack in-depth analytics.

Moreover, telerehabilitation enhances accessibility, allowing patients to engage in rehabilitation from home, reducing travel burdens, which can be a significant barrier for patients [52,53]. However, older adults with limited digital literacy or cognitive impairments may require additional support to engage effectively with technology-driven interventions. TeleRehab DSS addresses this by incorporating reminders, remote clinician supervision, structured guidance, and progressive task difficulty adjustments to accommodate varying user abilities. TeleRehab DSS can also facilitate regular virtual supervision with real-time feedback and monitoring by healthcare professionals, promoting improved adherence [52,53].

Limitations of TeleRehab DSS

Although TeleRehab DSS presents itself as superior to the included studies, it also presents limitations. Its high-tech integration may be challenging for patients or clinicians with limited technical skills, and advanced technology of this nature may require a higher upfront investment compared to simpler systems. While promising, long-term clinical validation and

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comparative effectiveness studies are needed to establish its superiority conclusively.

Furthermore, in comparison to the commercially available systems, TeleRehab DSS may incur higher costs, complexity of use, set-up demands, and internet dependence.

Summary

In comparison with other smart balance systems, TeleRehab DSS stands out as a highly adaptive and advanced smart balance system with remote balanced rehabilitation. It combines AI-driven personalization, AR-based real-world interaction, and comprehensive monitoring, creating a robust tool for balance rehabilitation in older adults at risk of falls. While cost and complexity may pose challenges, the potential benefits for patient outcomes, clinician oversight, and data-driven therapy adjustments underscore TeleRehab DSS's value in the current market. By addressing these limitations, TeleRehab DSS can strengthen its position as a leading solution in balance rehabilitation and support a broader range of patients.

Discussion

This scoping review and SWOT analysis identified 17 smart wearable technologies for balance rehabilitation in older adults at risk of falls, comprising 10 investigational systems and 7 commercially available solutions.

Comparison With Investigational and Commercial Systems

Across the investigational systems, the findings highlight key trends among smart wearable technologies for balance rehabilitation, including the widespread integration of VR (9/10 studies), the reliance on motion tracking (8/10 studies), and gamification (8/10 studies), but limited adoption of AI-driven personalization (1/10 studies). In addition, clinician involvement varied, with only 5 studies reporting clinician supervision, and even fewer (4/10 studies) providing clinician reports. Remote accessibility remained limited, with only 2 studies incorporating fully remote delivery models.

Compared to commercial systems like XRHealth, Evolv Rehab, Reflexion Health's VERA, Jintronix, and TRAK, TeleRehab DSS offers greater adaptability, clinician oversight, and AI-driven decision making. Unlike VR-based platforms such as XRHealth, its AR-based approach enhances real-world applicability. HOLOBalance shares some features, but TeleRehab DSS extends these with advanced AI personalization for broader populations

The comparative analysis revealed that, while many investigational and commercial systems integrate immersive environments and gamification, they often lack AI-based decision support, real-time feedback, and comprehensive remote monitoring—features that define the TeleRehab DSS. The SWOT analysis positioned TeleRehab DSS as an innovative system that enhances balance rehabilitation through AI-driven personalization, AR-based real-world interaction, and clinician-integrated monitoring.

However, usability challenges remain, particularly for older adults with lower digital literacy or mild cognitive impairments. While TeleRehab DSS provides clinician-guided monitoring, further adaptations may be necessary to ensure ease of use, including simplified user interfaces, voice-guided instructions, and adaptive difficulty levels. Cost, accessibility, and user training requirements also remain barriers to implementation, emphasizing the need for inclusive design strategies. Future research should focus on validating the long-term clinical effectiveness of AI-driven balance rehabilitation solutions and expanding accessibility for diverse populations.

Comparison With Conventional Rehabilitation Interventions

While this review contrasts TeleRehab DSS with existing smart balance rehabilitation systems, it is also important to consider how it compares to traditional balance rehabilitation interventions. Conventional rehabilitation typically involves face-to-face sessions with a physiotherapist, in either an individual or group format, where balance exercises and modifications are manually guided in real-time [54-57]. This approach offers personalized and immediate feedback, which can be beneficial, however, participants are often left to complete exercises alone and unsupervised between therapy sessions with inadequate exercise progressions that do not address real-world situations such as dual-task training simulating everyday challenges [56,58-61]. Access barriers, including geographical constraints, high costs, and scheduling difficulties, may also contribute to reduced adherence among conventional rehabilitation interventions, particularly for older adults with mobility limitations [56,58-60]. Additionally, clinic-based therapy often relies on subjective assessments rather than continuous movement tracking, which may impact precision in monitoring progress over time. In contrast, TeleRehab DSS enhances accessibility by providing a home-based, AI-supported rehabilitation platform that allows for continuous motion tracking, real-time feedback, and remote clinician monitoring. The integration of AR-based exercises further supports real-world functional training, which may improve carryover to daily activities.

Alignment With Previous Work

Our findings align with previous reviews [13,14,34,43], which highlight the role of VR, wearable motion sensors, and telerehabilitation for improving balance rehabilitation. TeleRehab DSS advances this field by integrating AI-driven personalization and AR-based exercises, addressing previous limitations of static exercise programs and limited clinician oversight [25,26]. Unlike traditional VR-based systems, such as XRHealth (XRHealth R&D Ltd) and Evolv Rehab (Evolv Rehabilitation Technologies SL), TeleRehab DSS emphasizes real-world interactions through AR, enhancing the transferability of rehabilitative exercises to daily activities. This aligns with the findings by Man et al [26], emphasizing the role of telerehabilitation in increasing therapy accessibility and adherence, particularly among older adults.

Additionally, the inclusion of protocols in this scoping review highlights ongoing advancements and emerging research priorities in the field of wearable balance rehabilitation. These

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protocols highlight future directions and may evolve to address existing gaps with more of the key features, posing as a potential competitive threat.

Limitations

This study has some limitations that should be considered. First, the scope of the review was confined to English-language studies, potentially excluding relevant research in other languages. Second, if system features were not documented or could not be retrieved in the literature, they were considered as not included, potentially introducing bias. Third, the reliance on publicly available data and published literature for the analysis constrained the depth of the evaluation. Some systems may have additional proprietary features or unpublished validation studies that were not captured in this review. Fourth, the inclusion criteria focused on technologies with motion tracking and rehabilitation applications, excluding systems primarily aimed at fall detection or prevention without a rehabilitation component. While this was necessary to maintain the scope of the review, it may have excluded hybrid solutions with potential relevance. Finally, TeleRehab DSS is still in its early stages of implementation and validation, and therefore its evaluation is based on theoretical potential rather than long-term empirical data.

These limitations highlight the need for multilingual reviews, proprietary data access, and longitudinal validation studies to assess the real-world effectiveness of TeleRehab DSS and similar systems.

Conclusions

This scoping review identified 17 smart balance systems (10 investigational and 7 commercial) designed for balance rehabilitation in older adults at risk of falls. The findings highlight key trends in the field, including the dominance of VR-based platforms, widespread motion tracking, and increasing gamification. However, AI integration, real-time feedback, and remote rehabilitation remain underdeveloped areas—features that define TeleRehab DSS. While the SWOT analysis positions TeleRehab DSS as a promising solution with AI-AR personalized balance rehabilitation and integrated clinician monitoring, challenges such as usability remain a critical factor for adoption. Older adults with cognitive impairments or limited digital proficiency may require additional support, including simplified interfaces, adaptive training, and structured clinician-guided engagement. Future research should focus on developing user-friendly interfaces and tailored digital training programs to ensure accessibility across diverse populations.

This review underscores the critical need for ongoing research and development in smart balance telerehabilitation technologies. Future efforts should prioritize large-scale validation studies, user-centered design improvements, and cost-reduction strategies to enhance accessibility, usability, and effectiveness. AI-driven balance rehabilitation systems like TeleRehab DSS can revolutionize fall prevention and rehabilitation for older adults worldwide.

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Conflicts of Interest

BN is involved in the development and evaluation of the TeleRehab Decision Support System (TeleRehab DSS) platform as part of a broader research initiative. The other authors have no conflicts to declare.

Multimedia Appendix 1
Database search syntaxes.
[DOCX File, 14 KB - rehab_v12i1e69589_app1.docx]

Multimedia Appendix 2
Characteristics of included studies and commercial systems.
[DOCX File, 49 KB - rehab_v12i1e69589_app2.docx]

Checklist 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.
[PDF File, 172 KB - rehab_v12i1e69589_app3.pdf]

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Abbreviations

AI: artificial intelligence
AR: augmented reality
HMD: head mounted display
IMU: inertial measurement unit
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
SWOT: strengths, weaknesses, opportunities, and threats
TeleRehab DSS: TeleRehab Decision Support System
VR: virtual reality

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Effectiveness of Robot-Assisted Upper Extremity Function Training (Gloreha) on Upper Extremities Function After Stroke: Systematic Review

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Abstract

Background: The Gloreha (Idrogenet SRL) is a robotic device that enhances conventional rehabilitation for improving upper extremity function after stroke, but comprehensive evidence on its effectiveness is still lacking.

Objective: The objective of this study was to evaluate the effectiveness of the Gloreha device on upper extremity function and activities of daily living (ADLs) in patients with stroke.

Methods: PubMed, Cochrane CENTRAL, CINAHL, Embase, and EBSCO Open Dissertations were searched from January 2013 to January 2024. The inclusion criteria were randomized controlled trials involving adult patients with stroke that compared rehabilitation with the Gloreha device to conventional rehabilitation and reported upper extremity function or ADLs outcomes. All included studies underwent bias risk assessment using the Revised Cochrane risk-of-bias tool for randomized trials.

Results: Out of 1123 studies identified, 3 randomized controlled trials involving 83 participants were included. Of these, 2 trials combined Gloreha training with conventional rehabilitation, while in another trial, patients engaged solely in the training by the Gloreha device. The Gloreha, whether integrated with conventional rehabilitation or used independently, has the potential to enhance motor function and functional ability in survivors of stroke.

Conclusions: Gloreha passive training with conventional rehabilitation improves upper extremity function post stroke, but ADL effects and long-term optimal dosing require further research.

Trial Registration: PROSPERO CRD42024509492; https://www.crd.york.ac.uk/PROSPERO/view/CRD42024509492

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KEYWORDS

rehabilitation; robot-assisted therapy; stroke; systematic review; upper-limb; PRISMA; Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Introduction

Stroke is the second leading cause of death and the third leading cause of disability worldwide [1,2]. In 2019, there were 12.2 million new cases of stroke, and 101 million people were living with stroke-related conditions [2]. Furthermore, the rate of new strokes appears to be increasing [3]. Studies have shown that up to 50% of the survivors of stroke experience more than 6 impairments [4,5], with upper extremity dysfunction being particularly debilitating [6-9]. Upper extremity dysfunction limits the ability of the survivors of stroke to perform daily activities independently [10-12]. Despite efforts to improve motor function through conventional rehabilitation approaches, achieving optimal recovery outcomes remains a challenge [13].

Various interventions exist to improve upper extremity function after stroke, including bilateral arm training, constraint-induced movement therapy, robotics, strength training, task-specific training, virtual reality, and mirror therapy [14]. In recent years, robot-assisted therapy (RAT) has emerged as an innovative technology to augment conventional rehabilitation [15]. RAT offers high-repetition or high-intensity practice, which may induce neuroplasticity in patients with stroke [16]. Recent

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evidence suggests RAT is more effective than traditional therapy approaches for stroke rehabilitation [17]. Robotic devices have shown a moderate positive effect on improving hand and arm function in patients with stroke, with effects on activities of daily living (ADLs) and upper extremity function comparable with conventional therapy (CT) [17]. Although mechanically guiding patients' hands through grasping tasks is a relatively novel approach, various commercially available robotic devices have been developed [18]. One such device is the Gloreha (Idrogenet SRL), a robotic glove that allows customized therapy sessions focused on specific tasks. It consists of a glove and monitor providing visual feedback, with its key innovation being precise control of sequential finger movements to enhance the learning process [19]. Gloreha was selected for this review due to its unique ability to provide precise, individualized, finger-by-finger training and integrated visual feedback, features that are particularly important for restoring fine motor skills in survivors of stroke [19].

Despite growing interest in its clinical application, comprehensive evidence regarding the effectiveness of Gloreha, especially its impact on upper extremity function and ADLs after stroke, remains limited. Although 2 systematic reviews and meta-analyses suggest that RAT, including Gloreha, can enhance upper extremity function post stroke [20,21], further investigation is needed. These reviews evaluated various robotic devices, including exoskeletons and end-effector machines, which may activate different brain pathways during the recovery process. For example, devices such as AMADEO (Tyromotion Inc) and Hand of Hope (Rehab-Robotics Company Ltd) are generally designed to facilitate finger movement in a static arm position with a linkage system, whereas Gloreha facilitates finger movement in a dynamic arm position through a cable-driven mechanism [22]. However, they did not provide specific insights into the influence of Gloreha on upper extremity function and ADLs. Furthermore, although Gloreha has potential applications in other populations with upper-limb disabilities, the high prevalence of fine motor impairments in survivors of stroke and the consequent impact on daily living justify focusing this review exclusively on the population with stroke. Comprehensive evidence on the effects of Gloreha device would equip health care professionals with the reliable information needed to deliver personalized, high-quality rehabilitation interventions for patients with stroke. Thus, this research aims to systematically collect evidence from the literature and summarize the effects of robot-assisted training on upper extremity function and ADLs in patients post stroke, with a specific focus on the Gloreha device.

Methods

Ethical Considerations

This systematic review was reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [23] (Checklist 1). The study protocol received exempt approval from the Ethics Committee, Faculty of Associated Medical Sciences, Chiang Mai University.

Data Source

Randomized controlled trials (RCTs) were identified by searching the following databases: PubMed, the Cochrane Central Register of Controlled Trials, CINAHL, Embase, and EBSCO Open Dissertations from January 2013 to January 2024. Our research focused on the effects of robot-assisted upper extremity function training, a field that has advanced rapidly in recent years. To ensure that the included evidence reflects current robotic technologies, treatment protocols, and clinical applications, we limited our search to studies published between 2013 and 2024. This 10-year time frame was selected based on evidence suggesting that restricting the search to the past decade yields credible and timely results [24]. Studies published before 2013 were excluded, as they may involve outdated technologies and methodologies, limiting their relevance to modern rehabilitation practices. The following keywords were searched: stroke, Gloreha, robotics, and upper extremity. (Refer to Multimedia Appendix 1 for a comprehensive list) Search strategies were developed for each database using both free-text terms and the controlled vocabulary. The reference lists and tracked citations of included studies were searched to identify additional trials through the Scopus database. Scopus was included in our search strategy to extend coverage beyond primary health care databases by enabling reference list screening and citation tracking. Its broad disciplinary scope and built-in citation analysis tools allowed us to identify additional relevant studies that are not indexed in primary databases, recommended in the Cochrane Handbook, ensuring a more comprehensive literature search.

Study Selection

Records were screened through a systematic review application, Catchii [25]. Duplicate removal was performed using Catchii's duplicate detection method, and the results were manually verified before removal. The selection process occurred in 2 stages. First, the titles and abstracts of identified studies were screened, followed by full-text screening. Study inclusion was decided independently by 2 reviewers (CT and SA) based on the following inclusion criteria: (1) the studies were RCTs, (2) the participants were adult patients (≥18 y) affected by ischemic or hemorrhagic stroke, (3) the rehabilitation involved Gloreha robotic device compared with other rehabilitation methods (conventional occupational therapy or physiotherapy or both), and (4) the studies included upper extremity function or ADLs outcomes, assessed by validated measures. Disagreements were resolved through discussion between the 2 reviewers or with a third reviewer (JPD) when consensus could not be reached.

Data Extraction

Two reviewers (CT and SA) independently extracted data from each included trial using a predefined data extraction form. Disagreements were resolved through discussion or, if necessary, adjudication by a third reviewer (JPD). The following variables were extracted: title, authors, year of publication, journal of publication, participants (number, mean age, and gender), study design, rehabilitative intervention details (frequency and duration of sessions, and Gloreha parameters such as passive mode and active assistive mode), conventional rehabilitation intervention details (frequency and duration of sessions,

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rehabilitation techniques, and provider), outcome measures, results, and conflict of interest of each trial.

Assessment of Methodological Quality

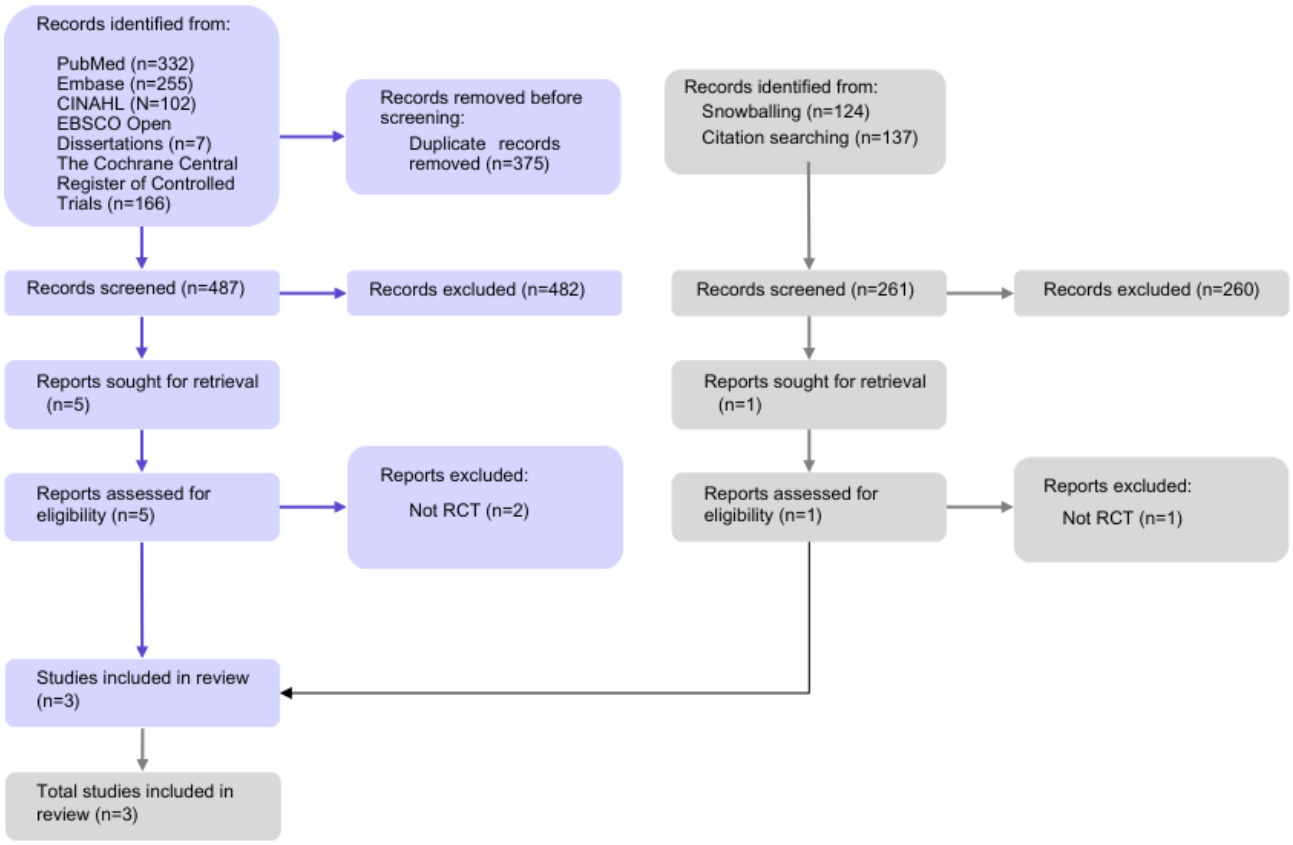
The methodological quality of the included trials was measured using the Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) [26]. The RoB 2 scale includes 5 bias domains (bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result). The overall risk of bias for each trial was determined as low, high, or some concerns.

Results

Study Selection

The primary search identified 862 references, as illustrated in Figure 1. After removing duplicates, 487 references were screened, and 482 were excluded because they did not meet our criteria. Furthermore, 5 full-text publications were reviewed, and finally, 3 met the inclusion criteria. An additional search was conducted on the reference lists and citation tracking, yielding 261 references. After screening, only 1 reference was reviewed as a full text, but it did not meet the inclusion criteria since the design was not an RCT (refer to Multimedia Appendix 2 for a list of excluded studies). In total, 3 studies were included.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram of study selection. RCT: randomized controlled trial.



Study Characteristics

The study characteristics of the 3 included studies are summarized in Table 1. Furthermore, 1 study used randomized cross-over trial design [27] and 2 studies had a parallel randomized controlled design [28,29], and were conducted in Italy [28,29] and Taiwan [27].

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Table . General characteristics of the 3 included studies.

Study	Country	Study design	Sample size	Characteristics of participants, n (%) or mean (SD)						Reported COI[a]
				Age	Sex	Etiology	Affected side	Baseline-motor performance	Poststroke duration (d)	
Lee et al [27]	Taiwan	RCT[b] with crossover	• N=24 • RAT[c]=14 • CT[d]=10	• RAT: mean 59.56 (SD 8.29) • CT: mean 53.50 (SD 12.33)	• RAT: male=9, female=5 • CT: male=7, female=3	• RAT: infarction=9 (64%), hemorrhage=5 (36%) • CT: infarction=4 (40%), hemorrhage=6 (60%)	• RAT: left=9, right=5 • CT: left=8, right=2	• MAS[e] • Brunnstrom stage	• RAT: mean 882.00 (SD 957.67) • CT: mean 883.30 (SD 1020.49)	Not reported

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Study	Country	Study design	Sample size	Characteristics of participants, n (%) or mean (SD)					Reported COI[a]
				Age	Sex	Etiology	Affected side	Baseline-motor performance	Poststroke duration (d)	
Vanoglio et al [28]	Italy	Pilot RCT	• N=27 • RAT=14 • CT=13	• RAT: mean 72 (SD 11) • CT: mean 73 (SD 14)	• RAT: male=7, female=7 • CT: male=7, female=6	• RAT: infarction=12 (75%), hemorrhage=4 (25%) • CT: infarction=12 (75%), hemorrhage=4 (25%)	• RAT: left=11, right=4 • CT: left=10, right=5	• RAT: mean 15.2 (SD 6.8) • CT: mean 17.8 (SD 7.9)	None declared	
Villafañe et al [29]	Italy	Double-blind RCT	• N=32 • RAT=16 • CT=16	• RAT: mean 67 (SD 11) • CT: mean 70 (SD 12)	• RAT: male=11, female=5 • CT: male=10, female=6	• RAT: infarction=10 (67%), hemorrhage=5 (33%) • CT: infarction=9 (60%), hemorrhage=6 (40%)	• RAT: left=9, right=7 • CT: left=8, right=8	• RAT<90[f] • CT<90[f]	None declared	

[a]COI: conflict of interest.

[b]RCT: randomized controlled trial.

[c]RAT: robot-assisted therapy.

[d]CT: conventional therapy.

[e]MAS: Modified Ashworth Scale.

[f]All participants had the onset not more than 3 months.

Participants

The total number of participants from all the included trials was 83, with mean ages ranging from 53.5 to 73 years old. All trials included both male and female participants. Regarding etiology, most participants had experienced ischemic strokes, while a smaller percentage had hemorrhagic strokes. The studies differed in the timing of therapy initiation after stroke. Furthermore, 2 studies focused on the acute to subacute phase (less than 3 mo post stroke) [28,29], while 1 study included participants in the chronic phase (more than 6 mo post stroke) [27].

Intervention

In 2 trials, training with the Gloreha was combined with conventional rehabilitation programs and compared with conventional rehabilitation programs alone [28,29]. In another trial, patients engaged solely in upper extremity training with the Gloreha device, which was also compared with conventional rehabilitation programs [27]. The passive mode of the Gloreha device was consistently employed across the studies [27-29], in which participants' fingers were guided through various movements, such as finger counting, making a fist, pinching, and synchronous finger movements. In 1 study, the Gloreha device was used in an active-assisted activities mode combined with game mode and task-oriented activities, such as grasping a box [27]. On average, treatment lasted 3 - 6 weeks, with each session lasting 30 - 60 minutes per day, and a frequency of 2 - 5 times per week. Details of the interventions among included trials are summarized in Table 2.

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Table . Intervention details of the 3 included studies.

Study	Characteristics of intervention					
	Intervention	Comparator	Duration (wk) and duration per each session (min)	Duration of therapy (wk)	Follow-up	Outcome

Lee et al [27]	60 minutes session of robot-assisted therapy which included 20 min warm-up, 10 min passive ROM[a] with Gloreha, 30 min active-assisted activities (eg, task-oriented bimanual activities active-assisted activities and game)	60 minutes of conventional therapy which included 20 min warm-up and 40 min conventional OT[b] program (eg, task-oriented bilateral hand, grasp-and-release, and pinch activities)	2 days a week, 60 min	6 weeks (1 month washout period)	Baseline and postintervention	• Upper extremity function
						  • FMA-UE[c]
						  • BBT[d]
						  • Grip strength
						• Sensory function
						  • Sensory test
						  • ADL[e]
						  • MBI[f]

Vanoglio et al [28]	Standard rehabilitation (PT[g]/OT) 6 days per week plus 40-min robotics rehabilitation session, 5 days/week. In this program, the affected hand was passively moved by the Gloreha. Each training session consisted of 6 parts (7 min for each part): 17 cycles of digital joint flexion and extension, 23 cycles of movements (counting from 1 to 5), 70 cycles of thumb-finger opposition, 28 cycles of wave-like finger movement, 42 cycles of fist opening and closing, and 20 cycles of flexion and extension of the finger alternated with flexion and extension of the thumb.	Standard rehabilitation (PT/OT) 6 days per week plus 40-min hand rehabilitation session, 5 days/week. In this program, the affected hand was passively moved by PT. The activities were: flexion and extension of the fingers (10 min), thumb opposition (10 min), adduction and abduction of the fingers (10 min), global movement of the hand (drinking water; 10 min)	5 days per week for additional intervention, 40 min	6 weeks	Baseline and postintervention	• Upper extremity function
						  • MI[h]
						  • NHPT[i]
						• Grip and pinch strength
						  • Quick-DASH[j]
						• Pain
						  • VAS[k]

Villafañe et al [29]	Standard rehabilitation (PT/OT) 5 days per week plus 30-min sessions for 3 days per week using the Gloreha program including number, fist, pinch, and synchronous.	Standard rehabilitation (PT/OT) 5 days per week plus 30-min sessions for 3 days per week using assisted stretching, shoulder, and arm exercises, and functional reaching tasks.	3 days per week for additional intervention, 30 min	3 weeks	Baseline and postintervention	• Upper extremity function
						  • MI
						  • Quick-DASH
						• Pain
						  • VAS
						• ADL
						  • MBI
						• Severity
						  • NHSS[l]

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[a]ROM: range of motion.
[b]OT: occupational therapy.
[c]FMA-UE: The Fugl-Meyer Assessment for Upper Extremity.
[d]BBT: Box and Block Test.
[e]ADL: activity of daily living.
[f]MBI: Modified Barthel Index.
[g]PT: physical therapy.
[h]MI: Motricity Index.
[i]NHPT: Nine-Hole Peg Test.
[j]Quick-DASH: Quick Disabilities of the Arm, Shoulder, and Hand.
[k]VAS: visual analog scale.
[l]NIHSS: National Institutes of Health Stroke Scale.

Comparator

All included trials used a conventional treatment as a comparator. Specifically, the activities reported included stretching of the affected arm and hand, passive hand movement, and reach-grasp-and-release activities. On average, the duration of the treatment was 30 - 60 minutes per day, 2 - 5 times per week, over a total period of 3 - 6 weeks. In all trials, both the intensity and frequency of the rehabilitation programs were comparable between the study group and the control group.

Outcome

Effect on Upper Extremity Function

Motor function: Two trials reported a significant difference between the baseline and end scores of the Motricity Index in the Gloreha training group [28,29]. One reported a significant difference between Gloreha training and conventional rehabilitation (*P*=.002) [28], while 1 trial reported a large effect size of Gloreha training (Cohen *d*=3.65) [29]. Lee et al [27] investigated the effect of Gloreha training on the upper extremity motor function through the Fugl-Mayer Assessment for upper extremity. In this study, the effect of Gloreha training was shown in the Fugl-Meyer Assessment for upper extremity proximal domain (*P*=.03) and the total score (*P*=.046) within the group.

Grip strength: A study by Vanoglio et al [28] shows a greater improvement in grip and pinch strength compared with conventional rehabilitation (*P*=.003 and *P*=.04). On the other hand, Lee et al [27] found no significant difference in grip strength from baseline (*P*=.55) and between groups (*P*=.59).

Dexterity: Vanoglio et al [28] measured the effect of Gloreha training on manual dexterity with the Nine-Hole Peg Test, and it showed a significant improvement compared with conventional rehabilitation (*P*=.009). Lee et al [27] used the Box and Block Test and found no statistical difference within and between groups (*P*=.10 and *P*=.79).

Functional Ability

The Quick Disabilities of the Arm, Shoulder, and Hand (Quick-DASH) was used to assess the functional ability of the upper extremity in 2 trials. Vanoglio et al [28] showed a significant difference in the Quick-DASH score between the Gloreha training group and conventional rehabilitation (*P*=.048). Another trial by Villafañe et al [29] found a significant improvement within the group. They also reported a small effect size of Gloreha training (Cohen *d*=0.42).

ADL Performance

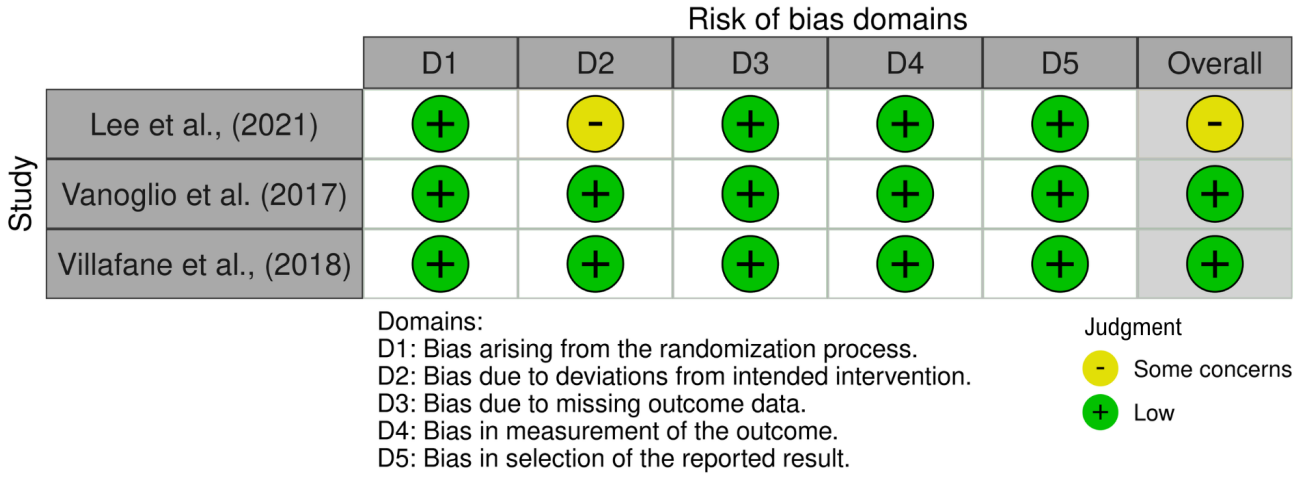
In total, 2 trials investigated the effect of Gloreha training on ADL performance. Villafañe et al [29] found that the Barthel Index (BI) score for both groups was significantly improved from baseline with a moderate effect size (Cohen *d*=0.5). Lee et al [27] used a modified BI to measure the ADL performance and found that the Gloreha training showed a significant improvement from baseline (*P*=.04) but no significant difference between groups.

Risk of Bias in Individual Studies

Figure 2 illustrates the assessments of the risk of bias for individual studies. Overall, 2 out of 3 trials were deemed to be at low risk of bias [28,29]. However, 1 trial was judged as having some concerns regarding bias due to deviations from the intended intervention. This concern arose because it could be assumed that the reasons for participant dropout were related to the intervention context [27].

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Figure 2. Risk of bias assessment [27-29].



Discussion

Principal Results

This systematic review aimed to synthesize evidence on the effects of robot-assisted training using the Gloreha device on upper extremity function and ADLs in patients post stroke. Overall, the results suggest that Gloreha training, whether integrated with conventional rehabilitation or used independently, has the potential to enhance motor function and functional ability in survivors of stroke. However, multiple methodological issues, including risk of bias, heterogeneous interventions, and limited sensitivity of certain outcome measures, necessitate a more cautious and critical interpretation of these findings.

The evidence suggests that Gloreha training contributes to improvements in motor function, as demonstrated by the significant gains in the Motricity Index in 2 of the included trials [28,29]. The device appears to target upper extremity strength, with 1 study reporting a large effect size of Gloreha on motor recovery [29]. In addition, the improvements in the Fugl-Mayer Assessment scores, particularly in the proximal domain (which measures shoulder and elbow function), suggest that Gloreha training may be particularly beneficial for enhancing motor function [27]. The positive changes in the total score further support the overall effectiveness of the intervention in improving upper extremity motor function. The device's design—combining passive movements with active-assisted and game modes [19]—might be a key contributor to these improvements, particularly in survivors of stroke who struggle with initiating movement.

Strength improvements were notable in one of the studies, with greater gains in grip and pinch strength in the Gloreha group compared with CT [28]. This aligns with existing literature on RAT, where repetitive, high-intensity practice has been shown to enhance motor recovery [30-32]. The Gloreha device provides consistent and controlled finger and hand movements [19], which are likely critical for rebuilding strength in the affected limbs. However, one study did not observe significant improvements in grip strength [27]. This discrepancy may stem from differences in participant characteristics, particularly in stroke chronicity. Vanoglio et al [28] included individuals with stroke in the acute to subacute phase (less than 3 mo post stroke), whereas Lee et al [27] enrolled participants in the chronic phase (more than 6 mo post stroke) as defined by Bernhardt et al [33]. Since spontaneous neurological recovery is most pronounced in the early poststroke period, reaching a plateau around 3 months and slowing thereafter [34], the diminished neuroplastic potential in chronic-phase patients could contribute to the less favorable outcomes observed in grip strength improvements.

Functional ability, assessed through the Quick-DASH, also showed improvements in some studies. For example, significant differences were observed between the Gloreha group and CT in 1 trial [28]. These functional ability improvements could potentially impact patients' daily lives, as the Quick-DASH assessment is designed to measure symptoms and ability to perform various activities, which are particularly relevant for survivors of stroke who often experience upper extremity impairments [35,36]. These findings indicate that the Gloreha device may have a valuable role in enhancing upper extremity function and functional capability.

The observed improvements in motor function and strength align with existing studies on robotic-assisted rehabilitation, which have shown that RAT could promote motor recovery and functional improvements in survivors of stroke [17,20,21]. The repetitive, high-intensity practice provided by the Gloreha device facilitates motor relearning by enhancing cortical plasticity [16,37,38]. Robotic devices like Gloreha offer the advantage of delivering precise, task-specific movements crucial for retraining motor circuits [39].

An added feature of Gloreha is its action observation component, which allows patients to observe hand movements on a screen before attempting them [19]. While this mechanism may theoretically stimulate neural pathways involved in motor learning [40], empirical validation within the included studies was limited. Caution is warranted in generalizing potential benefits from action observation without stronger direct evidence. This consideration aligns with experience-dependent plasticity theories [37,38], which posit that repeated, meaningful practice reinforces neural connections in the damaged motor cortex.

While Gloreha demonstrated significant improvements in motor function and strength, its effect on ADL performance was less

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pronounced. Furthermore, 2 of the studies found improvements in ADL performance within groups, but no significant differences between Gloreha and conventional rehabilitation were observed [27,29]. This finding is consistent with previous meta-analyses, which have shown that while RAT can improve upper extremity function, it often does not translate into significant enhancements in ADLs [17,41]. Potential explanations include the low sensitivity of certain ADL scales, insufficient intensity or duration of the Gloreha training, and a lack of comprehensive, task-oriented practice that might better transfer to real-world functional tasks. The BI, used to assess ADL performance in these trials, may lack the sensitivity needed to detect subtle changes in patients, especially those with mild or severe impairments [42,43]. More sensitive outcome measures, such as the modified Rankin Scale [42] or functional independence measure [43], could provide more accurate assessments of functional gains. Also, the dosage of Gloreha training in these studies was less than 15 hours, below the threshold identified in previous research for translating motor improvements into significant functional gains [44]. Higher intensity and longer training durations might be necessary to induce clinically meaningful changes in ADL performance. Furthermore, research highlighted that high-intensity training alone may be inadequate if the quality of tasks is not sufficiently relevant to daily living [44].

Several factors may account for the variability in outcomes across the included trials. First, the intervention protocols differed substantially—ranging from passive to active-assisted modes, with varying frequencies and session lengths—which may obscure the dose-response relationship and hamper replication. Second, risk of bias remains a concern as the participant dropout in Lee et al [27] could have introduced attrition bias, and small sample sizes in other trials reduce the generalizability of findings. Third, the inconsistency in stroke phase (acute versus chronic) among participants raises questions about whether Gloreha's beneficial effects might diminish over time or require different protocols for long-term recovery. Earlier work [45] showed no superiority for fully robot-driven movements compared with CT, underscoring the value of active engagement. Indeed, active-assisted modes that require patient effort appear to yield more robust outcomes [45,46].

Furthermore, neurorehabilitation principles emphasize the importance of task-specific practice for motor learning and brain plasticity [38,47]. Task-oriented approaches, which integrate real-world tasks into therapy, have been shown to improve ADL performance in patients with stroke [48]. It is possible that integrating Gloreha into a more comprehensive, task-oriented rehabilitation program could yield better functional outcomes.

For clinicians, these findings underscore the potential of the Gloreha device to improve upper extremity strength and function in patients with stroke. It may be particularly useful for individuals in the acute, subacute, or chronic phases of recovery. The combination of passive and active-assisted modes allows the device to be adapted to patients with varying levels of impairment. However, the variability in outcomes suggests that Gloreha is not a one-size-fits-all solution. Clinicians should assess each patient's specific needs and consider combining Gloreha training with other interventions, such as task-oriented training, to maximize recovery.

Further research is needed to optimize the use of Gloreha in stroke rehabilitation, particularly regarding the ideal dosage, timing, and integration with other therapies. In addition, long-term studies are required to determine the sustainability of motor and functional improvements. Finally, comparing the clinical and cost-effectiveness of Gloreha with other robotic devices will be crucial for informing health care policies and reimbursement decisions.

Limitation

While the examined evidence base provides valuable insights, it is important to acknowledge certain limitations. First, the number of included studies was relatively small (n=3), with a total sample size of only 83 participants across the trials. This limited sample may affect the precision and generalizability of the findings. However, considering the comprehensive search employed in this study, we are certain that our findings represent the existing evidence in the field. In addition, the studies varied in terms of time since stroke onset, with some focused on the acute or subacute phase and one on the chronic phase. Rehabilitation effects may differ based on stroke chronicity. Furthermore, the trials had somewhat heterogeneous intervention protocols in terms of Gloreha modes used, duration or frequency of training sessions, and comparator treatments.

Conclusions

This systematic review revealed that the Gloreha robotic device shows promise for improving motor function in patients post stroke, particularly in upper extremity strength and dexterity. However, its impact on ADLs remains inconsistent, possibly due to limited task specificity in training, insensitive outcome measures, and insufficient training dosage, as most studies provided less than 15 hours of intervention—below the threshold suggested for meaningful functional gains. Future research should explore integrating Gloreha with task-oriented rehabilitation, assess its long-term effects on specific ADL tasks, and include a broader range of survivors of stroke to determine its optimal dosage and functional utility. Clinicians should use Gloreha as a motor recovery tool but combine it with other interventions to enhance real-world functional outcomes.

Acknowledgments

Two out of four researchers involved in this study, CT and SA, visited Idrogenet S.R.L., the manufacturer of Gloreha, for firsthand observation of the robot used in this research. It is important to note that Idrogenet S.R.L. did not provide any financial or material support for this study. The visits were solely for the purpose of gaining insight into the functionality and capabilities of the robot. The company had no role in the design, conduct, or reporting of this study.

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Authors' Contributions

CT performed the original search and data analysis. CT and SA undertook study selection, data extraction, quality assessment, and data analysis. JPD and TD assisted in data analysis synthesis, and interpretation. CT wrote the first draft of the manuscript with SA, TD, WC, and JPD. All authors revised and approved the final version of the manuscript. All authors had full access to all the data in the study. CT and SA have accessed and verified the data.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Keywords used in searching strategies.
[DOCX File, 17 KB - rehab_v12i1e68268_app1.docx]

Multimedia Appendix 2
Characteristics of excluded studies.
[DOCX File, 15 KB - rehab_v12i1e68268_app2.docx]

Checklist 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[PDF File, 136 KB - rehab_v12i1e68268_app3.pdf]

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Abbreviations

ADL: activity of daily living
BI: Barthel Index
CT: conventional therapy
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
Quick-DASH: Quick Disabilities of the Arm, Shoulder, and Hand
RAT: robot-assisted therapy
RCT: randomized controlled trial
RoB 2: Revised Cochrane risk-of-bias tool for randomized trials

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Review

Advances in Infant Cry Paralinguistic Classification—Methods, Implementation, and Applications: Systematic Review

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Abstract

Background: Effective communication is essential for human interaction; yet, infants can only express their needs through various types of suggestive cries. Traditional approaches of interpreting infant cries are often subjective, inconsistent, and slow, leaving gaps in timely, precise caregiving responses. A precise interpretation of infant cries can potentially provide valuable insights into the infant's health, needs, and well-being, enabling prompt medical or caregiving actions.

Objective: This study seeks to systematically review the advancements in methods, coverage, deployment schemes, and applications of infant cry classification over the last 24 years. The review focuses on the different infant cry classification techniques, feature extraction methods, and practical applications. Furthermore, we aimed to identify recent trends and directions in the field of infant cry signal processing to address both academic and practical needs.

Methods: A systematic literature review was conducted using 9 electronic databases: Cochrane Database of Systematic Reviews, JSTOR, Web of Science Core Collection, Scopus, PubMed, ACM, MEDLINE, IEEE Xplore, and Google Scholar. A total of 5904 search results were initially retrieved, with 126 studies meeting the eligibility criteria after screening by 2 independent reviewers. The methodological quality of these studies was assessed using the Cochrane risk of bias tool (version 2; RoB2), with 92% (n=116) of the studies indicating a low risk of bias and 8% (n=10) of the studies showing some concerns regarding bias. The overall quality assessment was performed using TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) guidelines. The data analysis was conducted using R (version 3.64; R Foundation).

Results: Notable advancements in infant cry classification methods were realized, particularly from 2019 onward, using machine learning, deep learning, and hybrid approaches. Common audio features included Mel-frequency cepstral coefficients, spectrograms, pitch, duration, intensity, formants, 0-crossing rate, and chroma. Deployment methods included mobile apps and web-based platforms for real-time analysis, with 90% (n=113) of the remaining models remaining undeployed to real-world applications. Denoising techniques and federated learning were limitedly used to enhance model robustness and ensure data confidentiality from 5% (n=6) of the studies. Some of the practical applications spanned health care monitoring, diagnostics, and caregiver support.

Conclusions: The evolution of infant cry classification methods has progressed from traditional classical statistical methods to machine learning models but with minimal considerations of data privacy, confidentiality, and ultimate deployment to practical use. Further research is thus proposed to develop standardized foundational audio multimodal approaches, incorporating a broader range of audio features and ensuring data confidentiality through methods such as federated learning. Furthermore, a preliminary layer is proposed for denoising the cry signal before the feature extraction stage. These improvements will enhance the accuracy, generalizability, and practical applicability of infant cry classification models in diverse health care settings.

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KEYWORDS

infant cry classification; machine learning; audio feature extraction; pitch analysis; hybrid models; denoising techniques; federated learning; real-time analysis; pediatric healthcare; signal processing; data confidentiality

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Introduction

Infants can only express their needs through cries as a way of communication before developing proper linguistic ontological organs as they grow. During these early stages, their needs are crucial and must be promptly attended to, as they are vulnerable to neglecting basic needs such as sleep, diaper changes, medical care, and general attention. Misunderstanding their needs can exacerbate problems, leading to further complications and health-related issues as they continue to cry if their needs are unmet [1]. Understanding and addressing the needs and health conditions of newborns are therefore paramount, given that infants cry an average of 25 minutes per day in their first week, increasing to nearly 2.25 hours daily by 6 weeks [1,2]. Infant cry analysis is crucial for identifying medical conditions such as neurological disorders, respiratory issues, and early signs of sepsis [3], as well as aiding in infant care and bonding [4]. Historically, the study of infant cries began in the 1960s, with Wasz-Höckert et al [5] categorizing distinct types of cries related to pain, hunger, birth, and pleasure through auditory analysis by trained nurses.

Infant cries usually serve as the first form of early verbal communication, conveying both physiological and emotional needs to parents and caregivers such as nannies [6]. Different infants' cries tend to have associative distinctive acoustic signals that can be characterized by variations in pitch, duration, and intensity, providing vital information about an infant's well-being [7]. Timely and precise response to these cues is linked to the infant's continuous emotional development, according to the study by Caulfield [8].

In most instances, traditional methods of infant cry classification rely on manual subjective observations and rudimentary acoustic features, which inadequately capture the rich spectrum of cries and their underlying causes with less accuracy and reliability [9]. The field of parenting and caregiving has been phenomenally enriched with the adoption of machine learning and neural networking that can process complex audio datasets efficiently for so many diversified pattern identifications in infants' cries. These technologies have not only enhanced the accuracy of infant cry paralinguistics analysis and discriminations but also allowed real-time analysis, which is crucial in health care settings anytime and anywhere. In comparison, this could also substantially accelerate the achievement of sustainable universal health coverage for infants' well-being and growth when properly adopted and implemented.

Early research on infant cry classification, such as the use and adoption of machine learning algorithms by Mukhopadhyay et al [10], demonstrated a substantial significant improvement in accuracy over human listeners. However, most traditional observational methods, such as the Neonatal Infant Pain Scale [11] and the FLACC (Face, Legs, Activity, Cry, Consolability) scale [12], were subjective and significantly varied among different observers. This variability, therefore, highlighted the need for objective tools and technologies to measure and categorize infant cries.

The integration of advanced neural network architectures, such as convolutional neural networks and recurrent neural network models, has shown promise in capturing complex patterns in audio data for spatial-temporal components of the signals. Most recent advancements in signal processing tend to leverage the power of hybrid models, such as convolutional recurrent neural networks and ensemble modeling, which potentially capture both spatial and temporal information within cry signals [13]. Current research has limitedly also explored state-of-the-art federated learning for privacy-preserving analysis and the use of denoising techniques to enhance model robustness for signal data points.

The evolution of infant cry analysis reflects a continuous effort to move from subjective assessments to more objective, quantitative, and technologically advanced approaches. This progression aims to improve the early detection of health issues and facilitate timely interventions, ultimately enhancing the quality of infant care. This study, therefore, seeks to systematically review the advances in infant cry classification, encompassing a broad spectrum of methodologies, deployment strategies, and applications. Given the diversity of approaches, spanning from traditional observational techniques to modern machine learning and deep neural networks, the following relevant key research questions were considered: How do the reviewed key models generalize across diverse infant populations given the variability in cry characteristics?

This study discusses various methods, such as auditory analysis, signal processing, and statistical approaches, with ultimate deployment in real-world scenarios. It provides a comprehensive overview of how these empirical methodologies have evolved and their current applications in enhancing the accuracy and effectiveness of infant cry classification anytime and anywhere.

Methods

Goal and Review Questions

The main goal of this study was to systematically review and synthesize studies that focused on the classification and interpretation of infant cries. This includes an in-depth examination of the methodologies, deployment strategies, and the ultimate practical applications of these techniques.

Furthermore, this study aimed to identify recent trends, coverage, and directions in the field of audio classification to highlight opportunities for future research from both academic and practical perspectives. Based on the established guidelines for conducting systematic literature reviews by 2 studies [14,15] and for reporting findings by 2 other studies [16,17], the selection and review process was thoroughly developed and documented. Based on this goal, the following review questions (as illustrated in Table 1) were formulated and adopted:

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Table 1. RQs[a].

Category and RQ	RQ	Focus
General RQs		
RQ 1.1	Contributions of the studies	Methods, models, tools, or applications for infant cry classification
RQ 1.2	Research methods used	Empirical, theoretical, or hybrid approaches
RQ 1.3	Geographical distribution of studies	Regional trends, dominant research locations, and gaps in global representation
Topic-specific RQs		
RQ 2.1	Methods for cry classification	Statistical models, traditional techniques, or machine learning
RQ 2.2	Feature extraction methods	MFCC[b], spectrogram, or other audio features
RQ 2.3	Types of datasets used	Primary (collected) or secondary (public repositories)
RQ 2.4	Accuracy and precision	Performance comparison of methods or models
RQ 2.5	Denoising techniques	First-layer noise reduction methods
RQ 2.6	Data confidentiality and privacy	Federated learning or other privacy measures
RQ 2.7	Model deployment	Practical use in real-world applications
RQ 2.8	Applications of findings	Hospitals, home care, or other settings
RQ 2.9	Limitations and challenges	Data quality, model robustness, and generalizability

[a]RQ: review question.

[b]MFCC: Mel-frequency cepstral coefficient.

Search Strategy

To ensure transparency and completeness in our systematic review, we followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines as outlined by 2 studies (the PRISMA checklist provided in Multimedia Appendix 1) [16,17]. Our search spanned 7 databases, covering literature from their inception up to 2024, to identify relevant articles on the methodologies, deployment strategies, and practical applications in infant cry classification. This broad time frame ensures the inclusion of both foundational and recent advancements, allowing for a comprehensive understanding of research trends [9]. Previous systematic reviews have similarly adopted this approach to track methodological evolution and identify gaps in infant cry analysis [1]. These databases comprised the Cochrane Database of Systematic Reviews, Web of Science Core Collection, Scopus, PubMed, ACM, IEEE Xplore, and Google Scholar. Our search strings, structured according to the PICO (Problem, Intervention, Comparison, and Outcome) framework by Petersen et al [18] (Multimedia Appendix 2), were designed to address the overarching question: "Can advanced methodologies and models enhance the classification and interpretation of infant cries?" We tailored the PICO structure as follows:

1. Problem: We searched for studies focusing on infant cry classification and its various aspects, encompassing terms such as "infant cry" OR "infant crying" OR "baby cry" and "infant vocalizations."
2. Intervention: Our search targeted studies exploring methodologies, techniques, and approaches used for infant cry classification, including terms such as "machine learning" OR "neural networks" OR "signal processing" OR "auditory analysis" and "spectrogram."
3. Comparison: Due to the specificity of our research objectives, direct comparison studies were not applicable in this context.
4. Outcome: We sought outcomes related to model accuracy, deployment, and practical applications of infant cry classification methodologies, incorporating terms such as "accuracy" OR "deployment" OR "application" and "real-time analysis."

By using "AND" and "OR" operators, we formulated a general search phrase: ("infant cry" OR "infant crying" OR "baby cry" OR "infant vocalizations") AND ("machine learning" OR "neural networks" OR "signal processing" OR "auditory analysis" OR "spectrogram") AND ("accuracy" OR "deployment" OR "application" OR "real-time analysis"). The variations in these search phrases were adapted accordingly depending on the specifications of different databases that were taken into consideration (Multimedia Appendix 3).

Eligibility Criteria

Overview

The eligibility criteria for inclusion were established to comprehensively evaluate studies that focused on the classification and interpretation of infant cries, considering a wide range of methodologies and relevant research. The criteria were precisely crafted to ensure the inclusion of studies that aligned with the objectives of this review. The studies were also evaluated to check if they were addressing the diverse needs and challenges in the methodologies, deployment schemes, and practical applications of infant cry classification in different domains of interest.

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Initial Screening

During this preliminary phase, articles that were identified through database searches and manual exploration underwent early screening based on titles and abstracts. The aim was to ensure that the screened studies were aligning with the study's goal of systematically reviewing studies on infant cry classification. Emphasis was placed on filtering out irrelevant studies and identifying those contributing to the examination of methodologies, deployment strategies, practical applications, recent trends, and future research opportunities. Adherence to established guidelines ensured comprehensive documentation of the selection process, facilitating the formulation of research questions and ultimate findings.

Inclusion and Exclusion

Overview

Out of 5904 search results, a total of 126 studies were included for review. Studies that were included must have fulfilled the following criteria: (1) studies that focused on methods for infant cry classification, (2) studies that detailed the deployment strategies of these methods, and (3) studies that clearly defined practical applications of cry classification techniques.

To ensure precise and robust findings, this study used exclusion criteria guided by specific thematic considerations. (1) Irrelevant topics: Literature investigating other aspects of infant behavior not related to cry classification. (2) Incomplete focus: Studies focused solely on other signal processing tasks, such as noise reduction without subsequent classification. (3) Lack of technological interventions: Literature that did not apply technological interventions, such as those focusing purely on theoretical aspects without practical deployment. (4) Insufficient application: Literature that only described features of infant cries without using them in classification models. (5) Limited scope: Studies that solely focused on the intelligibility of infant cries without addressing their classification. (6) Non-English publications: Studies that were not available in English due to language proficiency constraints of the review team. The 10 additional papers were identified using citation tracking and backward snowballing techniques, ensuring that they served as anchor papers closely aligned with this study's focus on infant cry classification, feature extraction methods, and deployment strategies.

A 2-stage screening process was used to ensure thoroughness and reduce the bias arising. Two reviewers independently screened all titles and the corresponding abstracts in the first step to assess relevance based on the inclusion criteria. Afterward, the papers were advanced to the next stage if and when at least one reviewer deemed them relevant. In cases where consensus at the title and abstract level could not be achieved between the 2 reviewers, an adjudication by a third person was sought on a consultation basis and on the purpose. During the second stage, 2 independent reviewers performed a full-text blind review. Consensus was obtained through deliberation between reviewers when required. Consensus meetings were held to resolve any disagreements and uncertainties. The objectivity of the criteria was assessed either prereview on a test set by measuring agreement or postreview.

Data Synthesis and Comprehensive Analytical Approach

In alignment with the review questions, the following information points were recorded and analyzed: (1) year of publication, (2) contribution of each study, (3) categorization of each study per the relevant research method type, (4) classification techniques and methods used in each study, (5) nature of feature extraction methods used, (6) deployment strategies discussed, (7) practical applications and settings where the techniques were applied (eg, hospitals or home-based care), (8) reported accuracy levels of the classification methods, and (9) data sources used in the studies. Tables and graphs were developed to summarize these information points, providing a comprehensive overview of the advances in infant cry classification methods, deployment strategies, and practical applications. The oldest paper in our analysis was from 2003, with a trend of increasingly more publications Table 2, which speaks to how this is an emerging area of research and interest.

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Table 2. Distribution of study designs and deployment strategies.

Study design and deployment strategy	Values, %
Not deployed	109 (86.5)
Experimental study design	103 (81.7)
Primary dataset used	85 (66.7)
Secondary dataset used	46 (36.5)
Denoising performed	31 (24.6)
Descriptive study design	20 (15.1)
Correlational study design	11 (8.7)
Confidentiality compliance	10 (7.9)
Quasi experimental or causal-comparative study design	9 (7.1)
Software	6 (4.0)
Android	4 (2.4)
IoT[a]	3 (1.6)
Web	2 (0.8)

[a]IoT: Internet of Things.

Quality Assessment

The objective of this quality assessment was to evaluate the significance and validity of each selected document in the context of advances in infant cry classification. As much as the quality rating did not significantly influence the selection of the primary investigations, the assessment aimed to reflect the overall validity of the chosen studies. The TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) standard [19] was used as a measure of conventional quality standards. Each paper was scored based on adherence to the TRIPOD checklist, with binary scores assigned as either 1 (compliant) or 0 (noncompliant). Moreover, all the reviewed papers were additionally required to achieve a score higher than 50%. For a detailed checklist of the TRIPOD assessment, see Multimedia Appendix 4.

The TRIPOD checklist was used to evaluate the reporting clarity and comprehensiveness across all the studies that were considered and selected. Each study was evaluated by the dint of key TRIPOD components, with a maximum score of 5 points. All studies achieved the highest score, reflecting ample adherence to the TRIPOD guidelines. The high degree of compliance ensured transparency and thoroughness in reporting, thereby facilitating the reproducibility of the final study results.

This study relied on the Cochrane Risk of Bias 2 (RoB2) tool to assess the risk of bias (RoB) in the selected studies. Given that the main participants of the reviewed studies were infants with varied audio cry characteristics, the RoB2 tool was deemed appropriate for evaluating domain-specific and overall risks of bias. The RoB assessment covered the following five key domains: (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias arising from missing outcome data, (4) bias in the measurement of outcomes, and (5) bias in the selection of reported results. The results of the RoB assessments were summarized in Table 3, and detailed individual RoB ratings were made available in Multimedia Appendix 5.

Table 3. RoB[a] assessment.

RoB	Low, n	Some concerns, n	No information, n
Randomization process	121	1	4
Deviations of interventions	125	1	0
Missing outcome data	31	95	0
Measurement of outcome	124	2	0
Selection of reported result	122	4	0
RoB overall	116	10	0

[a]RoB: risk of bias.

The assessment of the randomization process bias indicated that most studies, 96% (n=121), were considered to have a low RoB, suggesting minimal influence from human choices or external factors on outcomes. A small portion, 1% (n=1) [20], raised some concerns, while 3% (n=4) lacked sufficient information to assess bias accurately. These findings imply that, overall, randomization in most studies was robust, supporting the credibility of their results.

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The assessment of deviation from intended interventions bias showed that 99% (n=125) of studies had a low RoB, indicating a strong alignment between intended and actual interventions. Only 1% (n=1) [21] of studies presented some concerns, suggesting that, overall, most studies maintained consistency in their intervention protocols, minimizing the RoB in this area.

The assessment of missing outcome data bias revealed a significant area of concern, with 75% (n=95) of studies flagged for potential bias due to incomplete or missing outcome data. Only 25% (n=31) of studies were considered low risk in this domain, suggesting that missing data may introduce biases that could affect the reliability of the study outcomes and their interpretation.

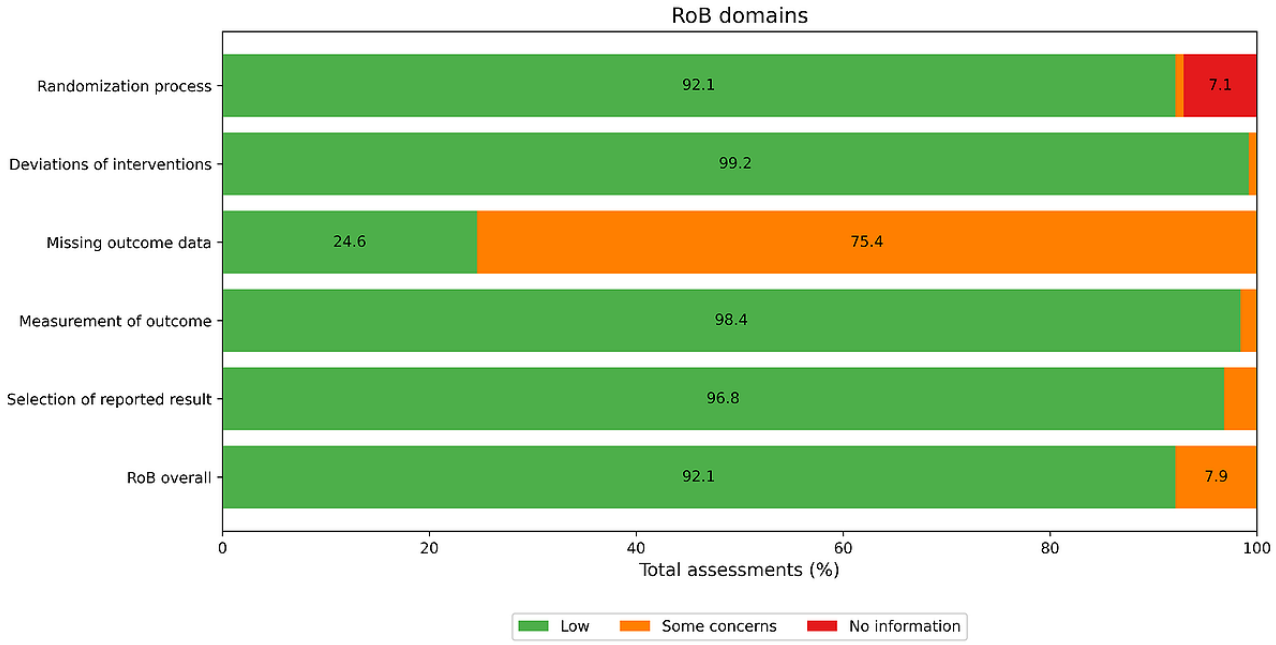
The assessment of measurement of outcomes bias indicated that 97% (n=122) of studies were at low risk, demonstrating the use of robust measurement techniques across most studies. Only 3% (n=4) showed some concerns, suggesting that outcome assessments were generally reliable and unlikely to introduce significant bias.

The assessment of selection of reported results bias showed that 97% (n=122) of studies were at low risk, indicating that most studies reported results comprehensively without selective bias. Only 3% (n=4) raised minor concerns, suggesting minimal issues with incomplete reporting across the studies.

The overall assessment of RoB indicated that 92% (n=116) of the studies posed a low risk, while 8% (n=10) showed some concerns. These concerns were mainly related to handling and reporting missing outcome data, suggesting that most studies were methodologically sound, with only a few displaying minor issues that could impact data reliability.

The RoB2 assessment affirmed the overall reliability of the included studies, with low risk across most domains that were of interest. The TRIPOD assessment, however, confirmed that all studies met the reporting standards necessary for transparency and reproducibility, achieving the maximum score. The Cochrane RoB2 assessment supported the robustness of the reviewed studies, identifying consistently low RoB across most domains. However, missing outcome data was the primary area of concern in a subset of different studies. These findings reinforced the methodological soundness of the included research, contributing valuable insights to the field of infant cry classification as a whole. Figure 1 provides a visual representation of the distribution of risk across all domains of interest, highlighting the minimal overall RoB.

Figure 1. Visual representation of the distribution of RoB. RoB: risk of bias.



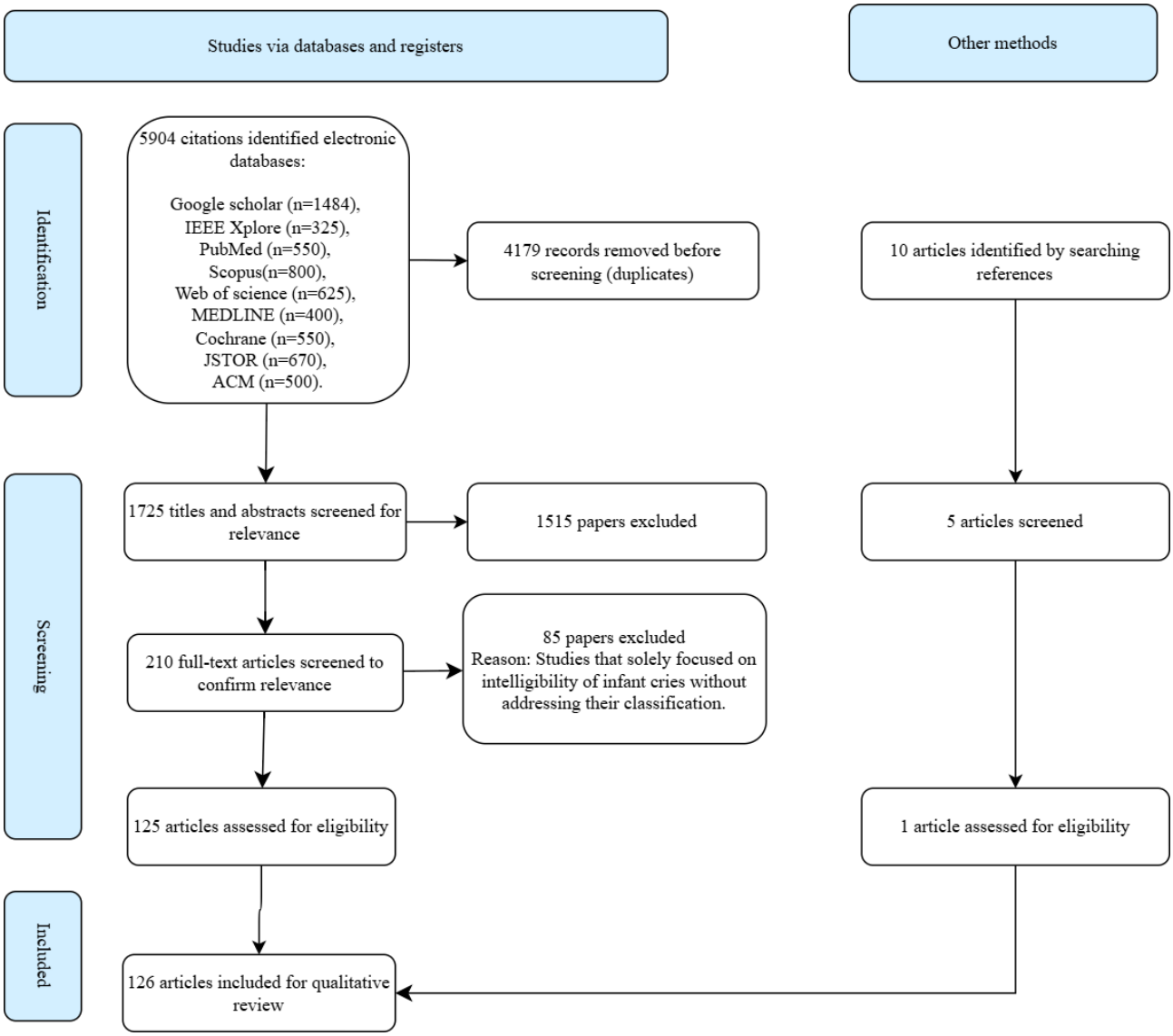
Results

Overview

The findings in this section have been structured according to the classification of studies reviewed and the technical considerations for contextualizing infant cry classification. The selection process was seamlessly done, as presented in Figure 2.

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Figure 2. PRISMA flowchart. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



Feature and Method Use Across Studies

The analysis of the reviewed studies revealed that there was a varied distribution of features and methods that were adopted for infant cry classification. According to the results from Figure 3, machine learning methods were the most applied techniques, used in 91.3% (n=115) of the studies that were reviewed. This reflects the increasing trend toward using machine learning models for complex data tasks in infant cry classification. Figure 4 shows the various features used by authors in classification.

Frequency domain features appeared in 79.4% (n=100) of the studies, citing their significance in signal processing tasks related to cry analysis. Other prominent methods included the time frequency domain 69% (n=87), cepstral domain 65.9% (n=83), and Mel-frequency cepstral coefficients (MFCCs) 57.9% (n=73), which are well-established in speech and audio signal processing. These methods highlighted the relevance of time-frequency representations and feature extraction in understanding infant cry patterns.

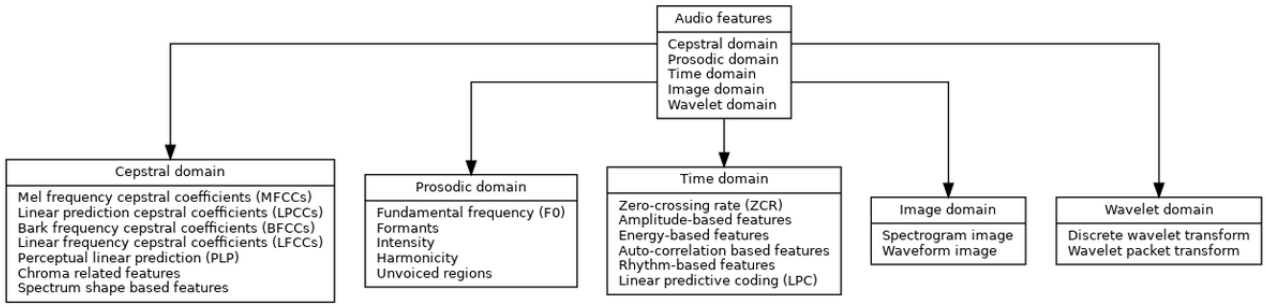
A relatively lower adoption was noted in image domain techniques 19.8% (n=25) and spectrograms 15.9% (n=20), which are visual representations of sound but are gaining traction in more recent studies. The wavelet domain and other features both constituted 8.7% (n=11) of the studies and were among the least used, while prosodic features were realized not to have been applied in any of the reviewed studies. The other features category (n=11, 8.7%) included nonlinear dynamical features such as Lyapunov exponents, correlation dimension, and entropy measures, as well as physiologically inspired features such as Bark frequency cepstral coefficients, Gammatone cepstral coefficients, and perceptual features such as perceptual linear predictive coefficients and harmonic-to-noise ratio. These findings suggest a strong preference for machine learning and signal processing techniques, particularly those that are rooted in frequency and time-frequency analysis domain, as core methodologies in infant cry classification research.

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Figure 3. Proportion of features and methods used over time.



Figure 4. Audio features relevant in classification. BFCC: Bark frequency cepstral coefficient; F0: fundamental frequency; LFCC: linear frequency cepstral coefficients; LPC: linear predictive coding; LPCC: linear prediction cepstral coefficients; MFCC: Mel-frequency cepstral coefficient; PLP: perceptual linear predictive coefficient; ZCR: 0-crossing rate.



Temporal Analysis of Feature and Method Use

The evolution of feature and method use across the reviewed studies was assessed over different 5-year time stamp periods, as shown in Figure 3. This analysis shows the findings of trends in the adoption of various techniques for infant cry classification between the years 2000 and 2024. From the study results, machine learning methods have shown a steady increase over time, starting at 18.6% (n=23) in the 2000-2005 period and rising to 19.1% (n=24) in 2021-2024. This reflects the growing reliance on machine learning models in cry classification tasks, particularly in recent years. Frequency domain features consistently remained a major component across all periods, with a peak use of 20.9% (n=26) between the years 2000 and 2005, though their application saw a slight fall to 14.5% (n=18) in the most recent period (2021-2024). MFCCs exhibited a notable rise in use from 4.7% (n=6) in the early 2000s to 13.2% (n=17) by 2016-2020, thereby affirming their importance in speech and cry signal processing–related tasks. Spectrograms and image domain features, although less prominent overall, demonstrated growth in adoption over time, particularly in the 2021-2025 period, where the use of spectrograms significantly increased to 5.9% (n=7), and the image domain rose to 6.6% (n=8). Statistical methods, however, showed a decline from 11.6% (n=15) in the 2000-2005 period to 7.2% (n=9) in 2021-2025, indicating a shift toward more sophisticated machine learning approaches over traditional statistical models. Time-frequency domain and cepstral domain methods maintained a relatively consistent usage across all periods, suggesting their continued potential relevance in the analysis of infant cry signals. Some methods, such as wavelet domain

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and other features, remained minimally applied, reflecting limited exploration in these areas compared to more dominant techniques such as machine learning. This temporal trend analysis highlights the increasing sophistication and diversification of methodologies applied in infant cry classification research over time. The growing use of machine learning and feature extraction techniques, such as MFCCs and spectrograms, indicates a shift toward more complex, data-driven approaches in the field.

Regional Distribution of Published Papers

The geographical distribution of published papers in the field of infant cry classification was one of the areas of interest and is summarized in Table 3. The data reveal a significant concentration of research efforts in specific regions, with Asia contributing to the highest proportion of papers, accounting for 54% (n=68) of the total. Most of these papers, 66.7% (n=45), were both primary and secondary research, indicating a strong engagement in both foundational and application-based studies in the region. Europe came at the second most active region, publishing 27.4% (n=36) of the total papers in this line of infant cries classification, with a notable portion of these being primary studies 30.3% (n=11). A further 16.7% (n=6) of European publications contributed to both primary and secondary research, while 26.3% (n=9) were secondary studies. In contrast, North America, including Canada and the United States, showed more limited contributions. The United States accounted for 9.7% (n=12) of the total papers, with the majority being primary studies 13.6% (n=2), and 5.3% (n=1) focused on secondary research pieces. North America as a whole contributed 3.5% (n=4) of the total papers, with a mix of primary and secondary research. Africa and Australia made smaller contributions to the research field, each contributing 1.8% (n=2) of the total papers. In these regions, primary research was minimal, with 1.5% (n=1) each for Africa and Australia, and a small percentage allocated to secondary studies 2.6% (n=1). This distribution, therefore, highlights a strong research presence in Asia and Europe, where substantial efforts are made in both primary and secondary research components. However, the comparatively lower research output from North America, Africa, and Australia suggests potential areas for increased research focus in future studies, thus increasing the diversity of datasets as shown in Table 4.

Table 4. Distribution of papers published in various regions.

Region	Primary, %	Primary and secondary, %	Secondary, %	Total papers published, %
Africa	1.5	0	2.6	1.8
Asia	47.0	66.7	57.9	54.0
Australia	1.5	0	2.6	1.8
Canada	3.0	0	0	1.8
Europe	30.3	16.7	26.3	27.4
North America	3.0	16.7	2.6	3.5
United States	13.6	0	5.3	9.7

Distribution of Study Designs and Deployment Strategies

A significant proportion of the studies did not implement or reach up to the deployment stage, accounting for 86.4% (n=109) of the total. This high percentage highlights a predominant focus on theoretical or experimental research without necessarily extending to real-world deployment and applications. This consequently portrays a gap in the practical application of the models and methods in infant cry classification systems. Experimental study designs were prominent, comprising 81.7% (n=103) of the reviewed studies, indicating a strong inclination toward hypothesis-driven, controlled investigations. This is consistent with the field's reliance on experimental setups to validate novel approaches in audio signal processing, particularly for infant cry analysis. The use of primary datasets was reported in 66.7% (n=84) of the studies, depicting the importance of curated, original data in this domain. In comparison, the secondary dataset was used in 36.5% (n=46) of the studies reviewed, demonstrating the occasional reliance on publicly available or previously collected data for further analysis or validation purposes. In terms of specific methods, denoising techniques were performed in 24.6% (n=31) of the studies. This correlates with a lower proportion of studies reaching the production level and reflects the significance of noise reduction in improving the quality and reliability of infant cry signals, which are often affected by environmental noise while in production. Other methodologies included descriptive study designs 15.1% (n=19) and correlational study designs 8.7% (n=11), emphasizing the exploratory nature of some research within the field. These designs aimed to map out underlying relationships and trends within the data but did not necessarily involve the manipulation of variables. However, confidentiality compliance was reported in 7.9% (n=10) of the studies [22-31], pointing to a growing but limited awareness of the ethical considerations in handling sensitive audio data, particularly when it involves infants who are deemed minors. Additionally, quasi-experimental or causal-comparative study designs were used in 7.1% (n=9) of the studies, suggesting that a subset of research explored the causal relationships between variables without random assignment, though this approach was notably less common. Deployment of models in specific platforms was minimal, with software deployment at 4% (n=5) [20,32-35], hardware-based at 4% (n=5) [36-40], Android-based deployment at 2.4% (n=3) [24,40,41], Internet of Things (IoT) integration at 1.6% (n=2) [29,36], and Web deployment at 0.8% (n=1) [25] being among the least used strategies. These findings indicate limited implementation of the developed models in

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real-world systems, highlighting a critical area for future research in translating experimental findings into practical, scalable solutions and ultimately expanding scientific discoveries at a practical view.

The distribution of application of the deployed models in infant cry classification studies shows clinical diagnosis as being the most prominent at 30.6% (n=39), highlighting a focus on using cry analysis for diagnostic purposes in health care. Hospital-based applications follow at 20.8% (n=26), indicating a strong interest in deploying cry classification in clinical settings to aid in patient monitoring. Home-based care represents 16.7% (n=21), suggesting a practical interest in enabling caregivers to interpret infant cries at home. Infant monitoring systems account for 13.9% (n=17), reflecting use cases in continuous monitoring setups. Research-focused applications make up 11.1% (n=14), emphasizing ongoing exploration and development in the field, while other applications comprise the remaining 6.9% (n=9). The other 6.9% (n=9) category included applications such as wearable technology integration and mobile applications for caregivers. This distribution underscores the versatility of cry classification technology across various settings, from health care facilities to home environments.

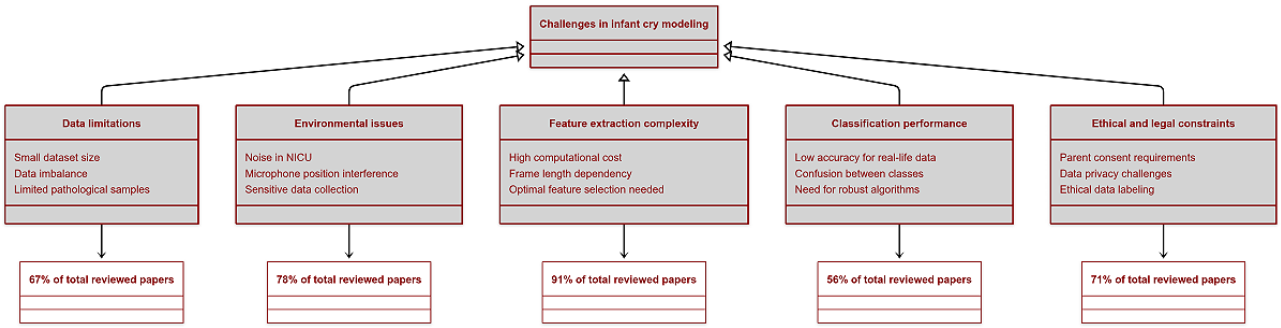
Model Performance and Evaluation

Supervised learning methods achieved the highest recorded accuracy, with a value of 0.9989, confirming the strong performance of supervised models when sufficient labeled data was available for training. Deep learning methods exhibited impressive performance as well, with the maximum accuracy reaching 0.9743. These methods have proven effective in handling complex, high-dimensional cry signals. Transfer learning models demonstrated robust accuracy, with the highest value at 0.9439. The use of pretrained models facilitated significant improvements in classification performance, particularly in cases where data were limited. Probabilistic learning methods recorded a maximum accuracy of 0.9848, indicating their capability to model uncertainties effectively in the cry signal data. However, the consistency of probabilistic learning across different datasets depends on factors such as dataset size, variability, and feature distribution. Unsupervised learning methods reached a maximum accuracy of 0.752, suggesting moderate effectiveness in infant cry classification without labeled data. Other methods, which may include less conventional or hybrid approaches, recorded the lowest maximum accuracy of 0.6743, indicating potential for further refinement or more specialized application in certain contexts.

Challenges in Infant Cry Modeling

The reviewed studies highlighted some of the challenges that researchers experienced in modeling the infant audio cry as depicted in Figure 5. The predominant challenges from the reviewed studies are comprised of data limitations, environmental issues, feature extraction complexity, classification performance, and ethical and legal constraints. The challenges culminated in the adverse impact on development, accuracy, and deployment of infant cry classification models, thus highlighting areas to be explored by the researchers to enhance methodologies and deployment schemes. Data limitations constituted emerged to be one of the challenges from 67% (n=84) of the reviewed studies, pinpointing issues with small dataset sizes, data imbalance, and limited availability of pathological samples. The scarcity of the labeled data, more so from the rare pathological conditions of interest, was realized to be negatively affecting the generalizability of the model and thus necessitates advanced data augmentation methodologies. However, the environmental challenges affected nearly 78% (n=98) of the reviewed studies, mainly due to background noise or within the neonatal intensive care units, which tends to interfere with the microphone placement and sensitivity during data collection processes. The studies showed that ambient noise and microphone variability distorted audio recordings, pausing challenges for models to accurately classify infants' cry signals. The complexity of the feature extraction of infant audio cries was identified from the 91% (n=115) of the reviewed papers as a technical challenge in modeling of infant needs through audio cries. The process of extraction was associated mainly with the high computational costs and frame length dependency, which in most instances necessitates careful parameter tuning to ensure optimal performance.

Figure 5. Limitations in infant cry modelling. NICU: neonatal intensive care unit.



Classification performance constraints arose from 56% (n=71) of the reviewed studies with common challenges in attaining high accuracies from models that were deployed into production. From the studies reviewed, it was realized that high performance in controlled environments does not translate to real-world settings, thus presenting a gap in model robustness and the necessity for improved algorithmic approaches with a relatively dynamic generalizability power.

Ethical and legal constraints were realized from 71% (n=89) of the studies as major challenges during data collection. These challenges were as a result of parental consent, data privacy, and ethical considerations in data labeling.

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Discussion

Summary of Findings

The aim of this systematic review piece was to comprehensively analyze the current state of infant cry classification research work, focusing on the methods, trends, and deployment strategies used across different studies. The results indicate a clear preference for machine learning methods, which were applied in over 91% (n=115) of all the studies that were under consideration. This trend, therefore, reflects the continuous adoption of data-driven techniques in infant cry analysis, as machine learning models offer more significant advantages in handling complex and high-dimensional data, such as audio signals in space and time domains. The temporal assessment review pointed to the realization of the substantial application of machine learning gaining upward steady adoptions from the early 2000s to the present day as an audio modeling technique. This evolution highlights a shift from traditional statistical methods, which have seen a notable decline in usage and applications, toward more advanced approaches such as deep learning, transfer learning, and probabilistic learning methods. These trends suggest that the field has embraced modern methodologies, but there remains a gap in the deployment of these models in real-world applications, as indicated by the limited use of platforms such as IoT and Web deployment on the same. Moreover, the geographical exploratory analysis showed that most studies were conducted in Asia and Europe, with Asia accounting for about over 50% (n=63) of the total research output from all studies that were under consideration. This distribution pinpoints the region's strong research engagement in both foundational and applied studies. However, regions such as North America, Africa, and Australia contributed fewer papers, suggesting potential areas for increased research focus in the future. The performance of the models was largely consistent with expectations. Supervised learning methods were realized to be achieving the highest accuracy, followed closely by deep learning methods, probabilistic learning, and transfer learning models. In contrast, unsupervised learning and other methods showed a notably lower performance, emphasizing the need for further exploration of these approaches in the context of infant cry classification.

Feature Extraction Methods

Feature extraction plays a pivotal role in signal processing and the infant cry classification process by transforming raw audio signals into relevant attributes and features that can be used to train the model. From the reviewed studies, it was evident that MFCCs were the most used feature across most studies that were under consideration (n=73, 57.9%). MFCCs' robust ability to capture the perceptual aspects of sound signal, particularly through the representation of the spectral envelope, qualifies them to be highly effective for infant cry discrimination. In extension, this is consistent with the broader field of speech processing, where MFCCs are widely accepted for their potential effectiveness as the foundational representation of both speech and audio signals, thus reflecting inherent ways of human hearing.

Spectrograms were used in 15.9% (n=20) of the studies and emerged as an alternative prominent audio signal feature extraction method. Spectrograms potentially provide a time-frequency representation of the cry audio signal, which enables models, particularly those using convolutional neural networks, to robustly identify patterns and variations in cry characteristics over time. This comprehensively covers both time and space, components forming a strong method for the spatial-temporal domain feature extraction method. The patterns of the infant's cry signal can be spatially and temporarily represented as either 2 dimensions or 3 dimensions. The notable rise in the use of spectrograms in conjunction with deep learning models highlights a shift toward even more sophisticated, data-driven approaches for infant cry classification. Apart from MFCCs and spectrograms, other commonly used features include pitch, duration, intensity, and 0-crossing rate, all of which tend to provide insights into the acoustic properties of infant cries. These time-domain and frequency-domain features, though less complex than MFCCs or spectrograms, still contribute valuable information to classification tasks, especially in traditional machine learning methods where simpler feature sets are often favored for their interpretability. One notable observation from the studies is the minimal use of wavelet domain features (n=11, 8.7%) [28,42-51]. Wavelet transforms offer the potential to capture both time and frequency information across multiple resolutions, which could enhance the detection of transient events in cry signals, such as sudden changes in pitch or loudness. Despite their theoretical advantages, wavelet-based features have not been as extensively explored, indicating a potential area for future research.

Additionally, the results indicate that prosodic features—such as rhythm, stress, and intonation—were not applied in any of the reviewed studies. Given their importance in speech analysis, prosodic features could be beneficial in understanding the emotional and physiological states conveyed through infant cries [52]. Incorporating prosodic features into future studies may offer deeper insights into the cry patterns associated with different needs or health conditions.

Implications

The findings of this review offer several important implications for the future of infant cry classification research and shift. The dominance of machine learning techniques indicates that data-driven methods will likely continue to play a pivotal role in advancing the field of applied sciences. However, the moderate performance of unsupervised approaches highlights the need for more research into models that can work with unlabeled data. This is particularly relevant as unsupervised learning methods could prove useful in cases where, for example, large volumes of labeled infant cry data are unavailable or difficult to obtain.

Notably, almost all the proposed models for audio classification are expected to be applied and implemented in a real-world environment where there could be potential background noise. Therefore, the growing use of denoising techniques in 24.6% (n=31) of the studies reflects the significant challenges posed by real-world noise in infant cry audio recordings. As most infant cry recordings are potentially prone to environmental

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disturbances, future research should focus on developing noise-robust models capable of maintaining high performance without extensive preprocessing. This has been realized in most of the studies showing how small perturbations could affect the precision of the audio signal classification, thus relaxing some of the model parameters.

However, another notable key finding was the limited deployment of these audio classifier models in real-world applications. Despite the advances in model accuracy and precision, very few studies reported actual deployment in mobile or Ios systems, which could bring these novel methodologies closer to practical use in health care or parenting contexts. Researchers and scientists should, therefore, prioritize translating these experimental models into deployable systems that can be tested and validated in real-world environments present with noise sound disturbances.

Limitations and Challenges Arising From the Reviewed Studies

Challenges arising from classification accuracy under real-life applications show that current algorithms may require enhancements to achieve generalizability from unseen input datasets. Models are preferred to accurately discriminate subtle variations in the infant cries, which potentially reflect different needs or conditions that necessitate more advanced architectures, such as ensemble or multimodal learning frameworks for signal processing and discriminations [53]. The challenges that were encountered in infant cry modeling from the studies reviewed potentially unveil important areas for future innovation and research gaps.

Feature extraction emerged as a primary technical barrier, with high computational requirements and dependencies that may constrain near real-time application solutions [54]. To that extent, optimizing the feature extraction process for efficiency purposes without sacrificing accuracy could be essential for the ultimate deployment of the models in both clinical and parental support applications. For example, empirical approaches such as automated feature learning coupled with adaptive extraction methods could streamline and minimize this challenge [55]. Furthermore, minimizing computational overhead could also smoothen the feature extraction process while enhancing classification precision as the ultimate reward. Background acoustics factors, such as ambient noise and variability in data acquisition, require robust noise mitigation and preprocessing audio methodologies. The infant cries recordings captured in real-world setups, especially in neonatal intensive care units and home environments, are highly susceptible to significant interference where even minor disturbances can significantly impact the audio quality [56]. One way to potentially address this challenge would be to integrate adaptive denoising techniques that can dynamically adjust to various noise conditions as the intermediate layer before the classification stage, which could enhance model reliability and applicability in diverse environments. However, the data constraints observed from the reviewed studies pin the importance of larger, more varied datasets to improve model generalization and reduce overfitting. Collaborative efforts for data-sharing schemes, synthetic data generation, and augmentation could be some of the ways to address these limitations in both quantity and diversity. Ethical and legal considerations, particularly around data privacy and parental consent, are also paramount due to the sensitive nature of infant cry data. Privacy-preserving methods, such as federated learning and differential privacy, could facilitate model development without compromising data security [57]. Standardizing ethical guidelines and consent procedures will not only protect participants but also reinforce public trust in these technologies, essential for broader adoption in health care contexts [58].

Conclusion

This systematic review has indeed provided a detailed examination of different methods, trends, and strategies used in infant cry classification across different regions in the world. The findings suggest that while supervised learning and deep learning methods currently lead the field in terms of accuracy and performance of audio classification, there is a need for further exploration of other techniques such as unsupervised learning and the ultimate deployment of these models in practical, real-world settings. Moreover, the growing adoption of advanced feature extraction techniques such as MFCCs and spectrograms reflects the increasing sophistication of infant cry analysis models. However, real-world deployment and validation remain limited, pointing to a critical area for future research. By focusing on noise-robust models, unsupervised learning, and practical deployment in health care settings, the field of infant cry classification can continue to evolve and contribute to improved health outcomes for infants. Additionally, there remains an unequal distribution of infant cry classification studies across continents, thus pointing to opportunities for more geographically diverse research. Focusing on these areas will enable continued advancements in infant cry classification, ultimately supporting improved health outcomes for infants and availing audio data for further experimental research.

Acknowledgments

This research was supported by the Google 2024 PhD Fellowship. We gratefully acknowledge their invaluable support, which has been instrumental in advancing this work.

Authors' Contributions

GO was responsible for the conceptualization of the systematic review and contributed significantly to the drafting of the introduction, methodology, results, discussion, and conclusion sections. GO also prepared the original paper and took part in its validation. BS contributed through paper review and editing, provided oversight for this study, and assisted in validating the research and advising.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA checklist.
[DOCX File , 31 KB - rehab_v12i1e69457_app1.docx]

Multimedia Appendix 2
PICO framework of the research questions.
[DOCX File , 15 KB - rehab_v12i1e69457_app2.docx]

Multimedia Appendix 3
Databases and search terms used in the literature search.
[DOCX File , 15 KB - rehab_v12i1e69457_app3.docx]

Multimedia Appendix 4
TRIPOD checklist for quality assessment of the prediction models.
[DOCX File , 20 KB - rehab_v12i1e69457_app4.docx]

Multimedia Appendix 5
Cochrane risk of bias. Assessment of the risk of bias for each study.
[DOCX File , 42 KB - rehab_v12i1e69457_app5.docx]

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Abbreviations

FLACC: Face, Legs, Activity, Cry, Consolability
IoT: Internet of Things
MFCC: Mel-frequency cepstral coefficient
PICO: Problem, Intervention, Comparison, and Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RoB: risk of bias
RoB 2: Risk of Bias 2
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Review

Utilizing Smart Televisions as Assistive Technology to Enhance Communication and Social Lives of Older Adults: Systematic Review

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Abstract

Background: Over the past decade, the proportion of the world's population aged ≥65 years has grown exponentially, presenting significant challenges, such as social isolation and loneliness among this population. Assistive technologies have shown potential in enhancing the quality of life for older adults by improving their physical, cognitive, and communication abilities. Research has shown that smart televisions are user-friendly and commonly used among older adults. However, smart televisions have been underutilized as assistive technologies.

Objective: This study aimed to explore the state of the art in using smart televisions as assistive technologies to enhance communication and social interactions among older adults.

Methods: The search was conducted following the guidelines for performing a systematic literature review, which included 6 databases, that are, the IEEE, ACM, Google Scholar, ScienceDirect, Engineering Village, and Springer. A range of keywords were used in different combinations, including "smart TV," "older adults," "elderly," "communication," "messaging," "video call," and "application." A set of inclusion and exclusion criteria was defined before the search, and the screening was performed by 3 researchers. We analyzed the selected articles in accordance with the review's aim and the established inclusion and exclusion criteria. None of the articles were subjected to quantitative synthesis because of the significant variations in the data measured.

Results: After screening 2671 records from the abstract level to full text, 30 articles were identified as relevant studies, demonstrating both direct and indirect impacts on the social lives of older adults through the use of smart televisions as assistive technology. Some articles were part of the same or larger studies, which makes the number of actual projects even smaller. This indicates that smart televisions have been underutilized as assistive technologies for enhancing older adults' communication and social lives. More than half of the articles proposed their own prototype, and these prototypes were primarily targeted for use at home, while some were targeted for use at geriatric care units or nursing homes. User involvement among older adults was high among the included articles, and some also included other users, such as health care personnel, administrative staff, and engineers. The included studies were mostly from Europe.

Conclusions: This review highlights the potential of smart televisions as assistive technologies to enhance social connectivity among older adults, and identifies several research gaps. Most studies focus on short-term usability and are geographically limited to Europe. Future research should include longitudinal studies, explore diverse cultural attitudes, and focus on adaptive solutions for various health conditions. We hope this review will inspire research on smart televisions as assistive technologies, enhancing social interactions and quality of life for older adults.

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KEYWORDS

smart television; assistive technology; older adults; communications; social lives; elderly people; social contact

Introduction

Background

Over the past decade, the proportion of the world's population aged ≥65 years has grown exponentially. Researchers have taken an interest in this growth and have recognized the importance of exploring ways to accommodate the older adult community. The older adult population faces numerous challenges, ranging from physical decline to cognitive dysfunction. However, one of the most notable barriers that older adults face is social isolation [1]: the disconnection from friends, family, and the world around them. Loneliness is 1 of the 3 main factors leading to depression, a prominent condition among older people [2]. Social isolation and loneliness in old age have significant negative impacts on both physical and mental well-being [1]. As the world's population of older adults grows, digital technology has increasingly and significantly influenced their daily lives. As we continue to age globally, it is critical that assistive technology is used to our advantage as a tool for ensuring that older adults age with a good quality of life. The World Health Organization defines assistive technology as an umbrella term for assistive products and their related systems and services [3]. Assistive technologies can help improve an individual's functioning regarding cognition, communication, hearing, mobility, self-care, and vision; thus, enabling their health, well-being, inclusion, and participation. Although a large population of older adults hesitate to use technology, many of them, as well as their caregivers, benefit greatly from assistive technologies [3]. In many countries, research has shown that the number of users of assistive technologies seems to increase with age. A study in a subsample of a population aged 79 years showed that 64% of them had one or more assistive technologies, specifically for bathing [4]. Wheelchairs and stairlifts also enhance the mobility of older adults [5]. Hearing aids and automated lighting systems support older adults with both activities of daily living and independent activities of daily living [6]. At the same time, the rapid growth of the older adult population has also raised awareness of the importance of aging at home. Extending the time before older adults need to move into long-term care facilities or nursing homes can be achieved by creating a comfortable environment for aging at home. However, one of the challenges older adults face as they age is maintaining connections with friends, family, and society as a whole. Older adults who live at home are more susceptible to feelings of loneliness and depression [7]. Despite the development of information and communication technologies over the past decade, Choi and Lee [8] in their systematic literature review, found only 23 relevant studies that used information and communication technology to improve social participation among older adults and reduce their loneliness. On top of that, future research needs to look more into emerging technologies such as the Internet of Things, augmented reality, and virtual reality, as older adults are often not sufficiently addressed in the design and implementation of these technologies, as reported by Thangavel et al [9] in their scoping review. A study conducted in China on implementing smart homes to build connectivity discussed how most research and development of smart homes has actually focused on younger people, leaving little attention to older adults [10]. In addition, around 63% of older adults in Canada are either nonusers or basic users of the internet and digital technologies [11]. On average, 22.3% of the older population in Europe uses computers, and 16.8% are internet users, with large differences between age groups [12]. These disparities and usability barriers pose significant challenges in implementing assistive technology intended to enhance social interactions among older adults.

Tapia et al [13] argued that the introduction of computer-based technologies for social interactions has negatively affected the ways older adults interact with their family members. This can be attributed to a lack of technological knowledge in this demographic and to their reluctance to adopt new technologies. Rather than utilizing computer-based technologies and other touch screen devices, such as smartphones and tablets, research has shown that it can be more effective to utilize smart televisions as an assistive technology for older adults, to provide them with opportunities for social interactions. A study in Portugal has shown that integrating technology into already familiar objects can reduce this reluctance to adopt new supports [14]. Among all familiar objects, smart televisions appear to be one of the most promising. Smart televisions offer unique advantages that make them particularly suitable for enhancing accessibility and convenience in everyday life among older adults. Their widespread availability ensures that many older adults already have access to this technology, reducing the need for additional purchases or installations. The integration of smart televisions as assistive technologies into daily life has high potential, as many older adults already use televisions as a central part of their routine. This approach not only facilitates the adoption of new technology but also enriches the user experience without overwhelming them with unfamiliar devices. A study conducted by Wang et al [15] reported high television watching time among 252 older adults aged between 65 and 88 years, where approximately 25% of them spent more than 4 hours per day watching television. According to a study conducted by Alaoui and Lewkowicz [16], smart television applications to support socially oriented activities for older people have been designed. They propose that integrating smart television as an assistive device considers quality of life by improving their well-being and self-esteem [16].

Objectives

To the best of our knowledge, despite the advantages offered by smart television design, its potential as an assistive technology for enhancing social communications among older adults has not been thoroughly explored. Thus, this study aimed to explore the state of the art in utilizing smart televisions as assistive technology for older adults to improve their communication and social lives.

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Methods

Search Strategy

We performed the search based on the guidelines for performing a systematic literature review. A total of 6 databases were recommended: the IEEE, ACM, Google Scholar, ScienceDirect, Engineering Village by Brereton et al [17], and Springer by the Evidence-Based Software Engineering Technical Report [18]. This review was conducted without registering a protocol. The inclusion and exclusion criteria were defined before the search, as provided in Textbox 1.

Textbox 1. Inclusion and exclusion criteria for the study.

Inclusion criteria

- Only articles published in the last 12 years were included; the concept of smart televisions is fairly new. Smart televisions only became mainstream in 2015. Before that, they were known as internet televisions [19], and there is a clear difference in what a smart television can do as compared with an internet television.
- The target group of research studies must be older adults aged ≥60 years; this is based on the World Health Organization definition of older adults [20].
- Articles must focus on how smart televisions are used as assistive technology, specifically as tools to improve the health, well-being, and quality of life of older adults. They must include an aspect of communication and social interaction among older adults.
- Articles must focus on assistive technologies that aim to provide a supportive living environment for older adults living at home or by themselves.
- Only peer-reviewed publications were included.
- Only English articles were included.

Exclusion criteria

- Articles where smart televisions are not used as assistive technologies, such as those purely focusing on entertainment without any implications on communication or social interaction, were excluded.
- Articles focusing on technologies, such as mobile phones, tablets, laptops, or any technologies other than smart televisions, were excluded.
- Dissertations, theses, and gray literature (eg, patents, research reports, and policy documents) were excluded.
- All non-English articles were excluded.

Screening and Analysis

The search was conducted from February 20 to February 27, 2024. A range of keywords were used in different combinations, including "smart TV," "older adults," "elderly," "communication," "messaging," "video call," and "application." The search yielded 6829 results: 169 (2.47%) from ScienceDirect, 13 (0.19%) from Engineering Village, 2 (0.03%) from the IEEE, 133 (1.95%) from the ACM, 4649 (68.08%) from Google Scholar, and 1863 (27.28%) from Springer. The screening process was conducted separately by the JL, CTC, and WKB. We removed 4158 (60.89%) duplicates and screened the remaining records. Their titles and abstracts were read for this round of screening, which resulted in the exclusion of 2610 (38.22%) records. The remaining 61 (0.89%) articles were read in full text to assess for eligibility. A total of 31 (51%) articles were excluded at this round of screening, and 30 (49%) articles were included. None of the articles were subjected to quantitative synthesis because of the significant variations in the data measured across the 30 included articles. Throughout the process, any disagreements were resolved through consensus.

On the basis of the aim of the systematic literature review, the included articles were analyzed according to the criteria described in Textbox 2.

Textbox 2. Criteria for analyzing the included studies.

- Objective or objectives of the study
- Outcomes of the study, whether design, development, or framework or guidelines
- Methodology focusing on design
- Methodology focusing on evaluation
- New technology developed (what kind of technology and where it should be used)
- Impact on social interactions, whether direct or indirect
- Sample size and demographics (either during the design or evaluation process)
- User involvement; if yes, at which stage?
- Country or countries

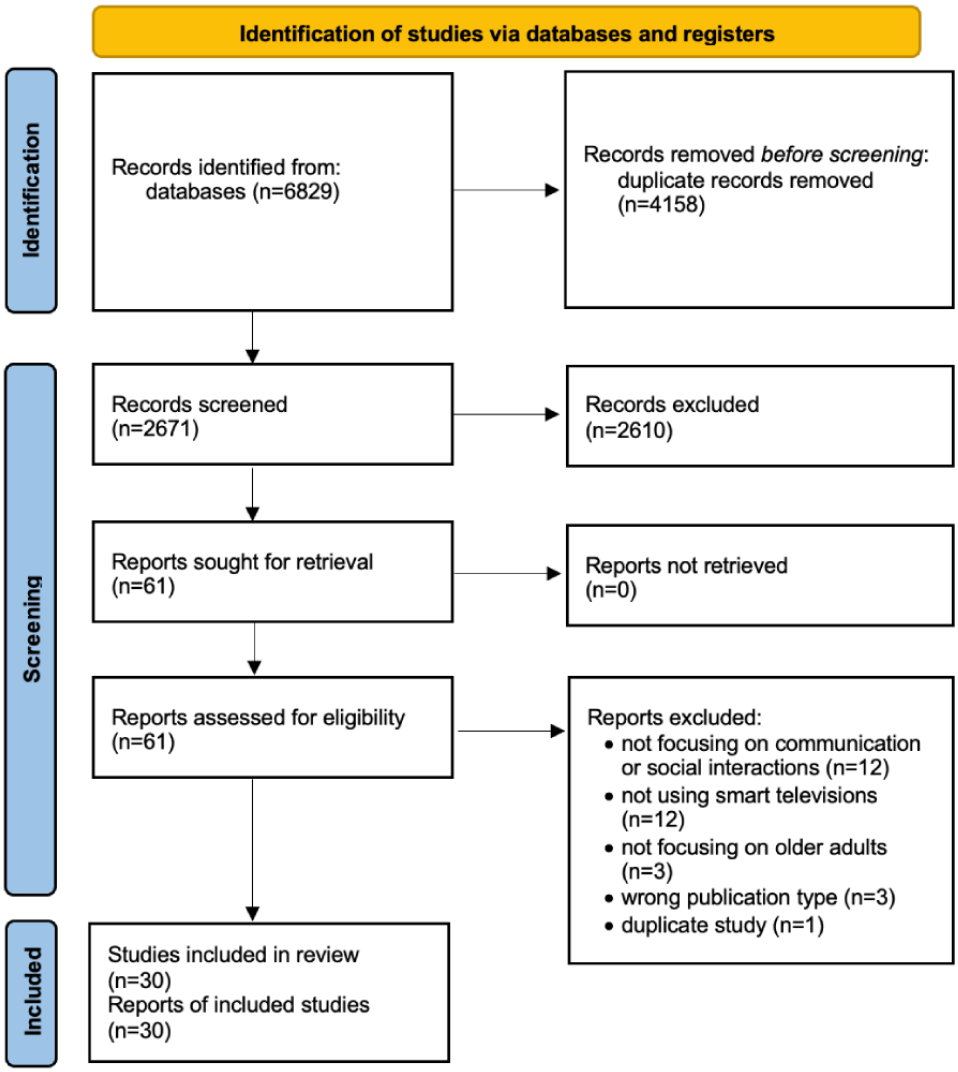
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Results

Study Selection

Figure 1 depicts the entire process using a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram [29], providing details on the reasons for excluding certain articles along with their corresponding quantities. Table 1 summarizes the details of each of the 30 included articles according to the analysis criteria. Six studies are related to the fostering social interactions for better life experience (FoSIBLE) project, which aims to provide bridging spaces to foster social interactions and experiences among older adults [16,21-25]. Despite focusing on the same project, we included all 6 studies and identified them as relevant through the search and screening process, as the objectives and reported outcomes of these articles were not exactly the same. Other than the FoSIBLE project, López et al [26], López et al [27], Tapia et al [13], and Gutierrez et al [28] were also from the same project.

Figure 1. The PRISMA flow diagram.



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Table 1. Summary of the review results.

Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
Alaoui and Lewkowicz [16]	To investigate the use of interactive televisions for virtual networks and online generational communities as a means to compensate for the lack of relationships, prevent isolation, and enhance self-esteem among older individuals living alone at home.	• Design: a living laboratory approach, including semistructured interviews and scenario presentation to end users, was conducted iteratively. • Evaluation: proposed user testing using mock-up and focus group only; evaluation yet to be conducted.	The daily habits, lifestyle, and actual needs of participants in using television for group activities and communication, including product design, functionalities, and usability.	Yes, the FoSIBLE[a] platform using HBBTV[b]. End users were able to use functions such as widgets, chat, book club, and vital date.	Yes, during the design phase; home setting.	A total of 10 older adults (8 females and 2 males), aged 65-90 years; France.
Alaoui et al [25]	To present the FoSIBLE and PaeLife[c] projects, which propose solutions to support social interaction and social life among older adults. To describe the living laboratory approach and the ways in which the services were defined based on user analysis.	• Design: a living laboratory approach, including semistructured interviews. • Evaluation: usability testing for FoSIBLE and qualitative and observational analysis for PaeLife.	Accessibility of the application content and the device platform, feedback on the design of the device, and the interface of the smart television widget.	Yes, the FoSIBLE platform and the PaeLife application, a personal life assistant designed to enhance the social life of older adults.	Yes, during the design and evaluation phases; home setting.	The study included 10 older adults (8 females and 2 males), aged 65-90 years; France.
Alaoui et al [22]	To report the strategies and outcomes of implementing a UCD[d] approach when designing interactive television-based services for older adults under the FoSIBLE project.	• Design: (1) a UCD approach, including semistructured interviews and focus group, and (2) persona creation. • Evaluation: iterative focus group sessions with mock-ups presented.	User feedback concerning needs, user acceptance, functionalities, and usability.	Yes, FoSIBLE platform using HBBTV.	Yes, during the design and evaluation phases; home setting.	The study included 10 older adults (8 females and 2 males), aged 65-90 years; France, Austria, and Germany (the authors noted that the interviews were conducted in all 3 countries, but the demographic information was only provided for the interviews in France).
Drobics et al [24]	To showcase the initial outcomes of the approach in using various multimodal interaction techniques for an integrated solution combining smart television with a social community platform, as part of the FoSIBLE platform.	• Design: N/A[e]. • Evaluation: End-user evaluation using a Kinect device.	Suitable mode of interaction and set of gestures.	Only specialized software components for gestures and a tablet interface to interact with the smart television were developed.	Yes, during the evaluation phase only.	The study included 24 participants, but no demographic details were reported; Austria.

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
Alaoui and Lewkowicz [21]	To contextualize the FoSIBLE project by highlighting the challenges of an aging population and the potential solutions offered by social television. To address issues related to the design and assessment of technologies through a living laboratory approach. To reflect on lessons learned and pinpoint recommendations.	• Design: a living laboratory approach, including semistructured interviews. • Evaluation: a 2-step evaluation; the first step was heuristic evaluation through expert testing sessions; the second was a system usability and usefulness assessment.	The usability of the proposed social television and the appropriateness of the design for older adults.	Yes, but no technical details were provided.	Yes, during the design and evaluation phases; home setting.	No information was provided about experts performing heuristic evaluations. The study included 5 older adults (2 males and 3 females), aged 67-92 years; France.
Müller et al [23]	To investigate the use of social television systems by older adults concerning how these systems interweave with sociocultural issues via a living laboratory approach and to reflect on the methodological approaches throughout the process.	• Design: not reported in detail; previous user studies and a living laboratory approach were mentioned. • Evaluation: a questionnaire, followed by individual demonstration sessions for usability testing; qualitative interviews were also conducted.	Questionnaire: an overview of the participants' actual use of technologies. Demonstration sessions and interviews: the usability and functionality of the FoSIBLE program for older adults on social television.	Yes, Android television, with the FoSIBLE platform.	Yes, during the design and evaluation phases; home setting.	France: the study included 5 older adults (2 males and 3 females), aged 67-92 years. Germany: the study included 5 households comprising 9 individuals (all couples living together except for 1 single man; 6 males and 5 females).
Camargo et al [30]	To investigate whether linking intelligent personal assistants to television systems can enhance the social interactions of older adults with their family members, friends, and caregivers.	• Design: not reported. • Evaluation: a questionnaire and interviews.	The usability and acceptability of the proposed system, as well as perceptions of decreased feelings of loneliness among participants.	A prototype developed by integrating Google Assistant, Amazon Fire TV, and a notifications app for television.	Yes, during the evaluation phase only; home setting.	The study included 6 older adults, aged 64-90 years. Testing was conducted in Brazil; however, all authors were affiliated with a university in Portugal.
Coelho et al [31]	To propose the design of the SNSs[f] that adopt technologies already familiar to older adults, such as televisions, to improve their ability to interact with these systems.			You, me & TV prototype, providing 3 modalities (remote control, voice, and gesture) and 3 features (content publishing, content visualization, and group management) was created, but had not yet been fully developed.	Yes, during the design phase; home setting.	Population characterization: the study included 31 participants (20 female and 11 male), aged ≥60 years, approximately 93% of the participants had visual impairments, 36% had hearing impairments, and 33% expressed difficulty remembering past events. Participatory design: the study included 17 participants (14 female and 3 male), aged ≥60 years; Portugal.

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
		• Design: (1) a population characterization phase using semistructured interviews and (2) a participatory design phase through focus groups. • Evaluation: only user testing was proposed, but it had not yet been conducted.	Population characterization: user requirements to effectively use SNS technology, preference, and perspectives on using different technologies to access SNS. Participatory design: recommendations to improve the UI[g].			
Cortellessa et al [32]	To present ongoing work in designing and developing the TV-AssistDem solution, which aims to enable remote assistance for patients by using television-based data transmission and video interactivity among patients, family members, caregivers, and health care professionals.	• Design: cocreation with potential end users through focus groups at different phases of the design and development process. • Evaluation: (1) internal testing with health care professionals, experts, and caregivers for iterative improvement and (2) feasibility study with 2 subphases. The first phase involved usability testing (with data collection through observation, think-aloud protocols, and the SUS[h] questionnaire). The second phase involved a prepilot study (including use observation and feedback collection).	Design: usability and functionality, specifically relating to existing and additional services for the management of dementia; improvements to the current UI; and identification of user needs (people with MCI[i] and their formal and informal caregivers). Evaluation: (1) internal testing—iterative feedback regarding usability and functionalities aligned with user requirements and (2) feasibility study—assessment of the functionalities and usability of the TV-AssistDem platform, closely resembling the first phase of a larger-scale clinical trial, and assessment of the platform's use in participants' homes and its impact their well-being for the second phase.	Yes, the TV-AssistDem system which uses a set-top box, a webcam, and a dedicated remote control.	Yes, during the design and evaluation phases; home setting.	Design: (1) the study included 90 patients aged ≥60 years, who scored 23-27 points on the MMSE[j] and had self-perceived or caregiver-perceived cognitive impairment that had been present for >6 months; and (2) health care workers specializing in dementia and cognitive decline, and informal caregivers. The number of participants who were health care workers and caregivers was not reported. Evaluation: (1) internal testing—the study included 7 participants comprising technology experts, usability experts, and health care professionals and (2) feasibility study—for the usability test, no details about the sample were reported other than the indication that it was a small group of representative users and a report on how they were involved. For the prepilot study, the study included 15 patients aged ≥60 years who scored 23-27 points on the MMSE and had self-perceived or caregiver-perceived cognitive impairment that had been present for >6 months. Design: Spain and Romania. Evaluation: Italy and Switzerland; the authors were from all 4 countries.

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
Costa et al [33]	To design, develop, and evaluate a smart television–based technology that delivers social and health services for older adults at home, while ensuring access to all services.	• Design: requirements capture and analysis with stakeholders. • Evaluation: a pilot test involving pre- and post-questionnaires with home users over a period of 7-15 days.	Design: identification of user requirements. Evaluation: usability, functionality, and acceptance. To validate the findings, the information gathered via questionnaires was compared with the data collected by the platform regarding the access of users to the system and applications.	Yes, hosted on a home theater PC (a computer designed to accompany a television set) and providing a variety of applications, such as social network clients, vital signs monitoring, interactive television contests, and conventional online care, including medication reminders and telemedicine.	Yes, during the design and evaluation phases; home setting.	Stakeholders: the social and health services of the regional government of Galicia, the most active senior associations, residential and day centers, in-home care solutions, and senior members of the engineering group responsible for the technical design. Older adults: 62 (50% male and female), around the region of Galicia. At least 65 years old (ie, retirement age in Spain at the time of the pilot). Spain.
Costa and Duarte [34]	To develop an adaptive multimodal fission component, integrated into the multimodal "Gentle UI for Elderly People" (GUIDE) framework, which aims to customize television-based application UI to suit specific user traits, enabling older adults and impaired users to interact through multiple output modes to address their interaction challenges.	• Design: a UCD. User studies were conducted with end users during the early phases. • Evaluation: user studies were conducted; however, no details were provided.	Usability, acceptance, and adoption of multimodalities when interacting with television-based applications.	Not precisely a technology but a framework, GUIDE was developed using hybrid television platforms and services, which include application platforms such as HBBTV and proprietary middleware solutions from television manufacturers.	Yes, during the design and evaluation phases; home setting.	Not specified; Portugal.
Doppler et al [35]	To develop "BRELOMATE," a television- and tablet-based communication and entertainment platform that fosters user engagement and promotes social participation among older people, with a focus on adopting a participatory design approach.	• Design: a UCD with iterations and a participatory design approach, including focus group and task-solving exercises. • Evaluation: a field trial with time slots (4-6 participants in 6-12 weeks; because of overlap, there were once 19 participants simultaneously).	Robustness, applicability, and feasibility of the platform; usability of the platform and the online communication and entertainment services.	Yes, the "BRELOMATE" platform.	Yes, during the design and evaluation phases; home setting.	Design: the study included 4 females and 3 males; age was not specified. Evaluation: at the start, 33 participants were enrolled. A total of 3 participants withdrew because of installation problems. At the end, 15 participants (females and males), aged 50-84 years, completed the trial; Austria.
Dragić et al [36]			N/A, as the study focused solely on system design.		Not reported for user involvement; home setting.	N/A for the sample; Croatia.

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
	To present the "Home Health Smart TV" platform, which provides access to multimedia eHealth content customized for older adults and aims to address social isolation among them by offering video communications.	• Design: not specified in detail; mentioned the involvement of both domains (eHealth and social networking) and described the platform's features and physical elements. • Evaluation: Not reported.		Not developed, but proposed applications for a smart television platform, including home, messages, education, measurement data, and social networking features on an Android television.		
Faria et al [14]	To understand how older adults perceive the use of the ProSeniorTV service, which aims to promote older adults' participation in social activities held in their residential area and to help them remember to take their medication.	• Design: not specified • Evaluation: focus group sessions were held, where 2 specific scenarios were studied.	Participants' perceptions of different scenarios when using ProSeniorTV, regarding the perceived usefulness of the program.	ProSeniorTV with use scenarios was proposed, but concrete development was not reported.	Yes, during the evaluation only; home setting.	The study included 6 Universidade Sénior de Cacia students (2 males and 4 females), aged 64-80 years (mean age 74 years; median 75 years). All were experienced ICT[k] users; Portugal.
Gusev et al [37]	To propose the SMILE[l] concept, which aims to develop a self-care social interactive television system as a service for older adults to support independent living and to prevent or delay dementia, by offering technologies, such as social networks, and personalized health monitoring.	• Design: literature review and thematic analysis of relevant projects, focusing on usability and technological barriers.	N/A	No, only the SMILE concept was proposed, focusing on innovating models for service delivery by combining traditional IP television services with emerging technologies.	No user involvement; home setting.	N/A for the sample; Macedonia, the United Kingdom, and Slovenia.
Gutierrez et al [28]	To design and deploy the SocialConnector system, a computer-supported family communication mediator intended to identify key factors that ease the adoption of ambient intelligent systems, thereby promoting intergenerational family communication at home.		Main barriers and perceived usefulness of the SocialConnector system.	Yes, the SocialConnector system, which can be used either on a smart television or in a hybrid format; allows older adults to connect with others using regular social media services.	Yes, during the design and evaluation phases; home setting.	The study included 8 older adult participants for both smart television and hybrid versions (4 females and 4 males). For the smart television version, participants were aged ≥60 and had low levels of technology appropriation. For the hybrid version, the participants' ages were not specified, and they also had low levels of technology use and no prior interaction with tablet PCs and smart televisions; Chile.

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
		• Design: a UCD with iterative and empirical experiments. • Evaluation: task-based user testing, followed by participants completing the SUS questionnaire and participating in individual and focus group interviews. The same methods were used for the Social Connector hybrid version (smart television and tablet PCs), except that the SUS questionnaire was not applied.				
Tapia et al [13]	To design and use a smart television application to promote social interaction among older adults and their family members through social media.	• Design: not specified; only presented the design. • Evaluation: heuristic inspection with expert users and usability study with end users (via think-aloud protocol and focus group discussion).	Heuristics inspection: usability issues identified before conducting user-based evaluation. Usability study: user experience and task completion success.	Yes, the SocialConnectorTV, consisting of an Android LED television equipped with a Google Chromecast device.	Yes, during the evaluation phase only; home setting.	Expert users: both authors and expert users; no further information was provided. End users: 8 older adults (4 males and 4 females), aged ≥60 years, with low-level technology appropriation; Chile.
Herrmanny et al, [38]	To design a system that supports the specific needs of older adults while preventing age-related isolation and loneliness by combining a social television community application with sensor-based and tangible social interaction.	• Design: an extensive requirements analysis was conducted as part of a broader research project; no further details were provided. • Evaluation: focus group sessions with hands-on interaction with the device and system, as well as group interview.	Technology acceptance, competence, and control among participants, as well as feedback on the design of the device and system.	Yes, a social television application developed for use with a Samsung smart television and a capacitive proximity sensor.	Yes, during the evaluation phase. The design phase is unknown, as no details were reported about the requirements analysis; home setting (senior housing facility).	The study included 15 older adults (10 females, 5 males), aged 62-77 years. Most participants watched television regularly; Germany.
Kakarountas [39]						

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
	To design a system that modifies familiar home appliances for older adults through commercial off-the-shelf products, so that HCI[m] is hidden from them.	• Design: a small survey. • Evaluation: not conducted.	Not reported, as the article presented only technical descriptions of the proposed technology.	Yes, a smart television equipped with an Android installed HDMI[n] dongle offering applications, such as weather information, video conferencing, and health monitoring.	Yes, during the design phase only; home setting.	The study included 4 males and 2 females, aged ≥70 years, diagnosed with various diseases, who expressed technology fear and were unwilling to learn new technologies; Greece.
Lee [40]	To identify the needs of diverse older adults and to determine which applications could improve their living conditions when introducing a smart home, with a particular focus on smart television.	• Design: interviews combined with a questionnaire.	The perceptions of participants regarding the adoption of the smart home concept to retain family values and their demand for smart home services, including how manageable and adoptable digital house applications are, and how they manage related activities.	No, the study only explored the concept of a smart home integrated with a smart television, where users could share content with the family's network and coordinate tasks with family partners such as supermarkets, schoolteachers, and health care centers.	Yes, regarding identifying needs.	No sample was reported; Taiwan.
Limdumrongnukoon et al [41]	To design and develop an interactive multimedia delivery system to distribute multimedia content among older adults, family members, relatives, friends, and health care providers.	• A conceptual model was proposed, providing a system's overview of interaction, functionalities, and technical specifications, based on existing literature and design guidelines.	N/A, as the study only involved a proposed conceptual model without validation.	No, the study only proposed a conceptual model.	Not reported for user involvement; home setting.	N/A; Thailand.
López et al [26]	To assess how patients with PD[o] accept and use smart television and how health professionals and caregivers perceive this use. To evaluate the smart television games developed specifically for patients with PD, alongside their caregivers and health professionals.	• Design and evaluation: testing was conducted individually and collectively, and focus groups were held with 3 user groups: professionals, caregivers, and patients.	Acceptance, usability, and engagement with the games.	Yes, cognitive games were developed and played on an Android television Box with minimum requirements: Android 5.0, HDMI, wireless remote control, and Ethernet or Wi-Fi connectivity.	Yes, during the design and evaluation phases; it was tested in care centers for patients with PD. The games were also suitable for those staying at home with caregiver assistance.	The study included 11 health professionals, 9 caregivers, and 16 patients with PD; Spain.
López et al [27]						

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
	To investigate the benefits of the proposed cognitive games on smart television platforms, including how continuous use affects cognitive abilities, how social aspects are influenced by collective gameplay, and how efficiently the cognitive status (ie, NCA[p], MCI, and MD[q]) can be estimated.	• Design: application of design guidelines and iterative testing with target users. • Evaluation: an experimental setup in which participants played the cognitive games.	Acceptance, usability, and user experience in gameplay, including social factors such as comparing collective gameplay in care centers with individual gameplay at home. Clinical effect was assessed through cognitive exercise and socialization outcomes.	Yes, cognitive games were developed as smart television applications, along with an automatic screening tool and a remote control. These applications were installed on an Android box connected to a television via HDMI.	Yes, during the design and evaluation phases; hospitals, day care centers, and patients' homes.	France: the study included patients with early-stage AD[r] or similar dementia and their caregivers. Spain: the study included patients with PD, caregivers, health professionals, social workers, and administrators. Hungary: the study included patients with AD, caregivers, health professionals, and doctors. The participants were divided into 3 cognitive ability groups: MD —with 14 participants, 5 patients (2 males and 3 females), based on the MoCA[s] scales, aged 71-80 years; MCI—with 26 participants, 12 patients (5 males and 7 females) based on the MoCA, aged 62-80 years; and NCA—with 45 participants, 5 patients (2 males and 3 females) based on the MoCA, aged 62-80 years.
Macis et al [42]	To propose a framework for a novel ICT system coupled with smart television to support active aging. In doing so, the authors outlined the rationale for developing the proposed framework and presented the current state of the system, along with possibilities for future expansions that are natively supported by the framework.	• Design only: Desk and field research; user sessions conducted in 3 European countries using a user profiling questionnaire and a usability study (observation, think-aloud protocols, and post-session questionnaires). Older participants were invited and encouraged to work and engage with a variety of existing service platforms.	Demographic background that is linked to the usability of different systems, with potential for using those systems, including the willingness to adopt such service platform, the perceived added values, and the price participants were willing to pay.	A proposed prototype using an Android television box and a television with HDMI connectivity, but the system was not fully developed.	Yes, during the design phase; home setting.	The Netherlands: the study included 13 older adults (average age 71.24, SD 6.88 years; 8 male and 5 female; relatively highly educated). Belgium: the study included 13 participants (average age 78.15, SD 4.26 years; 6 males and 7 females; relatively highly educated; less ICT use than Dutch participants). Italy: the study included 29 participants (14 males and 15 females; average age 70.1, SD 5.8 years; less ICT use than Belgian participants)
Ribeiro et al [43]				Not specified, but participants tested the AAL*MEO prototype.	Yes, during the evaluation phase; the settings were not specified, but the collaborators involved in the study were those providing care to older adults.	The study included 30 collaborators (average age 58 years; oldest participant aged 67 years and youngest aged 54 years). All the participants were female, with varied education levels, although the majority had completed the fourth grade; Portugal.

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
	To aggregate technological solutions supporting home care by exploring the use of a television set as the central device for interaction and communication at home. More precisely, the article aimed to investigate how the proposed solution, Active Assisted Living (AAL@MEO), could be advantageous for older adult who are not familiar with technological advances but are used to controlling their television set.	• Design: not reported. • Evaluation: 3 stages—pretest, during-test, and posttest. The pretest involved the application of a demographic questionnaire to characterize participants. During the test, the participants completed several tasks using AAL@MEO. The posttest involved completing usability and evaluation instruments.	Usability; the primary focus was on critical incidents observed when participants completed tasks and how they performed these tasks. The incidents were categorized as authentication, interaction using the remote control, menu navigation, use of measurement instruments, measurement confirmation, general application behavior, and user-application interaction.			
Wang [44]	To assess the usability and functionalities of a virtual fitness platform on smart television with multiple users.	• Design: design guidelines were presented. • Evaluation: Two experiments—(1) usability testing with a questionnaire and (2) longitudinal field study with observation and interview.	The system functionality and usability, including use, interaction with others, motivation, perceived ease of use, and perceived usefulness.	Yes, a fitness platform that enables multiuser virtual situations on a smart television using an Android television system.	Yes, during the evaluation phase; home and care centers.	The study included 40 older adults aged 60-80 years (6 at home and 34 in 3 day care facilities); Taiwan.
Wang and Wu [45]	To explore the digital experience of older adults concerning digital feedback, technology anxiety, and the influence of existing familiar skills on their digital habits. More precisely, to use digital devices (ie, smart television) to overcome the digital divide and demonstrate how such use may impact intergenerational relationships.	• Design and evaluation: N/A; a questionnaire was used for data collection. Data analysis was conducted using the partial least squares method for structural equation analysis.	Demographic information; associations between technology anxiety, digital feedback, familiarity with technology, technology habits, and intergenerational relationships.	No.	N/A	Older adults aged >55 years were invited to complete the questionnaire. The study included 233 male and 246 female participants. Approximately 50% of the participants were aged 60-69 years, 20% were aged 55-59 years, and the remainder were aged ≥70 years. A total of 43% of the participants had completed elementary school, 24% had completed junior high school, 20% had completed senior high school, and the remainder had completed junior college or higher. Forty percent were retired; Taiwan.
Wu and Hu [46]					Yes, during the design stage; home setting.	

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Study	Study objective	Methodology (design and evaluation)	Measured outcomes	New technology developed	User involvement and settings	Sample and country
	To examine the possibilities for older adults in using intelligent television. To investigate significant differences in physiological and psychological characteristics among older adults living in small cities and big cities. To identify existing issues and the real needs and preferences of older adults when using intelligent television; and to provide important references and theoretical grounds for markets and relevant stakeholders in this area.	• Design: the study involved the application of the 5W2H (Who, What, When, Where, Why, How, and How Much) design and analysis, and participatory design through questionnaires and in-depth surveys with participants from different cities. • Evaluation: N/A; the study involved only investigating possibilities.	Using the developed "3E" (easy and efficient for the elderly) model, the researchers aimed to measure usability (ie, whether intelligent television was easy and efficient for older adults) and satisfaction.	N/A; the study only constructed a theoretical framework, that is, the "3E" model, based on the iterative innovation design method and outcomes.		Questionnaires: a total of 150 questionnaires were distributed in 3 groups of older adults aged >60 years living in new urban areas, small cities, and big cities; only 117 valid responses were collected. In-depth surveys: 3 participants from Maanshan (a typical case of urbanization development), 1 from Wuhua (a small city with a smaller population), and 1 from Guangzhou (a big city); China.
Naudé et al [47]	To identify the barriers and enablers for older adults in using DiTV[t], which could help identify potential action levers to improve the implementation of the DiTV system and its telecommunication functionalities.	• Design: not reported; the DiTV system, e-lioTV, had already been developed before the study. • Evaluation: case study with observations of participants performing tasks (older adults only) and semistructured interviews.	The stages of DiTV integration in geriatric institutions; the role of care professionals in this; and the perspectives and user experiences with the DiTV system.	The DiTV system, e-lioTV, had already been developed by a start-up company; further details were not provided in this study.	Yes, during the evaluation phase; geriatric care.	The study included 18 residents (11 females and 7 males) aged 68-90 years. Six care professionals (3 sociocultural animators, 1 deputy director, and 2 technical managers) living or working in nursing homes also participated; France and Ireland.
Santana-Mancilla and Anido-Rifón [48]	To examine the acceptability of interactive television care by older adults and its suitability and potential for improving their quality of life in an age-friendly environment.	• Design: UCD. • Evaluation: the study used interview, user testing, and a questionnaire incorporating the technology acceptance model.	Technology acceptance, system usability, and user attitude.	Yes, an interactive television care platform using Google TV.	Yes, during both the design and evaluation phases; home and nursing home settings.	The study included 50 older adults during the pilot test. A total of 500 older adults and caregivers participated in interviews, but no details were provided regarding the process and their involvement; Mexico.

[a]FoSIBLE: fostering social interactions for better life experience.

[b]HBBTV: hybrid broadcast broadband television.

[c]PaeLife: personal life assistant.

[d]UCD: user-centered design.

[e]N/A: not applicable.

[f]SNSs: social networking systems.

[g]UI: user interface.

[h]SUS: system usability scale.

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[i]MCI: mild cognitive impairment.
[j]MMSE: Mini-Mental State Examination.
[k]ICT: information and communication technology.
[l]SMILE: stimulating intellectual activity with adaptive environment.
[m]HCI: human-computer interaction.
[n]HDMI: high-definition multimedia interface.
[o]PD: Parkinson disease.
[p]NCA: normal cognitive abilities.
[q]MD: mild dementia.
[r]AD: Alzheimer disease.
[s]MoCA: Montreal Cognitive Assessment.
[t]DiTV: digital interactive television.

Study Characteristics

More than half of the studies explicitly focused on the context of home care. The studies that were not included in this category either did not specify a context or were conducted in geriatric care units or nursing homes. For instance, Naudé et al [47] focused on identifying enablers and barriers to the use of digital interactive television (DiTV) in nursing homes. According to Naudé et al [47], DiTV is a system that allows viewers to engage actively with content in real time. Examples of this include online shopping via television and being able to vote or comment on social posts via television, with the latter being considered a form of asynchronous communication.

More than half of the studies focused on designing or evaluating attitudes toward technology and assistive technologies, while the remainder focused on proposing concepts and frameworks. Wu and Hu [46] discussed the 3E model, known as easy and efficient for the elderly. This model was developed to better study behaviors related to the use of smart televisions among older adults. The discussion of this model was presented in a theoretical manner to analyze its framework. Although not focused on the 3E model, Gusev et al [37] proposed the stimulating intellectual activity with adaptive environment (SMILE) framework, which aims to prolong independence and improve the quality of life through cognitive stimulation, social inclusion, and personalized self-care systems. Various projects focusing on support for older adults were analyzed, including medical sensors installed in home products; the use of mobile phones and smartphones as personalized devices; and the Vital Mind project, which aims to increase the lifespan of older adults by enabling them to participate in cognitive fitness exercises actively while watching television.

Regarding the sample size of the participants, 5 articles did not report any sample size or demographics [34,36,37,40,41]. The sample sizes ranged from studies with only 5 participants to studies with more than 200 participants per sex. These variations were related to the differing methodologies of the articles. The studies that focused on assessing the accessibility of content and device platforms typically included a small number of participants, as demonstrated in the study by Alaoui et al [25], whereas studies that focused on measuring technology habits, technology skills [42], or intergenerational relationships [45] included larger sample sizes. Results from larger sample sizes were obtained through surveys as the mode of data collection. For example, Wang [44] and Cortellessa et al [32], who used surveys to measure attitudes, included between 30 and 100 participants. Geographically, all but 8 studies were conducted in Europe. Other studies were conducted in China [46], Thailand [41], Taiwan [40,44,45], Chile [13,28], and Mexico [48]. No studies from other regions, such as Africa and North America, were included.

Similarly, not all articles provided information about the participants. Most articles specified the age, gender, and demographics of their study population. The participants across all included studies ranged in age from 50 to 92 years, but most information was drawn from the participants aged 60 to 80 years. Some studies were conducted in the context of geriatric care units or nursing homes [26,27,38,44,47,48]. In these facilities, care professionals and older adults living there were interviewed regarding the DiTV system that was implemented [47]. In addition to Naudé et al [47], López et al [26] and López et al [27] also specifically mentioned the inclusion of administrative staff, ranging from health professionals to formal and informal caregivers.

The topics included in the articles covered different aspects of utilizing smart televisions as assistive technology for older adults. Most of the articles reported some form of newly developed technology, while 6 articles reported no technology development [30,37,40,43,45,47]. The technologies that were proposed and developed across all articles were various forms of interactive television. These included Android televisions and Google televisions; almost half of the included studies did not specify the type of smart television proposed or developed.

Approximately half of the articles were directly related to the social aspects of health in older age. The other half was indirectly related, addressing social health through other factors. For example, Wang [44] examined the usability of a virtual fitness platform on smart televisions for health promotion among older adults. This was indirectly related to social health because older adults were given the opportunity to interact with others via the virtual fitness platform, even though its purpose was to improve physical health.

Discussion

Principal Findings

To the best of our knowledge, this review is the first to summarize the state-of-the-art research on the use of smart televisions as assistive technologies for communications and

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social life among older adults. Andreadis and Zambon [49] in their survey, provided an overview of compelling studies that used television devices as the primary user interface to address the social exclusion and digital barriers encountered by older adults. However, almost all studies included in their review involved the use of traditional televisions, rather than smart televisions. In many other studies, smart televisions have been used to collect data to assist with everyday life activities (eg, reminders, health status monitoring, and calendar management) [50,51]; as smart decision support systems to support healthy aging [52]; and as rehabilitation tools [53]. Although some of these studies incorporated certain social elements, such as shared training and gaming activities, their primary focus was not on fostering social communications among older adults to reduce exclusion and loneliness. Wong et al [54] published a scoping review protocol to provide an overview of existing research findings on factors that aid or hinder the use of smart televisions by older adults in care settings. However, at the time of writing this review in November 2024, their scoping review remained unpublished. Another review conducted by Carvalho et al [55] reported solely on television remote controls and their use by older adults. Their findings included usability issues faced by this user group when using television remote controls and proposed solutions to address these issues.

Comparison With Prior Work

Evidence and the Number of Included Studies

Although 30 relevant studies were included in this review, this number indicates that smart televisions have been seldom utilized as assistive technologies to enhance communication and social lives among older adults. Despite several of the included publications stemming from the same or larger studies, it is notable that these publications involved participants from multiple countries. Conversely, some publications that were not part of larger studies also included participants from different countries. For example, Alaoui et al [22] conducted interviews with participants living in France, Austria, and Germany, while Müller et al [23] included participants from both France and Germany. In addition, Gusev et al [37] involved users from Macedonia, the United Kingdom, and Slovenia when proposing a socially interactive television–based self-care system tailored for older adults to support independent living and aid in the prevention or delay of dementia. These studies show that the same technology developed has potential for use across diverse geographical areas.

When considering the countries involved in the included studies, the majority were conducted in European countries or other technologically advanced countries. This geographic concentration may limit the generalizability of the findings, particularly in non-Western or resource-limited settings where cultural, economic, and technological factors differ significantly. Our findings indicate that no studies from Africa or North America were represented. This is unsurprising, as research on more advanced technologies has historically been concentrated in regions with greater access to resources, infrastructure, and technological expertise. This aligns with the work of Ondiek and Onyango [56] and Bosch and Currin [57], who highlight both the challenges and efforts involved in engaging user groups from these underrepresented regions. Therefore, when generalizing these findings, it is crucial to consider the unique challenges and needs of such regions, as the effectiveness and applicability of the technology may vary.

As most studies focused on designing, developing, and evaluating prototypes, many also proposed some design guidelines [27,44]. These guidelines may be useful not only for researchers and policy makers, but also for designers working in this field. Almost all articles reporting on prototypes indicated that the technology had been developed by the researchers themselves. By contrast, Carvalho et al [55] was one of the few studies to include a smart television application, e-lioTV [58], which was developed by a private start-up named Technosens [59]. Costa et al [33] also involved an engineering group responsible for technical design in their study. These findings indicate that there may be a lack of collaboration between the public and private sectors, which could potentially limit the use of smart televisions as assistive technologies for enhancing social interaction among older adults.

Finally, it is worth mentioning that some of the included articles did not prioritize social communication as the main aspect of their functionalities. However, they highlighted the impacts such functionalities had on influencing the social lives of older adults. For instance, Wang [44] proposed a virtual fitness platform on smart television with multiple users, and Gusev et al [37] and Lee [40] proposed self-care interactive smart television applications that incorporated social interactions as one of their features. We acknowledge that social interactions can occur in various forms—both synchronous and asynchronous—and with different people, including peers, family members, and formal and informal caregivers. For this reason, these articles were included in this review.

User Involvement

Older adults often face unique challenges related to mobility, sensory perception, and cognitive function, which can vary significantly from person to person [60,61]. Involving older adults in the design of assistive technologies is essential for creating effective and user-friendly solutions tailored to their specific needs. By including them in the design process, developers can gain valuable insights into their preferences, limitations, and everyday experiences, ensuring that these technologies are relevant and accessible. Research has shown that user involvement of older adults has been low in the design of assistive technologies intended for this user group [62]. However, our findings indicate that user involvement has been high regarding the utilization of smart televisions as communication-type assistive technologies for this group. Among the 30 included studies, almost all involved users during the design and/or evaluation phases. A few articles specifically mentioned that they adopted a user-centered design approach [22,28,34,35,48]. From these studies, it was evident that feedback from older users contributed to identifying potential usability issues and informing design features that truly accommodate their capabilities and needs. It is worth noting that involving older adults can promote a sense of ownership [63] and acceptance of the proposed technology [62]. This may also contribute to the scalability of the use of technology [64].

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These articles not only demonstrate user involvement, but also show careful considerations when involving older adults. One of the reasons for utilizing smart televisions as social communication–type assistive technologies is because of their familiarity. Hence, older adults with low technology use have been one of the main target groups. Gutierrez et al [28] and Tapia et al [13], in their studies, specifically targeted older adults with low technology use. In addition to this primary group of end users, some studies also involved secondary end users. Cortellessa et al [32] conducted initial internal testing to gather feedback from experts, caregivers, and health care professionals. This internal testing aimed to inform iterative technological refinements before engaging end users, which could enhance the prototype's technical stability, usability, and design quality before involving older adults and proceeding to a feasibility study. When the proposed technologies were intended for use by older adults with dementia, health care personnel and caregivers (formal or informal) were involved as well [27,32].

Attitudes in Using Smart TVs for Communications

Older adults often hold diverse attitudes toward using smart televisions as a means of communication, shaped by factors, such as familiarity with technology, perceived usefulness, and social needs. Depending on their backgrounds, some older adults have more proficient digital literacy than others. Age has been shown to be one of the strongest predictors in online participation, but race, gender, and education play a role as well [65]. In Finland, 80% of people aged between 65 and 74 years have used the internet, and 57% use it daily [66]. However, these numbers drop to approximately 41% of internet use and 23% of daily use among adults aged between 75 and 89 years. This difference in internet use highlights discrepancies in digital literacy and varying attitudes toward technology based on age. In addition, a study found that females were more likely to show lower global and technical confidence and to have lower operational and less positive attitudes toward technology compared with males [67]. Generally, older adults tend to feel more comfortable operating a television with a remote control than a smartphone or tablet. Therefore, we believe that many older adults will hold more positive attitudes toward a smart television interface as a means of improving social connection.

Limitations

Although this study contributes to the understanding of the state of the art in using smart televisions to improve social connectivity among older adults, several limitations must be acknowledged when interpreting the findings. First, the study only included literature published in English. By only reviewing articles written and published in English, important findings from studies conducted in other languages may have been missed. Second, articles published more than 10 to 12 years ago were excluded. As mentioned in our inclusion and exclusion criteria, the concept of smart televisions is relatively new. While this ensures that the review focuses on recent advancements, it may also limit the inclusion of foundational research that could provide context for the transition of smart televisions into assistive technologies. Third, only peer-reviewed literature was included. The exclusion of gray literature may result in missing valuable information that is not traditionally found in academic publications. While this study focused on peer-reviewed literature, future studies could incorporate gray literature, such as patents, white papers, ongoing research, and dissertations, to gain a broader understanding of the real-world applications of smart televisions as an assistive technology [68].

The next limitation of this study is the potential exclusion of relevant studies because of the search strategy. Although we carefully selected search terms to capture both the direct and indirect impacts of smart televisions on the social lives of older adults, there may still be relevant articles that used different terminology. Consequently, some studies that explored the social implications of smart televisions in alternative ways may not have been included. Expanding the search strategy in future reviews by incorporating a broader range of keywords and synonyms could help address this limitation and provide a more comprehensive understanding of the topic. Regarding the generalizability of the findings, it is important to note that the geographic concentration may have affected the results, particularly concerning the non-Western or resource-limited settings. As mentioned earlier, most of the included articles were from Europe, and European contexts often differ culturally, economically, and technologically from other regions. Therefore, the applicability of the findings to diverse global populations may be limited. Finally, this review was conducted without registering the protocol. While this practice is not mandatory, we acknowledge this as a limitation.

Conclusions

With people in today's society living longer, the shift toward an aging population is undeniable. As people age, significant declines in both physical and cognitive health are common and are often accompanied by an increased risk of social isolation, which can further impact well-being. Because depression or the onset of depressive symptoms is a prevalent issue among older adults, introducing assistive technologies to enhance their communications and social life is crucial for supporting holistic well-being. While numerous assistive technologies present usability challenges for older adults, smart televisions stand out as one of the most familiar and frequently used technologies within this demographic. Thus, this research is essential for understanding the potential of smart televisions as an assistive technology to enhance social connections and communication among older adults, thereby addressing the challenges of exclusion and loneliness.

This review reveals that smart televisions hold significant promise as an assistive technology to enhance social connections and communication for older adults. The number of articles included in this study is 30, which is relatively low considering that smart televisions have been on the market for more than 10 years. Of these 30 studies, 6 were associated with the same project, that is, the FoSIBLE project [16,21-25]. In addition, López et al [26], López et al [27], Tapia et al [13], and Gutierrez et al [28] were from the same respective studies. Many studies examined the use of smart televisions for social connectivity in home settings; however, some also explored their application in senior housing facilities, care centers, hospitals, and nursing homes, highlighting their potential across diverse environments.

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Most of the articles focused on user attitudes toward the design and evaluation of the technology, while others focused on conceptual and framework proposals. Of the 30 articles, 24 either proposed or developed interactive smart television applications and platforms that used a variety of smart televisions, including Google and Android. A wide range in participant sample sizes was observed, varying from 5 to more than 200 participants, depending on the research methodology. In addition, not all articles provided detailed information about the participants. User involvement emerged as a key factor in the development and evaluation of the proposed technologies. Although research has traditionally shown low user involvement in designing assistive technologies for older adults, this review indicates that most studies integrated older users at various stages of the design and evaluation. Finally, the review highlights the distinction between the direct and indirect contributions of smart televisions to the social lives of older adults.

While this review provides valuable insight into the role of smart televisions as assistive technologies for enhancing the social connectivity of older adults, several research gaps remain. First, most of the studies focused on short-term usability and initial user experience. There is little research on how smart televisions can impact and change the trajectory of the social well-being of older adults over time. Future studies should conduct longitudinal research to assess the long-term impact of smart televisions on the social well-being of older adults. This includes examining whether smart televisions can be used sustainably over extended periods and whether their sustained use can foster social engagement and improve quality of life over time. Second, 22 studies were conducted in Europe, 5 in Asia [40,41,44-46], and 3 in South America [13,28,48], with no representation from North America and Africa. This underscores the need for future research to engage participants from underrepresented regions to ensure that findings are more globally applicable and inclusive of varying needs, preferences, and challenges. To address this knowledge gap, cross-cultural research should also be conducted. Future studies should focus on these underrepresented regions to understand how different cultural attitudes toward technology and access to smart televisions may influence the adoption of assistive technologies for older adults.

Third, while some studies have explored how smart televisions can be used as assistive technologies for social connection among older adults with specific health conditions, such as Parkinson disease, dementia, and other health-related challenges, research on adaptation for these users remains limited. There is limited information on long-term adaptation for improving their social connectivity. Future research should explore adaptive accessibility solutions and features in smart televisions that evolve with users' changing abilities and assess the long-term impacts of smart televisions on social engagement and quality of life for older adults with diverse needs. These solutions and features may include voice commands, improved remote control design, and other innovative interaction methods and modalities for interacting with smart televisions. By prioritizing these solutions and features, researchers may better address the diverse health conditions of older adults. In addition, bridging these research gaps to reduce barriers to adoption is essential for developing a more comprehensive understanding of how smart televisions can support long-term social engagement, be adopted across diverse cultural contexts, assess their actual impact on the social well-being of older adults, and adapt to the progressive needs of older adults with health conditions. In addition, future research should explore how smart televisions could serve as more accessible assistive technologies for older adults with disabilities. Smart televisions may be easier to interact with compared with smaller touchscreen devices. For instance, a remote control with larger buttons may be more manageable for older adults with disabilities than small touch-sensitive devices such as smartphones and tablets.

We hope that our review will inspire others and pave the way for future research exploring the potential of smart televisions as assistive technologies. These technologies hold promise for fostering meaningful social interactions, reducing social isolation, and enhancing the health, well-being, and overall quality of life of the aging population. Stakeholders, such as policy makers, decision makers, and designers, can also refer to our work, as it provides a comprehensive summary of the state of the art in this field. By understanding the current advancements and gaps highlighted in our review, they can develop strategies and design solutions that are better aligned with the needs and preferences of older adults.

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Data Availability

The data and other materials used in this study are available upon request from the corresponding author, WKB.

Conflicts of Interest

None declared.

Multimedia Appendix 1

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PRISMA checklist.
[DOCX File , 23 KB - rehab_v12i1e73050_app1.docx]

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Abbreviations

DiTV: digital interactive television
FoSIBLE: fostering social interactions for better life experience
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SMILE: stimulating intellectual activity with adaptive environment

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Family Members' Experiences of a Person-Centered Information and Communication Technology–Supported Intervention for Stroke Rehabilitation (F@ce 2.0): Qualitative Analysis

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Abstract

Background: Stroke often leads to long-term effects on daily activities and participation. Consequences impact not only stroke survivors but also their close networks, and capturing their experiences is crucial for the development of effective interventions. F@ce 2.0 is a person-centered, information and communication technology (ICT)–supported stroke rehabilitation intervention currently being evaluated.

Objective: This study aims to describe family members' experiences of the F@ce 2.0 intervention from the perspective of being a caregiver to a stroke survivor.

Methods: Participants were family members (n=7) of stroke survivors participating in the intervention. Semistructured interviews were conducted at 2 time points, postintervention and 6 months postbaseline, resulting in a total of 13 interviews. Data was analyzed using qualitative inductive content analysis.

Results: An overarching theme was developed from 4 categories. The main theme was the potential of F@ce 2.0 as a support for family members of stroke survivors in the sudden change of life. The categories were: dialogue and partnership with the F@ce 2.0 team, resuming daily activities lowers the demand for family support, support and involvement through the ICT component of F@ce 2.0, and engagement in F@ce 2.0, leading to suggestions for development.

Conclusions: This study aligns with previous research delineating the effects of stroke on family members of stroke survivors. Participants highlighted the positive impact of the focus on daily activities within the intervention. Furthermore, the ICT component was perceived as a support in structuring rehabilitation. Participants, however, suggested further development, both in terms of content and technology.

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KEYWORDS

significant others; informal caregivers; SMS; smartphone; goal setting; eHealth; digital health; telehealth; interdisciplinary rehabilitation; occupational therapy

Introduction

Background

Stroke is a major noncommunicable disease and a leading cause of long-term disability globally [1,2]. In Sweden, around 25,000 people have a stroke each year [3]. Stroke can lead to significant changes in participation in daily activities [4], work roles [5], and social life [6]. These negative consequences in everyday life affect not only the stroke survivor but also the close network. A need for rehabilitation teams to rethink who is considered a part of this network has been suggested [7]. In this study, the focus is, however, on family members, since all participants were either spouses or children of stroke survivors.

Being a family member to a stroke survivor has been described as a process changing over time [8], where the initial situation often entails being thrown into a changed role with new responsibilities but without enough information [9]. Experiences of loss of independence and inability to plan for the family's daily life and future have been portrayed by family members, leading to feelings of being burdened, anxious, insecure,

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frustrated, and fatigued [9,10]. In a Swedish report, 45% of family members stated that the stroke survivor was dependent on their help with all or parts of daily activities. Furthermore, 9% of family members reported that they could not pursue their leisure interests, and 9% of those in the working age group had quit their jobs or reduced their working hours to take on the role of informal caregiver [11]. The report also revealed evident shortcomings in the support family members experienced receiving from the health care system.

Family members' experiences of being involved in a client-centered activities of daily living (CADL) intervention for stroke rehabilitation has been explored [8]. Although the CADL intervention [12] did not specifically address family members (in this case, spouses), they described their involvement in the rehabilitation process. Family members experienced the rehabilitation process as twofold, encompassing both the aspects of caring for their partner and regaining their former roles and habits. In this strive, family members expressed feeling encouraged by their partners with stroke to spend time pursuing their own interests, which reduced their level of worry and fatigue [8]. The reciprocity in the interaction between the spouses and stroke survivors made it possible for spouses to continue being active while adjusting to a new life situation. This illustrates how interdependency can form a basis for resuming daily activities and accentuates the need to explore experiences and roles of family members in stroke rehabilitation [8].

The development of rehabilitation programs targeting both stroke survivors and their close network has been suggested [12-14] and can be a way of responding to the European Care Strategy for caregivers and care receivers [15]. Interventions with a focus on information, education about stroke, and problem-solving appear to benefit the relatives of stroke survivors [16], and combining this with a focus on activities can be favorable [16].

The role of digital health in developing rehabilitation programs is being increasingly discussed. Digital rehabilitation has been proven effective and applicable in various areas, including the improvement of motor and cognitive functions, mood, and daily activities [17,18]. The World Health Organization has suggested digital health as an umbrella term encompassing provision models for health and rehabilitation that use information and communication technology (ICT) [19]. ICT aims to facilitate communication between people and health care providers and can be achieved through various technological solutions, such as phones, computers, and tablets [20]. Digitalization is progressing rapidly, and according to Statistics Sweden, 84% of 65- to 74-year-olds and 62% of 75- to 85-year-olds used smartphones and apps in 2023 [21]. The use of ICT in rehabilitation after stroke is increasing, and there is a rapid development of apps as aids and as training tools [20]. However, cognitive, communicative, fine motor, and memory impairment connected to stroke can lead to challenges in handling technology [22]. To be successful, ICT-based interventions, therefore, need to be integrated into rehabilitation programs, including an educational component for caregivers paired with technical support [17].

The importance of investigating how the transition to digital health affects the close network around stroke survivors has been highlighted [23]. Furthermore, conducting qualitative studies on the need for support in the dyad of stroke survivor and family member has been emphasized as a key to evaluating intervention benefits over time [17]. This study explores family members' experiences of an ICT-supported intervention, F@ce 2.0, that was integrated into rehabilitation for stroke survivors.

F@ce 2.0 is a person-centered, ICT-supported, team-based 8-week intervention for home-dwelling stroke survivors [24]. F@ce 2.0 has been developed through an iterative process in both Sweden and Uganda [25,26]. The intervention targets stroke survivors, aiming to improve their performance in daily activities and enhance their participation in everyday life. The rehabilitation team supports participants receiving F@ce 2.0 in formulating 3 goals related to activities they need and want to be able to perform in everyday life, as well as in finding strategies for accomplishing these activities. Reminders to perform the activities are sent through SMS text messaging each morning. Later in the day, participants receive a new SMS text message asking them to estimate how well the activities were carried out during the day. F@ce 2.0 has been evaluated in a full-scale, nonrandomized, controlled trial (trial registration NCT043511789; manuscript under review). In addition to the ongoing effectiveness study, there is a need to explore how the intervention was experienced by family members [26]. In a previous study, family members of stroke survivors receiving F@ce in Uganda expressed having a challenging everyday life with numerous responsibilities as well as financial strain because of having to give up work. Still, they felt supported by the F@ce intervention as it provided information on stroke and advice on training [27]. The experiences of family members of stroke survivors who received F@ce 2.0 in Sweden are not yet known and would add insights needed for further development of the intervention and the ICT support, taking family members' need for support as well as the need for support within the dyad into consideration.

Aim

This study aims to describe family members' experiences of the F@ce 2.0 intervention from the perspective of being a caregiver to a stroke survivor.

Methods

Design

This study has a qualitative design and is based on semistructured individual interviews with family members of stroke survivors who participated in F@ce 2.0 as a complement to usual rehabilitation after their stroke. Furthermore, to describe participant characteristics, structured questionnaires and assessment instruments were used.

Study Context

The study is part of an ongoing research project "F@ce 2.0 - Implementation and evaluation of a global model for a person-centered, ICT- and team-based rehabilitation intervention for people who have had stroke" at Karolinska Institutet. The aim is to evaluate the effect of integrating the F@ce 2.0

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intervention in ordinary intervention, that is, if there are differences between the intervention group receiving F@ce 2.0 compared with those receiving usual intervention (controls). A total of 12 Swedish home rehabilitation teams, operating in both rural and urban settings, participated in the study, with 5 serving as control teams and 7 delivering the intervention [24].

Participants

Participants were recruited among family members of stroke survivors receiving F@ce 2.0. Recruitment of stroke survivors was carried out by the rehabilitation teams participating in the effects study (manuscript under review). Within the F@ce 2.0 project, 100 stroke survivors were recruited into either the intervention group (n=45) or the control group (n=55) and were subsequently asked to identify a family member who could participate in the study. Family members were then contacted by a researcher who gave them more information about the study. If willing to participate, they also received written information along with a consent form. The total number of family members who accepted participation in the study was 38, with 20 in the intervention group and 18 in the control group. Recruitment of family members for this study started 9 months into the project, at which point 13 family members were already included in the intervention group. Of the 7 family members invited after this point, all agreed to participate in this study, resulting in a total of 7 participants: 4 husbands, wives, or partners, and 3 children.

Within the larger research program evaluating F@ce 2.0, additional data on family members' situation was collected. To provide a more detailed background of the participants in this study, selected data is provided. The perceived burden after the 8-week intervention had ended was assessed using the Caregiver Burden Scale [28]. The scale ranges from 22 to 88, with a higher score indicating a more significant burden. Overall life satisfaction was reflected by the answer to the first question in the Life Satisfaction checklist [29], which uses a 6-graded ordinal scale from 1 (very dissatisfied) to 6 (very satisfied). The scale was dichotomized, and scores of 5 - 6 were considered indicative of being "satisfied." To give a background on the stroke survivors, stroke severity and perceived recovery are presented. Stroke severity was rated using the Barthel Index [30] (score range: 0 - 100), where scores of 0 - 49 points was considered severe to moderate, 50 - 94 points was considered mild, and 95 - 100 points was considered very mild [31]. Perceived recovery since the onset of stroke was rated using the visual analogue scale from the Stroke Impact Scale [32], ranging from 0 (no recovery) to 100 (full recovery). The characteristics of the participants and the stroke survivors are presented in Table 1, where the names are fictitious to maintain participant confidentiality.

Table . Characteristics of the participants and stroke survivors.

Name of family member	Relationship to person with stroke	Age (years)	Housing situation	Caregiver Burden Scale total score when intervention ended[a]	Family member response to LiSat-11 (life as a whole) at end of intervention[b]	Estimation of provision of help (0 - 100)[c]	Gender of person with stroke	Person with stroke's age (years)	Stroke severity at inclusion (Barthel index)	SIS[d] 3.0 self-reported stroke recovery at inclusion
Christos	Son	36	Partly cohabiting	32	Unsatisfied	12	Man	71	Very mild	Missing
Farida	Daughter	28	Cohabiting	58	Unsatisfied	50	Woman	65	Very mild	40
Aino	Wife	87	Cohabiting	38	Satisfied	34	Man	93	Mild	60
Sara	Daughter	54	Living separately	55	Satisfied	50	Woman	86	Mild	90
Christina	Wife	86	Cohabiting	51	Unsatisfied	79	Man	89	Moderate to severe	20
Lennart	Husband	68	Cohabiting	33	Satisfied	70	Woman	72	Mild	30
Jan	Partner	84	Cohabiting	36	Satisfied	22	Woman	77	Very mild	50

[a]Caregiver Burden Scale consists of 22 items rated on a scale from 1 to 4. Score range: 22-88.

[b]LiSat-11: Life-Satisfaction Questionnaire-11; a rating of 5 or 6 is considered to indicate satisfaction.

[c]Participants' self-rated estimation of the degree of assistance given to the stroke survivor (0 - 100; 0=not at all, 100=to a large degree).

[d]SIS: Stroke Impact Scale; subscale for global rating of perceived recovery (0-100).

Research Team

The research team consisted of 2 experienced researchers in both qualitative and quantitative research (GE and SG), 1 doctoral student (KS), and 1 clinician (ME), all of whom identified as female. All researchers had extensive clinical experience in stroke rehabilitation. GE, SG, and ME are all occupational therapists. KS is a speech-language pathologist. All researchers had in-depth knowledge of the F@ce 2.0 intervention.

Ethical Considerations

The larger project of which this study is a part has ethical approvals from the Regional Ethical Review Board in

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Stockholm, Sweden (2013/1801-31, 2017/1420 - 32), with a supplement (2020-01124) by the Swedish Ethical Review Authority. All participants received both verbal and written information about the study, including their right to withdraw their participation at any time. After receiving information and giving verbal consent, participants were asked to sign a written consent form. No compensation was offered. Aliases were used during data analysis to deidentify participants and data were accessible to the authors only.

Data Collection

Semistructured interviews were conducted between January 2022 and December 2022 by an experienced clinician and researcher within the research group. The interviews were based on an interview guide and were performed on two occasions: when the 8-week intervention had concluded and again 4 months later (ie, 6 months after the intervention began). The interview guide was focused on 2 themes: perceptions of the life of the stroke survivors and the situation of being a family member to a stroke survivor. The first theme included questions such as "Can you recall how it was when your family member started the F@ce 2.0 intervention?" and "What is your perception of the SMS reminders?". The second theme included questions such as "Are there activities that you used to do but no longer do?" and "Can you tell me how you have helped or supported a family member during the F@ce 2.0 intervention?" The second interview aimed at capturing the continued rehabilitation process after the intervention as well as experiences of the intervention over time. To address the issues that had emerged in the first interviews, specific follow-up questions were added to the interview guide before the second interview [33]. Of the 13 interviews, seven were conducted after 8 weeks. A total of 6 of the participants took part in a follow-up interview while one was present only for the first interview and then discontinued his participation due to lack of time.

Before the qualitative interview was conducted, the participants answered a questionnaire based on established assessment instruments. The interviews, both the quantitative part and the open-ended interviews, were conducted by an experienced researcher in the research group. The interviews were conducted by telephone due to both geographic distance and restrictions related to the COVID-19 pandemic, and were recorded and coded for deidentification before being stored in a secure database. The interviews were transcribed verbatim, and on occasions where words were difficult to ascertain, this was noted in the transcribed text. Field notes written down during the interviews were discussed in the author group during analysis to deepen the understanding of the context.

Data Analysis

The analysis method chosen was a qualitative inductive content analysis, according to Graneheim and Lundman [34]. The analysis was planned to be kept as close to the text as possible, with the manifest content as the basis [34]. Initial coding was carried out by ME and later discussed with GE. As a first step, the transcribed texts from the interviews conducted at 8 weeks were read in their entirety several times to gain an understanding of the text. During this step, thoughts and reflections about the interviews were written down in a separate document. Parts of the text that were considered to have extra weight and corresponded to the study aim were marked. The second step involved extracting meaning units from the text [34]. This was done by using a scheme where the meaning units were condensed into shorter paragraphs, which were then coded (see Table 2) [34]. This part was kept as close to the text as possible. When the codes were set, the author went back and adjusted so that the code fitted into the context from which the meaning unit emanated, according to the process of working back and forth between the different parts of the analysis [34].

The codes from the different interviews were compared to discover if there were any similarities and differences. The next step after coding entailed categorizing codes based on their descriptions of the content on a more abstract level [34]. After analyzing the interviews conducted at 8 weeks, the same procedure was followed for the interviews conducted after 6 months, using a separate coding document. In this analysis, the experiences among the participants after the intervention had ended deepened the content of the previously developed categories, but no new categories were created. At this stage, KS entered the research process after having read through all interviews.

Table . Example of meaning units, condensed meaning units, and codes.

Meaning unit	Condensed meaning units	Codes
Yes it's a lot very much.. She has trusted them almost a little more than she has trusted me to do things like walk without a walker and try it she would never have done with me if they hadn't been here, no she trusts them a little more because they were used to this kind of thing. [Lennart, husband]	It's a lot, she has trusted them more than me to do things like walk without a walker. She would never have done that with me. She trusts them more because they are used to this kind of thing.	Positive to get support from the team.
It's a really positive thing that he himself is kind of reminded because I think he sometimes forgets to do it but. [Farida, daughter]	Positive that he himself is reminded, because I think he forgets.	SMS text messaging made a difference.
This has kind of felt like some kind of step one as well.. This is like the beginning of something that can be or will surely be even better. [Christos, son]	This has felt like the beginning of something that can be good.	The technology does not feel fully developed.

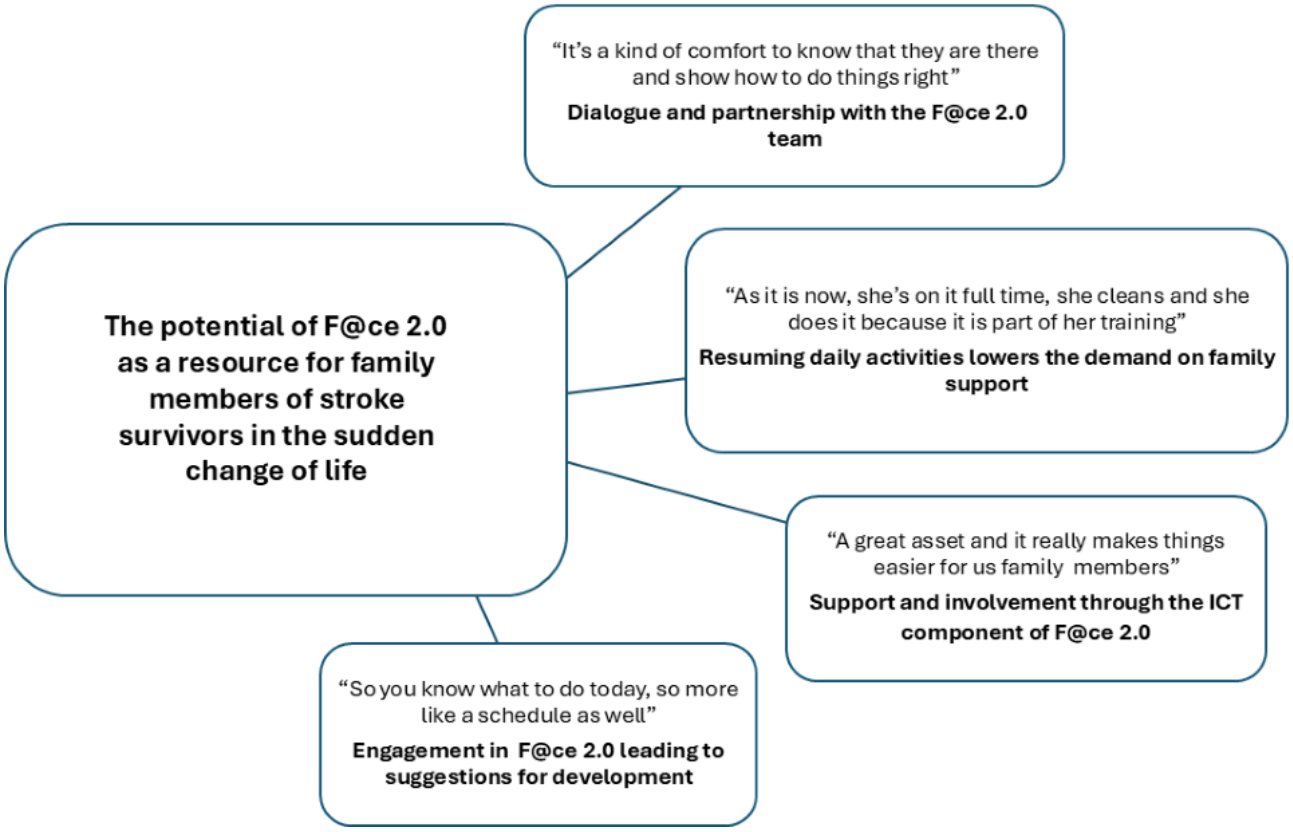
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Results

Overview

The analysis resulted in an overarching theme: the potential of F@ce 2.0 as a support for family members of stroke survivors in the sudden change of life. This theme was developed against the backdrop of participants' descriptions of life disruption invoked by the stroke as well as their perspectives on the need for support. A total of 4 categories formed the basis for this theme: dialogue and partnership with the F@ce 2.0 team, resuming daily activities lowers the demand on family support, support and involvement through the ICT component of F@ce 2.0, and engagement in F@ce 2.0 leading to suggestions for development (see Figure 1).

Figure 1. Overarching theme and categories.



Potential of F@ce 2.0 as a Support for Family Members of Stroke Survivors in the Sudden Change of Life

The study participants depicted profound life changes. Several of them had altered their habits and daily activities in a way that was described as undesirable but necessary and could be linked to a modification of roles related to living with a stroke survivor participating in rehabilitation. Both the onset of stroke in general and the participant's involvement in the F@ce 2.0 intervention influenced these changes. Involvement in F@ce 2.0 could lead to changes that make everyday life more compatible with home visits by the rehabilitation team or with self-training of activity goals set up by the stroke survivor. A participant, for instance, mentioned getting up much earlier than usual to be ready for the teams' visits, while others described adjusting their work hours to be there for their family members.

Dialogue and Partnership With the F@ce 2.0 Team

Experiences of receiving support from the team varied among participants, but most described being pleasantly surprised by the support offered. They particularly appreciated it when the team took responsibility for the rehabilitation and ensured that follow-up appointments were scheduled. Positive experiences of the different professions in the team were narrated, along with the view that they, as family members, were seen and supported by the team.

> *Because we had so many questions as well because we wondered so much. Or I wondered so much. Even though there is so much to read, I still thought it was good to have a person you could bounce thoughts and ideas with regarding the training and the relationship to food.* [Christos, son]

Participants talked about anxiety connected to their family member having a stroke. An example is Christina (wife), who expressed that "It's so silly, but I still have a bit of a hard time leaving him alone here at home. I know he'll be fine, but the thought of him lying here alone..." This anxiety was described as decreasing when improvements were seen and when the stroke survivor received support from the team on how to act in different situations. Anxiety was discussed as a factor both for family members and stroke survivors, and participants highlighted that there sometimes was a need to have this as the initial focus of rehabilitation, creating a foundation for the rest of the process. Family members described how the presence of the team invoked a sense of safety in the overwhelming time

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after a stroke when they often felt insecure. The team's engagement in discussion with the stroke survivor on how to perform activities in new ways, as well as leaving written instructions, was appreciated, for instance, by Christos (son), who stated, "It's a kind of comfort to know that they are there and show how to do things right."

The meaning of having a rehabilitation team present was accentuated during the second interview, where some participants shared a concern that the stroke survivor's performance of activities was decreasing and a fear that these changes could lead to various deteriorations. Participants associated this change with a reduction in both the quantity and quality of training when the team was not present to follow up. "That's precisely why I think it's become that way, that he doesn't train as hard as when they're here," said Christina (wife).

Resuming Daily Activities Lowers the Demand on Family Support

The focus on daily activities in F@ce 2.0 was described as supporting both the participants and the stroke survivors in resuming their activities over time. Participants sometimes felt insecure about what support to offer the stroke survivor and recounted that the team provided information and engaged the stroke survivor in discussions about various ways to perform activities. In relation to this, setting goals for daily activities was discussed as one of the strengths of the F@ce 2.0 intervention. Christina (wife) expressed that "Just the fact that you have three goals, it is enough and that are not insurmountable, so you notice that it can be done...it was great."

The participants described how the stroke survivor used daily activities as a form of training during the intervention, depicting how this made the stroke survivor more independent and able to practice without family members present to assist. "As it is now, she on it full time, she cleans and she does it because it is part of her training," said Jan (partner).

The impact on the participants' activities was described as most substantial in the first months after their family member had a stroke. With time and rehabilitation, participants felt that they had been able to resume more of their previous activities.

> *The way we've had it, I've stopped right away, I had some courses and stuff like that that I stopped doing because I didn't want to leave him alone. But then I will take it up again this fall, absolutely.* [Christina, wife]

Support and Involvement Through the ICT Component of F@ce 2.0

The ICT component of F@ce 2.0, specifically daily goal reminders and ratings of goal achievement, was initially directed towards stroke survivors but appears to have the potential to support family members as well. Participants expressed wishes to be there for the stroke survivor and depicted how the daily reminder in that sense became relevant for both parties. Christina (wife) said, "It's the thing with this reminder that first came in the morning… Then I only had to read to him and then it said that he should remember to do this and that and that...."

The text messages were also described as alleviating since they meant that participants did not have to be responsible for reminding the stroke survivor about the intervention goals and related activities. Being the one coming with constant reminders affected the relationship negatively as illustrated by Farida (daughter), "In that way, it's also good that you don't have to be the one who nags like… that you don't have to be that character." In relation to this she stated that the reminders were "a great asset and really makes things easier for us family members."

Participants further described the SMS text messaging as a way for the stroke survivor to invite family members to be engaged and involved in the intervention. Sara (daughter) portrayed how her mother used SMS text messaging to engage her family in rehabilitation, "...and then she also sort of turned to us children and grandchildren and showed [the ICT part of the intervention] and thinks it's exciting."

Some participants depicted a deeper involvement that emanated from the stroke survivor needing support in handling the mobile phone. To overcome difficulties handling technology, the SMSs were sent to the family member instead of to the stroke survivor. This commitment was characterized as leading to shared reflection between the participant and the stroke survivor.

> *It's probably the understanding he has himself... he actually has that because we've both discussed and seen how things have gone and it's also... thanks to the SMSs this follow-up that happens that is done...* [Christos, son]

Participants viewed the commitment as something natural, connected to the needs of the stroke survivor. Some participants described how the intervention strengthened their relationship, despite initial apprehension.

> *Perhaps you could say that it would potentially be annoying, maybe it would be something negative, but it's absolutely nothing like that, I wouldn't say that, it's only positive.* [Christos, son]

Participants outlined differences in involvement in F@ce 2.0 over time. They found that the initial phase required a greater commitment, which could later be reduced and ultimately perhaps ended.

> *At the end here I was able to sit in another room and that was just fine... X [name] looked at me a little bit when she was going to answer questions and then I thought no, it's better that you do it yourself.* [Lennart, husband]

Engagement in F@ce 2.0 Leading to Suggestions for Development

Engagement in the intervention led to reflections on the need to further develop it, particularly in terms of technology. Participants considered the intervention to be a good basis for rehabilitation support but identified several ways in which the ICT component could be improved. An aspect highlighted was the need to upgrade the goal ratings sent each afternoon. Although these questions were based on individual goals, participants perceived them as standardized and reported

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frustration because the goals were not updated when they proved too challenging or when they had been achieved. Participants reported that the stroke survivor became irritated when the questions remained the same all the time, without any development.

Participants also expressed a wish for a more significant part of the intervention to be digitalized. As Chrisos (son) expressed it "There is room for improvement, like more digitalization." Family members' experience was that after a stroke and in connection with rehabilitation, the health care system delivers a lot of information. To address this, there was a desire to have everything collected in one place, such as an app.

> *That way, you know what to do today, so it's more like a schedule as well.* [Christos, son]

Participants also suggested making more use of video calls to facilitate communication with people who, for example, have aphasia. Video calls could also make it easier for the family members to participate in conversations with the rehabilitation team, even if they were not at home during team visits.

Discussion

This qualitative study revealed that although the F@ce 2.0 intervention is primarily focused on stroke survivors, it also has the potential to support family members in adapting to life after stroke. The potential of F@ce 2.0 as support for family members was discussed by participants in terms of the meaning of the team's presence, the focus on daily activities, and the support provided through ICT. Participants also offered suggestions on how to develop the F@ce 2.0 intervention further.

Experiences shared by participants in this study align with previous research, which portrays the effects of stroke on the entire family [35]. Participants depicted how the stroke survivors' reduced independence led to a change in family roles. Although acting as a support person or carer was seen as a natural part of the relationship, it affected daily activities in several ways. Participants discussed changing habits and adapting their work situation to fulfill this new role. These findings align with several previous studies [14], underscoring the importance of not only directing rehabilitation towards stroke survivors but also of including the individuals around them.

Another topic in the interviews was feelings of anxiety related to the sudden change in life situation and uncertainties about the future. Anxiety among family members of people with stroke has been identified as a predictor of perceived caregiver burden [36], and addressing this should, therefore, be a key issue in rehabilitation. Participants in this study expressed how these feelings subsided when contact with the rehabilitation team was initiated. One aspect highlighted was the relief they felt when the team took responsibility for planning rehabilitation and booking home visits. Family members often find the transition from a more intensive rehabilitation service to community rehabilitation unsettling due to the decreased support [37]. Having a plan for rehabilitation contacts may, therefore, be perceived as helpful, even if visits are less frequent.

The ICT component of the F@ce 2.0 intervention was designed to support stroke survivors' achievement of person-centered goals by daily reminders and follow-ups [38]. In previous research, health care professionals have suggested that ICT could play a role in supporting family members of stroke survivors by providing information as well as a framework for rehabilitation [39]. This study supports the idea that ICT can help family members by offloading them the responsibility for keeping up the structure in rehabilitation. For some, the SMS text messaging also led to a collaboration with the stroke survivor. This engagement could come from difficulties handling the mobile phone, but also from the stroke survivor wishing to share rehabilitation goals and progress.

Although the interviews demonstrated how F@ce 2.0 can support family members of stroke survivors, the results suggest that further development of the intervention is necessary to better meet the needs of family members. Despite the F@ce 2.0 intervention being home-based, some participants described having had no contact at all with the rehabilitation team. This finding aligns with other research indicating a paradoxical relationship between health care professionals' awareness of the importance of informing and involving the network and the lack of readiness within the rehabilitation system to do so [37,40]. Family members should be invited to participate in activities when the rehabilitation team is present in the home to ensure they feel safe and can provide adequate support in daily activities and training [40]. Family involvement is encouraged in the F@ce 2.0 intervention; however, the intervention lacks a clear structure for implementation. Previous research has illustrated that rehabilitation professionals other than medical social workers may lack confidence when it comes to identifying and working with the social network around stroke survivors [40]. Future research should focus on developing strategies to integrate family involvement into rehabilitation interventions in a way that makes it a natural part of the process.

The notion of applying a family-centered approach, including rethinking the role of the rehabilitation team in relation to the family, is not new [7]. When implementing the F@ce 2.0 intervention in a Ugandan context, it was crucial to apply this perspective because the notion of person-centeredness collided with the family-based culture [25]. A way to meet the needs of family members in the future health care system could be to use telehealth interventions specifically designed for informal caregivers and family members. Promising but mixed results regarding such interventions have been demonstrated, and further research is warranted [41,42]. Others have argued that, instead of creating specific interventions for family members, a more effective solution would be to incorporate family support into existing programs [10]. Participants in this study recognized the potential of the F@ce 2.0 intervention but felt that the technology was outdated and desired a more comprehensive ICT solution that included information on stroke and rehabilitation. A recent evaluation of a Danish eHealth app focusing on stroke rehabilitation revealed that family members of stroke survivors appreciated having information about stroke readily available in the app and used it to prepare for meetings [43]. Future development of the F@ce 2.0 intervention could include a module for family members, along with a structured

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approach to ensuring family involvement. Here, it is crucial to co-design the content with family members of stroke survivors to ensure that it is genuinely relevant to the users [44]. Previous research has identified stakeholder involvement as a key explanatory factor for the success of family-oriented eHealth interventions [41]. Interventions also need to be flexible and allow for personal adaptations, as family members' needs differ both individually and over time [45].

The findings of this study should be interpreted within the specific context of the Swedish health care system and society, where most of the population uses smartphone technology daily. Furthermore, data collection was initiated at a later stage of the overall F@ce 2.0 project, leading to a limited number of family members being represented. The diverse contexts of the different health care regions, as well as the participants' varied backgrounds, did, however, lead to a variety of experiences and perspectives that are relevant and essential for the future development of person-centered stroke rehabilitation. Due to the COVID-19 pandemic, all interviews were conducted by telephone. This may have resulted in a lower degree of engagement among the participants. Participants had never previously met the person conducting the interviews, which made it challenging to establish trust in the remote interview situation. An additional methodological caveat is that they followed directly on a structured interview where the data collector obtained participants' answers to the quantitative surveys. From the participants' perspective, this may have led to fatigue, as well as a sense of having already discussed some of the issues. Performing data collection in reverse order might have yielded richer material. The study, however, adopts an exploratory aim and does not claim to have identified all relevant perspectives possible. A strength of this paper is the active participation of GE, KS, and ME, who all read through the interviews and were well familiarized with the material in preparation for discussion during the analysis phase. All authors have extensive experience in rehabilitation.

More than 5 years have now passed since the World Health Assembly Resolution on Digital Health was unanimously accepted by all member states [19]. A multitude of digital health interventions for rehabilitation have been developed and tested worldwide [18]. This study contributes to previous research, which illustrates that both family members and stroke survivors are able and willing to use eHealth [17,18]. It is, therefore, time for the countries of the world to move beyond discussing these issues and start implementing the World Health Organization recommendations, including adequate governance, infrastructure, and training, to ensure that the benefits of e-health interventions become an integral part of future health care [19].

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Conflicts of Interest

None declared.

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Abbreviations

C-ADL: client-centered activities of daily living
ICT: information and communication technology

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Sustainability of Digital Home Care and Health Care Services in 2 Case Studies in Finland: Combined Climate and Social Impact Assessment

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Abstract

Background: Digitalization is seen as a way to reduce the negative environmental impacts of health care production, but research is still limited.

Objective: This study focuses on the assessment of the sustainability aspects of digital services in home care and health care. It demonstrates the approach to identify the climate impacts and social impacts—both positive and negative—on a selection of digital home care and health care services, such as medicine robot services for older home care clients, through 2 Finnish case studies.

Methods: Impacts are identified from interviews and statistical data collected from public service providers and technology suppliers using both quantitative and qualitative assessments.

Results: While a well-planned and well-implemented digital service is likely to be a climate-friendly option, every digitalization action carries at least some negative impacts. The design, architecture, and practical implementation of these services greatly affect their climate and social impacts.

Conclusions: This study uses a novel combination of impact assessment methods, highlighting the importance of qualitative understanding alongside quantitative approaches for interpreting results, especially when numerical data are limited. Advocating for multimethod impact assessments is crucial to properly capturing the service context and promoting holistic sustainability thinking.

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KEYWORDS

digitalization; climate impacts; social impacts; health care; home care; quantitative assessment; qualitative assessment

Introduction

Background

Digitalization of health care and care services typically aims to improve the availability of services for citizens in need. It is also viewed as a way to increase sustainability. Digital health care and care services, such as remote monitoring, medicine robots, automatic reminders, digital appointments, and other electronic services, as well as management of one's own data, have been found to support the prevention of health problems, self-assessment of service needs, and independent living [1,2]. An increasingly prevalent aim of digitalization strategies is for services to be implemented in a socially, environmentally, and economically sustainable manner (eg, [3]). The digitalization of health care and care services faces numerous challenges, including diverse ethical issues, data protection and privacy, and the fact that these services are typically related to citizens' challenging or fragile life situations [4]. Despite these challenges, the enabling role of digitalization in public healthcare and care services is intriguing due to its broad scope, societal significance, and potential to reduce the need for human labor (eg, [5]).

This study focuses on the climate impacts of the digitalization of public health care and home care services and its potential to mitigate the negative impacts of current practices, with an emphasis also on qualitative social impacts. Digitalization is seen as a way to reduce the negative environmental impacts of health care production (eg, [6,7]); however, research is limited, and assessment methods still require development, as discerning the impacts requires a multidisciplinary and holistic approach

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in both research and practice. It is unclear whether, for example, the increased electricity and rare material use due to digitalization will be compensated for by efficiency gains and sustainable behaviors fostered by digital innovations. Moreover, digitalization may, for instance, consolidate incumbents' power and unsustainable practices [8]. There is a tendency to consider digitalization as something automatically positive from an environmental perspective, which further highlights the need for robust and user-friendly assessment methods (eg, [9], focusing on evaluation).

In addition, the uptake of new services in health care requires a human-oriented perspective that takes into account patients or clients, their informal caregivers, and professional caregivers [9]. User adjustment is crucial when implementing disruptive technologies and practices, as their introduction entails more than mere adoption: users need to integrate novelties into their practices, routines, and organizations [10]. A detailed consideration of both the positive and negative impacts of digitalization still requires well-informed methods that include a strong human perspective.

Our main focus in this study is on the assessment of the sustainability aspects of digital services in home care and health care. Through 2 Finnish case studies, this study demonstrates the approach to identify the climate impacts and social impacts—both positive and negative—on a selection of digital home care and health care services, such as medicine robot services for older home care clients. The examination of other technologies and services, such as remote health care appointments, plays a supportive role. Digitalization plays an increasingly central role in the development of home care and health care services; however, its implementation should be supported by concrete tools to assess its impacts. Based on empirical data, the results of both quantitative and qualitative assessments are presented. The latter also includes social impacts related to and intertwined with climate impacts.

Sustainability of Health Care and Care Services

Until recently, the sustainability of health care and care services has been regarded particularly from the point of view of economic and social sustainability. However, the integration of environmental sustainability is inevitable [11] to recognize the connections between the climate crisis and the challenges of health care and care. Health and well-being, on the one hand, and environmental sustainability, on the other, are still often examined separately, although they have many mutual effects. The health care sector is directly affected by climate change impacts on patients and, at the same time, is responsible for over 4% of greenhouse gas emissions globally [12, 13].

Finland's journey in health care and care service digitalization has spanned decades, beginning in the 1960s, and gradually expanding to support client and patient care [14]. A major turning point came around the year 2000 with the introduction of a national strategy to advance digital technologies, and over the past 2 decades, digital solutions have become an essential part of health care and care delivery. Digitalization is driven by a combination of historical development, national strategies and reforms, technological advancements, efficiency and accessibility improvements, and support for the rapidly aging population (eg, [14]). A comprehensive national reform of health care and care services, social services, and rescue services of 2023 marked a significant shift also in the trajectory of digitalization. Digital tools are widely used in both primary and specialized outpatient care across the public and private sectors [15], but the environmental sustainability of digital health care and care services is still quite an emerging perspective.

While interest in "sustainable health care" has grown globally, there is still no consensus on its definition [11]. The definition (scope) of health care can also vary across countries and their different service systems. This paper concerns older people's home care as well as health care services, and in most instances, "health care" and "care" are thus used side-by-side in this text. The sustainability transition in health care and care systems is systemically linked to the transition in related systems on their periphery, such as the living environment, traffic, construction, education, and food production [13,16]. However, the core business of health care and care-related persistent problems, systems, and structures remain largely unchanged [16]. A transition perspective may help identify more promising ways of understanding and addressing the sustainability issues faced by contemporary health care and care systems [17].

Knowledge is needed about what constitutes sustainable digital health care and care services and how they are defined (eg, [5]). There are both challenges and opportunities in how digital technologies are integrated into existing health care and care services and systems, including the initiation of new services [18]. The structures and support systems of health care and care play a central role here; the sustainability of digital innovations depends on whether their integration is conducted in a way that supports their long-term stability [6,9]. Contextual factors, such as financing, organizational support, and people's capabilities, capacity, and education, affect the integration process [19,20].

The Broad Field of Digitalization

When considering environmental sustainability, it is essential to consider the digitalization of health care and care services from a broad perspective [7]. There are diverse types of services and patient or client groups, technologies and systems, and programs and infrastructures, and services are offered and used in very different circumstances and environments, from homes to various institutional settings. Nordic Innovation [21] reminds us that in addition to sustainable service environments and sustainable technologies, sustainable health care covers sustainable behavior and practices. From a human perspective, sustainable health care is related to sustainable health (well-being and disease prevention) and environmental health (health risks both outdoors and indoors and how they affect an individual), and it refers to treatments that take place after an individual has fallen ill (both out- and in-patient care), according to Nordic Innovation [21].

On the other hand, the digitalization of health care and care-related processes and improved cooperation (eg, between hospitals and product suppliers) can support decreasing the carbon footprint. Improved data availability may render decision-making in hospitals and healthcare centers more efficient. Beyond building design, it is crucial to consider the sustainability of materials used in new technologies, which

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necessitates procurement expertise. In addition to the above-mentioned perspectives outlined by Nordic Innovation [21], sustainability should not be limited to contexts in which an individual has already fallen ill and become a care receiver. If preventive services and technologies are taken more broadly into consideration, it should be possible to better harness the positive potential of digitalization and thus achieve more systemic results [10]. This could involve, for example, the earlier introduction of proactive digital services in home environments [22].

Digitalization in health care and care is also characterized by the so-called emerging technologies that are currently used to some extent in these services. The Finnish Ministry of Transport and Communications has determined that by means of new solutions implemented through technologies such as robotics, artificial intelligence, and automated systems, along with their support technologies (eg, cloud services), negative environmental impacts in different sectors (including health care and care) could be decreased [23]. Opportunities for these technologies have been recognized in health care and care services, but the use of robots, for example, remains relatively rare [24]. Ethical and legal issues, among others, may cause challenges in this area [25]. More traditional technologies can also be used to implement remote health care and care (also called eHealth, digital health, telemedicine, telehealth, or distance-spanning solutions), potentially affecting people's mobility and use of buildings. Indeed, remote health care and care services of different types are being increasingly adopted in various countries. A significant increase in their supply and use resulted from the COVID-19 pandemic [26]. Our impact assessments covered both emerging and more traditional technologies, while this paper concentrates on the emerging technology of medicine robots.

Methods

Background to Case Studies

This empirical study focuses on cases from the 2 Finnish regions of Päijät-Häme and South Karelia, particularly on home care services for older people (medicine robot and video call services), as well as remote health care appointments in dental care, nutritional care, and mental health and substance abuse services for children and youth. Most of this paper concentrates on the study of medicine robot services due to their enormous potential for global adoption, as well as their innovative use of remotely controlled hardware to complement or even substitute for human labor. Both cases are introduced to provide sufficient context for our work. Päijät-Häme is in Southern Finland, while South Karelia is in Southeast Finland. Both regions are rather sparsely populated, with long distances to services.

Case 1: Digital Home Care Services, Especially Medicine Robot Services

In Case 1, the home care services are provided by the older adult care services and rehabilitation unit of the Päijät-Häme Joint Authority for Health and Well-being (currently Well-being Services County of Päijät-Häme). The Päijät-Häme Joint Authority for Health and Well-being provides services for the more than 200,000 residents of the region, with its 7000 employees. Part of the home care services in this region is produced as remote care services. The remote care and technology unit, Severi, serves regular home care clients with the help of video calls and medicine robot services. Severi employs both nurses and assistant nurses. The Päijät-Häme region is a pioneer in remote care arrangements in Finland (for further information on the regional home care ecosystem, refer to [27]). At the time of data collection (2022), there were 257 medicine robot clients (15.3% of all clients) and 173 video call clients (10.1% of all home care clients). Medicine robots and video call services are not quite new in the field, although their use has proliferated quite rapidly. The environmental sustainability or climate impacts of medicine robots had not been studied in the region.

The primary use of medicine robots is as medicine dispensers; however, they can also be used to provide various reminders. Medicine robots are available to home care clients free of charge and can help provide regular medications just on time. A home care professional generally fills the robots for a period of 1 - 2 weeks. In the event of possible disturbances, such as power outages, the device sends an alert to a care professional. The devices also trigger an alarm if a client does not take the medicine offered or if there is an attempt to break into the device. The medicine robot can function as a service on its own or complement other home care services. The medicine robot technologies in use in the region are Evondos (since 2016; [28]) and Axitare (since 2020; [29]). The medicine robot requires mains power but no fixed internet connection, thanks to a built-in mobile modem. Employees can access the backend, as well as the robot itself, using a tablet, computer, or mobile phone with an internet connection, which the service organization must acquire, along with purchasing the overall service and a maintenance contract with a technology provider. One of the medicine robots dispenses medicine bags, while the other uses dose cups. The purpose of the medicine robot service is to replace one or more visits by care professionals, but not necessarily all.

Video call services are conducted on a 10-inch tablet provided to the home care client. The service provider conducts a needs assessment and, based on the service criteria and the assessment, tailors the client's services. This type of service can be offered to a client whose functional ability enables them to act according to instructions. A care professional contacts the client at a previously agreed time. Video call services can be used to guide and ensure medication intake (the client's functional ability permitting) and to monitor nutrition. The clients can also participate in group events organized by the service provider, such as rehabilitation exercise sessions. The tablet only has the video call app installed; it cannot be used for anything else. The care professionals use computers with separate displays and headphones when calling clients. An ordinary call lasts about 10 minutes, although 15 - 20 minutes is also possible (with group activities lasting 30 minutes). Video call services can be combined with other services, such as a safety alarm wristband, but such possible services were not taken into account in this study's calculation, nor were speakers, which can be provided to clients who are hard of hearing.

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Case 2: Remote Health Care Appointments

The South Karelia Social and Health Care District (currently Well-being Services County of South Karelia) provides several types of remote health care appointments. Our assessments covered the services of three units: (1) dental care (dental examinations of 1-year-olds), (2) nutritional care, and (3) mental health and substance abuse services for children and youth (family counseling and youth support). The South Karelia Social and Health Care District produces public social and health care services, employing about 5000 staff members to serve approximately 129,000 residents of the 9 municipalities in the South Karelia region. The 3 units represent both centralized and decentralized services. Remote health care appointments are available to all residents as an alternative to traditional on-site client or patient visits. The care professional offers the possibility of a remote appointment that is conducted with the help of either VideoVisit or Microsoft Teams. VideoVisit (currently Oiva Health, [30]) is a digital care platform used in the Nordic countries; it is designed for primary health care, social care, hospital health care, and long-term care services. The client's significant others or designated support persons can also participate in remote appointments. If needed, professionals from several different services can attend as a network (especially in mental health and substance abuse services). At the time of data collection, the percentages of remote appointments were as follows: (1) dental care (1-year-olds): 0.2% of all contacts (a 1-time visit for this age group), (2) nutritional care: 13.1% of all contacts, and (3) family counseling and support for youth: 11.3% of all contacts.

The original aim of the remote appointments was to improve the availability of services in a region where travel distances can be long; however, the COVID-19 pandemic accelerated adoption. No special dedicated equipment is required to provide or access the service, only a regular computer, a smartphone, or a tablet connected to the internet.

Research Methods

Data were collected for the qualitative assessment, the development of a calculation model, and the establishment of a quantitative assessment method. The collected data consisted of interviews with service providers and technology suppliers, as well as documents provided by the case organizations. These documents included log information about the use of digital services, evaluation reports, planning documents, and statistics and annual reports related to service use and development in the region. A list of relevant knowledge needs was drafted to guide the data collection, aiming to gather comprehensive information on both direct and indirect impacts. From the perspective of clients, care professionals, and the service system, data collection focused on a detailed description of the service (eg, devices used, architecture of the backend system, daily organizing of the service, and work environments or spaces), as well as the reasons for the introduction or digitalization of the service (economic reasons and those related to service quality) and its impacts (both intended and other impacts in a broad sense). Information was also collected on how the services had been organized in the past, how the digitalization of the service changed the operations of the affected parties, and patient or client satisfaction.

From the perspective of companies (technology suppliers), data collection addressed a description of the service from the company's perspective and matters related to manufacturing materials, production, electricity consumption, recycling, lifecycle of materials or parts, backend services, and network use. Similar knowledge needs applied to Cases 1 and 2, but the details were case-specific. The exact content of the interviews was tailored according to each interviewee's role and service type.

The interviews were conducted in January-March 2022 as remote Teams interviews. Most of the interviews were conducted individually, although a few were carried out as pair interviews. The interviewees were selected to obtain the most comprehensive information about the climate and social impacts from perspectives relevant to the services in question, such as backend and frontend services. The interviewees represented a wide range of professions and several organizational levels, including management, development, and planning of services, supervisors of patient or client service work, employees working in patient or client services, technology trainers, and technology suppliers.

The interviewees were selected in collaboration with the 2 service providers' contact persons so that their perspectives were complementary and covered the whole of the services in a sufficient manner. In Case 1, there were 12 interviewees: 9 from the service provider (assistant nurses, a registered nurse, an immediate supervisor, and management representatives) and 3 from the technology suppliers. In Case 2, there were also 12 interviewees: 11 from the service provider (a service designer, developer, management representatives, immediate supervisors, and personnel from the 3 units studied) and 1 from the technology supplier.

The interviews were recorded and transcribed. Due to different client or patient groups and service types, Cases 1 and 2 together offer a multidimensional picture of the digitalization of public health care and care services. While most of the results concern the medicine robot services, both cases are discussed.

Quantitative Assessment of Climate Impacts

The quantitative assessment of climate impacts was based on life-cycle assessment (LCA) methodology. LCA is a well-established method for studying complex value chains in order to understand potential environmental impacts. In LCA, all relevant elementary flows entering or leaving the studied system are characterized according to a defined impact category. In this assessment, the focus was exclusively on the impact category of climate impacts, using the indicator Global Warming Potential (*kg CO_2e*). LCA enables quantification of the potential environmental impacts of the entire product system, including upstream impacts. This is crucial when studying systems that are global in nature.

It was not possible to assess and compare complete services before and after digitalization due to limitations of data and the incremental way in which the studied services had been digitalized. It was therefore decided to calculate the impacts of

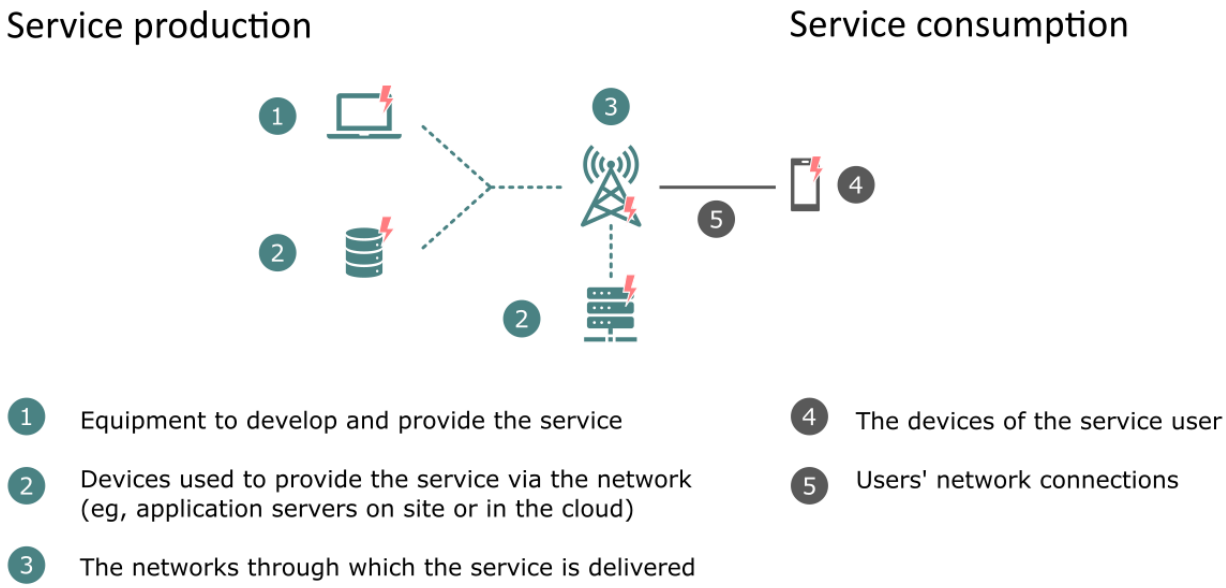
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the current digitalized services and then compare those impacts to commonly understood and case-relevant climate impacts of traveling via car or bicycle.

In LCA, impacts are calculated per defined functional unit, which is a measure of the performance of the product system being studied. It provides a reference to which all inputs and outputs of the system can be related. The functional unit was defined as 1 year of service usage of 1 client or patient in continuous services and a single session in other services. This definition of the functional units also facilitated the comparison of the climate impacts of digital services to the climate impacts of potentially saved travel.

Our framework for the quantitative assessment of the climate impacts of digital services is shown in Figure 1. This is a highly simplified framework; however, it still adequately describes all the digital components of the service. The production of a digital service requires user IT equipment, an internet connection, and servers. The consumption of a digital service requires an internet connection and an access device. The access device can either be dedicated to the service (eg, a medicine robot or dedicated tablet) or not (a personal computer, smartphone, or personal tablet used for other purposes as well).

Figure 1. Framework for the assessment of climate impacts of digital services.



This simplified framework allowed for the assessment of all the studied services based on the collected data. Calculations based on detailed solution architecture would have been practically impossible because, for example, the network component of a service can include hundreds of connections and processing units.

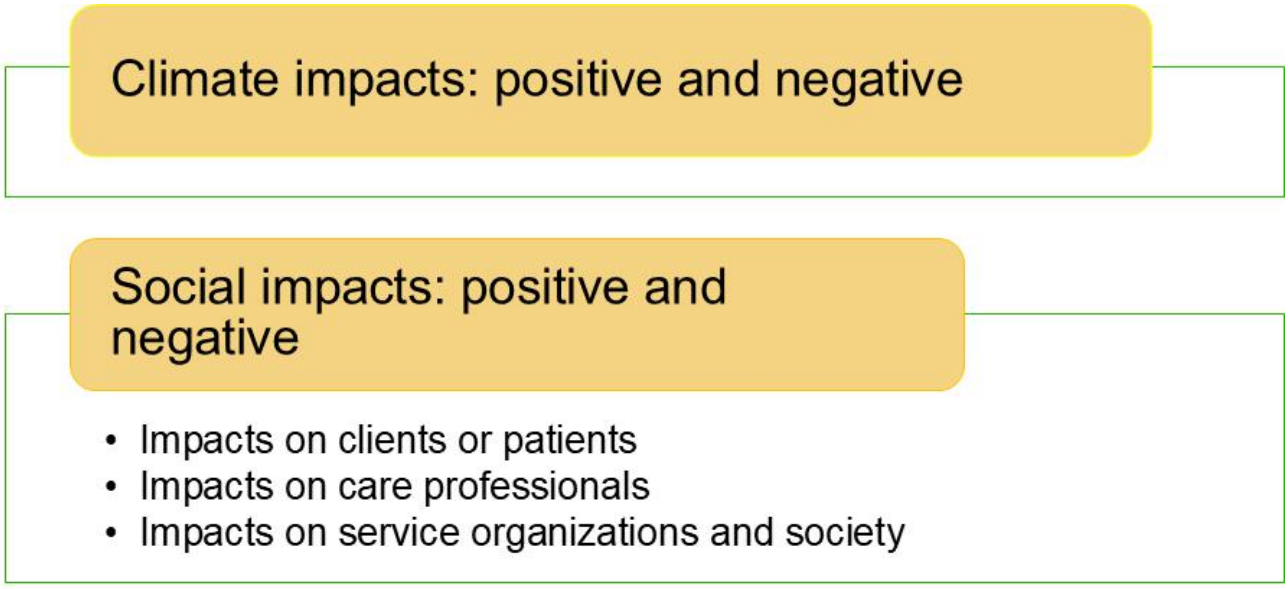
Qualitative Assessment

For the qualitative assessment, the interviews were analyzed using content analysis to identify climate impacts and related social impacts separately. The qualitative assessment method used in this study is based on the principles of human impact assessment (HuIA; eg, [10,31]). The assessment of human impacts can be used to structure new perspectives and to describe solution options. HuIA takes into account the fact that impacts can be planned or unintended and can be formed as a result of long chains or networks of impacts [31]. In this study, assessing impacts on people implies, for example, examining chains of impacts of digitalization, such as connections to well-being, relationships between people, and work. HuIA is comprehensive in nature—impacts are not limited in advance, and efforts are made to comprehensively identify them and make them visible. This approach has been used in studies on the digitalization of older adult care and health care services concerning traditional technology, such as safety alarm systems [32,33] and emerging technologies, such as care robots [10]. Its essence is to identify positive, negative, and neutral impacts on different groups of people involved holistically.

An inductive thematic content analysis [34] of the data was conducted. Accordingly, the transcribed text and notes were thoroughly read to capture the features associated with the research topic. The sentences and paragraphs from the interviews that were assessed as interesting or meaningful regarding the phenomenon under study were identified and marked, and initial codes were generated across the dataset. In this study, the codes were grouped into positive and negative climate impacts and related social impacts. The positive and negative social impacts were further grouped into impacts on clients or patients, impacts on care professionals, and impacts on service organizations and society (Figure 2). These were checked against the codes and the entire dataset for relevance.

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Figure 2. Categorization of the qualitative results.



Combining the Assessments

The interviews and the related document collection provided information on the context, components, and whole of the services, including the service production and service consumption, from different perspectives. They also enabled the development of a simplified framework for the quantitative assessment and the definition of the functional units for it.

Based on the interviews, statistics, and other documents, the material and energy inputs required by both the information and communication technology system and the physical service were investigated. For the calculation of climate impacts, quantitative data on direct and indirect factors were collected as comprehensively as possible. Comparable data about the service and deliverables before digitalization, in particular, proved to be difficult to obtain from the case studies. The calculation was made case by case on the basis of the data obtained.

The interview material provided a rich basis for the qualitative assessment, including analysis and results on how people's actions and ways of doing things affected the impacts. The quantitative and qualitative assessments fed into each other, at different phases, in gaining a comprehensive view of the topic of the study and understanding how mixed methods can be used and why they should be used in studies of digital services. As a practical outcome, the combination of the quantitative and qualitative approaches also led to the development of an online calculation service for practitioners [35-37].

Ethical Considerations

Ethical standards were maintained throughout the research. All interviewees provided informed consent for participation and subsequent interviews, and leaving midsession was permitted. Research permits were obtained from the appropriate authorities, and participants' privacy and confidentiality were maintained. The study was approved by the Ethics Committees of the Päijät-Häme Joint Authority for Health and Well-being (approval no D/38/13.00.00.00/2022) and the South Karelia Social and Health Care District (approval no EKS/583/13.01.05/2022).

Results

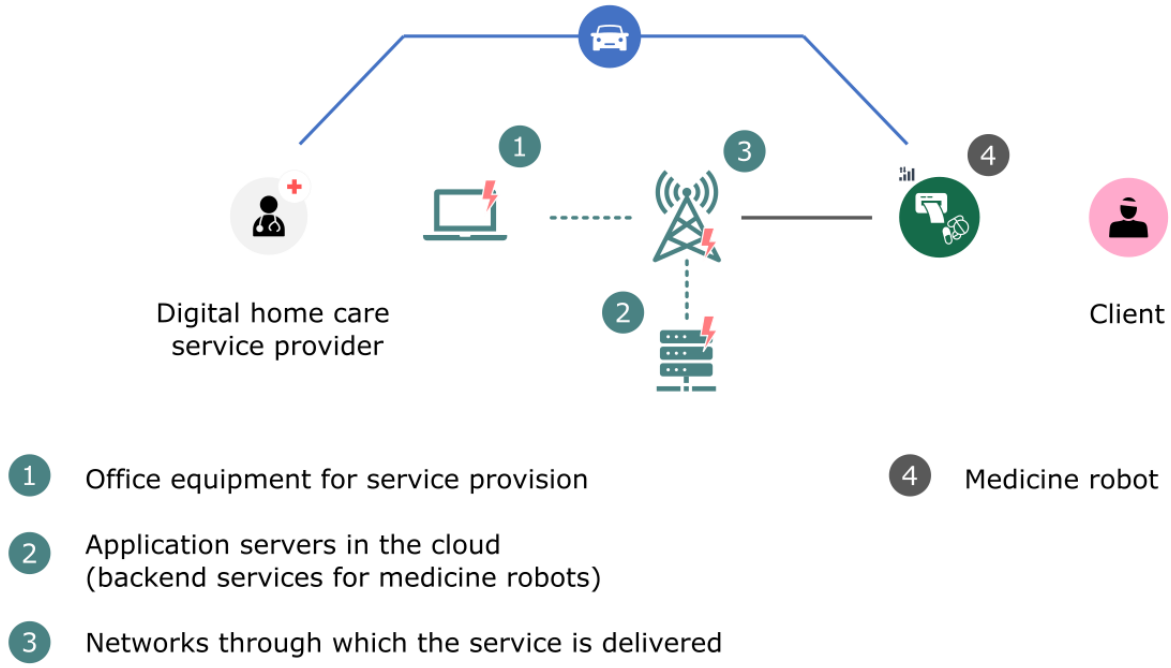
Quantitative Assessment Results Regarding Climate Impacts

Medicine Robot Services

The climate impacts of medicine robot services were calculated for a functional unit of 1 year of use of a medicine robot by a client who takes medication 3 times a day. Figure 3 shows the basic components of the service. These are the same components as in the framework shown in Figure 1, with the addition of physical visits to refill the medicine robot.

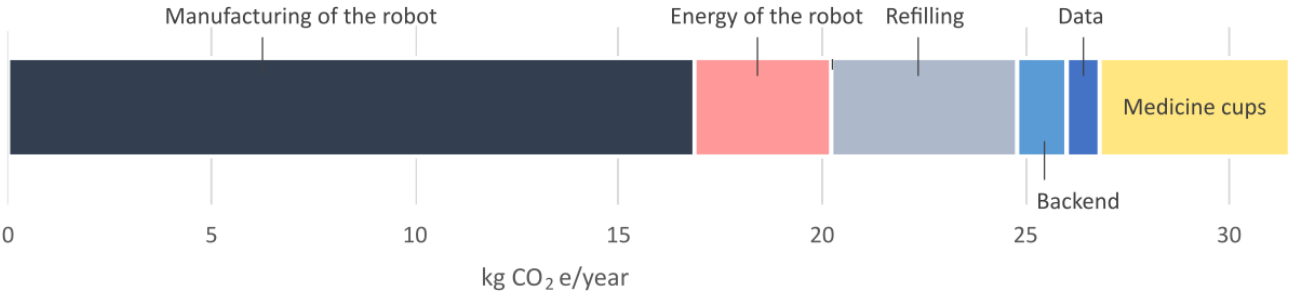
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Figure 3. Medicine robot service components for impact assessment.



The climate impacts were calculated for both medicine robot types, and the overall results were quite similar. The aggregated results are shown in Figure 4. The manufacturing of the robot dominates the climate impacts. Refilling and energy use together account for less than half compared with the impacts of manufacturing. The backend and the mobile data represent only a small contribution to the overall climate impacts. Medicine cups—used in one of the robots—cause more impacts than the energy consumed by the robot. The overall carbon footprint of a yearly medicine robot service was estimated to be about 30 kg CO_2e (carbon dioxide equivalent).

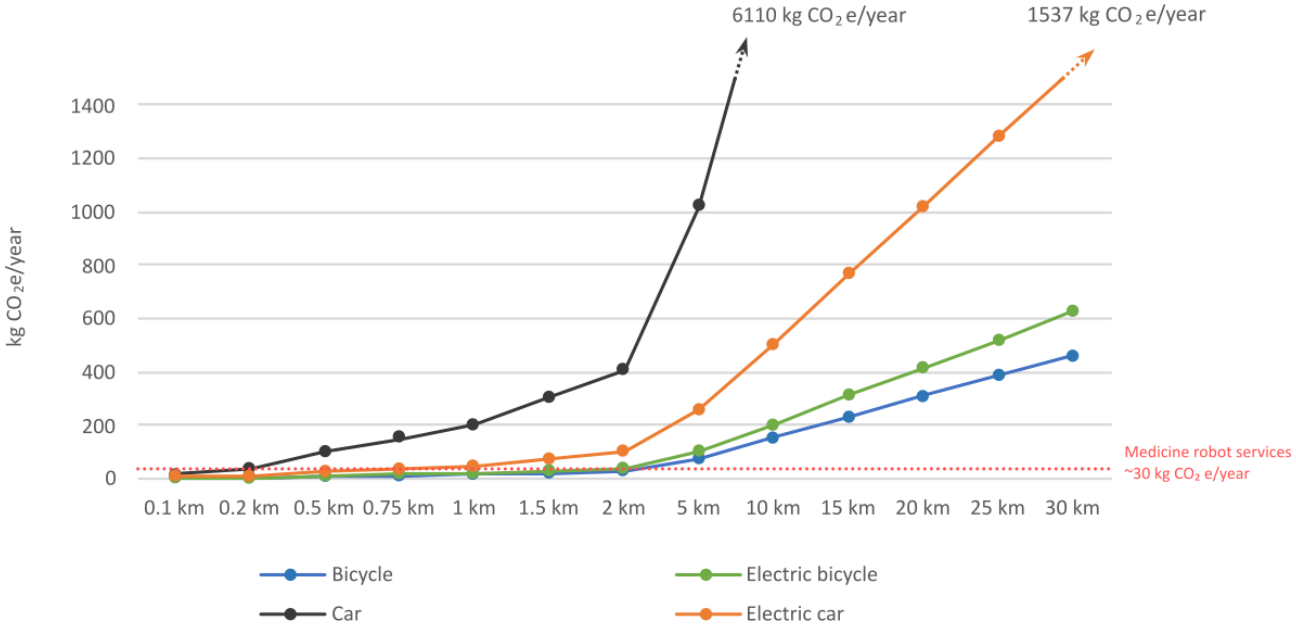
Figure 4. Climate impacts of a medicine robot (aggregated). CO_2e: carbon dioxide equivalent.



The medicine robot reduces the need to travel. Clients without a robot typically need 2 visits per day, while the robot requires a refill visit every 2 weeks. Figure 5 compares the climate impacts caused by the medicine robot service to alternative means of transport to fulfill daily medication needs.

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Figure 5. Comparing the climate impacts of the medicine robot service with the climate impacts of avoided travel. CO_2e: carbon dioxide equivalent.



In short, the medicine robot is a climate-friendly option when the distance to the client by car (even electric) is more than a kilometer (2 kilometers by bicycle).

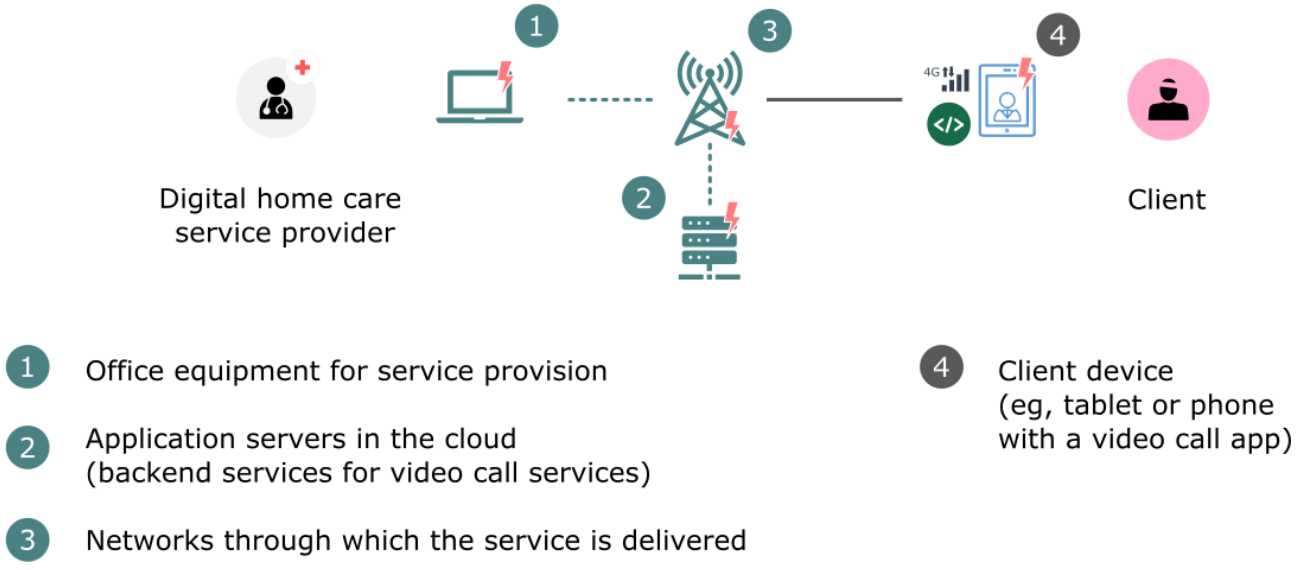
To conclude, the medicine robot demonstrates good potential from the perspective of reducing climate impacts. It is especially beneficial for rural areas, where client visits necessitate car usage.

Providers of technology and services are key to reducing carbon footprints. Manufacturing of the medicine robot causes over half of the assessed climate impacts. The carbon footprint of manufacturing depends not only on the design and use of materials, but also on its lifespan. Operational energy and data usage of the robot should also be optimized, but they have less impact on the carbon footprint. Requiring carbon footprint calculations from technology and service providers would be an effective way to ensure overall green services.

Other Services

The other services assessed were video call services, consisting of the same components as in the framework (Figure 1). The basic components of video call services are shown in Figure 6.

Figure 6. Video call service components for the impact assessment.



Remote health care appointments occur infrequently; therefore, a functional unit of an appointment was selected. This approach allowed for a direct comparison to traveling to an appointment at the health care facilities. Clients use their own smartphones, tablets, or computers for video appointments; therefore, the carbon footprint share of client device manufacturing is negligible. The calculated carbon footprint of a remote health care appointment was 0.044 kg CO_2e, which is about the same as driving 1 kilometer with an electric car. Remote health care appointments have a carbon footprint, but a low one compared to driving to an appointment.

Video call services for home care clients have the same basic components (Figure 6); however, calls occur frequently, and

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clients use a dedicated tablet reserved for this use only. The assessment was carried out for a functional unit of annual use of the video call services. The calculated footprint was 61 kg CO_2e, which is about twice that of the medicine robot services. The comparatively high climate impact is mainly due to the dedicated tablet with a short lifespan on the client side. The manufacturing of the tablet causes 73% of the yearly footprint. Video call services with a dedicated tablet are a good option in rural areas where distances to clients are longer; however, the results also show that a digital service is not automatically climate-friendly.

Qualitative Assessment Results

Positive Climate Impacts

Medicine Robot Services

Medicine robot services enable reducing the kilometers driven by care professionals. The number of care professionals' home visits may decrease from as many as 60 visits per month per client (to administer morning and evening medicine) to 2 visits (to refill the robot). In the studied regions, the distance from the home care office to the clients' homes can be tens of kilometers. A care professional noted:

> *I personally find these [medicine robots] useful. These have been well received in the work community. Suitable clients are suggested from the field. It's frustrating to drive 50 minutes to give the morning medicine.*

Usually, only some of the visits are replaced. Medicine robot services provide the opportunity to save on care professionals' protective equipment (eg, disinfectants, gloves, and masks). In addition, the medicine robot service may decrease medicine wastage. When only the right amount of medicine is dosed, there is no need for large medicine packages that may expire if the medicine is no longer needed. One aim is also to optimize routes and visits to clients' homes. The life cycle of medicine robots is quite long (7 - 8 years). The devices are considered durable and are repaired by replacing worn parts. The devices are reused by other clients, and the components are recycled.

Other Services

Video call services (including both home care services in Case 1 and remote health care appointments in Case 2) also enable reducing the total kilometers driven, either by the care professionals (Cases 1 and 2) or the patients (Case 2). The video call services in Case 1 can decrease the number of home visits (eg, measuring and dosing visits related to older adult care). If the client also has a safety alarm system, the video call service can be used to check the client's situation when an alarm has been triggered before driving to the client's home. Just as in Case 1, in Case 2, the service provider organization operates in a large geographical region, so remote appointments reduce the traveling of both care professionals and clients. This impact is mainly related to clients' traveling because the appointments in question have traditionally taken place in health care centers, not in clients' homes. According to the interviewees, remote appointments are popular in the region, especially in rural areas. In both Cases 1 and 2, the services do not require care professionals to use care equipment or protective equipment (eg, disinfectants, gloves, and masks); thus, the amount of waste is lower. According to the interviewees, actual savings on space have not yet been achieved, but there is more flexibility in the use of the workspace; for example, an ordinary office is sufficient for a remote dental care appointment. In Case 2, space savings were noted to be likely in the future. Paper use has decreased somewhat, as written materials are mainly delivered in electronic format. However, clients may print out the materials themselves. Not all materials exist in electronic format. Before the remote appointments, all materials were mailed to clients. As with the medicine robot services, one aim of the video call services in Case 1 is to optimize the routes and visits to the clients' homes. The life cycle of the video call tablets is about 3 years. The materials are recycled, and this service reuses the devices for other clients.

Negative Climate Impacts

Medicine Robot Services

The negative climate impacts of medicine robot services are related to both energy consumption and the manufacturing of the necessary service components (Figure 3). For the medicine robot, a battery is needed in addition to mains power to ensure an electricity supply during power outages.

When the device is brought to a client, guidance is always given by a care professional. If needed, guidance is given several times in the beginning. The interviewees noted that unnecessary driving sometimes occurs, which could be avoided with better planning. Ensuring that care professionals possess the necessary technical expertise is vital so that the professional who is present in the client's home can help when problems arise without the need to call for assistance. This is also vital from a more general perspective, as a technology supplier noted:

> *Thorough training and support produce [positive] environmental impacts by ensuring that the device is not left unused or that there is no return to giving the medicine on site.*

Even though the medicine robot generally reduces driving, there are times when error messages or alarms require a home visit. Most of these situations can be checked by phone, such as when the device triggers an alarm due to medicine not being taken. It is rare to have to call for a technician to repair the device. Medicine robot services do not affect the number of workspaces, as the services were provided earlier at clients' homes.

Other Services

The negative climate impacts of video call services (again, including both home care services in Case 1 and remote health care appointments in Case 2) are also related to both energy consumption and the manufacturing of needed service components (Figure 6). As for the tablets used in home care in Case 1, when the device is brought to the client, guidance is always provided by a care professional, several times if needed. Again, good planning is the key to avoiding unnecessary driving.

Despite the decrease in driving, negative climate impacts nevertheless arise. Different types of support services are

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necessary for remote health care appointments, which increase negative impacts. The number of workspaces is not directly affected, either because the services have been provided in the clients' homes (Case 1) or because some space is needed for remote appointments as well (Case 2). The interviewees, however, assessed that the need for workspaces may decrease in the future.

Social Impacts

Health care and home care services are a challenging field in which to conduct impact assessments, and the importance of including social impacts was reinforced by the fact that diverse, intertwined, and multidirectional impacts became visible in the study. Social impacts for Cases 1 and 2 are reported together and categorized into positive and negative impacts at different levels—clients, employees, organizations, and society (Tables 1 and 2). Such impacts may be intended (in line with the aim of the digitalization of actions) or unintended. A few descriptive quotations from the interviews are included as examples.

Table . Positive social impacts (Cases 1 and 2).

Category	Positive social impacts per case
Clients or patients	• Case 1: savings on service fees, improved accuracy of medication and care visit timing, decrease in medication errors, maintaining a sense of independence and autonomy, opportunity to focus on social interaction during video calls, and opportunity to participate in various activities from home. • Case 2: regional equality, accessibility of services regardless of place of residence, flexibility, and saving time, money, and effort spent on traveling.
Employees	• Both cases: reduction in the time required for traveling and mechanical tasks, easier planning of time use (more time for actual nursing work rather than, eg, changing protective equipment and disinfecting between client visits). • Case 2: networked multiprofessional collaboration is more flexible remotely; remote work was felt to increase workplace well-being.
Service organizations and society	• Both cases: more rational allocation of resources (face-to-face visits to those who really need them), possible increase in the appreciation of care work and its attractiveness. • Case 2: reduction of canceled appointments and no-shows. Practical experience has revealed new opportunities for remote appointments. Remote appointments and remote work are considered assets for recruiting.

Table . Negative social impacts (Cases 1 and 2).

Category	Negative social impacts per case
Clients or patients	• Case 1: not suitable for everyone (eg, possible delusions); perceived unsuitability of the devices (size and appearance) to the home environment. • Case 2: inequality of citizens (digital skills, opportunities to acquire devices, and internet connections). Remote appointments can exacerbate or sustain problems (eg, fear of social situations may not be visible).
Employees	• Both cases: change of work, new tasks (eg, responsibility for technology and assessment of service needs). Change requires learning, which can be overwhelming. • Case 1: no decrease in total workload because the number of clients is increasing all the time; easy visits have decreased; challenging ones have remained. • Case 2: it is not possible to observe the whole person or the living conditions when working remotely. Possible deterioration in interaction.
Service organizations and the society	• Both cases: challenges related to work culture and bringing technology into service processes (increased complexity of management); new and old ways of working collide (eg, engaging and assisting personnel, procurement expertise, support services, data security, data ownership and storage, and integration of different technologies).

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Positive social impacts included the preservation of clients' activity and independence, regional equality regardless of place of residence, the rationalization of employees' work, increased work flexibility due to a decrease in commuting time, and a more reasonable allocation of society's resources. A care professional noted:

> *Medication errors have decreased even though double checks are in place. Some clients have gained independence, meaning they can live at home on their own. Lots of things. Lonely clients may have made friends. And I think a couple of relationships have even blossomed.*

Negative social impacts included issues related to client inequality (such as differences in digital skills, financial opportunities, or the service being unsuitable for certain clients), increased employee workload during the transition to new working methods, and increased management challenges and complexity.

The detailed social impacts depend on the type of service and technology (refer to Tables 1 and 2). Medicine robot services, for example, such as the use of home care technologies in general, have led to savings in clients' care fees. Clients found the devices easy to use, as they are largely automatic, reliable, and require no technical skills. The use of the medicine robot also led to other positive outcomes, such as improved quality of medication care and fewer medication errors. The medicine robot always administers the medicine at exactly the specified time, which improves the accuracy of medication. When a care worker administers the medicine, the timing may vary. The robot also relieves the client of the mental pressure of remembering to take the medicine. Several reminders can be given by the robot. Furthermore, the service provides a sense of participation and accomplishment. Some clients do not like visits by care workers, and the medicine robot enables clients to maintain their independence while ensuring access to care.

The perceived unsuitability of the devices to the home environment was mentioned as a negative social impact from the clients' point of view. The large size of the medicine robot may come as a surprise, and clients may perhaps consider it ugly and inappropriate for their interiors. The medicine robot also does not promote social interaction, unlike a home care worker's visit or a video call service. Often, the medicine robot and the video call services work in tandem for the client. It is important to consider for whom the technology is suitable, especially in the case of people with memory and mental illnesses, as they may have delusions about, for example, spreading the image of a video call to outsiders. The client may also unplug the medicine robot or turn it upside down, causing the medicines to get mixed. Both situations trigger alarms. Technical problems, for example, when establishing a video call connection, also appear as negative impacts, although they are typically caused by network overload or a bad audio line. However, such problems are relatively rare.

The first reaction of clients and their loved ones to the introduction of technology to home care (Case 1) is often negative, as the care may be thought to be worse when provided with the help of technology. A care professional noted:

> *Clients and their families have individual attitudes. Often, there is initial resistance, but once they try it and learn how it works, they realize how convenient it is, and their attitude usually becomes positive, and they start using the service.*

The implementation of the technology in Case 1 always starts with a 2-week trial period, after which it is possible to stop using it. However, most clients were satisfied after the trial period and wanted to continue using the device. In Case 2, the negative social impacts differ somewhat; remote health care appointments can exacerbate or sustain clients' problems, and it is not possible to observe the client's situation as a whole. Interaction may deteriorate as well. A technology supplier explained management challenges:

> *The transition from traditional models to the use of technology is a change that requires change management and organizational involvement. […] It is often underestimated that once the purchase has been made, home care staff are told to start using the robots, and then there are many fears about how this will affect their work. "What if I don't know how to use this service?" Political decision-making, courage, change management, and organizational involvement are needed. […] Not just "Start using the robots."*

Discussion

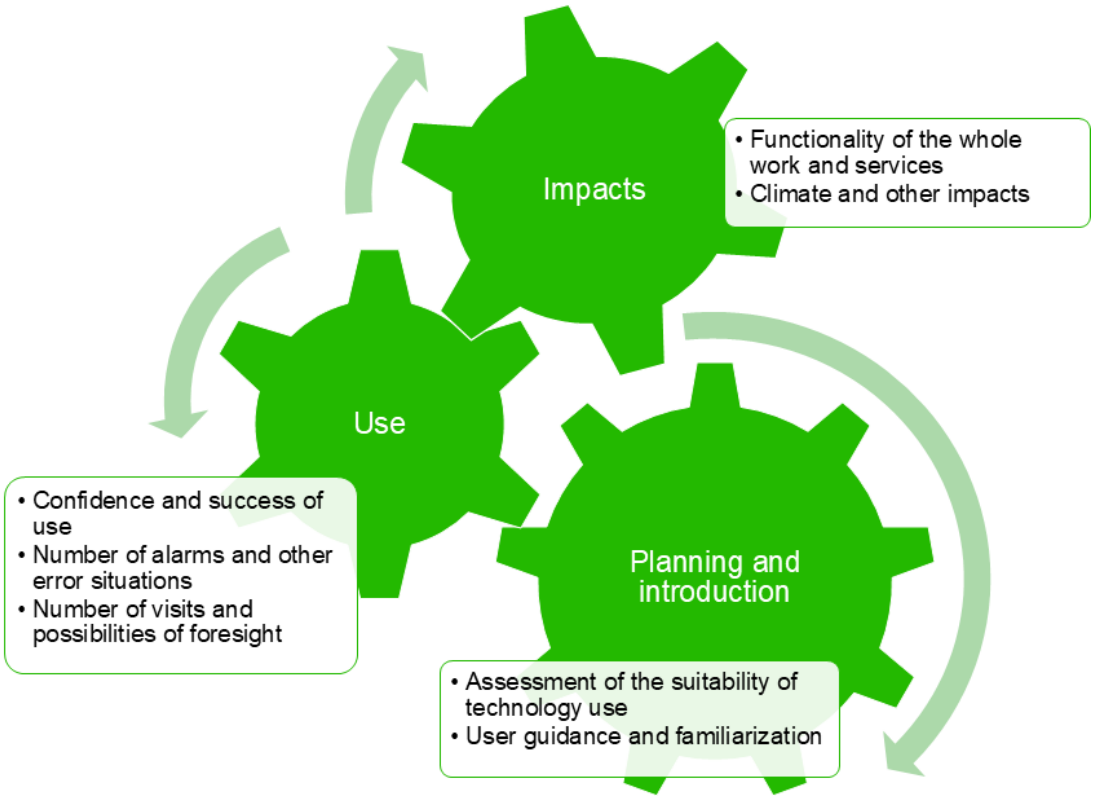
Principal Findings

The quantitative assessment showed that a well-planned and well-implemented digital service is likely to be a climate-friendly option. Digitalization is generally considered a positive measure for the environment; however, it does not automatically lead to positive climate impacts. Every digitalization action incurs some negative impacts due to the necessary equipment and energy consumption. The design, architecture, and practical implementation of digital services greatly affect their climate and other impacts, as shown by our study.

The qualitative assessment clearly showed the multidirectional, interconnected impacts of the studied digital services and the connections of the impacts to people's actions and ways of doing things. This emphasizes the need for contextual understanding enabled by qualitative assessment when making impact assessments. The results showed, among other things, that it is important to adequately assess the suitability of a digital service or its underlying technology for the client or patient before implementation and to carefully familiarize all parties involved to ensure safe and successful use. This, in turn, contributes to better planning and foresight, enhancing the functionality of the services and system as a whole, which increases the potential for positive climate impacts (Figure 7).

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Figure 7. An example of the intertwined and multidirectional impacts of medicine robot services.



Although this study had its limitations, as it concerned 2 Finnish case studies and a limited selection of digital services and technologies used in those, a variety of impacts were found in this study. Despite very different national service systems, services, digital technologies, etc, the findings can provide guidance and pave the way for increasingly multifaceted impact assessments and more sustainable, effective, meaningful, and balanced digital technology use in future health care and care services. Life cycle analyses and actionable strategies for a sustainable digitalization in health care systems have recently been called for by Berger et al [7] (also refer to [38] on the future potential).

In addition to Finland, health care and home care services are undergoing major changes in their operating environment in many other countries, such as increasing numbers of clients, changing organizational and service structures, challenges in finding enough staff, and financial challenges. Digitalization development is one such major change, representing a major socio-technical transition in which technological, social, and environmental aspects intertwine. Assessing the impacts of digitalization, especially before or after assessments, is therefore difficult. Even in Finland, where the health care and home care services have been digitalizing for decades, access to numerical data was also limited.

Practical Implications

The COVID-19 pandemic accelerated the introduction and use of various types of digital health care and home care services. However, climate impacts have not been the central drivers of the digitalization of these services in Finland. According to care professionals, these issues are not yet very actively discussed. One manager noted that environmental friendliness is considered "a positive byproduct." Wider adoption of emerging technologies (eg, robotics and artificial intelligence) will likely increase the challenges of environmental impact assessment (eg, [39]) globally. This development highlights the importance of increasingly proactive assessment activities in all countries in the future.

Based on the results, multiperspective and multimethod impact assessments should be promoted in studies of digital health care and home care services. To complement quantitative assessment methods—and aid in interpreting their results—qualitative insights into digitalization and its impacts are needed, especially when access to numerical data is limited. A systemic understanding of the service context, where "everything affects everything," is essential to understanding and advancing sustainability thinking in the complex context of health care and home care services. Sustainable digital health care and home care services need to address social, economic, and environmental aspects. Future research should explore various types of digital health care services for diverse clients and employees across different organizations, service systems, and societies.

Conclusion

To conclude, this study developed and used a novel combination of quantitative and qualitative methods to assess the climate impacts and related social impacts of the digitalization of health care and home care services. Digitalization is expected to play a central role in these services; however, the field is very complicated and challenging to digitalize in meaningful and effective ways. Thus, concrete practical tools are needed to assess the impacts of digitalization. The key results from 2 Finnish case studies of innovative digital health care and home

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care services offered a multidimensional picture of digitalization's impacts, including both climate impacts and intertwined social impacts, on different client or patient groups and professional groups in different types of services. Crucial lessons learned for the field of health care and home care services include that well-planned and well-implemented digital services are likely to be climate-friendly options. However, every digitalization action causes at least some negative climate impacts. The design, architecture, and practical implementation of digital services significantly affect their climate and social impacts.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CO_2e: carbon dioxide equivalent
HuIA: human impact assessment

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Validation of Gait Kinematics With Ramp and Stair Ascent and Descent Revealed by Markerless Motion Capture in Simulated Living Space: Test-Retest Reliability Study

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Abstract

Background: In recent years, there has been an increasing demand for markerless motion capture systems, which are being widely used in biomechanical and clinical research. Furthermore, by using a markerless motion capture system in a laboratory environment that mimics living spaces, the data acquired on various activities of daily living, such as level walking, ramp walking, and stair ascent and descent, should more closely resemble that of real-life activities. However, the absolute reliability of gait parameters in this context is still unclear.

Objective: The aim of this study was to evaluate the reliability of a markerless motion capture system in assessing the ascent and descent of ramps and stairs during walking in a simulated living space.

Methods: A total of 21 healthy participants performed level walking, ramp and stair ascent and descent on two separate days, with at least a 24-hour interval between sessions. Joint angles were measured using 27 synchronized cameras with a markerless motion capture application, Theia3D (Theia Markerless Inc), and analyzed in Visual3d for all planes of motion at the hip-, knee-, and ankle-joints. The absolute reliability of day-to-day reproducibility was assessed using full-curve analysis (root mean square difference [RMSD]) and discrete point analysis of gait events using the standard error of measurement (SEM). SEM was calculated only for level walking and ramp ascent and descent, where gait events were correctly detected.

Results: The SEM values for level walking and ramp ascent and descent were all below the 5-degree threshold. However, while RMSD values were generally below 5°, this threshold was exceeded for knee-joint flexion-extension angles during ramp ascent and stair ascent (5.07° and 5.64°, respectively).

Conclusions: The markerless motion capture system in the living laboratory setting demonstrated a high degree of accuracy for various environments and gait types. The low SEM values obtained indicate good reliability for joint angle measurements across different days. The slightly higher RMSD values for knee-joint angles during ramp and stair ascent may reflect the system's ability to capture the adaptations in joint kinematics in response to changes in gait conditions. These measurements in a living laboratory environment validated the absolute reliability of various gait parameters not only in level walking but also in ramp and stair ascent and descent. The findings suggest potential clinical applications and research opportunities, including the development of assistive devices and robots, using markerless motion capture in more natural living situations, rather than in controlled environments.

Trial Registration: UMIN Clinical Trials Registry UMIN000049284; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000056126

(JMIR Rehabil Assist Technol 2025;12:e66886) doi:10.2196/66886

KEYWORDS

markerless motion capture; living laboratory; level walking; ramp walking; stair climbing; kinematics; measurement error; absolute reliability; gait; walk; stair; ramp; rehabilitation; reliability; simulated living space; simulation; motion capture; gait kinematics

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Introduction

Gait serves as an indicator of an individual's health status and physical function [1]. In particular, gait speed has been widely used as a general assessment parameter due to its simple measurement [2], and issue with gait speed have been associated with cognitive decline [3], survival rates [4], and body-related quality of life [5]. However, gait is a complex biomechanical process that requires comprehensive assessment of cadence, rhythm, variability, and asymmetry [6]. Furthermore, incorporating biomechanical indices, particularly joint angles, enables identification of specific gait impairments that may not be detected by conventional parameters alone. A detailed analysis of this kind is essential for optimizing rehabilitation and robot-assisted interventions as it allows strategies to be developed that are tailored to individual movement patterns and pathological conditions.

To gain further insight into gait mechanics, data from 3D motion capture systems that provide joint angles have been used. This information allows the identification of specific joint angles that contribute to gait abnormalities, which can then be targeted for interventions by way of rehabilitation, assistive devices, and robotics. For example, Anang et al [7] used 3D motion analysis to identify a characteristic joint angle pattern in patients with chronic stroke, specifically a reduced knee-joint flexion during the swing phase of walking. They suggested that this finding could be a useful indicator for targeted interventions aimed at improving overall gait function in stroke survivors. Similarly, Schmitt et al [8] used 3D motion analysis to investigate the effects of knee osteoarthritis on lower extremity joint mechanics during walking. They found that patients with knee osteoarthritis exhibited reduced hip-joint extension and increased ankle dorsiflexion compared with healthy controls. These alterations in hip- and ankle-joint angles were attributed to compensatory mechanisms adopted by patients to reduce knee-joint loading and pain. These studies highlight the importance of considering the entire lower extremity when assessing the impact of disease on gait and when planning interventions. Furthermore, joint angle data can inform the design and development of assistive devices and robots. For instance, exoskeletons and powered orthoses can provide assistive torque at specific joint angles to support and enhance desired motions [9]. Similarly, robot-assisted treadmill training can guide patients through specific joint angle trajectories that promote optimal gait patterns [10].

Despite the benefits of kinematic data, traditional marker-based 3D motion capture systems present several challenges. These systems generally require subjects to wear specific attire and footwear, and the process of conducting full-body measurements can be time-consuming. In addition, markers must be attached to anatomical landmarks for accurate measurements [11]. In some cases, it is difficult to attach markers to landmarks while wearing orthotics or using robots, which may compromise the validity of the gait data collected. Under such constraints, subjects are often asked to walk as usual, but this may not accurately represent their natural gait patterns. Consequently, the validity of gait data collected using marker-based 3D motion capture systems has been questioned [11].

Recently, significant advancements in artificial intelligence have facilitated the development of markerless motion capture technology [12]. This technology offers a convenient method of measurement without the requirement to remove clothing or shoes, making it a promising option for integration in clinical [13] and sports settings [14]. However, although this simplifies the process of taking measurements, it should not be at the cost of accuracy, and the interpretation of data must be carefully judged. Among the many markerless motion capture systems, which include Microsoft Kinect [15], OpenPose (developed by Carnegie Mellon University) [16], and DeepLabCut (developed by Harvard University) [17], Theia3D (developed by Theia Markerless Inc) has achieved practical application in a wide range of clinical and sports research, as well as in the production of animations. This is because of its demonstrated accuracy and reproducibility in measuring level walking, as validated by several studies comparing its performance against traditional marker-based motion capture systems [18,19]. Therefore, it is expected that Theia3D can also be applied to various activities of daily living (ADLs) besides level walking, which has been the main target of measurements to date. However, how accurate measurements of such ADLs might be remains unclear.

Kato et al [20] have developed a "living laboratory" to facilitate ADLs assessment with Theia3D and to study the impact of assistive robots on ADLs in a simulated living environment. This living laboratory includes an indoor environment as well as a simulated outdoor environment to mimic natural living conditions. However, the reliability of markerless motion capture in the living laboratory setting has not been investigated in detail. Among the various ADLs studied previously, ramp and stair ascent and descent pose a higher risk of falls than level-ground walking [21,22], and ramp walking poses an even higher risk of falls compared with stair climbing [23]. These tasks require complex postural control and adaptations to environmental conditions, such as inclination and step height, making them particularly challenging for fall prevention [24]. Stair climbing was one of the more demanding tasks, as it required near-maximal muscle strength and a greater range of joint motion [25,26]; accordingly, it is included in the Barthel Index for the assessment of ADLs in older adults [27]. Therefore, it is clinically important to investigate the application and reliability of Theia3D for these activities. While previous studies have validated Theia3D for level walking, its reliability in assessing more complex movements in a simulated living environment remains unclear due to the increased variability and dynamic adaptations required for tasks such as stair and ramp walking. For gait analysis, reliability must be evaluated based both on overall movement patterns throughout the gait cycle and specific gait events, as these reflect both kinematic consistency and the precision of localized measurements [28]. Establishing its reliability for such movements is essential not only for research applications but also for clinical assessments and assistive technology development. Therefore, the purpose of this study was to evaluate the reliability of Theia3D in assessing the ascent and descent of ramps and stairs using the method of Riazati et al [29] to calculate between-day repeatability and representative values during walking.

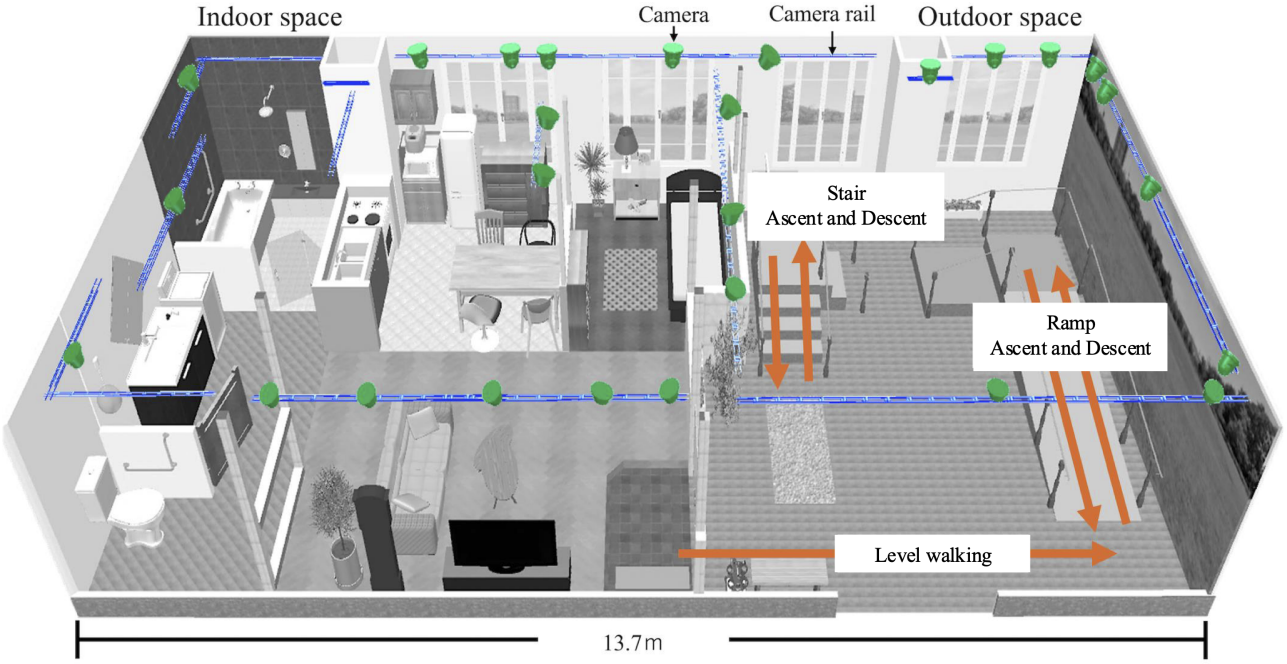
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Methods

Design of the Living Laboratory

The living laboratory (Figure 1) was designed to simulate outdoor, home indoor, and nursing home environments [20]. It includes an indoor living space with a bedroom, living room, dining room, kitchen, washroom, bathroom, toilet, and entrance, as well as outdoor spaces including rough terrain, stairs, and ramps equipped with removable handrails. The stairs and ramp configurations were designed in accordance with the Building Standards Act of Japan and its Enforcement Ordinance [30]. The gradient of the 3.25-m-long ramp outdoors was 1/8 (7 degrees). The stairs consisted of two configurations: one with a height of 15 cm and the other with a height of 20 cm. The 15-cm-height stair configuration had 4 steps, with a tread depth of 25 cm and a width of 90 cm. The 20-cm-height stair configuration had 3 steps, with a tread depth of 30 cm and a width of 90 cm. The height of the walls separating the indoor and outdoor spaces was 1.1 m high to avoid blind spots for camera measurements for the markerless motion capture system. A total of 27 cameras (DSC-RX0M2, Sony Group Corporation) were deployed in the living laboratory (Figure 1).

Figure 1. The living laboratory layout showing the positions of 27 cameras for markerless motion capture.



Participants

According to previous reliability studies [28], a minimum of 20 participants was required to ensure statistical robustness. A total of 21 healthy subjects participated in this study. Participants were recruited from staff at the National Center for Geriatrics and Gerontology. The average age of participants was 31.1 (SD 8.7) years, height was 1.67 (SD 0.09) m, and weight was 63.3 (SD 12.1) kg, with 14 males and 7 females. Those with neuromuscular or musculoskeletal disorders that could interfere with walking performance were excluded. Participants were not instructed in advance how they should dress or wear shoes in the study upon arrival. Participants provided written informed consent.

Data Capture

Measurements were taken using 27 synchronized cameras in the living laboratory. The sampling rate of the cameras was 60 Hz. All participants performed each set of tasks on 2 days separated by an interval of at least 24 h (124.6, SD 137.5 h; maximum interval: 671.3 h, minimum interval: 24 h). Each set of tasks was performed 5 times. One set of tasks comprised (1) a 7 m level walk, (2) a ramp ascent, (3) a ramp descent, (4) a 4-step stair ascent with a height of 15 cm, and (5) a 4-step stair descent with a height of 15 cm. For all tasks, participants were instructed to start on their right foot and walk normally at their usual pace. During the measurements, participants were instructed not to use the handrails on the stairs and ramps, although the handrails were kept in place. This allowed for the assessment of their natural gait patterns when negotiating stairs and ramps, without the aid of handrails.

Data Analysis

Video data were processed using Theia3D (version 2021.2.0.1675) to obtain 3D pose estimates of whole-body segments using default inverse kinematics and a two-degrees-of-freedom knee model (Multimedia Appendix 1). The resulting pose estimates for each body segment were exported to Visual3d (HAS-Motion) for further analysis. The gait events, initial contact (IC), and toe-off for all tasks were determined using methods described by Zeni et al [31], with quality checks performed in Visual3d. The hip-, knee-, and ankle-joint angles were calculated in the sagittal, frontal, and transverse planes and defined as the angles between the proximal and distal segments in the respective joint coordinate systems. The joint angles were time-normalized to the gait cycle, with 0% representing the IC and 100% representing the next ipsilateral IC. Representative values of interest were calculated from the gait cycle events (Table 1). However, the movements of (4) stair ascent and (5) stair descent were excluded from the

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analysis for the calculation of representative values because toe-off could not be determined accurately. All data were analyzed by combining the right and left sides.

Table . Gait event descriptions and abbreviations (adapted from Riazati et al [29]).

Gait event	Description
ST1	Stance phase 1, ipsilateral initial contact to mid-stance, representing the first half of the stance phase.
ST2	Stance phase 2, mid-stance to ipsilateral toe-off, representing the second half of the stance phase.
STSW	Transition from stance-to-swing phase.
RoM	The entire range of motion over the full gait cycle, presented for hip-, knee-, and ankle-joints in sagittal, frontal, and transverse planes.
MaxFlexStance	Maximum flexion angle (sagittal plane) achieved by the hip- or knee-joint during the stance phase.
MaxFlexSwing	Maximum flexion angle (sagittal plane) achieved by the hip- or knee-joint during the swing phase.
MaxFlexST1	Maximum flexion angle (sagittal plane) achieved by the knee-joint during stance phase 1.
MaxExtStance	Maximum extension angle (sagittal plane) achieved by the hip- or knee-joint during the stance phase.
MaxExtSwing	Maximum extension angle (sagittal plane) achieved by the hip- or knee-joint during swing phase.
MaxDorsiflexionST2	Maximum dorsiflexion angle (sagittal plane) achieved by the ankle-joint during the stance phase 2.
MaxPlantarflexion STSW	Maximum plantarflexion angle (sagittal plane) of the ankle-joint at stance-to-swing transition.
MaxAddDLS1	Maximum adduction angle (frontal plane) achieved by the hip-joint during double limb support phase 1.
MaxAbdSwing	Maximum abduction angle (frontal plane) achieved by the hip-joint during the swing phase.
MaxVarusSwing	Maximum varus angle (frontal plane) achieved by the knee-joint in the swing phase.
MaxInvSwing	Maximum inversion angle (frontal plane) achieved by the ankle-joint during the swing phase.
MaxEvST1	Maximum eversion angle (frontal plane) achieved by the ankle-joint during the stance phase 1.
MaxIntRotST1	Maximum internal rotation (transverse plane) achieved by the hip- or ankle-joint during the stance phase 1.
MaxExtRotST2	Maximum external rotation (transverse plane) achieved by the hip- or ankle-joint during the stance phase 2.
MaxExtRotSwing	Maximum external rotation (transverse plane) achieved by the hip- or ankle-joint during the swing phase.
AnkleInitialContact	Ankle-joint angle (sagittal or frontal plane) at initial contact.

Statistical Analysis

Statistical analysis was performed using the same approach as Riazati et al [29]. First, error evaluation was performed using the approach described in Kanko et al [18], where root-mean-square differences (RMSDs) were calculated to assess intersession differences of all curves for the 3 joints and plane of motion. RMSD analysis quantifies the magnitude of differences between sessions, with lower values indicating greater reproducibility between measurements. For each session, the average RMSD was calculated using the ensemble averages of the participants' within-session data. Second, a reliability evaluation was performed using the standard error of measurement (SEM) of representative values within gait cycles [32]. SEM provides the magnitude of measurement error in degrees between different days, allowing comparison with clinical acceptability criteria [28]. SEM was calculated using the following equation.

$$(1)ICC(3,10)=MSB-MSWMSB+(k-1)MSWk$$

$$(2)SEM=SD\times1-ICC$$

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Here MSB indicates the between-subjects mean square, MSW indicates the within-subjects mean square, and k is the number of trials. SD indicates standard deviation of the data of all subjects. The SEM provides an error value in the same units as the measurement. Measurement errors between 2° and 5° are considered acceptable [28]. All statistical analysis was performed in MATLAB (version 2017a; MathWorks) and Python (version 3.8; Python Software Foundation).

Ethical Considerations

The study was approved by the Committee on Ethics and Conflict of Interest of the National Center for Geriatrics and Gerontology (acceptance 1636).

Results

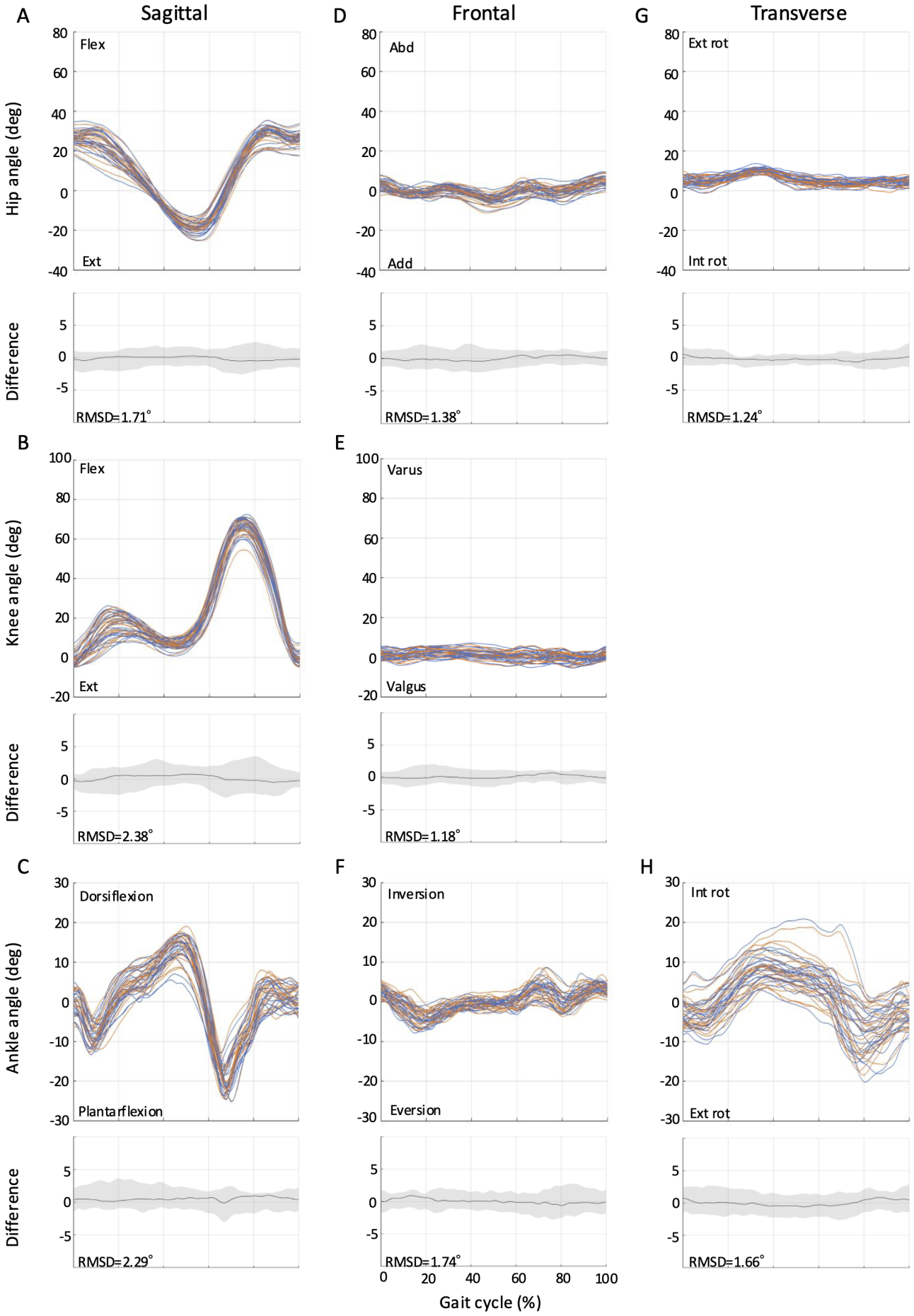
RMSD, SEM, and RoM Values

The RMSDs from full-curve analysis of the kinematics for all tasks (ie, level walking, ramp ascent, ramp descent, stair ascent, and stair descent) are shown in Figures 2-6. The SEMs of representative values within gait cycles are presented in Tables 2-4. Measurement errors as given by SEM and RMSD were <5° for the majority of variables, and were thus deemed acceptable [28]. Representative range of motion (RoM) for the hip-, knee-, and ankle-joint was also calculated and comparable values were extracted for most tasks over the study period. A summary of the RMSD, SEM, and RoM values for each task is given below.

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Figure 2. Between-session reproducibility of full-curve analysis of subject-average joint angles during level walking. Data description joint angles for hip (row 1), knee (row 2), and ankle (row 3) in the sagittal (A-C), frontal (D-F), and transverse planes (G-H). Each curve represents the ensemble average of each individual's trials on Day 1 (blue lines) and Day 2 (orange lines). The average RMSD across all subjects is shown below the respective joint angle plot; across all joints and planes of motion, the largest root mean square difference (RMSD) was 2.38°. deg: degree; Ext: extension; Abd: abduction; Add: adduction; Ext rot: external rotation; Int rot: internal rotation; RMSD: root mean square difference.

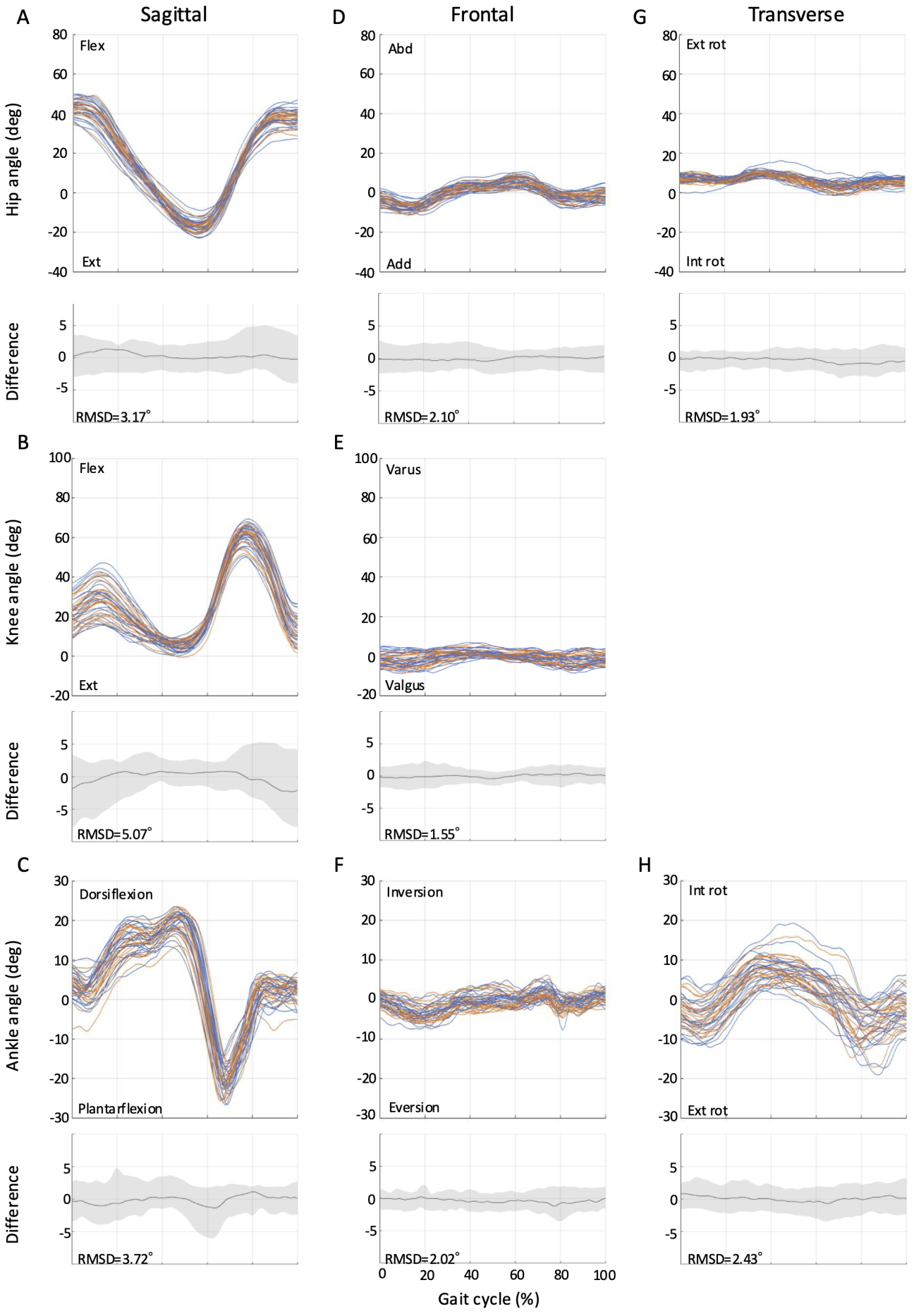
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Figure 3. Between-session reproducibility of full-curve analysis of subject-average joint angles during ramp ascent. Data description joint angles for hip (row 1), knee (row 2), and ankle (row 3) in the sagittal (A-C), frontal (D-F), and transverse planes (G-H). Each curve represents the ensemble average of each individual's trials on Day 1 (blue lines) and Day 2 (orange lines). The average RMSD across all subjects is shown below the respective joint angle plot; across all joints and planes of motion, the largest RMSD was 5.07°. deg: degree; Ext: extension; Abd: abduction; Add: adduction; Ext rot: external rotation; Int rot: internal rotation; RMSD: root mean square difference.

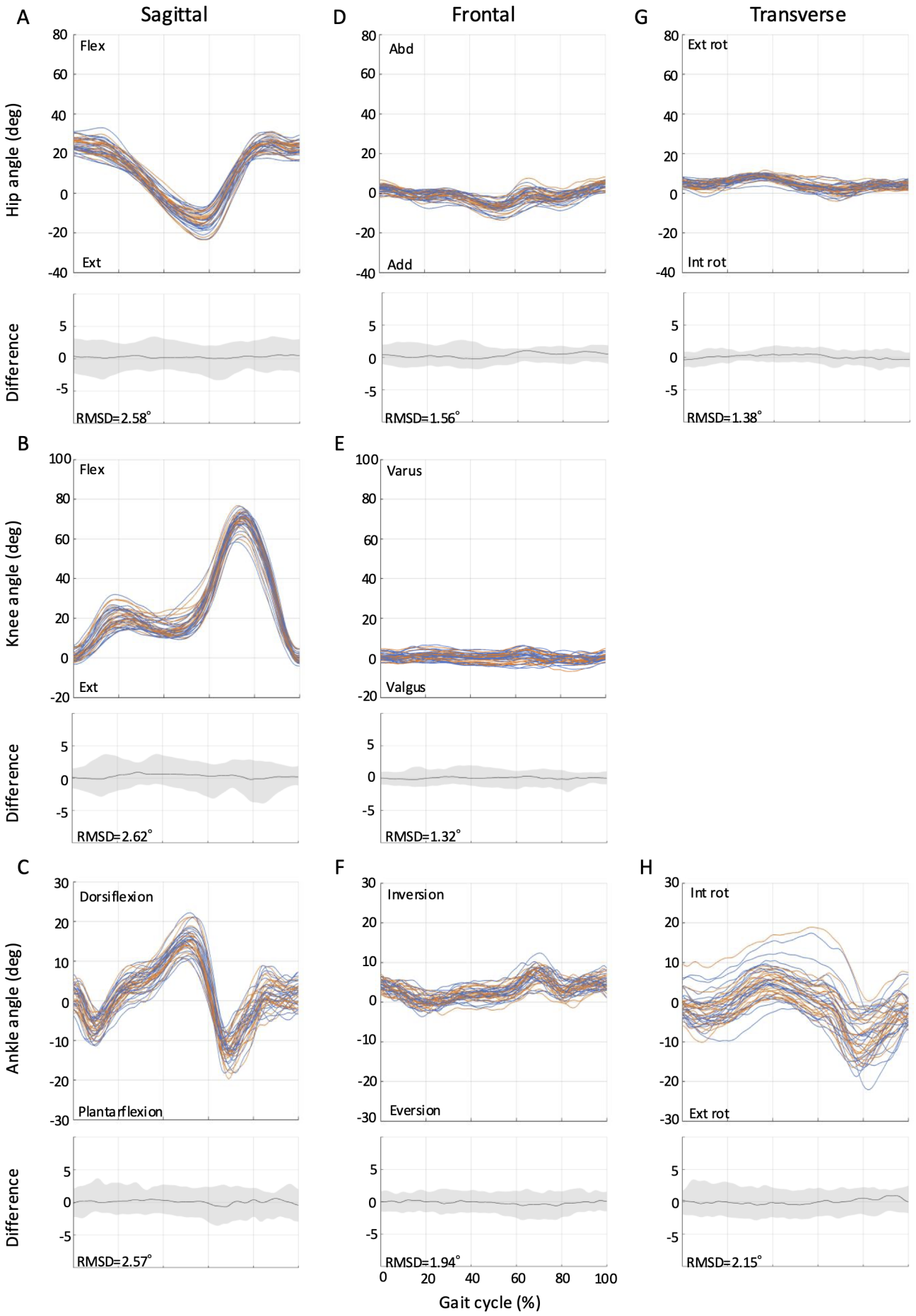
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Figure 4. Between-session reproducibility of full-curve analysis of subject-average joint angles during ramp descent. Data description joint angles for hip (row 1), knee (row 2), and ankle (row 3) in the sagittal (A-C), frontal (D-F), and transverse planes (G-H). Each curve represents the ensemble average of each individual's trials on Day 1 (blue lines) and Day 2 (orange lines). The average RMSD across all subjects is shown below the respective joint angle plot; across all joints and planes of motion, the largest RMSD was 2.62°. deg: degree; Ext: extension; Abd: abduction; Add: adduction; Ext rot: external rotation; Int rot: internal rotation; RMSD: root mean square difference.

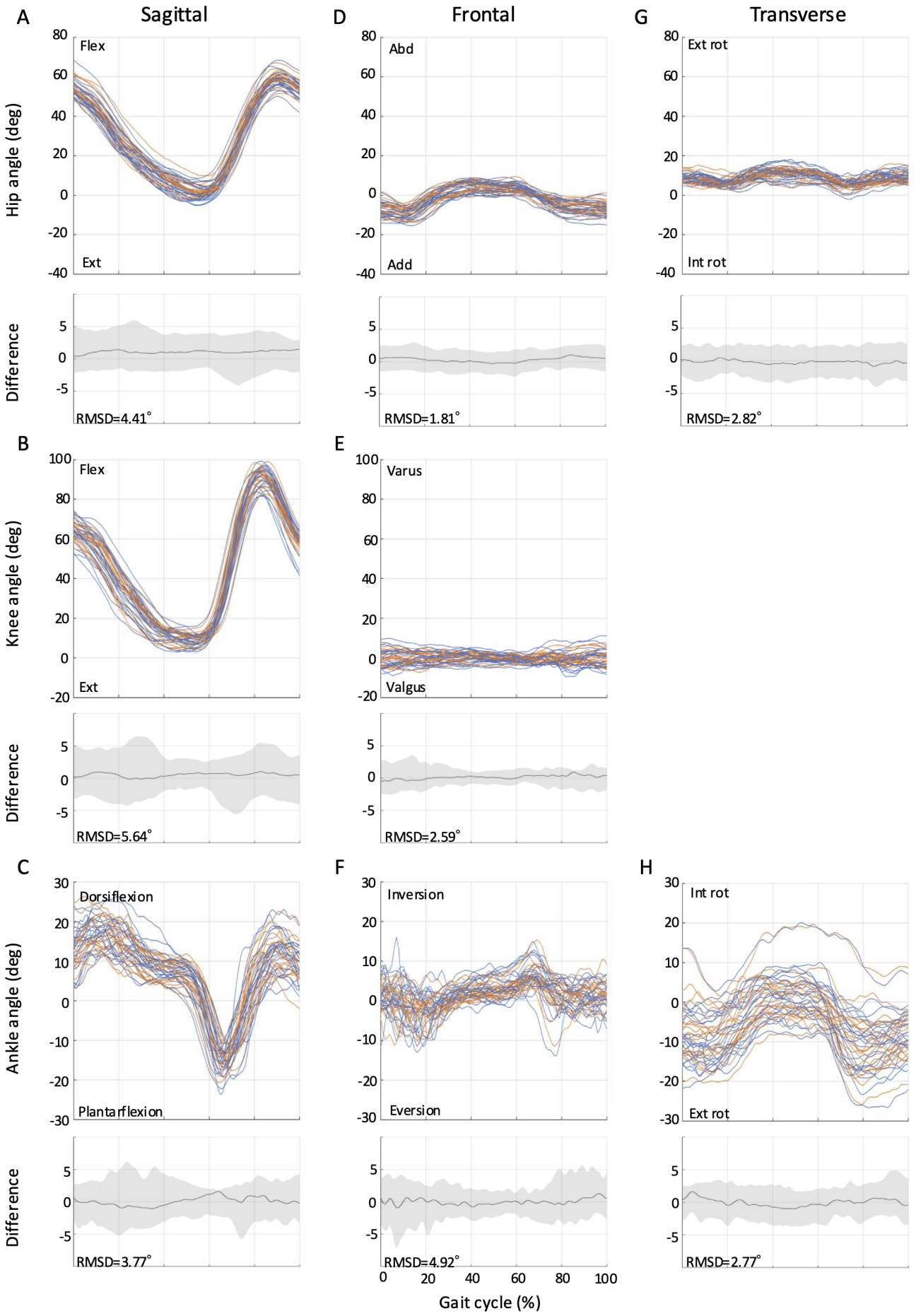
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Figure 5. Between-session reproducibility of full-curve analysis of subject-average joint angles during stair ascent. Data description joint angles for hip (row 1), knee (row 2), and ankle (row 3) in the sagittal (A-C), frontal (D-F), and transverse planes (G-H). Each curve represents the ensemble average of each individual's trials on Day 1 (blue lines) and Day 2 (orange lines). The average RMSD across all subjects is shown below the respective joint angle plot; across all joints and planes of motion, the largest RMSD was 5.64°. deg: degree; Ext: extension; Abd: abduction; Add: adduction; Ext rot: external rotation; Int rot: internal rotation; RMSD: root mean square difference.

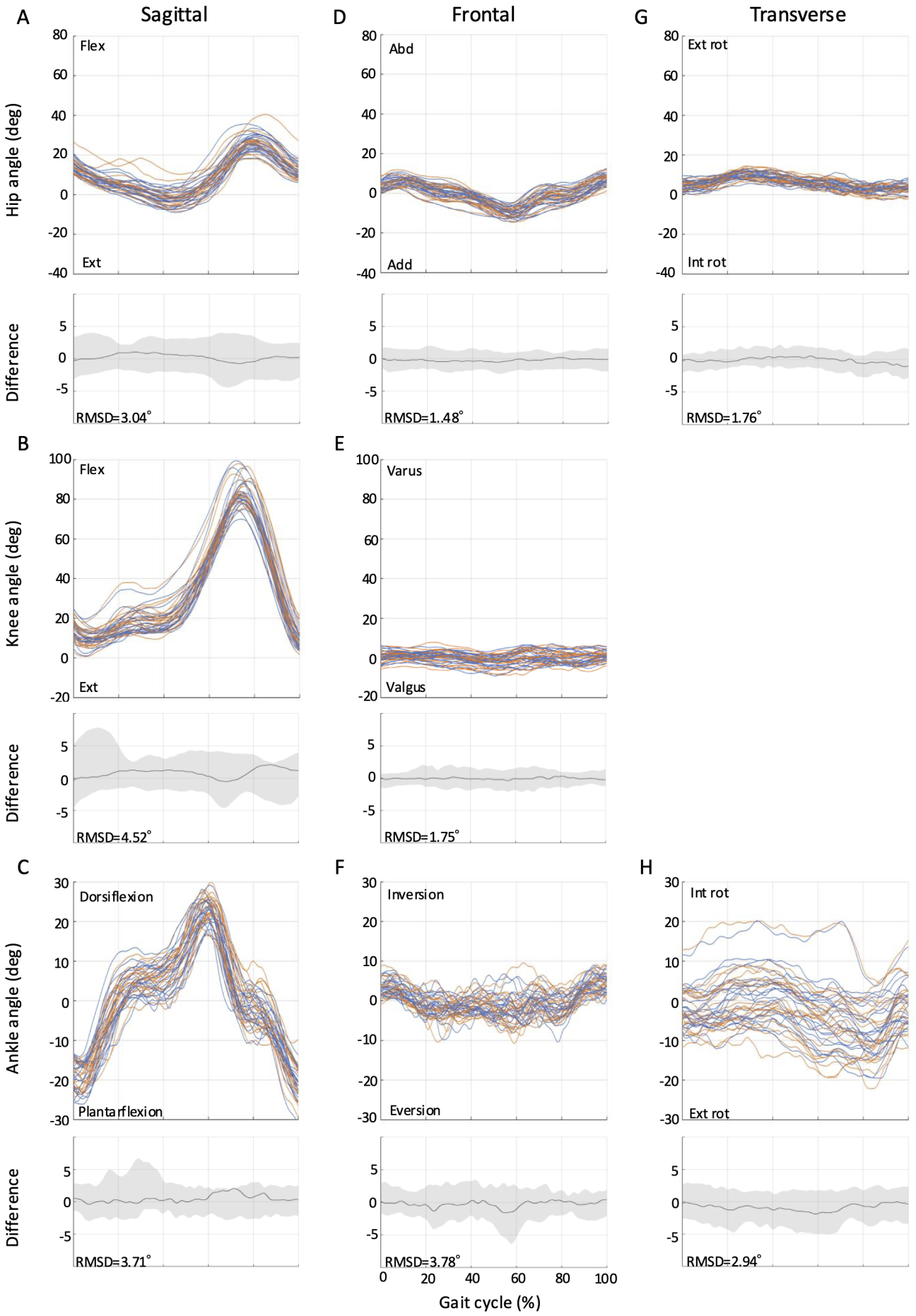
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Figure 6. Between-session reproducibility of full-curve analysis of subject-average joint angles during stair descent. Data description joint angles for hip (row 1), knee (row 2), and ankle (row 3) in the sagittal (A-C), frontal (D-F), and transverse planes (G-H). Each curve represents the ensemble average of each individual's trials on Day 1 (blue lines) and Day 2 (orange lines). The average RMSD across all subjects is shown below the respective joint angle plot; across all joints and planes of motion, the largest RMSD was 4.52°. deg: degree; Ext: extension; Abd: abduction; Add: adduction; Ext rot: external rotation; Int rot: internal rotation; RMSD: root mean square difference.

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Table . Level walking, mean (SD) for Day 1 and Day 2, and standard error of measurement (SEM).

Planes and joints parameters	Day 1, mean (SD)	Day 2, mean (SD)	SEM[a]
Sagittal			
Hip (degrees)			
RoM[b]	48.9 (5.7)	49.6 (5.8)	1.56
MaXFlexstance	27.0 (4.2)	27.3 (4.5)	1.30
MaxFlexswing	29.4 (4.0)	29.9 (4.1)	3.23
MaxExtstance	18.8 (3.5)	19.1 (3.9)	1.19
Knee (degrees)			
RoM	68.8 (4.6)	68.9 (4.8)	1.25
MaxFlexst1	18.5 (5.3)	17.7 (6.0)	1.70
MaxFlexswing	66.7 (4.7)	66.7 (5.2)	1.12
MaxExtstance	1.4 (3.3)	1.4 (3.2)	0.82
Ankle (degrees)			
RoM	36.6 (4.3)	36.3 (4.8)	1.60
InitialContact	0.3 (4.3)	–0.3 (4.3)	1.35
MaxDorsiflexionst2	14.9 (3.5)	14.3 (4.2)	1.13
MaxPlanterflexionststsw	21.5 (4.0)	21.9 (4.7)	1.42
Frontal			
Hip (degrees)			
RoM	12.4 (3.5)	12.3 (3.2)	1.08
MaxAddDLS1	1.8 (3.4)	2.1 (3.9)	0.89
MaxAbdswing	4.9 (3.9)	4.1.(4.3)	0.86
Knee (degrees)			
RoM	8.1 (2.2)	8.6 (2.4)	1.00
MaxVarusswing	3.9 (2.8)	3.6 (3.0)	0.71
Ankle (degrees)			
RoM	13.5 (4.0)	14.4 (3.6)	1.89
InitialContact	3.1 (4.6)	3.0 (4.7)	1.47
MaxInvswing	7.7 (5.7)	8.0 (5.3)	1.39
MaxEvst1	5.6 (4.7)	6.3 (4.8)	1.25
Transverse			
Hip (degrees)			
RoM	11.4 (2.7)	12.3 (3.0)	1.01
MaxIntRotst1	2.6 (2.9)	1.7 (3.5)	1.03
MaxRotst2	11.1 (2.6)	10.6 (3.1)	1.00
Ankle (degrees)			
RoM	21.1 (4.3)	21.8 (4.7)	1.47
MaxIntRotst1	8.4 (4.7)	8.9 (4.9)	1.27
MaxExtRotswing	4.1 (6.3)	4.6 (4.2)	1.51

[a]SEM: standard error of measurement.

[b]RoM: range of motion.

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Table . Ramp ascent, mean (SD) for Day 1 and Day 2, and standard error of measurement (SEM).

Planes and joints parameters	Day 1, mean (SD)	Day 2, mean (SD)	SEM[a]
Sagittal			
Hip (degrees)			
RoM[b]	62.7 (7.7)	61.3 (9.0)	4.20
MaXFlexstance	44.7 (5.4)	43.4 (6.7)	3.01
MaxFlexswing	39.5 (7.1)	40.6 (7.3)	2.73
MaxExtstance	17.8 (3.8)	17.5 (4.6)	2.23
Knee (degrees)			
RoM	59.4 (5.3)	58.8 (6.7)	2.61
MaxFlexst1	30.8 (9.8)	29.8 (10.6)	4.37
MaxFlexswing	63.7 (5.7)	63.5 (6.8)	2.85
MaxExtstance	4.2 (3.1)	3.7 (3.0)	1.40
Ankle (degrees)			
RoM	44.7 (5.2)	43.7 (6.0)	2.63
InitialContact	2.5 (5.0)	2.9 (4.5)	2.31
MaxDorsiflexionst2	21.0 (3.6)	20.5 (3.7)	1.98
MaxPlanterflexionststsw	23.4 (4.5)	22.9 (5.2)	2.18
Frontal			
Hip (degrees)			
RoM	16.1 (4.0)	15.8 (4.0)	2.07
MaxAddDLS1	8.3 (4.7)	7.1 (5.2)	1.48
MaxAbdswing	5.2 (4.8)	4.5 (4.4)	1.28
Knee (degrees)			
RoM	9.3 (3.2)	9.7 (3.6)	1.47
MaxVarusswing	2.7 (3.6)	2.4 (3.8)	1.50
Ankle (degrees)			
RoM	12.2 (4.8)	12.4 (4.4)	2.23
InitialContact	0.8 (5.4)	0.7 (5.2)	1.45
MaxInvswing	6.1 (6.6)	6.4 (5.9)	1.94
MaxEvst1	5.6 (5.9)	5.8 (5.9)	1.83
Transverse			
Hip (degrees)			
RoM	11.8 (2.9)	15.8 (2.7)	1.57
MaxIntRotst1	3.9 (2.7)	4.2 (2.8)	1.56
MaxRotst2	10.9 (2.6)	11.0 (3.3)	1.56
Ankle (degrees)			
RoM	19.6 (4.1)	20.0 (4.5)	2.10
MaxIntRotst1	7.7 (5.6)	7.3 (5.9)	2.50
MaxExtRotswing	2.4 (6.0)	2.5 (6.5)	2.57

[a]SEM: standard error of measurement.

[b]RoM: range of motion.

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Table . Ramp descent, mean (SD) for Day 1 and Day 2, and standard error of measurement (SEM).

Planes and joints parameters	Day 1, mean (SD)	Day 2, mean (SD)	SEM[a]
Sagittal			
Hip (degrees)			
RoM[b]	42.2 (6.5)	42.0 (7.0)	2.29
MaXFlexstance	25.5 (5.1)	24.9 (4.8)	1.86
MaxFlexswing	26.6 (4.1)	26.0 (4.0)	1.74
MaxExtstance	14.6 (5.2)	15.1 (5.6)	1.85
Knee (degrees)			
RoM	72.0 (4.9)	72.0 (5.4)	2.15
MaxFlexst1	22.6 (6.6)	21.5 (6.4)	2.12
MaxFlexswing	70.2 (5.2)	70.3 (6.3)	1.57
MaxExtstance	0.4 (3.6)	0.2 (3.4)	1.12
Ankle (degrees)			
RoM	33.4 (5.9)	32.7 (5.5)	2.42
InitialContact	1.3 (3.9)	1.7 (4.3)	1.53
MaxDorsiflexionst2	17.0 (3.9)	16.9 (4.1)	1.67
MaxPlanterflexionststsw	16.4 (5.0)	15.6 (4.3)	2.16
Frontal			
Hip (degrees)			
RoM	14.1 (4.0)	13.6 (3.5)	1.62
MaxAddDLS1	–1.0 (5.2)	0.4 (5.5)	1.09
MaxAbdswing	5.9 (4.6)	5.4 (4.5)	0.97
Knee (degrees)			
RoM	8.1 (2.4)	7.8 (2.1)	1.49
MaxVarusswing	3.2 (2.9)	2.9 (2.9)	1.03
Ankle (degrees)			
RoM	12.9 (4.0)	12.5 (3.7)	1.55
InitialContact	4.4 (4.9)	4.3 (4.8)	1.47
MaxInvswing	7.9 (7.0)	8.2 (6.8)	1.25
MaxEvst1	2.3 (5.1)	2.0 (5.2)	1.50
Transverse			
Hip (degrees)			
RoM	10.8 (2.7)	13.6 (2.7)	1.17
MaxIntRotst1	2.5 (3.1)	2.7 (3.1)	1.62
MaxRotst2	9.7 (3.0)	9.4 (3.0)	1.42
Ankle (degrees)			
RoM	19.1 (4.3)	19.7 (4.9)	1.83
MaxIntRotst1	5.1 (6.1)	5.3 (5.6)	1.67
MaxExtRotswing	3.7 (6.7)	3.1 (6.0)	1.51

[a]SEM: standard error of measurement.

[b]RoM: range of motion.

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Level Walking

The RMSD values ranged from 1.2° to 2.4° for level walking (Figure 2). For the same task, the SEMs ranged from 0.82° to 3.23° in the sagittal plane, 0.71° to 1.89° in the frontal plane, and 1.01° to 1.51° in the transverse plane (Table 2). Sagittal plane RoM values of 48.9° (SD 5.7°; Day 1) and 49.6° (SD 5.8°; Day 2) for the hip-joint, 68.8° (4.6°; Day 1) and 68.9° (SD 4.8°; Day 2) for the knee-joint, and 36.6° (SD 4.3°; Day 1) and 36.3° (SD 4.8°; Day 2) for the ankle-joint were obtained.

Ramp Ascent

The RMSD ranged from 1.6° to 5.1° for ramp ascent (Figure 3). The highest RMSD was observed for knee-joint flexion-extension angle as 5.1°. Otherwise, the RMSD values were less than 5°. The SEM ranged from 1.40° to 4.37° in the sagittal plane, 1.45° to 2.07° in the frontal plane, and 1.57° to 2.57° in the transverse plane for ramp ascent (Table 3). During ramp ascent, joint angle changes were larger compared to level walking. The sagittal plane RoM of the hip-joint was 62.7° (SD 7.7°; Day 1) and 61.3° (SD 9.0°; Day 2), which was 13.8° (Day 1) and 11.7° (Day 2) greater than level walking. The knee-joint flexion angle during early stance was 30.8° (SD 9.8°; Day 1) and 29.8° (SD 10.6°; Day 2), an increase of 12.3° (Day 1) and 12.1° (Day 2). In addition, the ankle-joint dorsiflexion angle during stance was 21.0° (SD 3.6°; Day 1) and 20.5° (SD 3.7°; Day 2), an increase of 6.1° (Day 1) and 6.2° (Day 2).

Ramp Descent

The RMSDs ranged from 1.3° to 2.6° for ramp descent (Figure 4), while the SEM values ranged from 1.12° to 2.42° in the sagittal plane, 0.97° to 1.62° in the frontal plane, and 1.17° to 1.83° in the transverse plane (Table 4). During ramp descent, joint angle changes were also compared with level walking. The hip-joint RoM was 42.2° (SD 6.5°; Day 1) and 42.0° (SD 7.0°; Day 2), a decrease of 6.7° (Day 1) and 7.6° (Day 2) from level walking. However, the knee-joint RoM increased by 3.2° (Day 1) and 3.1° (Day 2) to 72.0° (SD 4.9°; Day 1) and 72.0° (SD 5.4°; Day 2). The maximum ankle-joint plantar flexion angle decreased by 5.1° (Day 1) and 6.3° (Day 2) to 16.4° (SD 5.0°; Day 1) and 15.6° (SD 4.3°; Day 2).

Stair Ascent

RMSDs ranged from 1.8° to 5.7° for stair ascent (Figure 5). The RMSD of the knee-joint flexion-extension angle showed the highest value at 5.7°, but otherwise the RMSD values were less than 5°. The hip-joint RoM was 59.5° (SD 5.1°; Day 1) and 60.2 (SD 6.1°; Day 2), an increase of 10.6° (Day 1) and 10.6° (Day 2) compared to level walking. The knee-joint RoM was 86.4° (SD 6.2°; Day 1) and 86.1° (SD 7.4°; Day 2), an increase of 17.6° (Day 1) and 17.2° (Day 2) over level walking. The ankle-joint RoM was 40.0° (SD 8.3°; Day 1) and 41.6° (SD 7.8°; Day 2), which was 3.4° (Day 1) and 5.3° (Day 2) greater than level walking.

Stair Descent

The RMSD values ranged from 1.5° to 4.5° for stair descent (Figure 6). The hip-joint RoM was 30.1° (SD 3.6°; Day 1) and 31.0° (SD 4.4°; Day 2), a decrease of 18.8° (Day 1) and 18.6° (Day 2) compared to level walking. The knee-joint RoM was 81.9° (SD 7.3°; Day 1) and 81.5° (SD 7.8°; Day 2), which was 13.1° (Day 1) and 12.6° (Day 2) greater than for level walking. The ankle-joint RoM was 50.9° (SD 6.6°; Day 1) and 51.1° (SD 6.0°; Day 2), an increase of 14.3° (Day 1) and 14.8° (Day 2) over level walking

Discussion

Principal Results and Comprehensive Analysis

This study showed that the Theia3D markerless motion capture provides reliable joint angle measurements across a wide range of locomotion tasks, including level walking, ramp ascent, ramp descent, stair ascent, and stair descent in the living laboratory environment. This is evidenced by the low SEM and RMSD values extracted by full-curve analysis of the kinematics and their intersession differences. The SEM values for hip-, knee-, and ankle-joint angles were less than 5°, and the RMSD values were also generally below 5°. According to McGinley et al [28], measurement errors less than 5° are considered acceptable for clinical interpretation, indicating good agreement between the joint angle waveforms across days in our study. Previous research has examined the dependability of the Theia3D system in relation to level walking; however, to the best of our knowledge, this is the first study to assess its absolute reliability for stair and ramp walking tasks, and therefore, there is nothing in the literature with which we can compare these results. Our findings for level walking, however, are consistent with those of previous studies that investigated the reliability of the Theia3D system. For example, our SEM values for level walking (0.82° to 3.23°) are comparable to those reported by Riazati et al [29] (0.91° to 4.95°). Similarly, our RMSD values for level walking (1.2° to 2.4°) are also consistent with those of the same authors [29] (0.96° to 3.56°). Therefore, the markerless motion capture system in our living laboratory setting provides the same level of reliability as previous studies, suggesting that it can be applied not only to level walking but also to various other walking situations.

Notably, this study could extend the application of the markerless motion capture by demonstrating its absolute reliability across a broader range of locomotion tasks commonly encountered in daily life, including ramps and stairs. The SEM (1.40° to 4.37° for ascent; 0.97° to 2.42° for descent) and RMSD values (1.6° to 5.1° for ascent; 1.3° to 2.6° for descent) for these tasks suggest that the Theia3D system can reliably measure joint angles during ramp ascent and descent. Furthermore, this study was the first to report RMSD values for stair gait using the markerless motion capture system. The RMSD values for stair ascent (1.8° to 5.7°) and descent (1.4° to 4.5°) were slightly higher than those for level walking and ramp gait, which may be attributed to the greater complexity and variability of stair gait tasks [21]. Nonetheless, the majority of RMSD values for stair gait remained within acceptable limits, demonstrating the potential of the Theia3D system for analyzing these complex gait patterns in the living laboratory setting. Furthermore, the joint angles observed during stair ascent and descent showed patterns similar to those reported in previous marker-based motion capture studies [33,34], further supporting the validity

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of our markerless measurements in capturing movement adaptations during complex tasks.

Comparison With Previous Work

As reported in previous studies [35], the versatility of the Theia3D system in performing reliable measurements across a range of environments is particularly important considering the challenges traditionally faced by motion capture systems. One of these challenges is the difficulty encountered when accuracy is reduced due to imperfections in the experimental set-up, such as camera placement and the presence of obstacles within the measurement area [18,19,36]. The living laboratory has handrails on both sides of the stairs and ramps, as well as a 110-cm wall and pillars separating the indoor and outdoor spaces, which are considered poor measurement environments. Despite these challenges, the SEM and RMSD values in this study were low. This suggests that the Theia3D system can maintain high reproducibility and reliably measure joint angles, probably by complementing any blind spots of the 27 cameras, even in the presence of environmental barriers. Furthermore, Figure 1 shows that the suspension of cameras from the ceiling allowed measurements to be made without interfering with the range of human movement. The possibility of more efficient placement of environmental barriers and cameras need to be further explored, but our markerless motion capture system in the living laboratory opens up new possibilities for gait analysis in real-world settings and will provide valuable data to researchers and clinicians.

Implications and Applications of the Result

The uniqueness and novelty of this study lies in the fact that various gait data, such as ramp and stair ascent and descent, could be reliably obtained under conditions similar to those in everyday life. A system capable of precisely measuring the differences between such walking activities is crucial for understanding how an individual's gait pattern adapts to the diverse terrains encountered in daily life. For example, while joint angle variations are relatively small during level walking [37], joint angles may change significantly during ramp and stair walking in response to the demands of the task. Previous studies have revealed various adaptation and walking strategies that individuals use to cope with uneven terrain and stairs [38,39]. Further accumulation of longitudinal data on gait adaptation using the living laboratory fitted with various environmental barriers such as uneven terrain and stairs may provide new evidence for some aspects of the adaptive strategy mechanism.

Our results showed that, compared to level walking, ramp ascent increased the range of hip-joint motion by 13.8°, knee-joint flexion angle during early stance by 12.3°, and ankle-joint dorsiflexion angle during stance by 6.1°. In contrast, ramp descent decreased the range of hip-joint motion by 6.7° and maximum ankle-joint plantar flexion angle by 5.1°, while increasing the range of knee-joint motion by 3.2°. These findings are consistent with the increased hip- and knee-joint flexion angles during ramp walking reported by Lay et al [40] and the increased knee-joint flexion and decreased ankle-joint plantar flexion angles during ramp descent observed by McIntosh et al [41]. These joint angle adaptations are thought to reflect strategies for controlling the vertical movement of the body's center of mass during ramp ascent and descent. Furthermore, joint angle adaptations were even more pronounced during stair climbing compared to level walking. During stair ascent, the range of hip-joint motion increased by 10.6°, the range of knee-joint motion by 17.6°, and the range of ankle-joint motion by 3.4° compared to level walking. During stair descent, the range of hip-joint motion decreased by 18.8°, while the range of knee-joint motion increased by 13.1° and the range of ankle-joint motion by 14.3° compared to level walking. These results are consistent with the increased hip- and knee-joint flexion angles during stair ascent reported by Riener et al [33] and the decreased hip-joint flexion, increased knee-joint flexion and increased ankle-joint plantar flexion angles during stair descent observed by Protopapadaki et al [42]. Interestingly, this showed that RMSD values for stair ascent and descent were slightly higher at 1.8 - 5.7° and 1.5 - 4.5°, respectively, compared to level walking (1.2 - 2.4°), which may reflect the greater demands on balance and stability of this task [43].

In the future, it should be possible to apply the markerless motion capture system in the living laboratory to a wide range of research fields. For example, it could be used to investigate how environmental factors such as stair height and inadequate handrails affect changes in movement patterns between individuals [44]. An application might be where an individual, who is unable to perform certain essential ADLs in the home environment, might be able to simulate these tasks in the living laboratory before being discharged from the hospital [45]. It may thus be possible to assess whether this difficulty is due to a person's ability to adapt to the home environment. Such an approach could be useful in designing real-life living environments and improving welfare services to support independent living for older adults and people with disabilities. Furthermore, the Theia3D system is likely not only useful for evaluating the effectiveness of rehabilitation and training for patients with gait disorders but might also be applied in the fields of robotics and bioengineering to develop robots with adaptive walking mechanisms and to design walking support devices [46,47]. Our previous study demonstrated that this system can provide data for optimal selection of assistive robots by measuring changes in center of mass during robot use [20]. In this study, reproducibility was verified for the walking movements studied, as walking offers a relatively consistent movement pattern for reliability testing. However, expanding the scope of the analysis beyond gait to encompass more intricate ADLs, such as standing, sitting, and lifting objects, represents a key avenue for future research [48]. This could contribute to the growing body of ADL movement databases and enable various applications that consider differences in architectural and lifestyle patterns across different cultures. Furthermore, the importance of robot technology in supporting not only walking movements but also transferring and releasing a person from a bed has been described in the nursing and medical fields [49-51]. The living laboratory could provide information to further develop such assistive robots in the future.

Limitations

The study has several limitations. First, although previous studies have shown that markerless motion capture systems are

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less susceptible to the influence of subjects' clothing [52,53], this study did not directly verify this point. We did not standardize the subjects' clothing, but 13 out of 21 subjects wore the same clothing on both days. This might have contributed to the good results obtained in this study. Future studies should conduct measurements under various clothing conditions to investigate the impact of clothing in more detail. The second limitation is that the algorithm used to detect foot contact and foot lift events may not be applicable to all types of movements. The current algorithm relies on the positional relationship of the feet to determine foot contact and lift, which could make it challenging to use with patients who have conditions that cause irregular gait patterns. The third limitation is that the subjects in this study were all healthy young adults (14 males and 7 females), and no verification was conducted on older adults or patients with gait disorders. The gender distribution and ethnic homogeneity of our participants limit the generalizability of our findings to other populations. The advantages of markerless systems are expected to be greater for older adults and patients with gait disorders; therefore, future studies should include a variety of subjects to verify whether the results can be generalized across different age groups, genders, and ethnicities. The other limitation is the absence of concurrent validation with a marker-based motion capture system, which is considered the gold standard. Previous studies have demonstrated the importance of simultaneous comparison between two motion capture systems to evaluate systematic and random errors [54]. While such comparison would have provided additional validation through systematic error analysis, our study focused on the between-day reliability of measurements in a living laboratory setting. At last, while we used both RMSD and SEM to assess reliability, clinical application requires consideration of the Minimal Clinically Important Difference (MCID). Establishing MCID thresholds in future studies will be essential for determining whether observed changes in gait parameters are meaningful in clinical practice.

Conclusions

This study used the Theia3D markerless motion capture system in a living laboratory environment to evaluate the absolute reliability of joint angles during the various gait tasks, including level walking, ramp and stair ascent and descent using representative RMSD and SEM values. The results showed that our system could reliably measure joint angles during these tasks in a living laboratory setting. The observed joint angle adaptations provide valuable insight into the strategies individuals use to maintain stability and prevent falls when walking. These findings highlight the potential of markerless motion capture technology in real-world gait assessment. This evaluation system in living laboratories can be used more widely to explore rehabilitation strategies and robotics applications in a variety of subject groups, including older adults and patients with gait impairments.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Markerless processing.
[PNG File, 1136 KB - rehab_v12i1e66886_app1.png]

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Abbreviations

ADLs: activities of daily living
IC: initial contact
MCID: minimal clinically important difference
RMSD: root mean square difference
RoM: range of motion
SEM: standard error of measurement

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Capturing Objective Functional Measures Using Smartphone Inertial Sensors: Feasibility and Usability Study With Older Adults

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Abstract

Background: Digital platforms and smartphone apps have the potential to help patients with musculoskeletal conditions receive targeted interventions and physiotherapy support at home. As musculoskeletal conditions are much more prevalent in older adults, it is important to determine whether these technologies are accessible and acceptable to this demographic, who may possess lower levels of digital literacy compared to younger adults.

Objective: The study aims to evaluate the feasibility and usability of completing functional assessments while recording the activity using smartphone inertial sensors in adults 60 years or older.

Methods: Participants (N=21) were recruited from a range of community settings to complete a 4-week home-based trial, recording unsupervised sit-to-stand and single-leg balance activities at least once per week using their smartphone. We analyzed the data quality and adherence by number of assessments per week from the uploaded datasets. Feedback on usability was assessed using interviews and the System Usability Score.

Results: Inductive content analysis was used to identify 5 top-level categories: app, device, task, time, and personal perception. The mean System Usability Scale score was 81.2 (SD 17.5). The proportion of valid data uploads was 63.8% (81/127) for single-leg balance and 93.5% (58/62) for sit-to-stand measures. Adherence was high, with no significant deviations in the mean number of sessions completed or duration between sessions.

Conclusions: Smartphone-based monitoring of functional activities can facilitate unsupervised, remote assessments, thus reducing burden on physiotherapy services and increasing the ability to monitor progress objectively. Activities should be considered for complexity and, where necessary, increase in difficulty over time. App-based feedback is essential to inform users of the progress and adherence to the activities.

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KEYWORDS

physiotherapy; musculoskeletal; digital health; self-management; inertial sensors; smartphone; telerehabilitation

Introduction

Nonadherence to self-managed physiotherapy programs is considered to be high [1,2]. This can lead to poor outcomes when patients do not receive adequate support to complete their prescribed physiotherapy for musculoskeletal conditions. Digital platforms and smartphone apps can help patients with musculoskeletal conditions receive targeted interventions and physiotherapy support within their own home [3]. Traditionally, patients would receive a paper handout explaining the exercises; however, they can now use digital tools to receive guidance via videos and set the level of difficulty themselves [4]. These platforms offer an opportunity to provide continuous guidance and support to patients self-managing their physiotherapy by allowing them to take control of their routine; receive detailed instruction on the exercises; and in some cases, have a direct channel to chat or send messages to a physiotherapist [5].

However, while these platforms provide ample resources for patients, there is still limited feedback to clinicians on both adherence to the prescribed program and, moreover, how the patient is progressing and improving in terms of physical function. Most feedback relies on patient-reported outcome measures (PROMs) and other self-reported questionnaires, providing only a subjective insight into the outcomes [6]. App-based platforms can provide further quantitative statistics indicating the level of interaction with the app and thus the exercise routines but do not provide the required objective

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measures from assessments or any changes in physical function and performance of the patient over time [7].

Modern smartphones are equipped with an array of sensors that are primarily focused on tracking the movement of the user. Recently, the sensors have been limited for measuring the daily step counts of the user, with some more advanced approaches using the sensors for falls [8]. However, with the advent of apps to support physiotherapy self-management, there is an opportunity to use these built-in sensors to provide effective objective measures of both patient adherence and progression in self-managed physiotherapy.

In this study, a method that uses the sensors available in all smartphones to track and measure the activities used by physiotherapists to assess the physical function of patients with musculoskeletal conditions was developed. A number of studies have investigated the viability of using smartphones' inertial sensors for measuring functional activities such as sit-to-stand (StS). The results show that smartphone sensors are valid and reliable in capturing StS [9], timed up and go [10], and postural balance [11,12]. The smartphone sensors have been shown to be sensitive enough to differentiate StS activity in frail versus physically active older adults [13]. However, there is limited knowledge around the practicalities of older adults using smartphones to record their functional assessments in an unsupervised environment on a regular basis.

In this study, the feasibility and perceived usability of a smartphone app that allows the recording of two activities (StS and single-leg balance [SLB]) in the most likely user demographic of older adults (aged 60 years and older) were investigated. We evaluated the study outcomes in three ways: (1) engagement, evaluating whether participants completed the full program of assessments at least once per week over the 4-week period; (2) data quality, analyzing the resulting sensor data to examine the proportion of recordings that could be assessed by the algorithm; and (3) usability, detailed feedback from participants on usability using a standard questionnaire (System Usability Scale [SUS]) and a phone-based interview at the end of the trial.

Methods

Participants

Participants were recruited irrespective of whether they did or did not have any current musculoskeletal conditions. Similarly, we did not require participants to have any prior experience in using smartphone apps or other digital health platforms for managing musculoskeletal conditions or accessing services. This allowed us to gain a more generalized range of viewpoints from the trial. We used the following inclusion and exclusion criteria, which participants were screened against, before being onboarded into the study.

The following inclusion criteria were used:

- Adults aged 60 years or older
- Self-reported confirmation that they can walk >20 m without assistance
- Ability to move from sitting to standing without assistance
- Has access to Apple iPhone 6 or newer

The following exclusion criteria were used:

- Any current or previous knee, hip, or ankle injuries or conditions that could be exacerbated by repeated StS activities
- Any condition that may result in dizziness or loss of balance when standing

Recruitment

The research team was recruited from a wide range of community organizations and venues, including community centers, local charity groups, libraries, supported-living accommodations, and religious centers such as churches and mosques. A total of 21 local organizations were contacted with the support of the West Midlands Clinical Research Network [14]. Paper and digital format posters were distributed in these locations through relevant contacts at each organization or via an in-person visit by a member of the research team.

Participants registered their interest by providing their contact details (email or postal address) via (1) an online form, (2) email, or (3) telephone message. The participant information leaflet and consent form were then sent to those who were registered. For organizations and community sites where there were multiple participants, we coordinated via the organization's contact a suitable time to visit the site to onboard the group of participants. Individual participants were contacted directly to arrange a suitable date and location to attend the onboarding session, which was held at the university or a local community venue.

Ethical Considerations

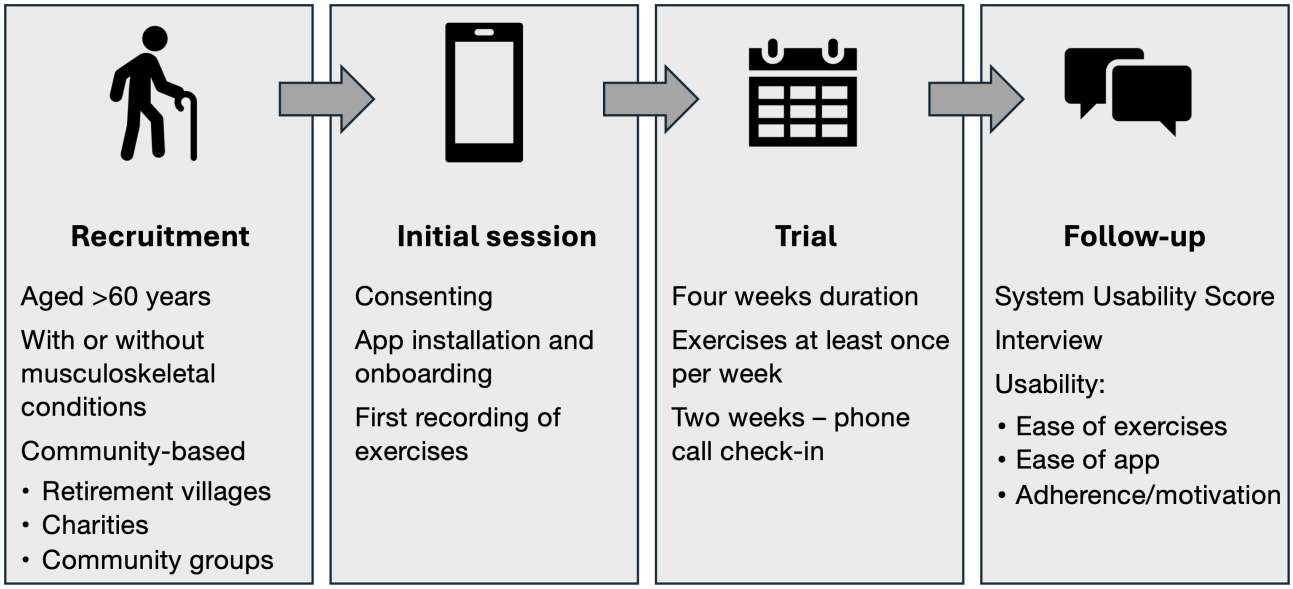
The study received ethical approval from the University of Warwick's Biomedical and Scientific Research Ethics Committee (ref. 147.20 - 21). Participants provided written consent prior to participation in the trial. All participants who engaged with the trial received a £20 (US $27) gift voucher for their participation. Participant data were pseudonymized using participant ID numbers assigned during the consenting process. A formal data sharing agreement was put in place between the researchers' host institution and the commercial organization that produced the app.

Procedure

The key stages of the project are shown in Figure 1. The trial began with an in-person onboarding session, where the participants were screened, consented, provided with guidance on installing and navigating the app, and demonstrated the functional activities. Initial recordings of the StS and SLB tasks were taken.

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Figure 1. Key stages of the project.



After the onboarding session, participants began the 4-week home-based trial. This involved using the app at least once a week to complete the two sets of assessments. Participants were able to complete the assessments at any time convenient to them during the week. No reminders were built into the app, so it was up to the participants to remember to complete the activities each week.

After the second week, the researcher contacted the participants over the phone to check that they were able to successfully complete the first 2 weeks of assessments. Any reported issues were subsequently resolved as necessary.

At the end of the trial period, the researcher arranged a phone interview for each individual participant to provide detailed feedback on their experiences during the trial. Interviews lasted approximately 30 minutes. A semistructured approach was taken using a list of guiding questions (provided in Multimedia Appendix 1). The researcher maintained detailed notes from the interview responses. Participants also completed the SUS [15] to provide a quantitative rating on the usability of the app.

Software and Installation

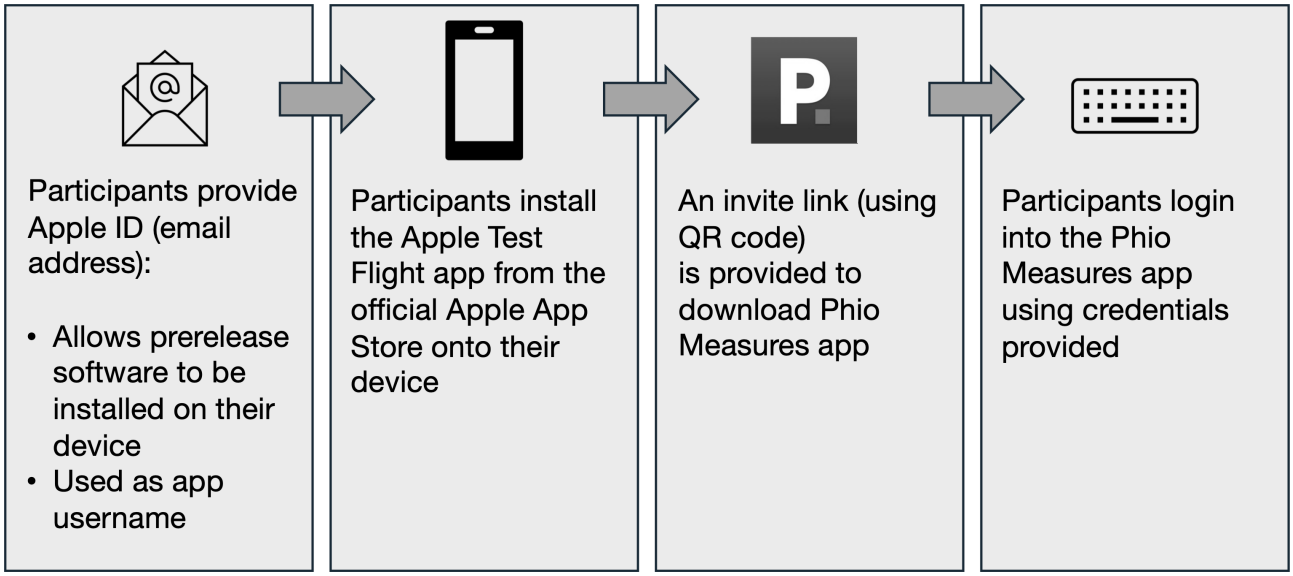
The prototype app, named Phio Measures, was developed by EQL Ltd. The app worked by recording the StS and SLB activities using the inertial measurement units built into smartphones. Thus, the raw data recorded were the 3D measures of acceleration (using the accelerometer), angular velocity (gyroscope), and magnetic field (magnetometer), sampled at 100 Hz. Inertial data and relevant metadata (eg, trial type, user ID) were automatically uploaded to a secure server. The research team accessed the data via an online dashboard.

Offline algorithms were used to identify and record the time duration to complete 5 repetitions of StS. This used a peak detection method applied to the gyroscope data to identify the repetitions of movement in this activity, which could be visually checked for accuracy. For the SLB task, the algorithm measured the magnitude of sway (using the accelerometer data in anterior-posterior and medio-lateral directions), as well as the duration of completing the task before returning the foot to the floor. Significant foot contact was identified by a clear impact spike in the sway data, which was detected using a threshold approach. In addition, participants were asked to end the recording once both feet were back in contact with the ground. In this project, we did not assess the accuracy of the algorithm but rather determined the proportion of uploaded trials that the algorithms were able to successfully analyze (ie, completed analysis without error and correctly identified the start, end, and repetitions of the movements). In the case of SLB, the algorithm typically required >11 seconds of data to calculate the measures.

The app was only available to Apple iPhone users, and this was made clear in all the recruitment literature and communications. However, 1 participant had to be excluded due to having an iPhone that was too old to install the software. After completing the consent process, participants were assisted with installing the software onto their smartphones. As this was prototype software, it involved installing an additional Apple app, TestFlight, which allowed the installation of prerelease software onto the phone. The steps for installation are shown in Figure 2. Participants were able to delete the software from their device at the end of the trial or at any time during the trial (which was subsequently noted as a wish to withdraw from the trial).

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Figure 2. App installation process.



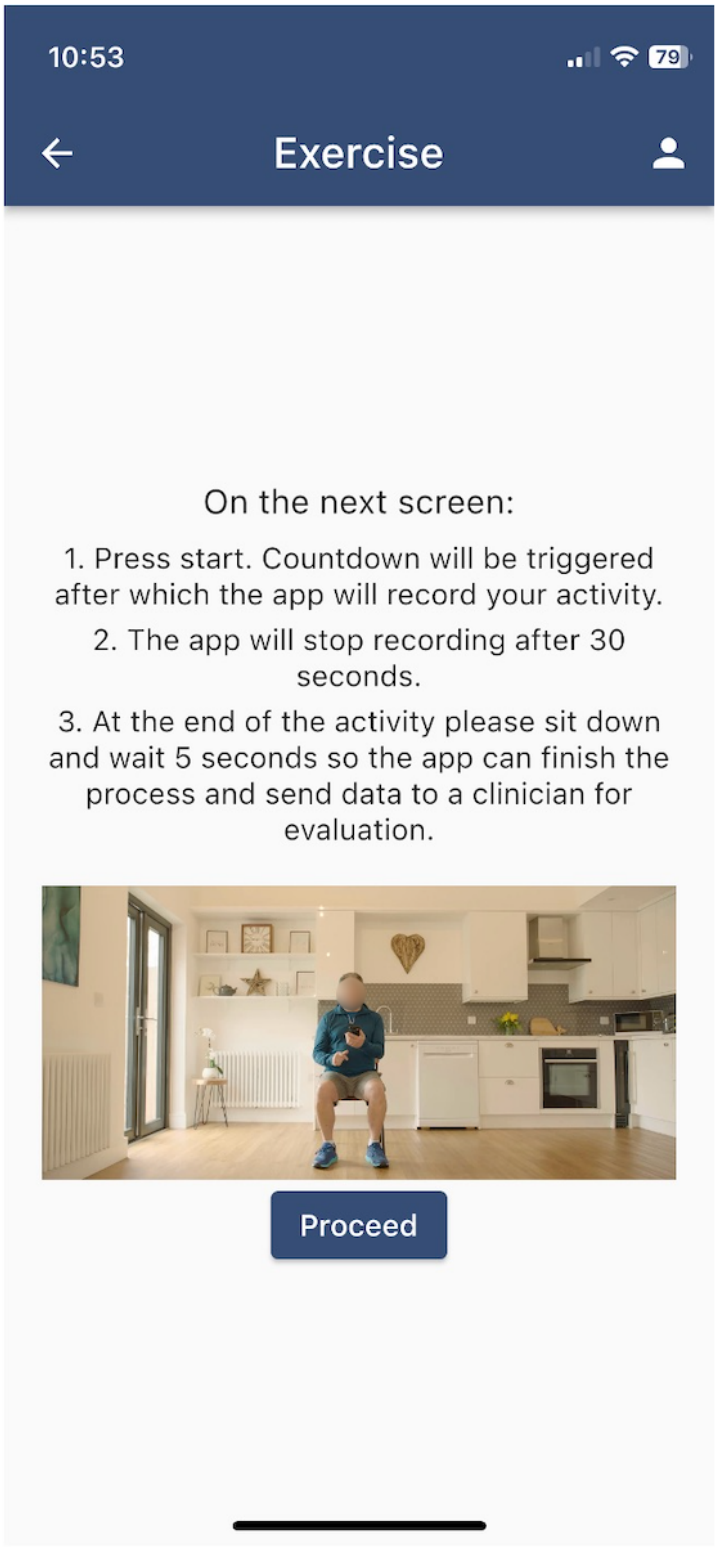
Functional Assessments

Overview

The trial involved completing 2 different types of functional activity on a weekly basis. A video was provided within the app to show the activity (Figure 3). At the onboarding session, the activity was demonstrated by the researcher, and an initial recording was taken. Each activity was completed with the participant holding their smartphone to the chest in portrait orientation (long axis vertical), with the inertial sensors recording movements. Participants were required to use a chair with fixed legs (no castors), a fixed seat, and no armrests (optional). The data from the smartphone sensors were uploaded automatically at the end of the recording to a secure online server.

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Figure 3. A screenshot of the app interface, showing a video and instructions of how participants record the sit-to-stand activity.



The activities were completed as follows (in no set order).

Sit-to-Stand Task

The participant was instructed to sit in the chair, holding the smartphone in their hand. When comfortable, they pressed the start button on the app, which counted down from 5 (with audio). During that time, the participant raised the phone to their chest (around the area of the sternum) and held it firmly in place (with the screen of the phone facing into the chest). The phone was held in place with both hands, one over the other, across the phone. Participants remained sitting still with their backs straight until they heard the countdown was complete.

After the audio tone, the participant began to complete the standard StS protocol, moving from the sitting to the standing position while keeping their hands on the phone to hold it to the chest as they moved. Participants were instructed that once fully standing, they should avoid unnecessary pauses and aim for a continuous movement when returning to the seated

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position. They repeated the process until they had done 5 repetitions or heard the audio tone to stop (which occurred after 30 s).

Upon completion, they resumed the seated position, remaining still for 5 seconds. They were then able to move the phone and press “stop” before returning it to the chest and remaining still for another 5 seconds, after which the recording stopped.

Single Leg Balance Task

The participant began in a standing position, positioned behind the back of a chair, which could be used for support if balance was lost during the task. Holding the phone in their hand, they pressed the start button on the app when ready. The app counted down from 5 (with audio). During that time, the participant raised the phone to their chest (around the area of the sternum) and held it firmly in place (with the face of the phone facing into the chest). The phone was held in place with both hands, one over the other, across the phone (although participants could use one hand to help maintain a steady balance during the task, if required).

After the audio tone, participants lifted one leg (participants could choose which leg to raise first), with the foot fully off the floor and with the eyes remaining open. They remained in this position until either a 30-second period passed or they could no longer maintain balance and returned the foot to the ground. After this, they remained standing still for 5 seconds. They were then able to move the phone and press “stop” before returning it to the chest and remaining still for another 5 seconds, after which the recording stopped.

The same task was repeated for the opposite leg.

Outcome Measures

The study focused on the usability of the app and the recording processed during the assessments. A mixed methods approach was used to capture smartphone measures, usability scores, and qualitative interview data.

The primary outcome measure was the qualitative results from the feedback interviews conducted after the trial period.

The secondary outcome measures included usability, assessed using SUS (0-100) during the posttrial interview; data quality, measured by the proportion of successful algorithmic assessments from unsupervised recordings taken during the trial; and trial adherence, evaluated by the number of recordings per participant and the time intervals between sessions [15].

Analyses

A fair notes approach [16] was used to record the responses from the interviews, which were facilitated by a member of the research team (CK). An inductive content analysis was used to identify the key categories and concepts that were mentioned by participants during the interviews. These were grouped and synthesized to identify the positive and negative recurring concepts along with any subcategories that emerged from the discussions. Analyses of the interview notes were undertaken independently by author MTE and subsequently cross-checked by CK, who suggested amendments to categories and content allocation.

The mean and SD of SUS scores were calculated across participants. The resulting value was translated to a percentile level compared to standardized usability scores from historic studies [17]. Descriptive statistics were used on other secondary objective measures.

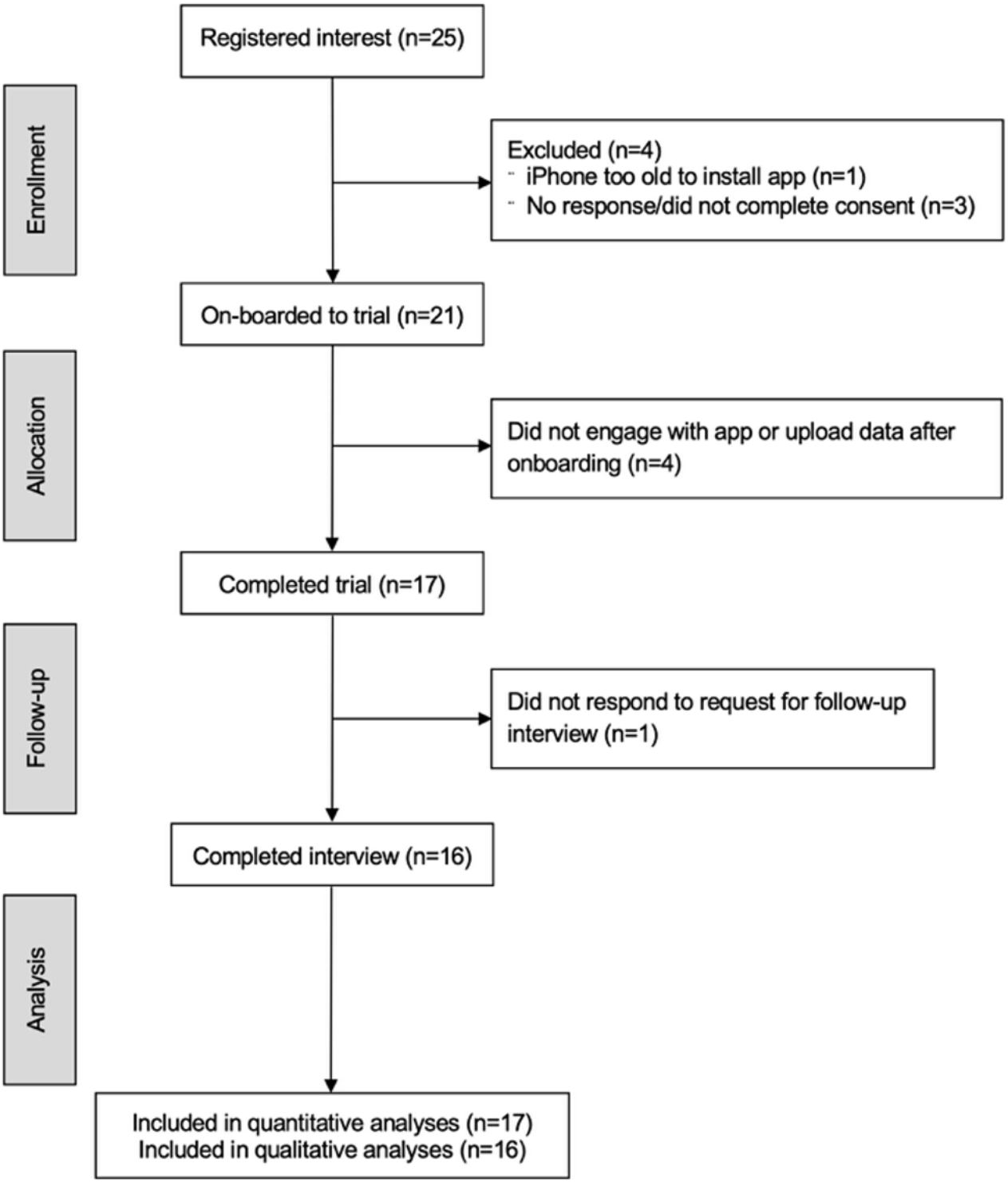
Results

Overview

A total of 25 individuals initially expressed interest in participating in the study (see Figure 4 for the CONSORT [Consolidated Standard of Reporting Trials] flow diagram for this study). Of these, 21 participants subsequently consented to take part in the study (female, n=15). One participant was unable to participate due to their Apple iPhone being too old to run the app; the remaining 3 did not respond to follow-up or complete a consent form. Finally, 17 participants completed the trial and provided valid data for analysis (female, n=12). The other 4 participants did not engage with the app, resulting in no data being uploaded (other than that collected during the initial onboarding session). One participant who completed the trial was unable to be contacted for the final interview.

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Figure 4. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the study.



Proportion of Valid Trials

A total of 192 data recordings were uploaded by the 17 participants over the duration of the trial. Of these, 142 out of 192 (74%) were valid for subsequent analysis by the algorithm. There were a lower number of valid SLB measures (81/127, 63.8%) than StS measures (58/62, 93.5%). It should be noted that there were generally double the recordings of SLB (n=127) compared to StS (n=65) due to the recording of both left and right legs. Most of the invalid uploads were due to insufficient data samples recorded to perform an analysis, likely due to the participant placing their foot on the floor (recognized by a signal spike in the sensor data) after a very short duration and stopping the recording.

Engagement

Participants were requested to complete both the StS activity and SLB for both legs at least once per week over the 4-week period of the trial. Participants, on the whole, adhered to the trial requirements (Table 1), completing a mean of 3.8 (SD 1.2) sessions for each activity, with just over a 7-day gap between sessions and a total duration between the first and the last

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sessions of just above the expected 21 days. Using 1-sample *t* tests against the target values, there were no significant deviations by participants from what was instructed (P>.05). Five participants were noted to have completed more sessions than requested (5 - 6 in total) by completing multiple sessions in 1 week or continuing beyond the 4-week period. In contrast, 7 participants completed fewer than the requested number of sessions (2 - 3 in total).

Table . Results indicating level of participant engagement and adherence to the 4-week trial period[a].

	Target	Mean	SD	Min	Max
Trial duration, d[b]	21	23.1	14.3	2.0	47.0
Days between sessions	7	7.9	6.1	1.0	23.0
Number of sessions (sit-to-stand)	4	3.8	1.3	1.0	6.0
Number of sessions (single-leg balance)[c]	4	3.8	1.2	2.0	6.0

[a]Target represents expected values if the protocol was exactly followed.

[b]Number of days between first and last session.

[c]Recordings of left and right leg classed as one balance session.

Objective Data Records

The overall mean time to complete the 5 repetitions of StS was 19.1 (SD 2.6) seconds. The overall mean time participants maintained SLB was 13.7 (SD 0.9) seconds. It was noted that the algorithms used were unable to calculate the sway measures when the duration of SLB was <11 seconds.

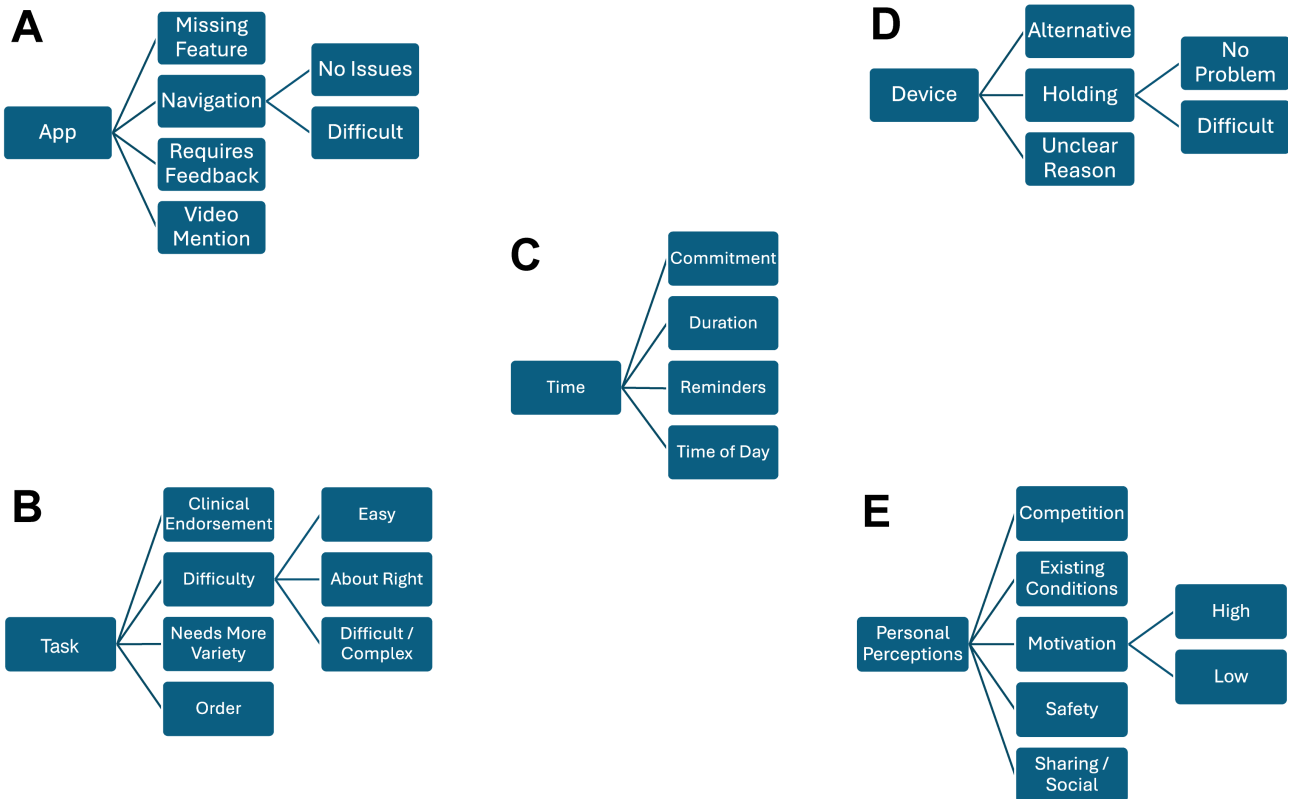
System Usability Score

The mean SUS rating across all participants was 81.2 (SD 17.5; range 45-100). This is equivalent to being rated in the 90th percentile against other studies reporting the SUS score [17].

Usability Feedback

A total of 16 telephone interviews were undertaken with participants. Five top-level categories of discussion were extracted: app, task, device, time, and personal perceptions. These categories are a mix of those that emerged directly from the subject of the questions asked, as well as those that emerged indirectly through the discussion and have been identified in the analysis. Within the top-level categories, the recorded notes and quotations were further classified into sub-concepts, as shown in Figure 5. The following section discusses the context of each category and subcategory, providing representative quotes that were identified from participant interviews.

Figure 5. Schematics of the main themes identified as (A) app, (B) task, (C) time, (D) device, and (E) personal perceptions. Themes were identified using content analysis, with the resulting subcontexts and subthemes shown for each of the 5 top-level themes.



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App

Missing Features

Many participants were forthcoming in identifying missing features within the app and made recommendations on what future versions should include. These included reminders to complete the assessments, acknowledging that the data have been saved and uploaded, more buttons for navigating the app, an option to use voice activation to start and stop recordings, a progress bar during the assessments, and audio descriptions for the currently silent instruction videos.

Navigation

Ten participants reported that they found the app easy to use, with no problem navigating, due to the basic but simple interface ("Is old school style - less sophisticated & very simple, which…some might appreciate"). It was highlighted that if the number of functional assessments or activities were to increase, then a "facelift" would be required to make it more personalized. Of the participants mentioning issues with navigating, this included issues around logging in ("loss of interest initially…due to needing to log in every time"). There were also challenges around starting/stopping recordings, and because the phone was held to the body, they also remarked on being unable to see the screen during use (therefore possibly indicating a need for audio or vibrotactile indicators).

Feedback

It was clear that receiving feedback from the app is an important requirement, with comments highlighting that this was a missing feature. Participants were particularly keen to receive feedback on the assessments and progression over time ("Not motivated - no telling why doing exercises, not tailored, no reminders, not even a smiley face"). Furthermore, feedback on whether the activity and recording were successful was also deemed important ("I'd like feedback to say it's definitely done. Would encourage me to do more and keep motivated").

Video

The instructional videos embedded in the app were described as a "very useful visual guide." It was highlighted that it would be better if they explained how they help with musculoskeletal conditions and why they are doing the activity.

Task

Clinical Endorsement

Two participants mentioned it would be useful to have input from a physiotherapist as part of the program or to allow physiotherapy endorsement or association with the program.

Difficulty

Just over half of participants (n=9, 56.3%) reported the functional tasks to be "easy" or about the right level of difficulty. They highlighted the simplicity and consistency of the program and recognized that "anything you do is better than nothing." The remainder had reported some difficulties, mostly related to SLB ("balance an issue," "tiresome standing on one leg," "[I] do wobble"). One specific issue related to StS was mentioned by a participant with current knee pain. The lack of feedback increased the perception that errors may have been made and concern that they were "cheating" when trying to steady themselves. A specific issue identified was that the 5-second countdown to the start of recording was not long enough to get "composure," particularly if other more complicated assessments or activities are introduced.

Needs More Variety

The two functional assessments used during the trial (StS and SLB) were commonly identified as limited and that there should be more variety in the activities recorded. This included the option for more "vigorous" exercise to raise heart rate and "pressure/strength monitoring." A "suite" of exercises or assessments was suggested ("Give choice of 3 a day out of a basket of 5…so it doesn't get boring") with the option of the physiotherapist being able to select the most relevant set for the patient. In addition, different levels of challenge were recommended including the use of gamification.

Task Order

Two participants mentioned the order of the functional assessments, generally selecting to do StS first.

Device

Holding

Six participants specifically mentioned difficulty holding the phone during the tasks, describing it as "cumbersome" and "too challenging." It was further thought that holding the device in the hand was affecting their balance. Additional difficulties faced while holding the device, due to conditions such as rheumatoid arthritis in the hand, were also highlighted. The remainder of the comments were positive, reporting no difficulties holding their device during the tasks, although one did forget to place it against their chest the first time they attempted it.

Alternatives

Alternatives to using the phone for recording activities were offered by participants during the interviews. These included smartwatches (eg, Apple Watch and Fitbit), tablets (eg, iPad), use of printed sheets for those who did not have access to a smartphone, and use of YouTube videos (for guidance only).

Suggestions of how to attach the phone were also made, including a "wearable chest strap" or "wear on the sleeve."

Unclear Reason

Although only mentioned by one participant, an important point was highlighted that there was "no explanation why the phone is being held there." They felt this diminished motivation to comply with requirements due to the lack of explanation.

Time

Commitment

The convenience of the short time commitment required to do the assessments once per week was acknowledged, and that even when busy, it was possible to commit the time to complete the activities due to the short exercises ("Enjoyed it. Didn't take much time, only minutes," "10 mins is nothing out of the day").

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Duration

The duration of both the StS and SLB tasks was 30 seconds. Only one participant mentioned this seemed a long time (to maintain balance). Another participant suggested gradually increasing the duration of tasks to improve ability over time.

Reminders

There were 8 specific mentions about having reminders in the context of timing of the activities (eg, "Would use a reminder if doing seriously, i.e., if it was led by GP", "…reminders…to do every 2-3 days"). However, a smaller minority of participants also mentioned that they did *not* require reminders and were able to remember ("No reminder needed. [Did exercises] whenever I had time."), with one person highlighting that reminders may not be practical if the assessments were done at varied times across different days to fit in with other priorities.

Time of Day

It was commonly reported on how the activities fitted into daily routines; this included doing them in the periods "when most convenient or when least busy," and more generally fitting it alongside other daily routines ("Usually around lunch, fits in after walking the dog," "Normally after taking painkiller," "Fit into own current exercises done frequently in the morning").

Personal Perceptions

The final theme captured any personal perceptions that completing the assessments had on participants or could have on participants, along with additional requirements identified for them to use this formally in the future.

Competition

Although one participant suggested gamification of the activities, when asked if there should be a competitive element to these activities (eg, use of leaderboards), there was no overall interest in adding these activities.

Existing Conditions

Participants with existing conditions mentioned how their condition impacted completing the tasks. In particular, a participant with dementia was unfamiliar with using a smartphone and needed substantial guidance. Cases of vertigo and instability in the right ankle also specifically impacted the SLB task.

Motivation

There were a small number of comments (n=6) relating to a lack of motivation to use the app or do the activities. The lack of feedback features led to statements that the app and activities were "dull and slow" and that the participant was "not motivated." Another highlighted that they were motivated by the fact that it was researching into "treating ailments" but were not so happy that it was developed by a commercial organization. In contrast, there were 10 mentions of being positively motivated by the app and the activities. Simplicity, accessibility ("Can do at home in front room"), and short time commitments were mentioned as reasons for being motivated to engage with the activities.

Safety

When asked, all but one of the participants were positive that the activities were safe to do at home without clinical supervision. However, one person mentioned the SLB task did feel unsafe and was "too worrying" to complete alone.

Sharing or Social

Only one participant shared details of the activities with other members of the community, of whom "many have knee osteoarthritis," while another discussed the trial with other "users" (based on the recruitment through community centers and supported living residences). Therefore, on the whole, there was limited evidence that participants shared their performance or experiences with their wider peer groups.

Discussion

Principal Findings

The aim of the digital platform trialed in this study was to be able to collect quantitative, objective measures of physical function when patients complete commonly used physiotherapy performance-based tests without clinical supervision. Our focus was to investigate the feasibility and usability of such a platform when used by older adults (aged 60 y or older), the group with the highest prevalence of musculoskeletal conditions [18]. The app was evaluated in three different ways: (1) engagement, evaluating whether participants completed the full program of assessments at least once per week over the 4-week period; (2) data quality, analyzing the resulting sensor data to examine the proportion of recordings that could be assessed by the algorithm; and (3) usability, detailed feedback from participants on usability using a standard questionnaire (SUS) and a phone-based interview at the end of the trial.

Our key findings were that overall, participants adhered to using the app at the minimum scheduled frequency over the duration of the trial. The quality of the data uploaded unsupervised by the participants during home-based completions of the activities was high for the StS task (93.5%), but much lower for the SLB task (63.8%), highlighting the challenges of completing a balance task by the participants. Despite its limited functionality as a prototype, the app scored highly on the SUS scale, likely due to the simplicity of the interface. However, this effectively provided a blank canvas for participants to recognize the desired features that were missing; they subsequently highlighted specifically the need for rapid feedback on their performance/outcome following completion of the tasks and the option for more activities to be made available to be chosen either by the individual or a medical professional (eg, physiotherapist, general practitioner). Short assessments or activities are essential and allowed participants to fit in alongside their daily activities. The proposed method of holding the phone to the chest while completing activities was considered feasible, but not ideal. Suggestions were put forward to improve this approach, including the use of a smartwatch; however, such devices are less prevalent in terms of ownership compared to smartphones, risking digital exclusion.

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Engagement and Adherence

Overall, there was a good level of engagement with the trial, with a total of 4 (19.1%) participants dropping out over the trial period. This contrasts with a meta-analysis study of mental health smartphone apps, which found an overall dropout rate of 26.2% (47.8% when accounting for publication bias) [19]. Our low dropout rate and high engagement are likely due to the short duration of the trial (4 wk). A longer-term program might result in a reduced sense of novelty and subsequently a significant dropout rate over time, without further intervention (eg, the use of incentives [20,21]). However, older adults are more likely to engage with remote digital health studies for a longer period than younger counterparts [22].

It was observed from the interview outcomes that the short, easy-to-complete activities were another driver of engagement, with participants able to fit them into their regular daily routines. While it may be considered that older adults have more leisure time than young adults to complete these activities, an Australian study found that 16% of inactive adults aged 65 - 69 years reported not having enough time as the first or second highest barrier to exercise [23]. While the activities in this study are functional rather than cardiovascular-type exercises, it is important that their duration remains short. The Osteoarthritis Research Society International recommended performance-based tests for osteoarthritis [24] include StS (chair stand), along with a number of other simple activities, such as timed up and go, 6-minute walk, and stair-climb. Technically, all these activities could be recorded using standard smartphone sensors, but as reflected by our findings, each should be tested for its feasibility in unsupervised conditions to allow for unforeseen complexities in the task.

Our results further highlighted that only the StS task was practical for unsupervised monitoring using a smartphone. The low data quality of the SLB task was further reflected by the participants' remarks, with some struggling to perform the balance task successfully. Participants also requested a variety of activities, which might involve more practical functional tasks such as a 10-m walk, timed up and go, or a stair climbing task [24].

Maintaining motivation to complete the activities is essential for longer term programs. While an increased range of exercises is one method of maintaining engagement, the other aspect highlighted by a substantial number of participants was to have feedback. The lack of feedback in the prototype was identified as a significant omission, with requests for both performance-based feedback (eg, time to complete 5 repetitions) and acknowledgments around the task (eg, task successfully completed, data uploaded). Performance-based feedback can give participants a sense of achievement, particularly if historical trends of performance are recorded [25]. However, it is noteworthy that when asked, no participants showed any desire to make these activities "competitive" (eg, using leader boards or comparing with friends).

Data Quality

A significant concern in collecting data for unsupervised activities using devices such as smartphones is the reduction in data quality [26,27]. The activities need to be clearly defined and simple to execute with limited opportunity for alternative interpretation. Algorithms must have a level of flexibility to ensure there is some resilience against variation in the orientation of devices and varied sensor performance across smartphone devices (usually compared using step count variance [28-30]). In this study, the data analysis algorithms were implemented offline, after the sensor was uploaded to the server (thus removing the provision of feedback that many participants desired); near real-time analysis will be required for the app to be practical in the future, and this will require suitable detection of invalid recordings to avoid false feedback, particularly for clinical assessments. Data quality remained high, however, particularly for the StS task, where 93.5% of recordings were valid and able to be analyzed. Other studies have also confirmed smartphone sensors can provide a reliable and consistent method of capturing this activity [9,31]. The SLB was more concerning, with only 63.8% of recordings being usable. This reflects the challenge of the task, highlighted by some participants in the interviews, with one participant stating it also felt unsafe. Therefore, it is recommended that the StS activity is an activity that produces robust data for smartphone assessments while also being a useful functional assessment clinically [24]. On the other hand, the SLB task in its current form used in the trial is less practical for unsupervised, digitally recorded assessments. This could potentially be resolved by gradually increasing the difficulty of such a task. For example, rather than immediately requiring participants to complete a full 30 seconds from the start, the duration could be slowly increased over time, monitoring and adjusting the difficulty as users achieve goals.

Usability

The mean SUS score provided by the participants after using the app for 4 weeks was somewhat surprisingly high. However, it has been noted that smartphone apps do typically score highly on the SUS, with a study investigating a range of apps reporting an average SUS score of 77.7 [32]. Our mean score of 81.2 is therefore in the upper range expected of apps. This is likely due to the simplicity of the interface we had in this prototype; the limited features and options implicitly made the app relatively easy to use. Adding more features (which participants strongly indicated were required) would therefore benefit from a co-design approach, such that potential end users would be involved in the design cycle to ensure usability is not lost as the complexity of the app increases.

Limitations of the Study

There were some limitations emerging from this study. Unfortunately, due to information not collected on some participants and issues with the lead university not agreeing to licensing terms on the musculoskeletal questionnaire to be used, we gathered limited demographic information—particularly in terms of the overall age distribution of participants and level of function and mobility. However, in a related study in which some of the participants from this study also participated, it was reported that 80% of participants had some form of current musculoskeletal condition [26].

In terms of the app, it is likely that the prototype nature of the app meant its interface and lack of feedback had some impact

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on perceptions. However, this also had the benefit of being able to assess the core features required to facilitate the use of the smartphone to record these functional activities. Moreover, the process of using and holding the phone to complete the assessments without supervision was a key aspect of the study, and one that was achieved using the prototype app.

Conclusions

It was found that it is feasible for people to use the built-in inertial sensors in a smartphone to record physiotherapy-related functions. However, activities should be limited to simple, stable activities such as an StS task, rather than activities that lead to instability, such as SLB. It is recommended that more exercises be evaluated from a clinical, patient, and data quality perspective to establish a portfolio of activities that patients can perform independently and be automatically monitored objectively via an app. Feedback is essential and therefore requires more study into how this can be optimized to achieve long-term adherence. Overall, smartphone-based monitoring of functional activities can facilitate unsupervised, remote assessments, thus reducing the burden on physiotherapy services and increasing the ability to monitor progress objectively.

Acknowledgments

This study was funded by the Medical Research Council (MR/W003775/1) and the National Institute for Health and Care Research (NIHR205809).

During the preparation of this work, the authors used ChatGPT-4 in order to assist with the formatting and ordering of text comments from the interviews. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Data Availability

All data generated or analyzed during this study are included in this published paper and its supplementary information files (Multimedia Appendix 2).

Authors' Contributions

MTE, PG, and KR obtained funding and conceptualized the research. PG and KR led the development of the prototype app; CK, SC, and MTE led recruitment and data collection; CK drafted initial qualitative interview questions and ran interviews; CK, KR, and MTE completed the analyses; and all authors reviewed the final manuscript.

Conflicts of Interest

KR and PG are employed by EQL Ltd. This study is part of a wider project that KR and PG helped to conceptualize with MTE. MTE was in receipt of Medical Research Council funding covering his time on secondment with EQL Ltd for 1 day per week at the time of this study.

Multimedia Appendix 1
Content analysis categories and subcontexts.
[DOCX File, 15 KB - rehab_v12i1e72511_app1.docx]

Multimedia Appendix 2
Quantitative and qualitative study data.
[XLSX File, 64 KB - rehab_v12i1e72511_app2.xlsx]

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Abbreviations

CONSORT: Consolidated Standard of Reporting Trials
PROM: patient-reported outcome measures
SLB: single-leg balance
StS: sit-to-stand
SUS: System Usability Scale

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Perspectives From Canadian People With Visual Impairments in Everyday Environments Outside the Home: Qualitative Insights for Assistive Technology Development

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Abstract

Background: Despite the abundance of assistive devices available, the accomplishment of many everyday tasks remains complex for people with visual impairments. While several studies have been conducted to identify the obstacles encountered when moving around outdoors, current knowledge is less abundant when it comes to the difficulties encountered in complex, indoor environments.

Objective: This study aimed to identify the most important obstacles and facilitators encountered in everyday indoor travel environments outside the home for people with low vision and blindness.

Methods: Data were collected from 20 participants with varying levels of vision from several cities across Canada in 2 web-based focus groups in both English and French. Using open-ended questions, participants shared obstacles and facilitators experienced or imagined during independent navigation in the following scenarios: coffee shop, hospital, big-box store, party with friends, and bus rides. Thematic analysis was conducted, and responses were either categorized as barriers or facilitators for each scenario. These were ranked by all participants via email according to their perceived importance in completing each scenario.

Results: Across scenarios, the principal barriers to perceived success were inaccessible signage, difficulties walking around, problems finding a specific location, and unsuccessful interactions with others. The main facilitators across scenarios were helpful interactions with others, planning, accessible signage, and websites. The use of mobile apps was discussed but ranked as less important by participants. Though similar among the French and English groups, the rankings of the different facilitators and barriers were largely scenario-specific. The most barriers were mentioned in the coffee shop (n=8), followed by the department store (n=7) and bus or metro (n=7) for the English group, whereas the most barriers were in the department store (n=9), followed by the hospital or clinic (n=7) and coffee shop (n=6) for the French group.

Conclusions: Though promising technologies have been developed to resolve some of the issues surrounding indoor navigation for people with visual impairments, they were not perceived as helpful as some other traditional methods of assistance, such as asking for help, by our participants. For the successful incorporation of indoor navigation technologies, it is important to understand how they integrate into the experience of people as they move in these dynamic environments. The successful use of technology is only possible if the physical environment permits and facilitates independent navigation.

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KEYWORDS

visual impairment; rehabilitation; mobility; accessibility; assistive technology

Introduction

Perspectives of Canadian People With Visual Impairments

Globally, over 2.2 billion people have visual impairments, with projections suggesting that this number could double by 2050 [1]. More than 1,519,000 Canadian people reported having a visual disability in 2017, representing 5.4% of the population [2]. These individuals experience barriers like reading and accessing textual information [3], participating in leisure activities, shopping [3,4], and using public transport [5] that hinder their full social participation. Key tasks impacted include reading labels and signs, operating appliances, locating items on shelves, and using computers [5,6]. These barriers affect

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social inclusion and therefore the quality of life of people with visual impairment [2,7].

Assistive Technology in Vision Rehabilitation

The Lancet Global Health Commission on Global Eye Health identified the provision of vision rehabilitation services and assistive technologies (ATs) as key to improving the functional abilities and quality of life of people with visual impairments [8,9]. People living with low vision or blindness often receive vision rehabilitation services from orientation and mobility specialists who instruct on the use of assistive devices that facilitate independent travel including optical aids (eg, magnifier and telescope), a long white cane for assistance with obstacle detection, and the use of a dog guide trained for obstacle avoidance while following route directions provided by the handler [10]. Low vision therapists often teach the use of assistive devices, such as screen enhancement software, magnification aids, or other visual enhancement devices to improve activities of daily living, such as reading, cooking, or watching television [11]. Vision rehabilitation therapists often provide training on screen reading software, refreshable braille displays, or other compensatory aids [12]. Once the individual has completed vision rehabilitation training, they should be able to perform many daily activities more independently or effectively, such as traveling, reading, or cooking.

Mainstream smartphones and tablets are increasingly being incorporated into vision rehabilitation training due to their built-in accessibility features (ie, screen magnification, electronic braille connectivity, and text-to-speech software) that can be activated by all users [13]. Their versatility makes them an affordable option [3], less socially stigmatizing, and generates fewer negative reactions than some specialized devices, such as electronic glasses and telescopes [14]. The accessibility features enable users to access apps that support daily living activities, including reading email, accessing websites, managing calendars, and providing GPS support during travel [15]. Recent studies have found that these modern devices are increasingly replacing the use of traditional visual aids (ie, specialized stand-alone GPS devices for blind users and optical magnification aids for those with low vision) for navigation-based tasks [14,15].

The use of these portable electronic devices enables people with visual impairments to maintain a previously unattainable level of independence [16]. Smartphone apps, like Seeing AI and Supersense, have been developed using artificial intelligence (AI)–based computer vision to provide object detection or scene description, while human assistance apps, like AIRA or Be My Eyes, may allow for remote assistance. Modern mobile GPS-based apps are often successful in facilitating outdoor navigation, allowing people with blindness or low vision to be able to plan a route, use public transportation, or identify their current location [15]. Though there are hundreds of mobile apps that could be used as AT, there is little knowledge as to their real-world benefits [17].

AT for Social Inclusion

Despite progress in promoting inclusivity for individuals with visual impairments in design, a recent review revealed that less than 4% of studies involved them in the design and development of AT [18]. This lack of inclusion and the feeling that devices do not meet their needs often result in abandonment, a common issue in vision rehabilitation [5,18-20]. A recent study with people with visual impairments points out that 57% of everyday tasks are still performed without the support of visual aids or adaptive strategies, making it impossible to perform them without the help of another person in a third of the tasks recorded in their study [7]. Despite the wide array of indoor navigation systems tested and developed [21], indoor navigation remains a challenge for people with visual impairments [15]. To develop versatile mobile apps that respond to the needs of people with visual impairments, it is important to identify the elements of a task that do not allow them to complete it. For example, the inability to identify an item at the store would not allow them to shop independently. However, hitting an object with the white cane would not necessarily hinder their ability to shop.

One of the major advantages of modern AT is its rapid response time. Unlike vision rehabilitation specialists, who cannot provide immediate assistance, smartphones can quickly deliver vital information using AI-based computer vision, such as identifying store items. While specialists can teach users how to navigate these technologies, they cannot be present for every situation, especially in dynamic environments like restaurants or public transport. Therefore, the responsiveness of AT can significantly influence a person's willingness and ability to participate independently in various settings. Since no single AT can address all needs, understanding the perceived barriers and facilitators among a diverse group of individuals with visual impairments is crucial.

Research Objectives

This exploratory research investigates the common barriers and facilitators that people with visual impairments experience in everyday indoor travel environments. A Delphi-style [22] mixed methods approach was used to inform AT developers about common obstacles that are encountered among people with a variety of visual conditions and lived experiences.

Five scenarios were selected based on previously identified challenges related to using current AT in indoor settings: (1) getting a drink at your favorite local coffee shop, (2) going to the clinic for a scheduled appointment, (3) shopping at a big box store, (4) going to a party to meet friends, and (5) taking the bus.

Specifically, the research questions addressed in each of these scenarios above were as follows: (1) Which barriers hinder your ability to successfully complete the scenario? (2) What facilitates your ability to successfully complete the scenario? (3) How do mobile apps assist you in completing the scenario? (4) Which of these barriers and facilitators are the most important to achieve success in the scenario?

This is the first study, to our knowledge, that examines the perceived importance of barriers and facilitators to completing a variety of everyday indoor tasks outside the home for people with low vision and blindness.

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Methods

Ethical Considerations

Data were collected from February through June 2023. Ethics approval consistent with the Declaration of Helsinki [23] was obtained through the Université de Montréal Clinical Research Ethics Committee (CERC 2022 - 1800) on January 13, 2023. Each participant provided their informed consent to participate via an accessible Microsoft Word document sent by email. Participants were compensated US $36.50 for their time. Data collected during the study were deidentified.

Study Design

Applying a phenomenological perspective, this research delved into the experiences of people with visual impairments in a variety of indoor, dynamic environments. This exploratory study embraces the principles of transdisciplinary development of AT [24] and user-centered design [25]. Thus, the opinions and perspectives of diverse groups of individuals with visual impairments were at the core of the study. To avoid influencing the responses of the participants, no specific technologies were mentioned throughout the study. This reduces the risk of participants being biased toward perceiving technology as the preferred method, thereby ensuring an open discussion about various means (eg, human assistance and physical accessibility measures) to resolve specific travel problems in these environments. The study methods and research findings were explicitly and comprehensively reported using the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [26], which is presented in Checklist 1. Important details about the research team, study procedures, study setting, results, analysis, and interpretations can all be reported with the use of this checklist. To reduce question wording and personal bias in the interview, moderators AC and FG followed an interview guide that was prepared and reviewed by the principal investigator JPN prior to the focus group meetings.

Eligibility and Recruitment

Participants were recruited between February 5 and March 26, 2023. Information was circulated by email to several organizations working with the visually impaired (eg, CNIB Foundation and Regroupement des Aveugles et Amblyopes du Montréal Métropolitain). A recruitment advertisement was also published on social media groups, such as Facebook. Finally, recruitment was carried out via a snowball effect, encouraging respondents to tell others in their circle who met the inclusion criteria about the project. The inclusion criteria consisted of choosing only participants 18 years or older of age who reside in Canada, self-identify as having a visual impairment (low vision, blindness, or deaf-blindness), are at least partially independent while traveling (make trips outside the home, independently, at least occasionally), are regular users of smartphones (at least once weekly for at least a year), can express themselves in French or English, have basic skills in using the internet and the Zoom (Zoom Video Communications) platform to participate adequately, have access to a good-quality internet connection to take part in a web-based audiovisual encounter, and declare that they had no intellectual or cognitive disabilities. Those who did not fulfill all these criteria were excluded from the study.

Individuals who expressed interest and self-identified as meeting the inclusion criteria were asked to contact the research team via the email addresses provided, whereby the research team provided the consent form in an accessible Microsoft Word format via their email correspondence provided to the researcher. A 20-minute phone or videoconference selection interview was performed to ensure the eligibility of the participants and classify them according to their age, gender, ethnicity, place of residence, travel habits, and level of vision (see Multimedia Appendix 1 for the full instrument). This information was recorded by the research team and was used to select a diverse group of participants corresponding to the categories (1-8). At least 1 participant who was classified into each category was requested to be present at each focus group. A participant may be classified into more than 1 category: (1) low vision and not legally blind, (2) low vision and legally blind, (3) low vision determined by visual acuity defect, (4) low vision determined by visual field defect, (5) low vision between 18 and 49 years of age, (6) low vision 50 years or older of age, (7) blind and between 18 and 49 years of age, and (8) blind and 50 years of age or older.

The individuals who expressed interest and were deemed eligible for selection interviews were contacted on a second occasion once they were selected by the research team based on their profile, considering the categories and encouraging the highest levels of diversity possible. The selected participants who agreed to participate in the web-based focus group were requested to respond to an accessible scheduling form to determine their availabilities, whereby the research team scheduled the web-based focus group session via Zoom.

Data Collection and Analysis

Selection Interviews

For the initial data collection from the selection interview, the researchers input information regarding the age, gender, ethnic origin, place of residence, travel habits, visual diagnosis, age of diagnosis, other disabilities, smartphone use, type of mobility aid used, level of vision, type of deficit, and category (1-8).

The goal was to gather 8 to 10 people for a focus group to encourage rich, diversified exchanges, as well as the participation of everyone in a pleasant atmosphere [27]. Considering potential attrition throughout the project, 12 participants were considered for the French and English-speaking focus groups, respectively. However, due to scheduling conflicts, only 11 and 9 participants were present for the French and English focus groups, respectively. All those who participated in the focus groups completed all the remaining steps of the study.

Focus Group Sessions

Two focus groups were chosen to encourage diversified exchanges of ideas through Zoom meetings being conducted in French and English, respectively, to allow the participants to express their thoughts and opinions in either of the languages and to examine any potential language-related differences in the responses (ie, inaccessibility of signage or apps in 1

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language). Each session, lasting a maximum of 2 hours, was moderated over Zoom by 2 members of the research team who provided the structure and rules for the session, managing time and taking notes. The moderators prepared open-ended questions and prompts to guide the conversation, but no limits were given to the type of response to be provided. All the recordings were done on the university premises, and no one else was present besides the participants and researchers during the recordings. There was no relationship established prior to the study commencement between the moderators and participants. The participants only had knowledge of the research project without any personal knowledge of either moderators AC or FG. Each of the everyday scenarios was addressed by discussing 1 subaspect at a time to help control the flow of discussion and order the data collection. For each subaspect or subtask, participants were asked to name an obstacle or facilitator or what made it harder or easier to accomplish that subtask independently. They were invited to share their opinions based on their own previous experience and expertise. If they had not experienced any of the scenarios independently in the past, they were asked to imagine themselves performing each subtask on their own. Each participant's intervention was limited to 2 minutes per subtask to encourage as many people as possible to speak.

Once all the scenarios had been discussed, more general open-ended questions were addressed to the participants, including the strengths and shortcomings of current mobile apps, the scenarios most difficult to complete alone, and the participants' wishes for tools to remedy the obstacles encountered.

The Zoom software was used to record the audio file of the session and transcribe it into English. The study team manually completed the French transcription. The transcriptions were validated to ensure accuracy. A third member of the research team (JPN) resolved any discrepancies after 2 team members independently identified themes in the participants' responses. Each participant's code, the scenario they described, and the frequency of each theme's occurrences were recorded. The list of themes was organized according to the scenario in which it was mentioned and whether it was considered a barrier or facilitator.

Email Ranking

The list of themes was then emailed to each participant for an individual ranking 2 weeks after the Zoom session. The participants were only sent themes mentioned during their focus group session. Thus, each focus group had a different set of themes to choose from, but each participant in that focus group received the same set of themes. Each participant was asked to rank the themes in each scenario according to their perceived level of importance in completing the scenario independently or having a pleasant experience. They were asked to write 1 for the most important facilitator or barrier, 2 for the second most important, and so on. For each scenario, participants could also add a new idea that was not included in the proposed themes, using the "Other" line. Their responses allowed the research team to reorder the themes based on the level of perceived importance. Themes with an average value closer to 1 were determined to have a higher level of perceived importance as either a barrier or facilitator in their respective scenarios. If 2 themes received the same average value, they received the same score of relative importance.

Data Analysis

The audio file of the session was recorded and transcribed into English via the Zoom software. The French transcription was performed manually by the research team. Transcriptions in both English and French were validated to ensure accuracy by the principal investigator. To reduce bias, AC and FG (both female members) coded the transcripts and derived their themes independently. Themes were compared by JPN to arrive at common themes for each focus group. Discrepancies were resolved by JPN reviewing the recordings and transcripts and subsequent discussions with AC and FG. AC and FG were students in the orientation and mobility program at the Université de Montréal, while JPN (male) was their professor and research director. The code of the participant that mentioned each theme, the scenario mentioned, and the number of occurrences of each theme were logged in Microsoft Excel. The list of themes was organized according to the scenario. Each participant was asked to rank the themes in each scenario according to their perceived level of importance, with 1 being the most important. Due to the limited number of participants and high level of diversity among the participants, the authors did not perform comparative statistical tests (ie, ANOVA and *t* tests) to analyze the ranking data. Instead, the themes were analyzed according to their level of perceived importance and the information received from each participant during the selection interview. The average ranking scores and number of occurrences of themes were taken for each scenario in each language.

Results

Demographics

In total, 38 people were interviewed between February 24 and March 24, 2023, using the selection questionnaire. A profile of each person can be found in Multimedia Appendix 2.

The selection for each focus group was made according to the methodology described earlier to have a diverse group of participants. In total, 10 English-speaking or bilingual individuals were selected for the focus group conducted in English, and 12 French-speaking individuals for the focus group conducted in French. One individual in each group did not attend their respective focus group.

The final portrait of the 2 groups is presented in Table 1. Participants who are English-speaking have a code beginning with A, and those who are French-speaking have a code beginning with F; bilingual participants are coded AF. Participants whose codes begin with "A" or "AF" were part of the English focus group, while those with codes starting with "F" were in the French focus group. Though recorded by the research team, the visual diagnosis, travel habits, and additional handicaps are not listed in the table to deidentify the participants.

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Table . Demographics of all participants in focus groups.

Code	Age (years)	Sex	Ethnicity	City, province	Age at diagnosis (years)	Mobility aids	Level of vision	Type of vision loss
A07	69	Male	White	Toronto, Ontario	Birth	None	LVB[a]	VA[b]
A10	75	Female	Asian and African	Ottawa, Ontario	68	None	LVB	VAF[c]
A18	24	Female	Afro-American	Edmonton, Alberta	12	Guide dog, white cane	LVFB[d]	VAF
AF03	62	Male	Indian	Montreal, Quebec	58	White cane	LVFB	VAF
AF08	60	Female	Middle Eastern	Toronto, Ontario	30	Guide dog, white cane	CB[e]	VAF
AF26	59	Male	White	Montreal, Quebec	Birth	White cane	CB	VAF
AF29	51	Female	White	Montreal, Quebec	Birth	Support cane, walker	LVNLB[f]	VAF
AF33	63	Male	White	Granby, Quebec	50	White cane	LVFB	VAF
AF37	30	Female	South American	Montreal, Quebec	Birth	White cane	CB	VAF
F01	50	Female	White	Montreal, Quebec	22	White cane	CB	VAF
F02	56	Female	White	Laval, Quebec	51	White cane	LP[g]	VAF
F05	50	Male	White	Mont St-Hilaire, Quebec	23	Guide dog, white cane	LVB	VAF
F20	57	Female	White	Laval, Quebec	27	White cane	LVB	VAF
F23	58	Female	White	Laval, Quebec	57	White cane	LVB	VF[h]
F25	66	Male	White	Quebec, Quebec	55	White cane	LP	VAF
F27	32	Female	African	Longueuil, Quebec	8	White cane	CB	VAF
F28	61	Male	White	Granby, Quebec	20	Guide dog, white cane	LP	VAF
F30	56	Female	White	Montreal, Quebec	Birth	White cane, support cane, telescope	LVNLB	VA
F35	58	Female	White	St-Hubert, Quebec	32	White cane	LVFB	VAF
F36	56	Female	White	Granby, Quebec	17	None	LVB	VA

[a]LVB: low vision and legally blind.

[b]VA: visual acuity loss.

[c]VAF: visual acuity and field loss.

[d]LVFB: low vision functionally blind.

[e]CB: completely blind.

[f]LVNLB: low vision not legally blind.

[g]LP: light perception.

[h]VF: visual field loss.

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Coffee Shop

The participants were asked to imagine getting a drink at their favorite coffee shop, and this scenario consisted of multiple steps (Multimedia Appendix 3). In each of the steps of this scenario, the participants in both focus groups were asked to indicate any obstacles and facilitators. They were then asked to rank these themes in an email. This process was repeated in each scenario. A heat map summary including the full list of themes along with the ranking of each across all scenarios is shown in Multimedia Appendix 4.

The themes extracted for the facilitators and barriers were reviewed and ranked by participants. The complete list of ranking of themes for this and each scenario are presented in Multimedia Appendix 5. The top 3 rankings of the barriers and facilitators in each group for the coffee shop scenario, and their averages, are indicated in Table 2.

Participant AF37 mentioned that human assistance is an important factor, stating that "If I go to a known place, I already know kind of the prices on what they sell, and so I just ask them, what do you have today?" More quotes on each theme used by participants are mentioned in Multimedia Appendix 6.

Participant AF08 mentioned that the precise location is difficult to find, stating

> *Locating where the terminal is very difficult. It's never in a standard place that is close to the customer. Sometimes you must reach and try to find where it is.*

Table . Top 3 rankings of facilitators and barriers in order of importance to visit a coffee shop.

Rank	English group	Average (SD)	French group	Average (SD)
Facilitators—coffee shop				
1	Human assistance	2.6 (2.0)	Human assistance	1.9 (0.9)
2	Preparedness	3.4 (1.7)	Accessible payment	2.4 (1.1)
3	Accessible physical space	4.3 (1.6)	Sensory cues	2.6 (1.0)
Barriers—coffee shop				
1	Difficulty finding an exact location	2.7 (1.8)	Lighting	2.0 (1.5)
2	Unsuccessful interactions with staff	3.1 (1.2)	Inaccessible signage	2.5 (1.0)
3	Inaccessible signage	3.8 (2.5)	Difficulty walking around	2.9 (1.1)

Hospital

The participants were then asked to imagine going to a hospital or a clinic for their regular checkup (Multimedia Appendix 3). The top 3 rankings, as determined by participants' averaged ranking scores, of the barriers and facilitators in each group are indicated in Table 3.

Participant AF28 mentioned that it was convenient to use human assistance, as he quoted, "Ask the security guard to go to the right floor. Then ask the receptionist and tell him or her."

Participant A07 pointed out the problem of finding a precise location by mentioning:

> *You've got to find the right floor. Just find the elevator. There are all kinds of challenges with that if you want to go a big place like, say, St. Michael's Hospital, and you have to go up to floor 8 or 10, which is very difficult to pinpoint.*

Table . Top 3 rankings of facilitators and barriers in order of importance to visit a hospital or clinic.

Rank	English group	Average (SD)	French group	Average (SD)
Facilitators—clinic				
1	Human assistance	1.4 (0.5)	Human assistance	2.1 (1.0)
2	Mobility aid	2.0 (0)	Preparedness	2.1 (1.2)
3	Preparedness	2.2 (1.0)	Accessible signage	2.7 (0.8)
Barriers—clinic				
1	Difficulty finding an exact location	1.9 (0.9)	Inaccessible signage	2.4 (1.4)
2	Unsuccessful interactions	2.3 (1.0)	Unsuccessful interactions	2.9 (1.4)
3	Difficulties walking around	2.6 (1.1)	Difficulty walking around	3.1 (1.4)

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Big Box Store

The participants were then asked to imagine shopping in a big box department store (Multimedia Appendix 3). The top 3 rankings of the barriers and facilitators in each group, and their averages, are indicated in Table 4.

Participant A10 mentioned the importance of human assistance by saying, "If you are making a comparison between items and prices. I find that having human intervention helps."

Participant AF33 mentioned the problems locating a precise item, quoting that "One thing that makes it difficult for me is, is it's either the top row or completely the bottom row."

Table . Top 3 rankings of facilitators and barriers in order of importance to shop at a department store.

Rank	English group	Average (SD)	French group	Average (SD)
Facilitators—shopping				
1	Human assistance	2.6 (1.9)	Website accessibility	1.9 (0.9)
2	Preparedness	3.9 (2.6)	Preparedness	2.5 (1.7)
3	Website accessibility	4.1 (2.0)	Human assistance	3.2 (1.9)
Barriers—shopping				
1	Difficulties walking around	2.8 (1.6)	Employee assistance request	1.0 (0)
2	Difficulty finding an exact location	3.1 (1.3)	Inaccessible signage	2.4 (1.5)
3	Problems locating a precise item	3.6 (1.6)	Difficulties walking around	2.5 (1.6)

Party

The participants were then asked to imagine going to a party with friends (Multimedia Appendix 3). The top 3 rankings of the barriers and facilitators in each group, and their averages, are indicated in Table 5.

Participant AF37 mentioned how help from friends can be an immense help to join a party by quoting:

> *I usually call when I am arriving, and how my friend, or whoever can you please meet me downstairs? That would be helpful because I usually will not know where the house is.*

Participant AF37 also mentioned how unsuccessful interaction with friends creates more difficulty by quoting:

> *For me the challenge is that in some kind, of course, people are moving around all the time, you know, going from group to group to group to group, and it's very over overwhelming to kind of follow that it's someone I know, and even work with there's people that I don't know, because I cannot pinpoint, or it's very hard for me to kind of just join a random group.*

Table . Top 3 rankings of facilitators and barriers in order of importance while going to a party with friends.

Rank	English group	Average (SD)	French group	Average (SD)
Facilitators—party				
1	Preparedness	2.0 (1.2)	Human assistance	1.2 (0.4)
2	Accessible physical space	2.4 (0.7)	Accessible physical space	2.7 (1.1)
3	Human assistance	2.6 (1.3)	Alternatives available	3.1 (1.2)
Barriers—party				
1	Difficulties walking around	2.6 (1.42)	Fear of spilling food or drink on others	2.0 (0.5)
2	Unsuccessful interactions	3.0 (1.7)	Noisy environment	2.5 (1.2)
3	High ambient noise	3.4 (2.2)	Difficulties walking around	2.5 (1.2)

Bus Travel

The participants were then asked to imagine going on public transportation such as a bus or metro station (Multimedia Appendix 3). The top 3 rankings of the barriers and facilitators in each group, and their averages, are indicated in Table 6.

Participant A10 mentioned what preparations could be made to make traveling on the bus more convenient, quoting:

> *There's a lot of research to be done ahead of time. You must know the stop numbers. You must know the intersections where those bus stops are. These are things you must know before getting there.*

Participant AF33 mentioned that the inaccessible signage was one of the major barriers, quoting that:

> *One thing is that the sign is way too high. It is sometimes 8 to 12, and even 14 feet high. I cannot*

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reach it by phone to be able to see if I am at the right spot.

Table . Rankings of facilitators and barriers in order of importance while going on public transportation.

Rank	English group	Average (SD)	French group	Average (SD)
Facilitators—public transit				
1	Accessibility of signage	2.8 (1.8)	Accessible signage	1.9 (1.1)
2	Preparedness	3.00 (2.2)	Accessible physical space	2.4 (1.1)
3	Accessible physical space	3.0 (1.3)	Human assistance	2.8 (1.5)
Barriers—public transit				
1	Inaccessible signage	2.1 (1.9)	Inaccessible signage	1.4 (0.9)
2	Unsuccessful interactions with staff or patrons	3.7 (2.2)	Difficulty finding an exact location	2.4 (0.8)
3	Difficulties walking around	3.9 (1.5)	Unexpected events	2.5 (1.3)

Scenario Comparison

Participants were asked which scenario was the most difficult to navigate on their own and were asked to explain their reasoning. The most barriers for the English group were indicated in the coffee shop (n=8) followed by department store (n=7) and bus or metro (n=7). For the French group, the most barriers were in the department store (n=9), followed by the hospital or clinic (n=7) and coffee shop (n=6). The fewest facilitators were mentioned in the hospital or clinic (n=5) for the English group, while it was the coffee shop (n=4) for the French group. For the French group, the department store had one of the largest barriers (n=9) and the largest number of facilitators (n=8). Meanwhile, the coffee shop scenario had both the most barriers (n=8) and facilitators (n=8) for the English group. Elaborated data are presented in graphs in Tables 7 and 8.

Among the facilitators identified, human assistance was consistently regarded as a major factor being present in all scenarios. Accessibility of physical space was also a significant facilitator observed in most scenarios (4 times in English and 5 times in French). Preparation was noted as a facilitator in 5 English and 2 French scenarios.

Regarding major barriers, nonaccessible signage and difficulty walking around were reported in almost all scenarios (5 times in English and 4 times in French). Unsuccessful interactions with others were identified in 4 English and 4 French scenarios. Difficulty locating precise locations also emerged as a barrier in 4 English and 4 French scenarios. Details for each scenario are tabulated in Multimedia Appendix 5.

When comparing the French and English groups, they were similar. While the groups perceived an equal number of barriers, the French group experienced fewer facilitators. The English group considered smartphone apps as one of the facilitators in every 5 scenarios, while the French group considered it as a facilitator in only 2 scenarios. Similarly, the English group seemed to be prepared and found preparedness as a major facilitator, while the French group pointed out preparedness as a facilitator in only 2 scenarios. Even though both groups had an equal number of barriers, nonaccessible signage, as well as difficulty walking around, were present in all 5 scenarios for the English group, while it was present in 4 scenarios for the French group.

Table . The number of barriers and facilitators experienced by people with visual impairments in each scenario among the English group.

English group	Barriers experienced, n	Facilitators experienced, n
Coffee shop	8	8
Hospital	4	5
Shopping	7	8
Party with friends	6	7
Public transportation	7	7

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Table . The number of barriers and facilitators experienced by people with visual impairments in each scenario among the French group.

French group	Barriers experienced, n	Facilitators experienced, n
Coffee shop	6	4
Hospital	7	5
Shopping	9	8
Party with friends	5	5
Public transportation	5	6

Use of Smartphone

To understand how smartphones can bring independence to people with visual impairments, we asked five questions, which were (1) What are the strengths and weaknesses of the currently available apps that you use? (2) What is missing from the currently available apps for the scenarios we described? (3) What would the ideal mobile app contain? (4) Among the above-given scenarios, in which situation would you prefer an app and in which one would you prefer human assistance? (5) Which of the above scenarios was the most difficult to navigate on your own?

For the first question, the participants provided examples of a few smartphone apps to share their strengths, such as being able to have voice commands and being user-friendly. Participants went on to discuss apps, such as Seeing AI, Google Maps, Soundscape, and BlindSquare, which they found especially useful and user-friendly. However, each app had its weaknesses. It was difficult to switch from one tab to another in Seeing AI. Google Maps is unable to work in indoor environments, and accuracy depends somewhat on the weather conditions. Soundscape, though, was very promising and user-friendly but was discontinued and required training. Similarly, the BlindSquare app also required training, which made the work tiring.

For the second question, participants explained that most of the apps do not have accessibility options like a back button. Furthermore, there was an issue with the GPS not being accurate, and a few participants mentioned the difficulty of navigating indoors. Additionally, all participants agreed that each app is incomplete and that to do each different task, they would have to switch between the different apps, which was troublesome. Further, they found it difficult to hold their phones to scan most of the time and advised creating a method with which they could be hands-free, which might not be as expensive as smart glasses.

For the third question, participants agreed that the ideal content would be to have all the features in 1 app so that they would not have to switch between the apps. Other ideal features included voice commands and hands-free operation. They also wanted the software to be sustainable and not drain excessive batteries from their phone.

For the fourth and fifth questions, there was a split in opinion among participants, while most of them agreed that any of them would love to have an app on their phone that would allow them to successfully navigate any of the given scenarios, a few participants expressed doubts about the feasibility of an app enabling independent travel in certain scenarios due to the complexity of tasks required in those environments.

More participant quotes can be found in Multimedia Appendix 6.

Discussion

Principal Findings

People with visual impairments encounter numerous issues in daily life that reduce their participation in social and leisure activities. The goal of our study was to better understand the perceived barriers and facilitators for everyday travel for 5 of these activities outside the home for people living with both low vision and blindness. This study was particularly focused on elucidating the context of the problems associated with everyday indoor travel environments to inform technology developers about priorities from those with a variety of lived experiences. This study takes a user-centered approach to enumerate perceptions and opinions even for individuals who may not be able to complete these tasks independently. Here, we discuss some of the major points that were prioritized by individuals in our focus groups and examine how technology developers may attempt to reduce the barriers while facilitating the use of mobile apps and other technologies to respond to the needs of people with visual impairments in the environments studied.

Barriers

Nonaccessible signage and difficulty walking around emerged as major concerns and were addressed in almost all scenarios. Particularly, inaccessible signage contributes significantly to the challenge of accessing written information for people with visual impairments, as highlighted in studies by Brown et al [23] and da Silva et al [3]. Several attempts have been made to improve the readability of signage for this population. For instance, Lan et al [28] developed lightweight smart glass equipped with a tiny computer to assist users in reading signage. While this technology proved helpful in reading street signs, it was not tested in people with visual impairments, and its functionality was limited to this single purpose. This might explain why the product has never reached the market yet. Similarly, Crandall et al [29] created an infrared audible signage system. However, it failed to gain popularity due to its complex sensor installation requirements and lack of usability. Even after training, the voice output was difficult for people with visual impairments to understand. To develop user-friendly technology, it is essential to involve end users from the prototype stage and

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conduct regular testing and refinements until the product meets their needs and ensures their comfort and satisfaction.

The theme of difficulties walking around, highlighted by the participants in our study, echoes the findings of Lamoureux et al [30]. For people with visual impairments, this remains a significant obstacle. One reason this challenge persists is that many systems are designed to either assist with outdoor navigation or indoor navigation, but rarely both. Transitioning between indoor and outdoor spaces is particularly difficult, possibly due to the challenge of recognizing entry and exit doors, sudden changes in lighting, the sensory overload caused by varying sounds and environmental conditions, and the absence of consistent orientation cues between these settings. The difficulty in finding a precise location and unsuccessful interactions with employees, volunteers, and other people present were identified as major obstacles in the proposed scenarios. Recognizing precise locations indoors is particularly challenging, as indoor environments hinder many sensory cues, and the widely used GPS does not function effectively indoors. To address these challenges, various alternative solutions have been explored, such as a guide beacon [31], Wi-Fi fingerprinting [32], and live streaming [33]. Each of these methods comes with its own advantages and limitations. Guide beacons, which are low-cost Bluetooth devices, must be strategically installed throughout the indoor spaces. Wi-Fi fingerprinting relies on consistent Wi-Fi signals and detailed floor mapping to operate effectively. Live streaming, on the other hand, requires a person to view the stream and provide location guidance, which is often impractical, inefficient, and expensive. Further research in these areas might provide us with better technology for overcoming these obstacles.

While human assistance was often a facilitator, unsuccessful interactions with employees emerged as recurring barriers in different scenarios. To improve social interaction, a Social-Aware Assistant was developed that could provide people with visual impairments cues to enhance their face-to-face interaction using a smart glass and haptic belt [34]. To achieve a level of independence for people with visual impairments, ATs and human assistance are inseparable [35]. Based on this, several attempts have been made such as FaceTime [36], AIRA [37], Be My Eyes [38], and Guide Call [39] to use human assistance in assistive devices. Even though these attempts have been made, they have not been widely popular during these scenarios. The major reason for this is being expensive if human agents are used and the unavailability of assistance when volunteers are used.

Facilitators

To overcome the obstacles encountered, the participants identified several strategies and tools that they use and the elements that assist them in accomplishing these everyday tasks. The findings indicate that the assistance of staff, volunteers, clients, or other bystanders is the most frequently used strategy, as identified in all 5 scenarios in each of the focus groups. This reliance on human assistance aligns with the results of the 2017 Canadian Survey on Disability [40], which reports that 58% of people with disabilities, including those with visual impairments, receive help with daily activities such as shopping or attending appointments. However, this dependence on others can be unsettling for people with visual impairments, as it limits their sense of independence. Therefore, technology could offer more empowering alternatives, allowing people with visual impairment to decide when to seek assistance. Some participants even expressed a preference for AI-based assistance over human help, as it made them feel more comfortable and in control.

Using smartphones with different functions was also one of the major facilitators. There is a huge improvement in technology, specifically in the smartphone, which has enabled several functions enabling people with visual impairments to perform most of their tasks conveniently. There are several apps designed for people with visual impairments with specific functions. Functions like zoom-in, improved camera quality, and voice command are the features that people with visual impairments mostly use. Mobile apps that were launched recently, such as Blind-Aid [41], HandyApps [42], AKSHI [43], and ARIANNA [44], which included multiple features for navigation for people with visual impairments, could be useful but were not mentioned by those in our study. Furthermore, there are other apps designed for specific tasks such as Farmaceutic App [45] for drug information, TransmiGuia app [46] for public transportation, and money-recognizing apps [47] could be useful as well. It was also interesting to find that smartphone apps were mostly found useful by the English group as opposed to the French group, which may be due to the language barriers provided in most of the apps. Mobile app creators should be conscious of the accessibility features in each of the available languages when creating and updating an app.

Preparedness emerged as an important facilitating strategy among study participants, alongside having an accessible environment and clear signage. Many participants relied on Google Maps and a mental image of the places they had previously visited. However, when traveling to unfamiliar locations, especially within complex indoor environments, there remains a lack of sufficient technology to assist people with visual impairments. Indoor maps are particularly challenging to create and maintain due to the complexity and frequent layout changes, making it difficult for existing technologies to offer reliable indoor navigation maps. Recently, SITUM [48] has been working to address this issue by developing comprehensive indoor mapping solutions through extensive global research. Furthermore, preparedness was found to be an important facilitator in the English group being present in all 5 scenarios but was only present in 2 scenarios in the French group. This might be linked with the use of smartphones, as preparation is mostly associated with smartphone use.

Signage is a key facilitator, benefiting both individuals with visual impairments and those with normal vision. To make signage more accessible, Rousek and Hallbeck [49] concluded that simple, high-contrast pictograms, depicting human figures, were most easily recognized by participants wearing glasses that simulated different visual conditions. They also recommend standardizing signage within hospitals to facilitate the cognitive processes related to understanding signs. Their findings can certainly be applied to written signage in complex environments.

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While several facilitators are used to navigate the obstacles experienced in various environments, some are implemented to avoid environments where these obstacles are particularly overwhelming. One such solution, adopted by many participants, is web-based shopping, which enables them to bypass department stores and grocery stores altogether. The ability to select items on the web and have them delivered at home not only eliminates the need for external assistance but also reduces the fatigue associated with in-store shopping. The significant benefit of web-based shopping for people with visual impairments is also highlighted by Kostyra et al [50], who studied the barriers and facilitators reported by people with visual impairments, including when visiting grocery stores. Indeed, they already pointed out a few years ago that the development of web-based shopping was a promising avenue for improving the satisfaction and independence of blind people, which is confirmed by our results. However, website accessibility remains an issue associated with web-based shopping for people with visual impairments.

Recommendations for Developers

The findings of this study offer direct implications for the design and refinement of ATs for people with visual impairments. Below, we outline several recommendations drawn from participant insights.

Human Interaction

In noisy, dynamic spaces like parties or coffee shops, participants described challenges in initiating and maintaining social interactions. AT could integrate features like facial expression recognition, conversational cueing, or proximity alerts to help users locate and engage with others more confidently.

Improve Indoor Navigation Capabilities

Participants identified difficulties in locating precise destinations indoors as a major barrier. Since GPS is often unreliable indoors, alternative technologies like Wi-Fi fingerprinting, Bluetooth beacons, or AI-powered computer vision should be explored to enhance spatial awareness and positioning accuracy.

Design for Multifunctionality and Hands-Free Use

Several participants expressed their frustration with switching between single-purpose apps. Developers should aim to integrate multiple features like object recognition, Optical Character Recognition, GPS, and communication support within a single platform. Voice-controlled or wearable solutions may further facilitate hands-free use and improve user experience.

Language and Accessibility Gaps

Participants from the French-speaking group noted that some apps lacked full functionality in French. Inclusive AT design must ensure multilingual support, compatibility with screen readers, and braille display integration to accommodate users across linguistic and accessibility needs.

Limitations

The data were only collected from people with visual impairments living in Canada, and most of our participants were from Quebec. Further research could collect data from all the provinces of Canada or other parts of the world to provide richer data. Since the data were collected from web-based interviews, it was only accessible to the individuals who had internet access and could use videoconferencing technology independently. In addition, though the sample size was diverse, it does not necessarily represent the views and opinions of many other Canadian people with visual impairments. Larger datasets around the world could help the AT industry to have better ideas of the requirements of people with visual impairments in their lived environments.

Conclusions

The results provide a better understanding of the realities of people with visual impairments in indoor, dynamic environments. Our results highlight that mobile technologies, though while facilitating, are not as critical to completing multiple everyday tasks outside the home. Human assistance, accessibility of physical space, and preparedness were found to be major facilitators but are considered barriers when absent or inaccessible. Smartphone apps should be considered within the larger context of completing daily tasks, as they may provide some assistance but will not be the universal solution. Additionally, language barriers must be considered, as many apps often do not have the full range of functionality in both languages, thus leading to a disadvantaged population of nonnative English speakers who may have encountered additional barriers, such as regarding preparedness. Further research should examine how mobile technologies perform when individuals are interacting with everyday environments outside the home in the context of other human factors (ie, communication) and accessibility of physical space (ie, available signage).

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Data Availability

All de-identified data generated or analyzed during this study are included in this published article in Multimedia Appendix. Any further datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

PRP contributed to data analysis, manuscript writing, and editing. AC and FG contributed to project development and data collection. SSK and DA contributed to writing and editing the manuscript. JPN guided the project from development to data collection to data analysis to manuscript writing. JPN is the co-corresponding author and can be reached via email at joe.nemargut@umontreal.ca or phone at 514-343-6111 (ext 4814).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire for selection of participants for focus group.
[DOCX File, 18 KB - rehab_v12i1e73380_app1.docx]

Multimedia Appendix 2
Profiles of 38 people interviewed, using the selection questionnaire.
[DOCX File, 35 KB - rehab_v12i1e73380_app2.docx]

Multimedia Appendix 3
Scenarios and subtasks.
[DOCX File, 21 KB - rehab_v12i1e73380_app3.docx]

Multimedia Appendix 4
Summary heat map of the facilitators and barriers (rows) in the French and English focus groups for each scenario (columns), according to their ranking order, as determined by the average responses from participants.
[PDF File, 103 KB - rehab_v12i1e73380_app4.pdf]

Multimedia Appendix 5
Complete rankings of the facilitators and barriers in order of importance to visit different scenarios for the English and the French focus groups.
[DOCX File, 40 KB - rehab_v12i1e73380_app5.docx]

Multimedia Appendix 6
Example quotes from participants for each theme.
[DOCX File, 35 KB - rehab_v12i1e73380_app6.docx]

Checklist 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File, 433 KB - rehab_v12i1e73380_app7.pdf]

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Abbreviations

AI: artificial intelligence
AT: assistive technology
COREQ: Consolidated Criteria for Reporting Qualitative Research

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Original Paper

Perspectives From Multidisciplinary Professionals in France on Shared Patient Portals for Integrated Pediatric Rehabilitation: Qualitative Study

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Abstract

Background: Providing integrated care is essential in pediatric rehabilitation, as children with disabilities often navigate complex, long-term pathways involving multiple professionals across health, education, and community services. Strengthening communication and partnership among children, families, and professionals is key to supporting meaningful participation in daily life. Shared digital health portals offer a promising solution to support integrated care, yet their potential remains underexplored in this context.

Objective: This study explores the perspectives of multidisciplinary professionals involved in pediatric rehabilitation on shared patient portals designed to support integrated care for children with disabilities.

Methods: An interpretive descriptive qualitative study grounded in a constructivist epistemological position was conducted. Data were collected through semistructured online interviews with professionals purposively recruited using maximum variation sampling. All were involved in the rehabilitation pathways of children with motor, cognitive, or mental disabilities in France. Interview verbatim transcripts were analyzed using NVivo (version 14, Lumivero) by an interdisciplinary team of researchers, including parents and clinicians, using a thematic analysis approach. Theoretical saturation was reached.

Results: A total of 32 professionals, including clinicians, educators, social workers, and coaches working in hospitals, rehabilitation centers, outpatient clinics, or private practices, integrated health and social services, schools, nurseries, leisure associations, and social services, participated in this study. Four themes captured professionals' ambivalent perspectives on portals, addressing their perceived contributions to integrated care, anticipated barriers, practical strategies for implementation, and expectations regarding features: (1) ensuring continuity across health, education, and recreation services: navigating transparency, confidentiality, and inclusion; (2) enhancing family partnership while preserving professional autonomy and navigating engagement diversity; (3) involving children in patient portals: from children's empowerment to professionals' ethical responsibility; and (4) the contrast between concerns about additional workload and beliefs regarding efficiency. Participants suggested features such as shared

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calendars, secure messaging, and tools to share videos, rehabilitation goals, and track progress, alongside practical strategies to support real-world adoption.

Conclusions: This study highlights the perceived potential of shared patient portals to strengthen partnerships and fruitful collaboration among children, families, and professionals involved in the pediatric rehabilitation pathways, including education and recreation providers. Professionals proposed concrete features to support integrated care, informing the development of tools likely to improve the quality of rehabilitation services. Future studies should explore the perspectives of children, families, and decision makers to support effective implementation and evaluate the real-world impact.

Trial Registration: ClinicalTrials.gov NCT06570148; https://clinicaltrials.gov/study/NCT06570148

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KEYWORDS

children with disabilities; pediatric rehabilitation; integrated care; shared health patient portal; patient and family-centered care; patient and family partnership; education; recreation and community; social; qualitative study

Introduction

Children with disabilities face "long-term physical, mental, intellectual, or sensory impairments that, when interacting with various barriers, may hinder their full and effective participation in society on an equal basis with others" [1]. Pediatric rehabilitation aims to support meaningful participation in daily life, not only through health care but also by addressing educational, social, and community dimensions [2,3]. Rehabilitation in childhood is inherently interdisciplinary and family-centered, requiring active collaboration between families and a diverse range of professionals [4,5]. This broad perspective requires coordinated and continuous support over time, between visits and throughout the child's development, including critical transitions into adulthood [6]. Therefore, effective communication and information sharing among all stakeholders are essential to ensure that care remains responsive to each child's evolving needs and preferences [7] and are key to delivering integrated care, which is characterized by coordination, continuity, and shared decision-making with patients and caregivers [8,9].

Nevertheless, effective communication in pediatric rehabilitation remains a significant challenge [10]. Children with disabilities have long-term needs that involve multiple settings, organizations, and professionals [11], who rarely share information systems or communication standards. The dynamic nature of child development also creates challenges for maintaining continuity and adapting care over time. As a result, care pathways are often fragmented, interprofessional collaboration is limited [12,13], and families are left to navigate complex systems alone [14]. For professionals, poor care coordination leads to redundant efforts, inefficient communication, and increased workload [15]. These issues undermine care quality, contribute to poorer quality of life for children and families, and heighten the risk of unsuccessful interventions [10], resulting in higher service use [16].

Digital solutions, including shared patient portals, offer promising ways to improve communication and care integration [17,18]. These tools can facilitate access to information, support shared decision-making, and enable better coordination between children, families, and professionals [19,20]. While patient portals are increasingly recognized as valuable tools in other health care contexts [21], such as among older adults [22] and in stroke care [23], the potential for their use remains underdeveloped and underexplored in the context of childhood disability. To our knowledge, no existing portal has been specifically designed for pediatric rehabilitation, which involves complex, long-term, and cross-sectoral care requiring coordination across evolving developmental stages [11,24]. As a result, there is a need to develop more knowledge and tools specifically designed to meet the requirements of integrated pediatric care and that are better suited to real-world practice.

Professionals are both primary users and key gatekeepers of these solutions. However, studies show that professionals often perceive significant barriers to adopting eHealth tools, including concerns about workload, data privacy, and the usability or relevance of available solutions [25,26]. Therefore, to ensure that digital tools effectively support integrated pediatric rehabilitation and align with professionals' practices, it is essential to gather their perspectives, including their concerns, needs, and expectations [27]. Taking this feedback into account and co-designing digital technologies with users ensures that they address real-world needs and challenges [28].

This study aims to address this gap by exploring the perspectives of professionals involved in pediatric rehabilitation regarding shared digital health portals designed to support integrated care for children with disabilities.

The following research questions guide the research:

- How do professionals perceive the potential contributions of shared digital health portals to integrated pediatric rehabilitation care?
- What barriers and concerns do they anticipate in using such portals in their practice?
- What practical solutions do professionals identify to support successful implementation in real-world settings?
- What are their expectations regarding key portal features to support integrated pediatric rehabilitation care?

This study is part of a broader research project exploring the perspectives of children with disabilities, their families, and professionals on shared digital health portals for integrated pediatric rehabilitation. As professionals play a critical role in implementing and supporting such tools, understanding their perceived usefulness, concerns, and constraints is essential for

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designing a portal that can meaningfully support integrated rehabilitation care for children and families. These findings will directly inform upcoming participatory phases involving children and families to co-design a portal that meets stakeholders' needs and can be realistically adopted in real-world settings.

Methods

Study Design

An interpretive descriptive qualitative methodology was used [29], as it offered an appropriate approach to explore complex experiential questions while producing practical outcomes [30]. We adopted a constructivist epistemological position, recognizing that reality is multiple, contextual, and socially constructed [31], to generate meaning through a collaborative dialogue between researchers and participants.

Semistructured individual interviews were conducted to explore professionals' thoughts, attitudes, and perceptions in depth [32]. An interview guide was designed by authors MK and CP, based on the research questions, with feedback from the researchers. The guide was pretested with a physiotherapist who had experience in different pediatric rehabilitation settings (hospitals, rehabilitation centers, and outpatient clinics or private practice) and modified throughout the interview process by the 2 interviewers (MK and TR). The final version of the guide contained 9 open-ended questions with prompts (Multimedia Appendix 1). The first part focused on the opportunities and concerns perceived by professionals about the role of **eH**ealth in facilitating the provision of integrated care in pediatric rehabilitation and suggested features to improve the pediatric rehabilitation pathway. In the second part, features of an existing health portal developed for adult rehabilitation (Deneo santé, Deneo SAS) were shown to the participants for (1) the sharing of reports, images, photos, and videos between patients and professionals, (2) a database of validated rehabilitation measurement scales and questionnaires, (3) the monitoring patient progress using graphs, and (4) the prescription of self-rehabilitation exercises. This demonstration aimed to help professionals visualize a concrete digital tool, explore the acceptance of using such a portal [33], and generate ideas for its features. Finally, participants were invited to recommend strategies for implementing such tools in their practice.

Study Participants and Recruitment

The inclusion criteria were professionals involved in the rehabilitation pathway of children with physical, cognitive, or mental disabilities working in France. Purposeful sampling with maximum variation [34] ensured participant heterogeneity based on work setting, profession, age, years of experience, digital literacy, and region of France. Regional variation was considered to account for differences in pediatric rehabilitation care coordination across France. First, participants were selected according to these criteria through FRISBEE (Fédération Médicale et Universitaire des SMR Pédiatriques de Bretagne Occidentale) [35], a network coordinating research, health care, and teaching in pediatric rehabilitation in France. Snowball sampling [36] was also used to recruit additional participants, particularly from the education sector. More specifically, the first 5 participants interviewed highlighted the need to involve school assistants and professionals from leisure and sports associations in shared patient portals and provided contact details for relevant professionals. For this reason, from an integrated care perspective, both professionals working in rehabilitation settings (eg, physiatrists, occupational therapists, physiotherapists, kinesiologists, psychologists, speech therapists, nurses, and educators working in hospitals, rehabilitation centers, outpatient clinics or private practice, and integrated health and social services) and those in education and recreation settings (eg, nurses, psychologists, teachers, sports coaches, and those working in elementary, middle, and high school and sports and leisure associations) were included. MK and CP discussed each participant's profile to ensure it differed from previous participants. Theoretical saturation was applied pragmatically to determine the final sample size [37], aligning with the constructivist epistemology of interpretive description, emphasizing practical, context-sensitive understanding rather than exhaustive thematic saturation.

Data Collection

Interviews were conducted in French via videoconference (Zoom Pro, Zoom Video Communications, Inc) between February and July 2024. They were audio-recorded and lasted between 36 and 88 (mean 60, SD 9.9) minutes. Two researchers conducted the interviews: MK, an occupational therapist trained in France and Canada, PhD candidate in rehabilitation sciences and experienced in qualitative health research, and TR, an occupational therapist pursuing a Master's degree in research. Both had received specific training in qualitative interviewing methods, including formal coursework and supervised practice. Neither researcher had any prior relationship with the participants. After each interview, they discussed the process to ensure consistency in the questions and to adjust the guide if needed, and took reflective notes to document their postinterview impressions and any issues for consideration in the analysis. Participants' sociodemographic data were collected at the end of the interview (Table 1). Digital literacy was self-assessed using a Likert scale between 0=no competence and 10=full competence. A score of 10 meant being able to download an application, share files easily, and take ownership of a new technology. eHealth use was defined as using apps, web platforms, or health portals (excluding electronic health records) to communicate with providers or monitor children's progress.

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Table 1. Sociodemographic characteristics of participants.

Characteristics	Values
Gender, n (%)	
Women	24 (75)
Men	8 (25)
Age (years)	
Mean (SD)	39.2 (8.1)
Range	26-55
French region, n (%)	
Brittany	11 (34)
Paris region	6 (19)
Auvergne-Rhône-Alpes	5 (16)
Pays de La Loire	2 (6)
Occitanie	2 (3)
Normandy	1 (3)
Nouvelle Aquitaine	1 (3)
Provence Alpes Côtes d'Azur	1 (3)
Bourgogne Franche Comté	1 (3)
Réunion Island	1 (3)
Grand Est	1 (3)
Profession[a]	
Rehabilitation professionals	14
Coordinator of a mobile team	1
Occupational therapist	3
Physiotherapist	3
Kinesiologist	3
Psychomotor therapist	2
Physicians	4
Physiatrist	2
Pediatrician	1
School physician	1
Psychologists	3
Psychologist	2
Neuropsychologist	1
Educators and educational assistants	4
Educators	2
Educational assistant	1
Childcare assistant	1
Teachers	3
Specialized teacher	1
Referent teacher	1
Coordinating teacher	1
Social workers	2
Social worker	1

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Characteristics	Values
Nurse	1
Sports coach	1
Team manager	5
Type of working facility[a]	
Hospital, n (%)	6 (19)
Rehabilitation center, n (%)	5 (16)
Integrated health and social services, n (%)	5 (16)
Outpatient or private practice, n (%)	4 (13)
Schools or nurseries	12 (38)[b]
Elementary school	3
Middle school	4
High school	1
All classes	2
Nursery	2
Leisure or sports associations	5 (16)[b]
Sport association	3
Leisure association	2
Social administration, n (%)	1 (3)
Years of experience in pediatrics	
Mean (SD)	12.9 (8.4)
Range	1-34
Pediatric specialty, n (%)	
General (any type of disability)	22 (69)
Specific (particular disability)	10 (31)
Digital literacy (self-rated 0-10)	
Mean (SD)	7.4 (1)
Range	4-10
Previous or current use of shared patient portal (excluding clinician-only electronic health record), n (%)	
No	25 (75)
Yes	7 (25)

[a]Participants could have multiple professions and work in multiple types of facilities.

[b]n (%).

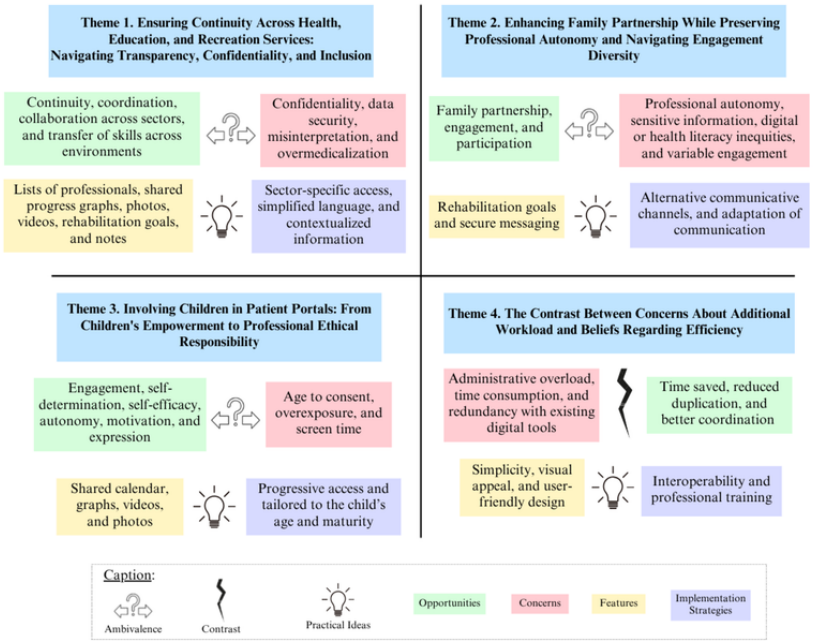
Data Analysis

Audio recordings were transcribed verbatim using artificial intelligence–based transcription software (Easy-Peasy.AI, Easy-Peasy.AI Pte Ltd) and double-checked by the interviewers for accuracy. Thematic analysis was conducted following the 6-step approach by Braun and Clarke (2006) [38]. First, 2 researchers (TR and GT) independently coded 4 interviews using NVivo (version 14), based on an initial coding tree informed by the interview guide and aligned with the research questions (see colored squares in Figure 1). The aim of this initial double coding was not to compare or validate interpretations, but to generate a broad range of codes and foster analytical and reflexive dialogue that enriches the interpretive process. The resulting codes and subcodes were discussed with MK to refine the coding framework inductively, grounded in the data. The remaining interviews were then coded individually by TR, GT, and MK. Weekly meetings with CP supported the iterative refinement of themes. Themes identified by the coding team were based on patterns across the data and refined with input from the broader research team. Two parent partners (CKC and AG) critically reviewed transcripts and theme labels to ensure balanced interpretation of the diverse professionals' perspectives and supported reflexivity by questioning assumptions embedded in the data. Their input contributed directly to the refinement of cross-setting themes, such as the

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ambivalence within the principles of family and patient partnership. MK and CP reviewed and renamed the themes and subthemes during this paper's preparation.

Figure 1. Thematic summary organized by the 4 research questions guiding this study (opportunities, concerns, desired features, and implementation strategies).



Data saturation was assessed as a practical and iterative judgment during data collection and analysis [39]. After each interview, the coders discussed emerging codes with CP to determine whether additional data contributed substantively new insights to the evolving interpretation [37]. After 30 interviews, no new codes or themes emerged; new data only confirmed or deepened existing themes. To confirm saturation, 2 additional interviews were conducted with participants from slightly different professional backgrounds (P31 and P32, see Table 1).

Trustworthiness and Reflexivity

To ensure trustworthiness, several strategies were adopted [31]. Credibility was supported by analyst triangulation involving researchers from diverse backgrounds (public health, physiatry, occupational therapy, and parent partners) [40]. Initial coding was performed independently by 2 researchers, followed by regular team discussions. Participants were invited to review their transcripts (5 accepted but none provided feedback), and an online member-checking discussion with 3 participants confirmed the findings' accuracy [41]. Transferability was enhanced with detailed sociodemographic reporting to support contextual interpretation and the contextualization of findings in the discussion, thereby aiding readers in assessing their applicability to other settings. Dependability was addressed through a reflexive journal documenting methodological decisions. The COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist was used to report the methodology of the current study and ensure that information was complete [42] (Multimedia Appendix 2). For confirmability, analysts individually responded to the reflexive question from the triangulated inquiry framework by Patton [43] to examine how personal and professional experiences influenced data collection and analysis, and they shared their reflections during team meetings to foster critical reflexivity [44]. For example, the principal investigator (MK) acknowledged that her strong commitment to patient partnership initially led her to emphasize data supporting this perspective. Through ongoing reflexive discussions within the team, particularly with parent partners, she critically re-evaluated her decisions to ensure a more balanced representation of diverse and contrasting viewpoints.

Ethical Considerations

This study was approved by the "Comité de Réflexion Éthique de Territoire"—Territorial Ethics Reflection Committee—of Brest University Hospital (B2024CE.05). All participants received an information and consent form and consented to the audio recording. Each participant was assigned a pseudonym, and any identifying information was removed from the verbatim transcriptions of interviews. The names of the children mentioned in the verbatim were changed. Participants did not receive financial compensation for their participation.

Results

Participants' Profiles

In total, 45 professionals were contacted by phone, email, or LinkedIn. Ten professionals did not respond, and 3 refused because they considered themselves inexperienced (n=2) or had recently changed jobs (n=1). The final sample consisted of 32 professionals, with 20 different professions represented, working in a hospital (n=6), rehabilitation center (n=5), outpatient clinic or private practice (n=4), integrated health and social services

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(n=5), high school (n=1), middle school (n=4), elementary school (n=3), nursery (n=2), sports associations (n=3), leisure associations (n=2), and social administration (n=1). Four professionals were working in 2 different settings. The median age of the participants was 39 (range 26 to 55, IQR 32.8-46.3) years, with a majority of women (n=24), and they came from 11 regions of France (out of 13). The median digital literacy score was 7.4/10 (range 4 to 10, IQR 7.0-8.0). Seven participants have already used shared patient portals. Participants' characteristics are described in Table 1.

Specific Results

Overview

The analysis revealed 4 themes related to the perspectives of professionals on digital health portals in pediatric rehabilitation: (1) ensuring continuity across health, education, and recreation services: navigating transparency, confidentiality, and inclusion, (2) enhancing family partnership while maintaining professional autonomy and navigating engagement diversity, (3) involving children in patient portals: from children's empowerment to professionals' ethical responsibility, and (4) the contrast between concerns about additional workload and beliefs regarding efficiency. The 4 themes are summarized in Figure 1, shown as colored squares linked to the 4 research questions on portal contributions, barriers, solutions, and key features. Colors represent different aspects of professionals' perspectives: green for opportunities, rose for concerns, yellow for features, and violet for implementation strategies.

Theme 1: Ensuring Continuity Across Health, Education, and Recreation Services: Navigating Transparency, Confidentiality, and Inclusion

All participants perceived shared patient portals as a meaningful opportunity to build a rehabilitation continuum, bridging existing gaps in collaboration between health care, education, and recreation services. For education professionals, this fragmentation was often attributed to differing professional cultures and practices:

> *[Health-school] meetings [once a year] are a battle to know who [health professional or teacher] is going to succeed in doing something. We're too much in opposition. We don't work together. There's a school-care divide.* [P21, psychologist in an elementary school]

> *The rehabilitation professional often works individually and observes things about behavior in a dual relationship. But these observations are not necessarily the same in a group setting like the classroom. It needs to be refined so that these two worlds, which work in completely different ways, can agree on each other's needs.* [P17, referent teacher in an elementary school]

To address this, some participants suggested identifying and clearly displaying all professionals involved in a child's care through a list, for example, to facilitate communication and collaboration:

> *If [with the app] we can link the school with rehabilitation and outpatient care. It would change our lives, that's for sure.* [P08, occupational therapist in health and social services]

> *A list and photos with regular monitoring, other professionals involved in the past, present, and future.* [P12, specialized teacher in an elementary school]

A shared portal was envisioned by professionals in the community as a tool to bring professionals together around the child and place them on equal footing, recognizing the valuable insights of education and recreation professionals:

> *For educational continuity [...] without splitting up the child and their pathway. [...] An educator in a leisure setting provides information just as important because it's a social space that differs from home or school. [...] It has to be put on the same level to create richness for individual and group observations.* [P19, educator and manager in a leisure association]

> *Being all together on one platform puts everyone on an equal footing [...] It could allow people to feel like they're functioning together in the same direction for the child.* [P21, psychologist in an elementary school]

To support this continuity, some participants suggested that shared progress graphs could strengthen the school's sense of involvement in the child's developmental journey:

> *Highlighting the child's shared progress would help the school feel more connected with the collective success.* [P21, psychologist in an elementary school]

Almost all professionals emphasized the importance of exchanging information updates about the child's development across different environments, considering the evolving needs of children with disabilities. They highlighted the value of sharing practical information about adaptations and tools familiar to the child in everyday contexts to support children's participation, through shared notes or secure messaging:

> *For young, autistic children in the early stages of the diagnosis, there is a very frequent need for information from the parents on all the stages of development, the children's progress, at home, at school, at the nursery, in the playground...* [P28, neuropsychologist in health and social services]

> *A chat, with one-on-one or group conversations, would be amazing. We could easily communicate with each other about the child.* [P03, psychomotor therapist in private practice]

Health care professionals valued the importance of sharing these daily observations with education professionals to help them understand how the child applies new skills across settings:

> *Something like a life notebook at school, to share everything the child does daily between partners, to be able to generalize all their learning.* [P28, neuropsychologist in health and social services]

> *To be able to exchange [with school] on useful adaptations [...] alternative and augmentative communication tools [...] how to avoid stimuli that*

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> *provoke a crisis [...] small things that we can all easily implement and that can be very, very facilitating for children.* [P15, speech therapist in health and social services]

To support this transfer of skills, some professionals also proposed sharing rehabilitation goals through visual content such as photos, videos, or daily observations, making it easier for other stakeholders to reinforce these skills in everyday situations:

> *Knowing what the goals of rehabilitation, medical follow-up, or school would allow us to say "perhaps we can do the same."* [P23, manager and kinesiologist in a leisure association]

> *Tying shoelaces is something we can do […] With a short video, we would know how to explain it to him.* [P26, childcare assistant in a nursery]

However, some participants warned of the risks associated with misinterpretation, especially when information is presented without proper context:

> *Control the dissemination of data to avoid interpretations that could be prejudicial to young people. [...] If you take an event out of its context and the whole history of the young person, it can be dangerous, because you can stick a label on a young person.* [P31, coordinating teacher in a middle school]

Therefore, a professional emphasized the need for systematically contextualized and nuanced information within portals to avoid reductive or inaccurate conclusions:

> *From one environment to another, children's reactions are going to be different. So, we can't restrict ourselves to the platform and information from other professionals.* [P23, manager and kinesiologist in a leisure association]

One participant explicitly opposed sharing information with professionals from the education sector, citing strong concerns about confidentiality:

> *In healthcare, there's a certain level of security, but when you mix with school... During team meetings with the school, we don't talk much about medical information in front of educators and teachers. So, there's a concern about data protection when you involve many people from different backgrounds.* [P24, physiotherapist in an outpatient clinic]

To mitigate these concerns (Textbox 1), several participants proposed sector-specific access to shared portals, including dedicated sections and simplified language for non–health care professionals:

> *We could imagine specific access for teachers [...] I used to write my reports so that they could be read by the teachers, always, always, always. So that this exchange could take place.* [P16, speech therapist in a hospital]

Textbox 1. A large majority of participants emphasized that improved information exchange could enhance children's participation in daily life contexts, such as home, school, and recreation. This continuity was seen as essential for children's inclusion. These are the quotes on this.

- A child with a motor disability can still participate in certain activities. I think this could reassure teachers about what they can expect from a pupil. Because they might be afraid of doing something wrong.

  [P20, social worker in a middle school]

- At school, after 3 minutes, Sacha was red-faced and couldn't take it anymore. So, they'd quickly get worried and put him aside. As a result, he didn't do any sports at school. It would have been a good idea to tell them no, he can do it, to show them Sacha's limits, they would have known what's possible for him.

  [P30, coach in a sports association]

- To have a real continuity. Learning happens through repetition, and a one-hour-a-week session isn't enough [...] If on the app we can see where the child is at and say to parents: "he's capable of doing this, this week, you can encourage him to do it." [...] About the child's skills during the session and how we can transfer them to the classroom.

  [P08, occupational therapist in health and social services]

However, one professional warned that shared portals could reinforce a specialized, overmedicalized framing of disability, blurring the line between inclusive practices and rehabilitative logics:

> *The kid already makes the effort to go to physio, OT… and now, they'll go to leisure activities the same way, as if it's just another rehab session. […] We have to be careful not to fall back into a logic where everything gets over-medicalized. Some families fought hard to get out of the specialized system. […] Even if the intention is inclusive, the tool could make it feel like we're going backwards.* [P19, educator and manager in a leisure association]

Theme 2: Enhancing Family Partnership While Preserving Professional Autonomy and Navigating Engagement Diversity

All participants mentioned communication gaps with families, and some professionals emphasized that this lack of coordination and communication compromised family engagement and continuity of care:

> *When there's a lack of communication between the different partners, the family might not adhere so well. [P31, coordinating teacher in a middle school]*

Portals were perceived by several participants as a potential tool to strengthen partnerships with families by facilitating sustained

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contact and transparency, which they felt was essential to effective rehabilitation:

> *An app would be great if it helped foster links between professionals and families.* [P15, speech therapist in health and social services]
>
> *[in rehabilitation] we have a different approach with children and families, considering them as partners, with a more inclusive approach, with the ultimate aim of achieving self-determination in adulthood. e-health has an important role in this follow-up and the participation of patients and families. [P13, physiatrist in a hospital]*

More specifically, 1 participant mentioned that portals could support active family involvement in setting and tracking rehabilitation goals, which could, in turn, foster greater family participation:

> *Seeing that they are the ones who set the goals, and the goals are worked on by all stakeholders, through something coordinated, families would be more willing to participate in rehabilitation.* [P01, coordinator of a mobile rehabilitation team]

A few professionals suggested integrating secure messaging for families, but with clear boundaries, to prevent overuse or intrusion:

> *A messaging system with families. But the framework would need to be defined with them to define boundaries. It shouldn't become overwhelming.* [P02, psychologist in a rehabilitation center and private practice]

However, participants expressed divergent views about the degree and nature of family involvement. Several professionals raised concerns about how parental access might limit open communication between colleagues, particularly when navigating complex or sensitive issues:

> *When children have behavioral or psychological difficulties, it's not easy. The child's legal representatives shouldn't have access because it's complicated. Sometimes, it's hard to talk about certain things.* [P16, speech therapist in a hospital]
>
> *There's information that I wouldn't want to tell the family, but that I would want to tell other professionals.* [P03, psychomotor therapist in private practice]
>
> *Sharing emotions between professionals is part of our job, and the parents should not necessarily take part in that…* [P06, occupational therapist in a hospital]

To mitigate this, 1 participant advocated full transparency with families but stressed the need for parallel channels to handle sensitive matters:

> *I wouldn't feel comfortable putting up documents that parents couldn't access. [...] For me, parents are 100% responsible for their child's care.* [...] I'm not going to share concerns about abuse on this app for the attending physician to see. I would drop in or make a phone call. It would be better for parents to keep control of the app. [P28, neuropsychologist in health and social services]

Other participants emphasized that if families were granted access, the information shared should be accessible and understandable to them, requiring professionals to modify how they communicate:

> *If they have access, the idea is for patients and parents to be partners. After that, it's up to the professionals to adapt, to share the difficulties they encounter with patients and parents, and to use words that everyone can understand.* [P06, occupational therapist in a hospital]

Still with an adapted language, several participants underlined structural barriers to family engagement in digital platforms, including digital literacy, language, and social precarity, which could exacerbate inequalities in access and engagement:

> *For foreign parents or those living in poverty, written information can be very difficult to access.* [P27, educator in a rehabilitation center]
>
> *In our area, we have quite a few illiterate parents, so that would be complicated.* [P13, physiatrist in a hospital]

Still, not all professionals believed that digital tools would necessarily foster stronger engagement. One participant expressed frustration with what they perceived as persistent family disengagement:

> *Sometimes, families just don't care at all. Depending on the families, but some don't help us.* [P24, physiotherapist in an outpatient clinic]

Theme 3: Involving Children in Patient Portals: From Children's Empowerment to Professional Ethical Responsibility

Participants highlighted the potential of patient portals to engage adolescents in their rehabilitation journey meaningfully. All participants mentioned at least 1 way these tools could empower children by increasing transparency around their health data. Given the long duration of rehabilitation and the potential fatigue children experience, many professionals viewed portals as a valuable tool to support self-awareness, particularly during adolescence, with features to visualize their rehabilitation goals and track their progress over time:

> *In high school, rehabilitation follow-up is often more difficult because it's the teenage period. Young people are a little fed up with rehabilitation. [The app] would give them a global vision of what it's all about, what the purpose is, and everything they've achieved.* [P20, social worker in a middle school]
>
> *Children could see their progress, with different levels along the way. If the goal is to ride a two-wheeled bike to school, and they're able to keep their balance on the way home, that's already great. It could encourage the child.* [P06, occupational therapist in a hospital]

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Most professionals also emphasized how patient portals could support clearer communication for children, helping them understand their rehabilitation journey and the purpose behind different interventions, through a unified discourse:

> *Children have a lot of different people working with them, and as it's always a dual relationship, if no one has a somewhat uniform discourse, it creates vagueness, and I think it's deleterious for the child.* [P29, physician in a middle school]

> *The coordination provided by the app would make it possible to have coherent and consistent care for children. They would see that everyone is working towards the same goal, and that there isn't one professional doing one thing, and another doing something else, and another different technique at school.* [P01, coordinator of a mobile rehabilitation team]

Maintaining motivation was another key opportunity. By allowing children to track their progress with visual tools such as graphs, videos, or photos, some professionals believed that portals could enhance self-efficacy and motivation, particularly for children with disabilities who do not realize their potential:

> *A lot of kids doubt their skills. [...] Having graphs could help them to see their progress from the beginning and see that they succeeded quite well in the exercises.* [P16, speech therapist in a hospital]

> *Being able to validate children's progress through videos would be motivating for the child. I am sometimes quite surprised by how a child does not realize the extent of their skills.* [P08, occupational therapist in health and social services]

One professional perceived patient portals as a way to address the communication challenges faced by some adolescents, especially those who struggle to express themselves during consultations:

> *A digital tool, especially for teenagers, who don't necessarily talk during consultations because their parents are present. [...] It has to be the child who fills in the application so that they're invested in it. That they have access to their data and distribute it to whoever they wish.* [P25, physiatrist in a rehabilitation center]

Several participants also recognized the importance of treating children as partners in their care, just as they did with families. This partnership dynamic was emphasized as a key advantage of portals:

> *The relevance of this tool compared to others would be the patient partnership. It's not a transmission software between professionals; it's rather a tool that enables collaboration with patients. That would be the real added value.* [P02, psychologist in a rehabilitation center and private practice]

Despite these promising aspects, several professionals expressed several concerns related to their ethical responsibility to protect children. Notably, there was a divergent view about the appropriate age for children to consent, with participants suggesting a wide range of ages. One key concern was granting children early access to health data, which they feared could complicate communication in sensitive situations:

> *We already use filters with parents, but if the child has access, we'll filter even more. […] There are meetings in which the situation is very complicated, but we don't want to hurt the parents, so nothing is said during the meeting. And then when we come out, no one is happy because we didn't address the real problems, and we didn't want to get in the way. So, I think it's better if the child is not in the app too early.* [P29, physician in a middle school]

Several participants also expressed concerns about the evolving nature of children's consent and the possibility that they might later regret having shared certain information:

> *There are perhaps not the same commitments in terms of consent when you are 6 years old or when you are 17.* [P19, educator and manager in a leisure association]

> *[For patients] not realizing what they are sharing and then regretting it, that's what scares me a little.* [P04, physiotherapist in health and social services]

To address these concerns, some professionals suggested that access to such portals should be progressive, tailored to the child's age and maturity. Early access could be limited to basic, visual elements, with more detailed features becoming available as children grow and develop autonomy:

> *It depends on each child's maturity and needs. At six, maybe they can just see photos of who's involved in their care, their role, the times or days. And then the rest can come gradually.* [P12, specialized teacher in an elementary school]

> *At first, they could use it with their parents. By around age 10, depending on maturity, they're usually able to say what they need, how it works, and whether it's helpful or not. They're beginning to show the ability to reflect and make informed judgments.* [P21, psychologist in an elementary school]

Even with gradual access, some professionals remained concerned about excessive monitoring of children through portals, which could compromise their privacy and autonomy:

> *Not everyone should know everything. We are in a bit of a culture today of sharing everything, and I think we have to be wary because it is good for a young person to go to a place where not everyone knows their whole life story and their whole disability.* [P14, community manager in a sports association]

> *We must give others the freedom to be and to do what they want, and not to be tracked in terms of behavior or events. I would freak out if I had information about me saying that I was at the leisure center this summer, I was nice, and then afterwards, I got a little angry. That's life! [...] There's a red flag on that.* [P19, educator and manager in a leisure association]

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Beyond age-related access concerns, 1 participant worried that full access to information might be too confronting for young people with severe or progressive disabilities:

> *It's complicated because these children often mourn a professional project incompatible with their condition. Having access to all exchanges might add another burden when they already have a lot to bear. It should be evaluated case by case, considering the young person's wishes and pathology.* [P29, physician in a middle school]

Finally, screen time was also raised as a concern by several participants, especially regarding its impact on children's health and development:

> *We are already trying to tell parents to reduce screen time so much! If we offer videos or things on screen to children who are non-readers, I think it will have to be done well.* [P15, speech therapist in health and social services]

> *We try to get them off the screens, and then we give them an app! But at the same time, it's also a tool that can be used positively, so it's both.* [P10, kinesiologist in a hospital]

Theme 4: Contrast Between Concerns About Additional Workload and Beliefs Regarding Efficiency

Almost all professionals mentioned the additional time burden posed by digital portals as a primary concern. One of the main reasons was the presence of multiple existing technologies, especially when professionals had to enter information into various systems, such as electronic medical records:

> *We're already swamped with paperwork and things to do. At work, they're already asking me to fill out more and more documents. If, on top of that, I have an app where I have to fill in even more, that would be a huge hindrance for me.* [P24, physiotherapist in an outpatient clinic]

> *The barrier is the time it takes to use it. Because the way things are going, we are using digital tools more and more, and that doesn't always save time [laughs].* [P29, physician in a middle school]

To overcome workload challenges, many participants stressed the critical need for interoperability, emphasizing that portals must integrate smoothly with existing digital systems and allow flexible, privacy-compliant data sharing:

> *It should be connected to the hospital's existing software, so that appointments scheduled can be automatically added to the shared calendar.* [P06, occupational therapist in a hospital]

> *It has to be developed in connection with the software used in the center. And for data sharing, ideally, there should be clear boxes you can tick to choose whether or not to share information.* [P27, educator in a rehabilitation center]

In addition to technical compatibility, some participants emphasized the importance of a simple, engaging, and visually appealing design to ensure adoption across diverse users. They advocated for an intuitive interface that avoids overwhelming users with too much information and instead allows such tools to evolve gradually, adapting progressively to users' needs and digital familiarity:

> *It needs to be fun, visual, with appealing images. […] Not too much information, so people don't get lost. The initial interface should be extremely easy to navigate, and then the platform can evolve gradually over time.* [P07, kinesiologist in a sports association]

By contrast, a few professionals viewed portals as a potential time-saving investment that could reduce repetitive communication and improve coordination:

> *I spend a lot of time and energy communicating the same information to everyone, and I find that quite exhausting. […] It would save time, because we'll get quick answers instead of making a phone call or send an email and wait for a reply.* [P01, coordinator of a mobile rehabilitation team]

> *I'm rubbish at computers. I'd say to myself, "Oh no, another tool!" [laughs]. It probably wouldn't be easy to use at first, and I'd have to learn to use it, but afterwards I'd save time. And there would be a more fluid link.* [P08, occupational therapist in health and social services]

Importantly, divergent perceptions did not appear to be linked to professionals' digital literacy, but rather to differing professional values and beliefs about coordination and the role of information sharing in care, as said by 1 professional:

> *It's typically the kind of platform where people believe that the more information we have and cross-reference, the better we manage to take care of the child. Some will see it as a kind of burden or extra work, and others will say it's a great tool and part of the job of taking care of young people.* [P31, coordinating teacher in a middle school]

To address these divergent perceptions, a few professionals proposed strategies, including training professionals and demonstrating the benefits of shared portals:

> *It's important to show them how the tool will help, focusing on time saving and improving daily practice. And how it will contribute to the student's success. Because that's why we're all here.* [P05, nurse in a high school]

Discussion

Principal Results

Overview

To our knowledge, this study is the first to focus on **eH**ealth to support integrated pediatric rehabilitation from the perspectives of health care, education, and recreation professionals. The findings revealed significant opportunities for shared patient portals to improve care continuity in rehabilitation by facilitating communication about children's participation across different environments and fostering ongoing engagement with children and families throughout the rehabilitation process. Several

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features were proposed, including a list of involved professionals, a shared calendar across services and providers, the ability to share photos, videos, and reports of the child's functioning in different environments, and the option to share progress with children and families. While many professionals perceived significant opportunities for improving care continuity and engagement through shared portals, divergent and at times contradictory views also emerged regarding confidentiality, collaboration across sectors, and the role of children and families in such systems. To ensure successful adoption, several strategies were suggested, including sector-specific access, adapted language, contextualized information, progressive access for children, system interoperability, and professional training.

Toward a Rehabilitation Continuum: From Greater Transparency to Fears About Confidentiality

Many professionals perceived shared portals as essential communication tools to ensure continuity across health care, education, and recreation services—a key determinant of integrated rehabilitation care [9]. This aligns with the need to redesign systems for children with disabilities using a systemic approach that addresses all health determinants, not just health care services [45]. Cross-sectoral collaboration is critical in pediatric rehabilitation, where providers and parents must work together across various environments to promote children's development and participation [12,46,47]. The findings suggest features to integrate, such as a shared calendar, goals, and options for sharing observations and monitoring children's progress through photos or videos. By providing structured and transparent communication, such features could support professionals in aligning their interventions and ultimately enhancing children's abilities to participate successfully in school [3]. Yet, a minority of professionals opposed granting educational staff access to portal data, citing confidentiality and contextual misinterpretation concerns. Beyond education, some professionals emphasized the need to collaborate with professionals from sports and leisure associations to foster inclusion in leisure activities, collaborations that are currently lacking. Despite its importance, this cross-sectoral coordination remains underexplored in the literature, especially regarding recreation and education professionals, who are often overlooked as key stakeholders [48]. By enabling real-time information sharing, patient portals could provide a more holistic understanding of children's needs and participation across different environments, supporting tailored interventions and aligning with the "F-word" framework, which highlights 6 key aspects of childhood disability: Functioning, Family, Fitness, Fun, Friends, and Future [49].

However, participants reported several barriers to cross-sectoral collaboration, particularly between professionals working in rehabilitation and education settings, including divergent work methods and approaches, which represent a significant challenge to inclusive schooling [50]. Although concerns about confidentiality are consistent with previous studies [20,51], deeper tensions emerged regarding giving non–health care professionals access to clinical observations in shared portals. In France, education professionals are bound by professional secrecy [52], which means they cannot access health data unless explicitly authorized by a major patient or legal representative, but they are authorized to have access to observations about children. These legal distinctions are reinforced by the European General Data Protection Regulation [53], which emphasizes the right of patients, or for minors, their legal representative, to control access to personal health information. This means that families must act as the gatekeepers of any cross-sectoral data sharing.

Participants' concerns thus reflect not only legal and ethical constraints but also deeper apprehensions about the potential misinterpretation or misuse of clinical information when transferred outside its original context. To mitigate these risks, some participants suggested sector-specific access protocols and stressed the importance of contextualizing shared observations to preserve the integrity and meaning of the information exchanged.

Family Engagement: From Genuine Partnership to Deeper Tensions in Power Dynamics

Most professionals identified the potential of patient portals to enhance family engagement in the rehabilitation process. Since family training and the codefinition of goals with parents significantly improve success in therapy [54], supporting rehabilitation continuity at home by involving parents is essential. Participants underscored the limitations of therapy time in transferring skills to the home environment, positioning portals as valuable tools for effective communication with parents. Furthermore, by promoting greater consistency, patient portals could help reduce family exhaustion, a critical issue given the challenges parents face in coordinating care [36,37]. Further, several professionals mentioned shared portals as a means to foster a genuine family partnership. Although patient- and family-centered approaches are frequently mentioned in pediatric rehabilitation, the concept of partnership remains less explored [55]. Partnership extends beyond a centered model, advocating for a more egalitarian relationship based on co-construction and shared decision-making [56,57]. Shared digital tools could reinforce this shift by enhancing transparency, offering parents access to rehabilitation goals and progress updates, and fostering their active engagement in the rehabilitation process [58]. Additionally, such tools could help professionals make their communication more accessible to children and families, thereby improving digital health literacy, which is a major determinant of health [59].

However, professionals' ambivalences about the extent of parental access reveal deeper tensions between the principles of partnership and preserving professional autonomy. Some participants saw parents as coactors in the care process, but others feared that parental oversight could inhibit candid communication among professionals. These tensions may reflect different perspectives regarding family-centered care [60], especially as some families perceive their role as collaborative partners [40,41]. These power dynamics in therapist-parent relationships may further challenge the use of shared health portals by hindering shared decision-making [61].

Importantly, these tensions are further complicated by legal considerations. In France, health information may be shared between professionals only if the patient does not object [62],

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and, in the case of minors, legal representatives have the right to access their child's health information and make decisions on their behalf [63]. This legal provision affirms the right of families to participate in their child's care, but may conflict with professionals' desires to preserve a confidential space for interprofessional collaboration. Designing patient portals in pediatric care must therefore navigate these complex dimensions, supporting meaningful family engagement, respecting professional communication needs, and ensuring their engagement while complying with legal requirements. These challenges reflect fundamentally different ethical stances on responsibility and access. As such, future implementations should consider flexible access models and co-designed governance frameworks to ensure shared ownership that honors legal and ethical responsibilities.

Children's Engagement: From Empowerment to Protective Gatekeeping

Professionals recognized that involving children in shared portals could promote key aspects of self-determination, such as autonomy, self-expression, motivation, and increased self-efficacy [64]. Features such as child-defined goals and progress graphs hold great potential to respond to these needs and to sustain motivation and long-term involvement, which is crucial in pediatric rehabilitation pathways that often extend over years [65].

However, participants also expressed multiple concerns about the risks of granting direct access to children. Concerns related to the age of consent echo the limited but growing literature on children's cyber safety [66]. This vigilance may be justified given the dual vulnerability of minors with disabilities, and highlights the need for strategies that consider children's evolving capacity to consent and support their gradual, developmentally appropriate access to such portals. Additional concerns were raised about increased screen time and the associated risks of excessive exposure in children [67]. However, the use of such a portal can be meaningfully distinguished from passive or recreational digital consumption, as it would be designed to involve adult guidance, whether by professionals during sessions or by parents, and to support goal-oriented, purposeful engagement with progressive access based on the child's capacities [68].

At the same time, this ambivalence between the need to improve the involvement of children and the need to protect them reflects a deeper ethical conflict, aligning with studies on barriers to participation in pediatric rehabilitation, highlighting protective attitudes toward children among professionals [69]. Additionally, this protective instinct may unintentionally conflict with contemporary rights-based approaches for children and the right to receive transparent health information and to participate in decisions affecting their care [70]. Ultimately, the inclusion of children raised a central dilemma for professionals: should portals serve as tools for empowerment, or could they risk overexposing children? Designing portals for children should therefore not revolve around binary choices between access and restriction, but rather nuanced, developmentally appropriate solutions that support gradual access and informed participation. Addressing these questions is essential for ensuring ethical and age-appropriate design but also for advancing equity and agency in pediatric rehabilitation [71].

Beyond the Time Required to Use Portals, a Matter of Professional Beliefs About Their Coordination Role

Issues regarding time required for portal use are consistent with previous studies [20,21,51]. However, this study revealed that professionals' willingness to adopt such tools goes beyond practical limitations. Their intention to use portals was closely linked to their belief that it could enhance their ability to deliver quality care. While some participants viewed portals as essential to improving coordination, others saw them as an additional burden. This ambivalence suggests a partial intention to adopt the tool, consistent with the Technology Acceptance Model, which posits that perceived usefulness influences user acceptance [72].

Beyond individual beliefs, this hesitancy also points to the need for targeted implementation strategies to support full adoption, in line with the Theoretical Domains Framework [73], which emphasizes the importance of addressing behavioral determinants of change. Participants' concerns must therefore be taken seriously to ensure the successful integration of portals in pediatric rehabilitation. This includes addressing the broader transformations required: strengthening interprofessional and cross-sectoral collaboration, particularly with schools, and promoting patient- and family-partnered care through shared decision-making.

These findings echo the argument by Goodwin [74] that truly integrated care requires a dual disruptive innovation: not only the development of digital tools, but also a transformation in the way professionals work together and engage with children and families to coproduce care.

Next Steps

The professionals' perspectives will be combined with families' and children's perspectives and carried forward as inputs into the upcoming phases of the project. Focus groups with stakeholders will be conducted to align needs and concerns across groups [75] and to refine portal features through participatory design [27]. This pragmatic approach will ensure that professionals' concerns are considered from the outset. Subsequent stages will involve defining implementation strategies with decision makers from health, education, and recreation settings, to support adoption in real-world settings, with particular attention to interoperability challenges with electronic health records. Ultimately, the portal will be developed in partnership with a technology company.

Limitations

The sample was unbalanced, with more health care professionals from rehabilitation settings than from education, recreation, and social services. This is due to the central role of these professionals in rehabilitation and the recruitment primarily occurring through the FRISBEE [35] network. Nevertheless, the maximum variation sampling across profession, age, digital literacy, and working facility—combined with snowball sampling—enabled the collection of rich and nuanced insights into the phenomenon under study [37].

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The individual interviews allowed us to explore a broad range of opportunities and concerns, which was relevant given the variability of rehabilitation settings in France. However, focus groups could have allowed participants to compare their viewpoints and generate additional ideas on the implementation strategies for portals, for example [76]. Regarding implementation strategies, it is important to note that the data collected here, although informative, is insufficient to draw conclusions on which specific strategies should be adopted for successful portal implementation [77]. This study is a preliminary step, and further research will be needed to identify the most effective strategies. Future work should incorporate solid theoretical frameworks in implementation science and involve key decision makers to understand the organizational factors influencing the implementation process [78].

The analysts were mainly health care professionals, sharing similar characteristics with some participants, which may have contributed to a greater emphasis on these perspectives. However, the broader team was multidisciplinary, and regular meetings were held for critical reflexive analysis. Moreover, the inclusion of parent partners' perspectives contributed to a more comprehensive and in-depth analysis [79].

Conclusions

This study provides valuable insights into how digital health portals could support integrated pediatric rehabilitation care, from the perspectives of professionals working with children with disabilities. Professionals emphasized not only the potential of these tools and key features to enhance care quality but also the ethical and legal challenges their use poses. Their ambivalence highlights the need for portals that facilitate communication while respecting professional roles, family engagement, and child participation. Developing such tools requires more than technical solutions—it calls for a rethinking of how professionals collaborate with children, families, and other professionals. Co-design with these stakeholders and decision makers will be essential to ensure relevance, usability, and real-world impact.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

MK, CP, SB, QNH, and MPP conceptualized this study. MK, EF, and CP recruited participants. MK and TR collected the data. MK, TR, GT, and CP analyzed the data. MK wrote this paper, CP edited it, and all the authors reviewed it. CKC and AG, as parents' partners, contributed to all these stages.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 23 KB - rehab_v12i1e73068_app1.docx]

Multimedia Appendix 2
COREQ checklist.
[DOCX File , 27 KB - rehab_v12i1e73068_app2.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
FRISBEE: Fédération Médicale et Universitaire des SMR Pédiatriques de Bretagne Occidentale

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Biomechanical and Kinematic Gait Analysis in Lower Limb Amputees: Cross-Sectional Study

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Abstract

Background: The quantification of gait parameters in amputees facilitates the assessment of their performance with prosthetic devices. These parameters often depend on measurements based on anatomical aspects that vary across different types of lower limb amputations.

Objective: This study aimed to investigate body weight distribution, and gait symmetry, quality, and propulsion, as well as pelvic kinematics in the amputee population.

Methods: The EcoWalk baropodometry platform was used to measure plantar pressure, and the G-Walk inertial sensor was used for accelerometry measurements in 29 unilateral lower limb amputees.

Results: Values were estimated for each variable under analysis, and the findings were categorized by the level of amputation. All variables exhibited normal distribution within each group under analysis , except for the symmetry index in above-knee (AK) amputees (P=.03). Regarding the body weight distribution (P=.11), velocity (P≥.99), propulsion (P=.38), and quality index (P=.10) of the amputated limb; no significant differences were observed between the AK and below-knee (BK) amputees. The most significant deviation was noted in pelvic obliquity, which was greater in AK amputees compared to BK amputees.

Conclusions: The values reported for the variables under analysis may enable the establishment of more precise reference levels for the amputee population, thereby contributing to a more accurate diagnostic process and aiding prosthetic fitting.

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KEYWORDS

amputee; gait analysis; body weight distribution; gait symmetry; prosthetics

Introduction

Lower limb amputation causes drastic changes in basic locomotion patterns [1]. Currently, these patterns are analyzed using a wide variety of methods [2], with a focus on different variables that describe their impact on gait conditions and normal posture. Evaluating these conditions is of paramount importance because restoring a normal gait constitutes a key objective in the physical rehabilitation of amputees. Moreover, such assessments may suggest various modifications to prosthetic devices [3].

Notably, spatiotemporal, kinematic, and kinetic variables dominate several gait studies [3-5]. Among these, the two-minute walking test (2MWT) is one of the most commonly used tests for assessing amputees' gait performance [6,7]. Nevertheless, given the particular gait conditions of amputees, pivotal emphasis is placed on aspects such as body weight distribution (BWD) and the propulsion, symmetry, and quality indices when analyzing gait parameters.

BWD denotes how the body weight is supported by the prosthetic device and sound limb in the orthostatic position [1]. The indices, for their part, are related to gait parameters. Specifically, the propulsion index describes individuals' ability to push the center of mass forward during the single support stance phase [8]. The symmetry index represents the difference between the value (expressed as a percentage) of the sound limb and that of the amputated limb in the stance or swing phases [9]. Finally, the quality index, unlike the symmetry index, expresses a characteristic of a single extremity. It evaluates

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individuals' ability to correctly divide their own gait cycle between the sound and amputated limb steps [10].

Although reference values for these variables exist for healthy individuals, there are limited data reported for the amputee population, except for the 2MWT. The reference values for such tests have been provided considering different amputation-related demographic characteristics, with, for instance, a reported distance of around 140 m [11].

In healthy individuals, body weight is evenly distributed between both lower limbs [12]. Nonetheless, this condition, changes in lower limb amputees. In the case of unilateral transfemoral amputees, a significant proportion of their weight is transferred to the intact limb during most movements [13]. In the case of transtibial amputees, Fontes et al [1] reported that, during the early stages of rehabilitation, the nonamputated limb supports up to 60% of the body weight.

Furthermore, walking patterns in healthy individuals are symmetrical, deviating only slightly from the ideal values. However, in a pathological gait, an asymmetry between the lower limbs can be noticeably observed, which can have serious implications for the health of the intact limb [14]. In a study involving transfemoral amputees, Winiaski et al [9] used the symmetry index based on time measures and vertical force and reported a difference between the two lower limbs of less than 6% for normal gait. For transtibial amputees, the absolute asymmetry index has been found to be approximately 0.632 during knee flexion at loading response [15]. In general, gait among individuals with transfemoral amputation appears to be more asymmetric than among those with transtibial amputation [3].

Importantly, all these reference values reported in the literature for BWD and gait symmetry in amputees differ in the way these variables were estimated and the anatomical reference points. These variations make comparisons difficult, as amputees contend with muscle absence, coupled with the fact that they behave differently during standing and gait depending on the level of amputation.

In this study, accelerometry was used to calculate different indices based on generic gait parameters, which facilitate making comparisons between populations with gait impairments using reference values reported for healthy individuals. Additionally, these acceleration data can be used to evaluate pelvic kinematic patterns across different planes, providing insights into pelvic tilt, obliquity, and rotation during the gait cycle.

Given these considerations, this study aims to provide an estimate of BWD based on pressure calculations between the lower limbs during the standing position, pelvic kinematics, and gait measurements in above-knee (AK) and below-knee (BK) amputees. Notably, this analysis will be exclusively based on the gait cycle duration in each limb for the entire sample of amputees.

Methods

Recruitment

The study participants were 29 unilateral lower limb amputees aged 18 to 59 years. Inclusion criteria required participants to be independent walkers, capable of gait without any external technical aids. Patients who had undergone lower limb disarticulation and amputation surgery within the preceding 12 months were excluded from the study. The participants who met the inclusion criteria signed the corresponding informed consent.

Among the 29 participants, 14 had AK amputations and 15 had BK amputations, with an even distribution in terms of laterality and amputation level. The average age was 41.2 (SD 11.4) years, and the mean BMI was 25.3 (SD 4.5). On average, participants lived with amputated limbs for 11.8 (SD 10.4) years and had prior experience using prosthetic devices.

Patient Instrumentation

Participants were instructed to stand on a plantar pressure platform, starting at a fixed point with both feet placed shoulder-width apart, and to hold this position for 60 seconds (Figure 1A). Then, they were directed to walk back and forth on a walking course as quickly as possible, without stopping, for two minutes. For this activity, an inertial sensor was placed on the participant's back at the level of the S1 vertebra (Figure 1B).

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Figure 1. Experimental setup for gait assessment. (A) Plantar pressure recording during static standing; (B) Inertial sensor placement at the S1 level for dynamic gait analysis.



Data Acquisition

The 2MWT was performed using a stopwatch and distance markers found in the facility. All equipment used for the assessments belonged to the Laboratory of Biomechanics and Rehabilitation of the Instituto Tecnológico Metropolitano (ITM), located in Medellín, Colombia.

BWD was measured using the EcoWalk portable plantar pressure platform (Ecosanit) with the EcoFoot software (version 4.0). This device comprises a 480 × 480 mm active matrix with 2304 sensors and an acquisition rate of 40 frames per second [16]. The pressure exerted by each foot activates the sensors, and the obtained data are used to calculate the distribution of body weight on the legs. BWD is determined as the difference between the weight distribution values of the sound and amputated limb. An ideal BWD would represent a difference tending towards 0% [12,17].

For the analysis of gait quality, the G-Walk inertial sensor (BTS Bioengineering) was used, along with the G-Studio software (version 3.2.25.0). This device operates wirelessly via Bluetooth 3.0 (Class 1.5, with a range of up to 60 m). In addition, it contains four sensors, each equipped with triaxial elements such as: an accelerometer (frequency range: 4 - 1000 Hz), a magnetometer (maximum frequency: 100 Hz), and a gyroscope (frequency range: 4 - 8000 Hz) [18]. The signal was acquired, and variables including velocity, cadence, and the overall symmetry index were calculated. Additionally, each limb's stride length, propulsion, and quality index were estimated.

The symmetry index measures the difference between the sound and amputated limbs during stance or swing phases, with values between 75% and 100% indicating high symmetry. It is calculated by analyzing the anteroposterior (AP) acceleration signals from both sides, computing the mean normalized values, and determining the Pearson correlation coefficient. This correlation is then mapped to a 0 to 100 scale, where higher values indicate greater symmetry [18]. To calculate the symmetry index, the following formula is used:

$$\text{Symmetry index} = \frac{\sum(AP_s - \overline{AP}_s)(AP_a - \overline{AP}_a)}{\sqrt{\sum(AP_s - \overline{AP}_s)^2 \sum(AP_a - \overline{AP}_a)^2}} + 1 \times 100$$

, where

AP is the anterior-posterior (AP) acceleration values for the sound (s) or amputated (a) limb throughout the gait cycle.

AP- is the mean AP acceleration value for the sound (s) or amputated (a) limb, respectively, representing the average acceleration over the gait cycle for each limb.

The propulsion index, is computed based on the gradient (in degrees) between the start and end of the monopodal support phase on the AP acceleration graph for each limb during gait [19]. The optimal value of this index is expected to be higher than 5.5°; this parameter describes the patient's ability to fully accept body weight on a limb after the deceleration phase and push the center of mass forward on the opposite limb (acceleration phase). A higher propulsion index denotes greater progression capacity of the participant during the single-support phase.

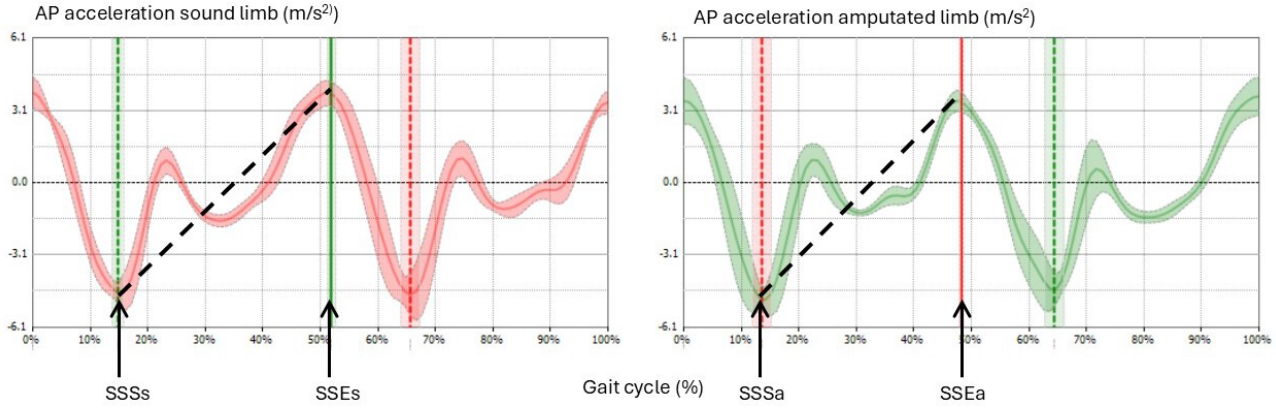
First, the mean normalized AP acceleration signal is obtained separately for the left and right sides (Figure 2). Then, the single support start and single support end are identified for the sound (s) and amputated (a) limb. A line is traced between the acceleration values at these points, and its slope is computed for both limbs. The propulsion index is determined using the following formula:

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, wherePropulsion index=tan−1ΔaΔt

Δa represents the difference in AP acceleration between the start and end of the single support phase for each limb and Δt represents the duration of this phase in seconds for each limb.

Figure 2. Acceleration graphs of the sound limb (right) and amputated limb (left) during gait. AP: anteroposterior; SSEa: single-support end for amputated limb; SSEs: single-support end for sound limb; SSSa: single-support start for amputated limb; SSSs: single-support start for sound limb.



Finally, the quality index is calculated by adding the absolute percentage differences observed between the stance and swing phases for each limb. Ideally, a value of 100 is attained when the stance and swing phases of each limb correspond exactly to 60% and 40%, respectively, of the entire gait cycle [18]. It is calculated using the following expression:

Quality index= ||(Dstance−− Dswing−)−20%|−100%|

Dstance- corresponds to the mean stance phase duration as a percentage of the gait cycle, and Dswing- corresponds to the mean swing phase duration as a percentage of the gait cycle.

Statistical Analysis

The Shapiro–Wilk test was used to assess normality of the data. For variables that met normality assumptions, the Student *t* test was applied, whereas the Wilcoxon test was used for those that did not. Data processing and figure generation were performed using R studio software (version 6.0; R Foundation for Statistical Computing), and the level of statistical significance for the entire study was set at α=.05.

Ethical Considerations

This study was approved by the Bioethics Committee of the Universidad de Antioquia (approval record number 21-21-954; June 2, 2021) and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent prior to enrollment and were informed that they could withdraw from the study at any time without any consequences. All data collected were fully anonymized before analysis to ensure privacy and confidentiality. No identifiable images or personal data were collected or included in this publication or any supplementary materials. No compensation—monetary or otherwise—was provided to participants for their involvement in this study.

Results

Knee braces were the most commonly used prosthetic suspension system among participants, followed by vacuum systems and belts.

The estimated values for each variable under analysis were divided by the level of amputation (Table 1, Figures 3 and 4). Table 1 shows the mean (SD) of the variables, while the figures display the quartiles, data dispersion, and confidence levels for normality and inferential tests. Also, mean (SD) pelvic kinematics across the entire gait cycle are shown in Figure 5. All variables exhibited normal distribution within each group under analysis, except for the symmetry index in AK amputees. No significant differences were observed between AK and BK amputees for BWD, velocity, or the propulsion and quality indices of the amputated limb. Although BK amputees exhibited a better BWD, with a value closer to zero, the asymmetry between both limbs still persisted in this group. Notably, weight loss as a result of amputation was not uniform among most amputees, which may have influenced these results.

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Table . Distribution of variables between the two amputation groups.

Variables	Amputation groups	
	AK[a], mean (SD)	BK[b], mean (SD)
BWD[c] (%)	35.5 (24.4)	22.7 (15.4)
2MWT[d] (m)	59.0 (22.1)	85.8 (28.9)
Velocity (m/s)	0.98 (0.18)	0.98 (0.21)
Cadence (steps/min)	82.9 (10.0)	90.5 (10.2)
Symmetry index (%)	63.5 (14.7)	81.7 (15.1)
Propulsion (°)		
Amputated limb	6.1 (2.5)	6.9 (2.0)
Sound limb	3.4 (1.5)	5.8 (2.4)
Quality index (%)		
Amputated limb	81.0 (14.6)	88.8 (8.1)
Sound limb	80.4 (10.6)	91.6 (8.2)
Stride length (m)		
Amputated limb	1.60 (0.39)	1.32 (0.17)
Sound limb	1.60 (0.39)	1.32 (0.17)

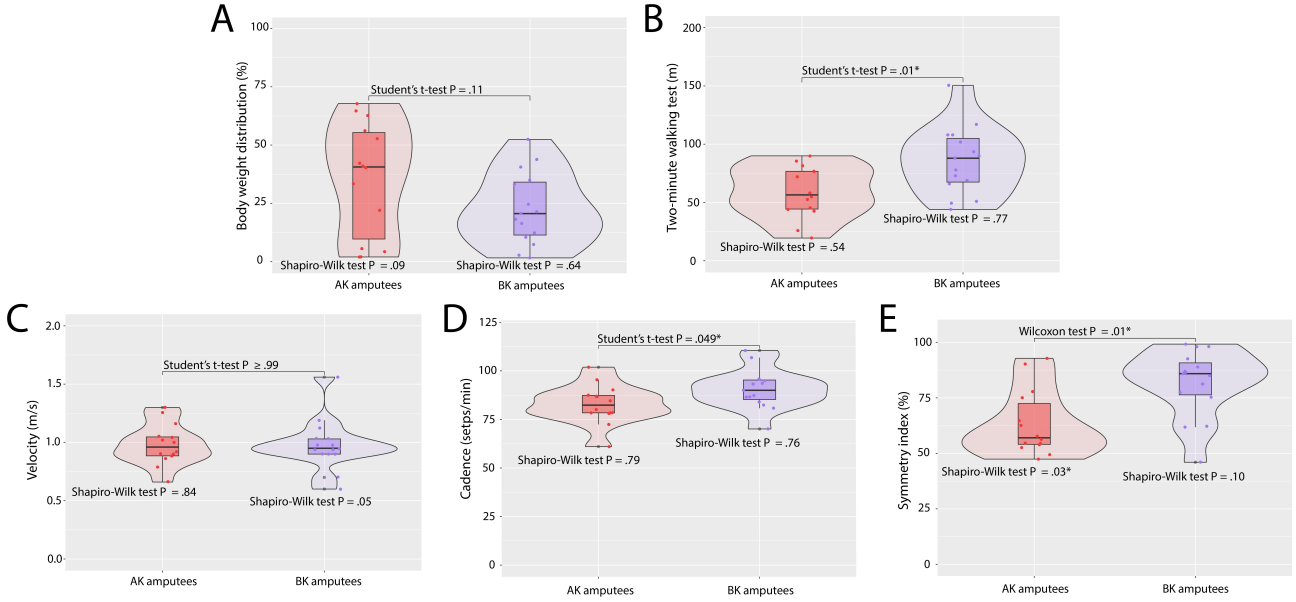
[a]AK: above-knee.

[b]BK: below-knee.

[c]BWD: body weight distribution.

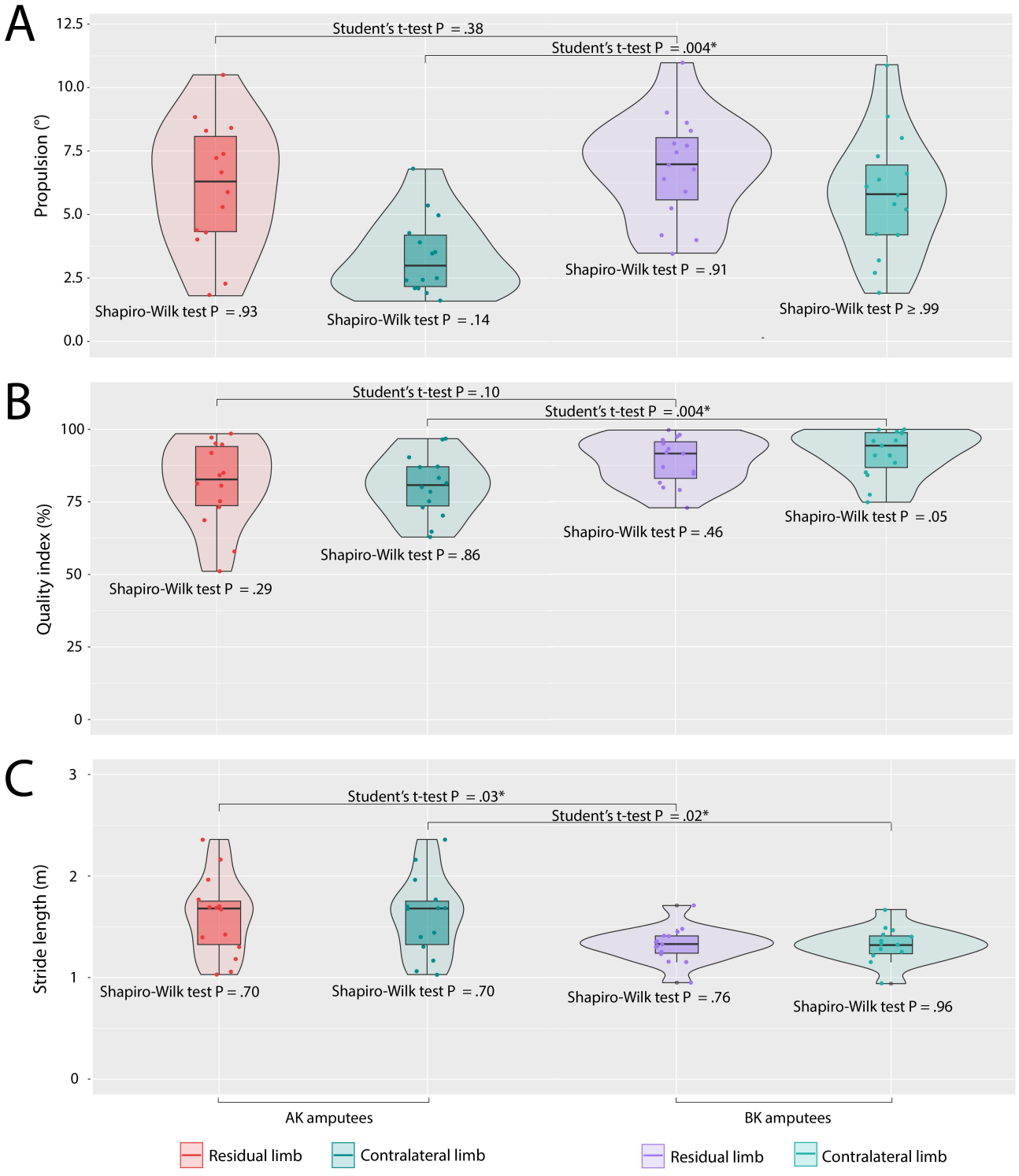
[d]2MWT: two-minute walking test.

Figure 3. (A) BWD is the absolute value of the difference in weight distribution, ideally close to zero (0%); (B) 2MWT measures the distance covered in 2 minutes; a greater distance indicates better endurance and mobility; (C) Velocity refers to an individual's walking speed, higher velocity reflects better functional performance; (D) Cadence measures steps per minute, with higher values indicating better mobility; (E) Symmetry index measures the difference between the sound and amputated limb, with 75% to 100% indicating high symmetry. *P<.05.



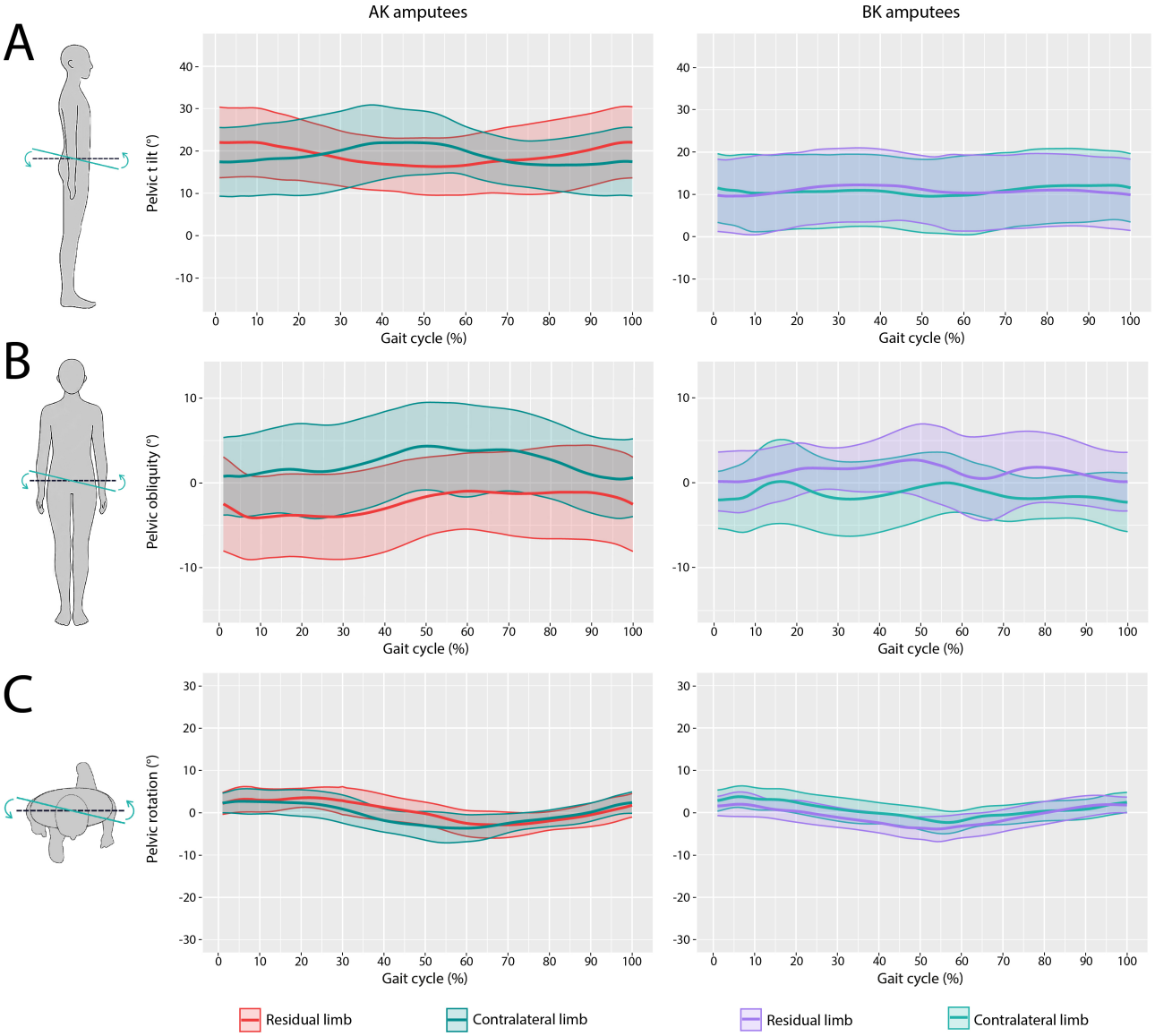
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Figure 4. (A)Propulsion index describes the ability to bear weight on one limb after deceleration and propel the body forward during acceleration, with higher values reflecting better progression; (B) Quality index measures how balanced the stance and swing phases are during a step, with a perfect score of 100 indicating an ideal distribution; (C) Stride length measures distance covered between two consecutive initial contacts of the same foot during walking. Although influenced by anthropometry, stride length is typically between 1 and 2 meters. *P<.05.



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Figure 5. Pelvic kinematics. This figure illustrates pelvic motion in three planes: (A) pelvic tilt, which represents anterior and posterior movement; (B) pelvic obliquity, indicating upward and downward tilting of the pelvis; (C) pelvic rotation, showing rotational movement around the vertical axis. Each curve corresponds to the movement of a limb during gait, and the shaded area represents the standard deviation, indicating variability among subjects. AK: above-knee; BK: below-knee.



The variables that exhibited significant differences across the groups included 2MWT, stride length, cadence, and the symmetry index, with AK amputees showing lower values, except for stride length.

Similar stride length between the amputated and sound limbs were reflected in kinematic behavior of the pelvis, as no alterations in pelvic rotation were observed for either level of amputation. Additionally, a lower SD was recorded throughout the entire cycle, with no considerable variation from the reference values for nonamputated individuals by Lewis et al [20]. The largest SD was observed for pelvic obliquity, which deviates from the trend observed in nonamputated individuals, with a reference range of 0°—5.6° [21]. This deviation was found to be more pronounced for AK amputees and lesser among BK amputees in the sound limb.

Regarding pelvic tilt, substantial alterations were observed in AK amputees, who exhibited a more pronounced anterior tilt throughout the cycle with an inverse relationship between both limbs. For BK amputees, a more conventional gait pattern with little difference between the amputated and sound limb was observed, although a large SD remained high.

Discussion

Principal Results

This study revealed significant variations in pelvic kinematics based on the amputation level. Most amputees favored their intact limb for weight-bearing. No major differences in walking speed or propulsion indices were found between AK and BK amputees; however, the AK amputees had lower scores in the 2MWT, cadence, symmetry index, and stride length, along with greater deviations in pelvic tilt and obliquity compared to nonamputated individuals. Accurate reference values for BWD, gait symmetry, and pelvic kinematics are crucial for improving diagnostic precision and customizing prosthetic solutions, given the variability in amputation conditions.

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Comparison With Prior Work

Regarding BWD, BK amputees showed better performance than AK amputees; however, both groups still exhibited asymmetry in weight-bearing between the prosthetic and sound limb. This may be attributed to the fact that most amputees tended to load the intact limb more heavily, than the amputated limb, regardless of the level of amputation. Asymmetrical BWD between sound and amputated limb was also reported by Fontes et al [1]. Factors such as pain, discomfort, and insecurity have been suggested as potential contributors to body weight asymmetry; however, it is worth noting that the patients participating in this study did not explicitly report such conditions. Nevertheless, we cannot rule them out at a subconscious level.

Conversely, discrepancies in the 2MWT, cadence, symmetry index and stride length findings may be attributed to the fact that the presence of the knee joint in BK amputees is related to proprioception and the placement of the center of gravity, leading to reduced energy expenditure during walking. This allows BK amputees to cover longer distances and take more steps per minute, contributing to a more adequate symmetry [22]. Additionally, a longer residual limb provides improved suspension and a greater lever arm for prosthetic control. Preserving the entire femur also enables the amputees to bear all their weight on the distal end of their amputated limb [23].

Regarding velocity, the obtained values closely align with those reported in the literature for amputees, ranging from 0.5 to 0.99 m/s [24,25], which is not far from the range for nonamputated individuals, which lies between 1.2 and 1.4 m/s [25] .

No significant difference in propulsion and quality indices could be explained by the compensatory adjustments made during the gait cycle; for example, the support time using the prosthetic device is shortened when compared to established values [26].

Moreover, the observed asymmetric gait differences confirm that lower limb amputees often exhibit asymmetrical gait patterns, which could lead to long-term health problems and ultimately affect their quality of life [27]. Symmetry measurement could provide clinically useful means of reliably capturing lower extremity motion asymmetries that are not evident while using typical temporal-spatial gait parameters or not easily quantifiable during physician observation [27].

Amputees tend to maximize the capabilities of the sound limb in order to counteract the limitations of the prosthetic device. However, these compensatory mechanisms can have serious consequences that could lead to new physical disabilities [28]. Investigating these strategies in depth presents an interesting avenue for research.

With respect to the shorter stride length observed in BK amputees, it could be linked to the type of suspension used. In this study, all BK amputees used a knee brace, while the majority of AK amputees used an atmospheric suspension system, which directly influences gait stability and, consequently, results in an increased stride length during walking [29].

Changes in pelvic kinematics may be attributed to compensatory adjustments of different prosthetic components. Particularly, pelvic tilt might be influenced by stability in re-establishing the center of gravity, and pelvic obliquity could be influenced by prosthetic adjustments such as suspension system or prosthesis length [30].

Limitations

This study has several limitations. The sample size was relatively small, which may impact the generalizability of the findings. The study focused on a specific demographic, potentially limiting broader applicability. Measurement techniques had constraints that may introduce potential errors. Regarding velocity, participants were instructed to walk at a self-determined pace in a controlled environment, which could have influenced the outcomes.

Conclusions

The differences in gait variables among amputees highlight the need for tailored approaches based on the amputation level. Symmetry and quality indices facilitate comparisons and can be applied to other populations with gait disorders. The values reported in this study provide reference levels that support diagnosis and prosthetic fitting. The increasing use of inertial sensors and pressure platforms reinforces their role as accessible clinical tools outside specialized gait laboratories.

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Authors' Contributions

Conceptualization: NOM, LMGH, CVB
Data curation: MMM
Formal analysis: NOM, LMGH, CVB, ICSC

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Methodology: NOM, LMGH
Project administration: NOM
Supervision: NOM
Visualization: LMGH, NOM
Writing – original draft: NOM, LMGH, CVB, ICSC
Writing – review & editing: NOM, CVB

Conflicts of Interest

None declared.

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Abbreviations

2MWT: two-minute walking test
AK: above-knee
AP: anteroposterior
BK: below-knee
BWD: body weight distribution

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Grab Bar Grasp Location During Bathtub Exit and Sit-to-Stand Transfers: Biomechanical Evaluation

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Abstract

Background: Grab bars are a multi-function bathing tool. While grab bars are commonly recommended by rehabilitation professionals, existing literature regarding optimal grab bar locations is focused on preference rather than function.

Objective: This study aimed to evaluate grab bar grasp location on 8 grab bar configurations during bathtub exit, with and without balance loss, and sit-to-stand (STS) from a bath seat.

Methods: Motion capture was used to evaluate grasp location during bathing activities in 28 older (65+ years) and 37 younger (18 - 35 years) adults. Grasp location was compared between age groups and balance loss conditions using ANOVA, and correlated with body height.

Results: Vertical grasp location varied from close to the bathtub rim to more than 1 meter above the bathtub rim (maximum 22.4 cm), while horizontal grasp location was close to the bathtub rim during bathtub exit, and close to the bath seat during STS. Young adult participants grasped 9.4% lower on vertical grab bars during perturbation trials than nonperturbation trials (P<.01). Body height was positively correlated with grasp height on a vertical grab bar during nonperturbation trials (r=0.67, P<.01), and negatively correlated with grasp distance on a low horizontal grab bar during STS (r=−0.37, P=.03).

Conclusions: Grab bar grasp location varied between proactive and reactive grasp scenarios and was linked to user height for some situations. These findings may be used to guide the selection of a grab bar installation location to support multiple bathing tasks.

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KEYWORDS

bathroom; accessibility; accidental falls; home modification; bathtub exit

Introduction

Grab bars serve multiple functions during bathing. While grab bars are a critical device for fall prevention [1-3], they are also used to support balance during bathtub entry and exit [4,5], and for tasks such as getting up from and sitting down on a bath seat [6].

Directing the installation of grab bars in bathing environments is a common task for occupational therapists and other rehabilitation professionals. However, there is a lack of agreement regarding the placement of the grab bars. Building codes [7] and accessibility standards [8] that exist to guide placement vary in their recommendations and are not necessarily based on empirical evidence supporting safety and usability. While tools exist to assist with the selection of assistive devices for bathing [9,10], there are no current tools to help occupational therapists decide where grab bars should be placed. Existing research on grab bar placement is primarily based on preference rather than effectiveness for balance support [3,11-13]. Sveistrup et al [11,14] found that users preferred configurations with grab bars positioned near the bathtub rim to assist with entry and exit transfers, but did not otherwise find differences between the configurations evaluated. Guitard et al [3] extended this work, finding that older adults prefer vertical grab bars for entry and exit. In contrast, Batista et al [12] found a preference for horizontal grab bars over vertical grab bars during a sit-to-stand (STS) task in younger adults. While these authors have presented findings regarding preferred grab bars, the researchers did not report where the participants grasped along the grab bar. It is unclear what grasp location is preferred to support bathing transfers and activities without balance loss, what grasp location is most effective for balance recovery, or whether the preferred grasp location differs from the reactive grasp location during balance loss.

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Functionally, grab bars are installed for both accessibility and fall prevention purposes, but it is not clear if the same grab bar placement is appropriate for proactive use for mobility, and reactive use for fall prevention. During bathing tasks such as STS, grasp location has a demonstrated effect on ergonomic factors, such as task speed or muscle activation [15,16], as well as factors related to fall risk, such as greater trunk flexion, trunk angle, or forward center-of-mass (COM) position [15-18]. While stored visuospatial information may influence grasp location during unexpected balance perturbation [19], other factors may also contribute. Grasp height affects COM control and physical demands associated with balance recovery [20,21]. In a loss-of-balance scenario during bathing tasks, managing rapid COM motion, compensatory reactions, and underfoot friction, the grasp location may differ from under nonbalance loss conditions. Determining an appropriate grab bar location to support daily use, as well as unexpected balance loss, would be valuable to improve the utility of grab bars and guide installation recommendations.

Further, age may play a role in the optimal location for grab bar placement. Guitard et al [3] found differences in grab bar use strategies and balance recovery reactions between older and younger adults. In some cases, the younger adult cohort avoided using a grab bar at all, while the older adult cohort was more proactive in using grab bars and other support devices. As summarized by Maki et al [22], reach-to-grasp reactions to balance perturbances are slower and smaller in older adults than younger adults. Reach-to-grasp reactions are also more variable in older adults and more reliant on visual targeting of the handhold than in younger adults [23]. Shoulder range of motion decreases with age, limiting the comfortable grasp location of an older adult compared with a younger adult [24]. These factors may contribute to differing grasp location strategies between younger and older adults.

Therefore, the purpose of this research was to evaluate the grasp location on a grab bar during bathtub exit and STS tasks. As a secondary goal, we aimed to determine whether grasp location differed between grab bar configurations, non-balance-loss and perturbation bathtub exits, and between older and younger adults. Finally, we wanted to know whether grasp location was related to the participant's body height.

Methods

Overview

Community-dwelling adults were recruited and consented to participate in either a bathtub exit task (EXIT) or a STS/stand-to-sit task with a bath seat (STS). For either study, participants were required to be able to enter and exit a bathtub independently and were excluded if they reported any mobility, orthopedic, or neurological conditions; used mobility aids; or had a recent injury (eg wrist sprain) or condition (eg, concussion or ear infection) that would affect their balance or ability to complete the protocol. Participants were grouped into older adults (65+ years) or younger adults (18 - 35 years). For both protocols, in order to limit the effect of fatigue, we limited the study duration, permitted breaks and snacks, and frequently questioned participants about their energy levels and interest in continuation.

Ethical Considerations

Both protocols (UHN REB# 17 - 6236 and 18 - 5406) were approved by an institutional research ethics board at the University Health Network. Participants provided written informed consent. Participant privacy and confidentiality were maintained throughout the study, and all data were deidentified. Participants were compensated for their time ($10 CAD per hour) and travel costs ($20 CAD). At the time of data collection, the compensation was approximately equivalent to US $7.75 and US $15.50, respectively.

Environment, Equipment, and Materials

Data were collected in the General Purpose Lab of the Challenging Environment Assessment Laboratory. The laboratory is a modifiable 5.55 × 5.15m space, which can be affixed to a 6-degree-of-freedom motion base (Rexroth, Lohr am Main, Germany) to evoke perturbations. A custom-built weldment was designed to permit the installation of vertically-, horizontally-, and diagonally-oriented grab bars (3.8 cm diameter, enamel-coated steel). A customized bathtub was modified so that all edges of the bathtub were removed and replaced with a foam block (41 cm in height, coinciding with the rim height of the bathtub in its initial state) to replicate the bathtub's rim. A plywood-backed white plastic sheet was placed behind the grab bars to reduce the contrast between the apparatus and the grab bars. For the STS protocol, a height-adjustable bath seat was placed at one end of the bathtub, so that when the participant was seated, the remainder of the bathtub would be in front of them, and the grab bars at their right.

A 15-camera motion capture system (200 Hz; Motion Analysis Corp, Santa Rosa, USA) was used to track wrist motion during EXIT and STS via reflective markers. Markers were placed on the right and left radial and ulnar styloid processes. Additional markers were placed on each end of the grab bar, on the outside corners of the bath seat, on the corners of the floor surrounding the bathtub, and along the bathtub rim.

One liter of diluted sodium lauryl sulfate (SLS) was poured into the bottom of the bathtub to simulate a realistic bathing environment. For STS, 1 g SLS per liter of water was used in accordance with the British Standard Institution slip-resistant test standard (BS EN 13845) to create a moderately slippery surface while maintaining the safety of participants with bathing difficulty. For EXIT, 2 g SLS/liter was used, as it more consistently resulted in slips during pilot testing.

EXIT participants donned a harness, tethered via a fall arrest line to a custom robotic overhead gantry (BerkelaarMRT, Delft, Netherlands) that permitted free motion, except in the case that the participant traveled downward >10cm. STS participants did not use a harness due to the lower risk of the task and the inability to move through a vertical space without the gantry locking. In both cases, participants wore knee and elbow pads. Additionally, EXIT participants wore a full-mask hockey helmet.

Finally, for EXIT with a perturbation, a laser sensor was affixed in line with the outer edge of the bathtub wall, such that when

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a participant lifted their leg over the wall and past the sensor, the perturbation (perpendicular to the direction of travel; 2m/s^2; peak velocity: 0.4 m/s; peak displacement: 0.08 m [3]) was triggered. No perturbations were delivered during STS.

Experimental Conditions

Several grab bar orientations were evaluated to represent a breadth of configurations in existing codes and standards or commonly used due to market availability or ease of installation. For the EXIT task, three grab bar orientations were evaluated: (1) a standard horizontal (SH) grab bar, 91.4 cm above the ground [25]; (2) a high horizontal (HH) grab bar at 102 cm above the ground (established as preferred [12] and superior for balance recovery [20]); and (3) a vertical (VRT) grab bar directly above the bathtub rim [7]. The EXIT task grab bars were placed along the side wall of the bathtub, centered above the bathtub rim. For the STS task, 5 grab bar orientations were evaluated; the grab bars were placed along the back (ie, long) wall of the bathtub. In addition to the SH and VRT grab bars, we also evaluated (1) a low horizontal (LH) grab bar 58.4 cm above the ground [7,25]; (2) a 45° incline (I45) grab bar (simulating a 24”/61.0 cm grab bar between two 16”/40.6 cm-spaced studs); and (3) a 60° incline (I60) grab bar (available in prefabricated angled designs). Each grab bar had a minimum graspable length of 1.2 m.

EXIT Protocol

For the EXIT protocol, the participant was instructed to enter the bathtub, turn around within the tub, take 3 steps in place, and exit the bathtub. Participants were asked to perform the bathtub transfer several times using a self-selected strategy. Participants were aware that a perturbation would be delivered during one of the transfers but were not alerted as to which trial the perturbation would be delivered. All older adults self-selected to use a hand-in-place approach, placing their hand on the grab bar prior to completing the transfer (older adult, hand-in-place group, OA-HIP). Ten younger adults self-selected to use a reach-to-grasp approach, initially exiting the bathtub without using the grab bar and reaching to grasp the grab bar once the lead foot had passed the laser sensor (younger adult, reach-to-grasp group, YA-RTG). Ten younger adults were asked to use a hand-in-place approach for comparison with the OA-HIP group (younger adult, hand-in-place group, YA-HIP). Only the perturbation trials were analyzed for OA-HIP and YA-HIP (one per grab bar), as participants were unaware of the timing of the perturbation and were not primed to alter their grasp location. Perturbation and nonperturbation trials (one each, for each grab bar) were analyzed for YA-RTG participants.

STS Protocol

For the STS protocol, the seat pan was adjusted to a comfortable height. The participant was asked to sit on the bath seat and use the grab bar to help them rise from the seat and return to a seated position. One trial was analyzed for each grab bar condition. Older adults and younger adults (YA-STS) completed the same protocol.

Data Analysis

Hand, bathtub rim, and bathtub seat pan positions were extracted using Cortex (Motion Analysis Inc). For EXIT, a single hand position was extracted, as participants did not remove and replace the hand during the transfer. For STS, a hand position was extracted for the STS direction, and a second hand position was extracted for the stand-to-sit direction. Positions were extracted in the vertical (VRT, I45, and I60) and horizontal (HH, LH, I45, and I60) directions, and along the hypotenuse of the grab bar (I45 and I60). All vertical positions were reported as distance above the bathtub rim. For EXIT, horizontal positions were reported as the distance from the center of the bathtub rim (negative for outside the bathtub, positive for inside the bathtub). For STS, horizontal and hypotenuse distances (for angled grab bars) were reported from the front edge of the bath seat (positive for in front of the bath seat, negative for behind the front edge of the bath seat).

Extracted data were analyzed using MATLAB (MathWorks). Hand position data were summarized for each grab bar and each task using heat maps. Separate ANOVAs were used to determine whether grasp location was affected by age (OA-HIP vs YA-HIP) or perturbation (YA-RTG perturbation vs no perturbation). In situations where there was only one grab bar for comparison (eg, VRT for vertical hand position during bathtub exit), a 1-way ANOVA was used. Where more than one grab bar was available (eg, VRT, I45, I60 for vertical position during STS), the grab bar was treated as a repeated measure, and age-grab bar or grasp-grab bar interactions were analyzed prior to main effects. Next, we evaluated whether grasp height (raw) was related to body height via correlation. For all statistical comparisons, a significance level (α) of .05 was used. Finally, position data were normalized to participant body height in order to make comparisons to the range of heights observed across the Canadian population.

Results

Participant characteristics are summarized in Table 1.

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Table . Participant characteristics.

Group	Protocol				
	EXIT			STS[a]	
	YA-HIP[b]	YA-RTG[c]	OA[d]	YA[e]	OA
Sex (n)					
Males	5	3	5	7	7
Females	5	7	6	10	10
Age (years), mean (SD)	24.6 (4.2)	23.7 (2.2)	67.7 (2.8)	24.5 (3.5)	71.6 (7.0)
Height (cm), mean (SD)	173.2 (11.8)	171.5 (9.0)	164.4 (8.2)	169.5 (9.8)	161.6 (9.0)
Weight (kg), mean (SD)	73.4 (15.5)	73.5 (14.2)	67.2 (12.1)	68.2 (16.3)	69.0 (14.5)

[a]STS: sit-to-stand.

[b]YA-HIP: younger adult, hand-in-place group.

[c]YA-RTG: younger adult, reach-to-grasp group.

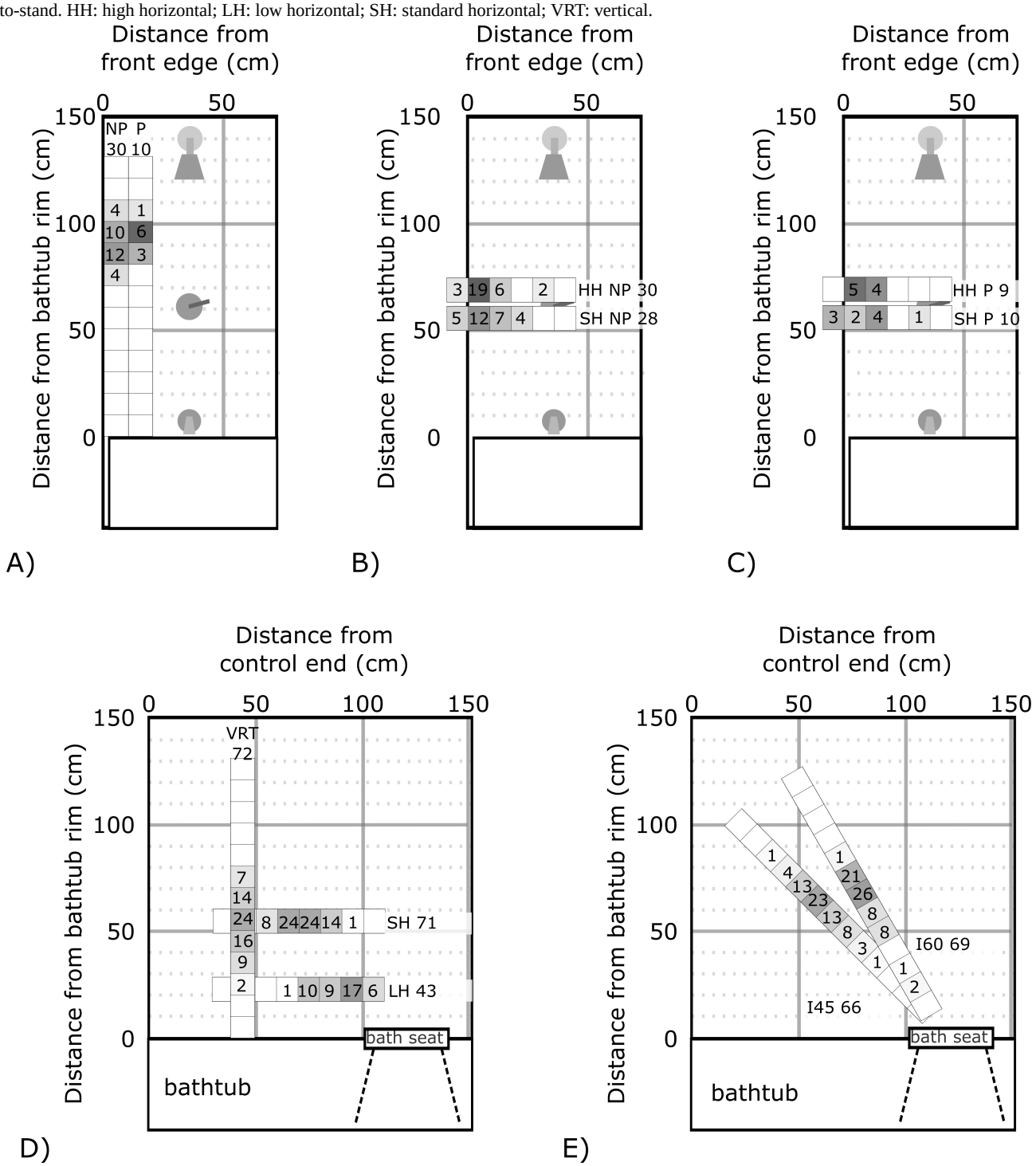
[d]OA: older adult.

[e]YA: younger adult.

Across tasks and grab bars, vertical grasp locations ranged between 75.3 and 105.3 cm above the bathtub rim for EXIT, and 2.2 to 87.4 cm above the bathtub rim for STS. For STS, maximum grasp height always occurred during STS, and minimum grasp height always occurred during stand-to-sit. Horizontal grasp location ranged from 35.4 cm inside the bathtub rim to 7.6 cm outside the bathtub rim, for EXIT, and 6.1 cm behind the front edge of the bath seat to 43.5 cm in front of the front edge of the bath seat for STS. Along the hypotenuse of the angled grab bars, participants grasped as close to the front edge of the bath seat as 5.4 cm, and as far as 92.5 cm during STS. Grasp locations are depicted in Figure 1. Normalized grasp location data are summarized in Table 2.

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Figure 1. Heat map of grasp locations during EXIT and sit-to-stand. While only one perturbation and grab bar condition was tested during a single trial, multiple conditions are presented in each panel for comparison. Perturbation condition (Perturbation [P]; No perturbation [NP]) and grab bar label (**VRT, HH, SH, LH, I45, and I60**) are indicated to distinguish between conditions, along with the number of samples for each condition. Shading and number overlay indicate the number of participants who grasped in each location. (A) Vertical grab bar grasp locations during perturbation and non-perturbation exits. (B) Horizontal grab bar grasp locations during non-perturbation exits for HH and SH. (C) Horizontal grab bar grasp locations during perturbation exits for HH and SH. (D) Vertical and horizontal grab bar grasp locations during STS. (E) Incline grab bar grasp locations during sit-to-stand. HH: high horizontal; LH: low horizontal; SH: standard horizontal; VRT: vertical.



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Table . Grasp location descriptive statistics, normalized to participant body height.

Task and direction of measure	Grab bar	Grasp height		
		Maximum	Minimum	Mean (SD)
EXIT, perturbation[a]				
Vertical[b]	VRT[c]	76.3	67.1	73.0 (3.5)
Horizontal	SH[d]	18.5	−4.1[e]	5.3 (6.5)
Horizontal	HH[f]	6.7	0.2	4.0 (2.4)
EXIT, no perturbation				
Vertical[b]	VRT	83.0	70.2	76.4 (3.0)
Horizontal	SH	15.0	−3.2[e]	4.1 (4.5)
Horizontal	HH	22.4	−1.4[e]	5.3 (5.2)
STS[g]				
Vertical[b]	VRT	80.9	46.3	63.3 (7.8)
Horizontal	LH	20.4	−3.3[h]	6.1 (5.5)
Horizontal	SH	29.6	3.3	17.2 (5.8)
Vertical[b]	I60[i]	73.7	39.5	61.2 (7.7)
Horizontal	I60	18.7	−1.5[h]	10.7 (4.3)
Hypotenuse	I60	52.6	13.6	37.9 (7.8)
Vertical[b]	I45[j]	70.5	24.3	55.1 (9.0)
Horizontal	I45	20.0	0.8	11.9 (4.8)
Hypotenuse	I45	45.8	3.4	32.8 (8.7)

[a]Only young adult participants.

[b]Normalized grasp location includes 41cm bathtub rim height (ie, normalized grasp location represents height from the floor).

[c]VRT: vertical.

[d]SH: standard horizontal.

[e]Signifies a grasp location outside the midline of the bathtub rim.

[f]HH: high horizontal.

[g]Considers both sit-to-stand and stand-to-sit.

[h]Signifies a grasp location behind the front edge of the bath seat.

[i]I60: incline 60°.

[j]I45: incline 45°.

Grasp location did not differ between SH and HH grab bars during EXIT (Table 3). For STS, grasp height affected grasp location, such that participants grasped highest on the vertical grab bar, and on average, 5.9% lower on I60 than VRT, and 22.1% lower on I45 than VRT. The same trend held for stand-to-sit, with participants grasping at similar heights for VRT and I60, and grasping, on average, 21.3% lower for I45 than VRT. Participants grasped furthest away from the bath seat using SH, followed by I60 (33.6% closer than SH), I45 (28.3% closer than SH), and LH (63.1% closer than HH). No differences were observed between grasp locations along the hypotenuse of I60 and I45.

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Table . Comparisons of grasp location between grab bars (ANOVA).

Task, direction of measure, and main effect factor	Grab bars	Interaction effect		Grab bar effect			Main effect	
		F test (*df*)	*P* value	*F* test (*df*)	*t* test	*P* value	*F* test (*df*)	*P* value
Exit								
Vertical								
Age	VRT[a]	—[b]	—	—	—	—	3.7 (1, 18)	.07
Horizontal								
Age	HH[c] and SH[d]	−2.5 (1, 17)	.13	−1.6 (1, 17)	—	.23	−2.3 (1,17)	.15
Vertical								
Perturbation	VRT	—	—	—	—	—	11.6 (1,18)	<.01[e]
Horizontal								
Perturbation	HH and SH	−0.1 (1, 17)	.82	−0.14 (1, 17)	—	.72	−4.5 (1, 17)	.05[e]
STS								
Vertical max								
Age	VRT, I60[f], I45[g]	1.3 (2, 60)	.28[h]	6.03 (2, 60)	—	<.01[eh]	0.0 (1, 30)	.968
Pairwise[i]	VRT and I60	—	—	—	3.9 (1)	<.01[e]	—	—
Pairwise	VRT and I45	—	—	—	6.8 (1)	<.01[e]	—	—
Pairwise	I60 and I45	—	—	—	5.2 (1)	<.01[e]	—	—
Vertical min								
Age	VRT, I60, and I45	2.1 (2, 60)	.13[h]	5.4 (2, 60)	—	<.01[eh]	0.4 (1, 30)	.51
Pairwise	VRT and I60	—	—	—	1.9 (1)	.06	—	—
Pairwise	VRT and I45	—	—	—	4.3 (1)	<.01[e]	—	—
Pairwise	I60 and I45	—	—	—	3.0 (1)	<.01[e]	—	—
Horizontal max								
Age	SH, LH[j], I60, and I45	1.9 (3, 84)	.14	4.7 (3, 84)	—	.04[e]	0.0 (1, 28)	.95
pairwise	LH and SH	—	—	—	−12.8 (1)	<.01[e]	—	—
Pairwise	LH and I60	—	—	—	−4.8 (1)	<.01[e]	—	—
Pairwise	LH and I45	—	—	—	−6.7 (1)	<.01[e]	—	—
Pairwise	SH and I60	—	—	—	8.6 (1)	<.01[e]	—	—
Pairwise	SH and I45	—	—	—	5.8 (1)	<.01[e]	—	—
Pairwise	I60 and I45	—	—	—	2.3 (1)	<.01[e]	—	—
Horizontal min								
Age	SH, LH, I60, and I45	2.0 (3, 84)	.12	3.2 (3, 84)	—	.03	0.1 (1, 28)	.81

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Task, direction of measure, and main effect factor	Grab bars	Interaction effect		Grab bar effect			Main effect	
		F test (*df*)	*P* value	*F* test (*df*)	*t* test	*P* value	*F* test (*df*)	*P* value
Pairwise	LH and SH	—	—	—	−10.6 (1)	<.01[e]	—	—
Pairwise	LH and I60	—	—	—	−3.5 (1)	.01[e]	—	—
Pairwise	LH and I45	—	—	—	−5.8 (1)	<.01[e]	—	—
Pairwise	SH and I60	—	—	—	5.5 (1)	<.01[e]	—	—
Pairwise	SH and I45	—	—	—	4.9 (1)	<.01[e]	—	—
Pairwise	I60 and I45	—	—	—	2.3 (1)	.03	—	—
Hypotenuse max								
Age	I60 and I45	0.6 (1, 30)	.45	0.2 (1, 30)	—	.62	0.1 (1, 30)	.75
Hypotenuse min								
Age	I60 and I45	0.0 (1, 30)	.99	0.6 (1, 30)	—	.45	0.0 (1, 30)	.96

[a]VRT: vertical.

[b]Not applicable.

[c]HH: high horizontal.

[d]SH: standard horizontal.

[e]Significant difference at $P<.05$.

[f]I60: incline 60°.

[g]I45: incline 45°.

[h]Outcome determined with Greenhouse-Geisser correction in consideration of violation of sphericity.

[i]Only significant pairwise comparisons reported.

[j]LH: low horizontal.

We did not observe any significant main effects of age, or age-grab bar interactions on grasp location.

A significant main effect of perturbation was observed, such that YA-RTG participants grasped 8.7 (6.6) cm, or, on average, 9.4% lower on the vertical grab bar during perturbation trials than nonperturbation trials ($F_{1,\ 18}=11.6$, $P<.01$). However, perturbation was not a significant main effect for horizontal grab bars HH or LH (all $P>.05$).

Body height was significantly positively correlated with grasp height on vertical grab bars during nonperturbation EXIT ($r=0.67$, $P<.01$). Height was negatively correlated with maximum grasp distance during STS when using LH ($r=-0.37$, $P=.03$). No other significant correlations with height were observed. Grasp location normalized to body height is presented in Table 2.

Discussion

Principal Findings

In this study, we aimed to evaluate the grasp location on grab bars during 2 bathing tasks. We found that grasp location ranged vertically from approximately 70 cm above the bathtub rim, to just over a meter above the bathtub rim during bathtub exit. However, vertical grasp location was much more variable during the STS task, with grasp height ranging from just above the bathtub rim to nearly 90 cm above the bathtub rim. Horizontal grasp ranges were narrow for both tasks, with participants grasping within a range of 35 cm inside to just outside the bathtub for exit, and within 45 cm of the bath seat. Grasp location was affected by body height, grab bar location, and perturbation, but not age.

Participants preferred to grasp within 70% - 90% of their total body height (approximately shoulder height) during the unperturbed EXIT task, and slightly lower when their balance was perturbed during bathtub exit. A higher vertical grasp location above the COM is critical for the maintenance of balance during a transfer task. Komisar et al [20,25] demonstrated greater control of trunk kinematics following perturbation for a 42” high handrail compared with shorter handrails, as well as reduced loading on the grab bar. In comparison to the participants in this study, a 42” high grab bar would land between 54.9% and 68.4% of body height. Similarly, Greene et al [26] found better control of trunk flexion during unperturbed bathtub exit for a vertical grab bar than low grab bars mounted to the rim of the bathtub. Sveistrup et al [11] found that older adults preferred grab bar configurations with tall vertical grab bars for bathtub exit over grab bar configurations with a horizontal grab bar or no grab bar for the exit, with approximately 1/3 of participants stating that their

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ideal grab bar configuration would contain a vertical grab bar for entry and exit transfers. A long, vertical grab bar accommodates users of differing heights as well as supports bathtub entry/exit transfers with and without balance perturbations. Some shorter grab bars may also not be long enough to accommodate a user if installed considering only the preferred (unperturbed) grasp location. Further, grab bars that are installed based on preference may be too high to grasp during loss of balance.

Grasp height during STS was affected by grab bar configuration, with participants grasping higher with more vertical grab bars, and lower as the grab bar angle decreased. Similarly, the horizontal grasp location was further away from the bath seat for higher and more steeply angled grab bars, and closer for lower and less steeply angled grab bars. This may signify a change in grasp strategy, with participants using the VRT and higher grab bars as an apparatus to hang from, and using the lower and less steeply angled grab bars as an apparatus to push off from. While a higher grasp height may provide a greater balance advantage, during STS, this grasp height requires flexion of the arm above the shoulder; extending the arm above shoulder height may present a greater risk of injury [27], and may not be possible for some users with impairments to the shoulder or upper back. In contrast, a grasp location selected for a "push off" strategy may require less muscular effort from the upper extremity and reduce the risk of injury or discomfort with more conservative shoulder flexion. Dekker et al [28] similarly reported that during a toileting task, older adults prefer a push-off strategy when using horizontal grab bars between knee and shoulder height, and pulling up or hanging strategies when using vertical supports. In recreationally active young adults, upper body strength in a push-up position is 1.5 - 2.7 times greater than that in a pull-up position [29]. While we did not observe any slips or falls in this study and did not measure balance outcomes, it may be valuable to understand the effect of pulling up compared with pushing off on balance metrics when using a grab bar for a STS task, as well as the impact of individual strength on selected grasp location and pull up or push off strategy. Additionally, the LH grab bar configuration we tested, specified in existing codes and standards [7,30] was below the preferred vertical grasp location for all but 2 participants, suggesting that the LH grab bar is inappropriately low for most people to use STS transfers.

We observed no change in horizontal grasp location between HH and SH during EXIT, and minimal changes in horizontal grasp location between SH, LH, I45, and I60 for STS. This echoes previous findings by Batista et al [12], who reported that participants most frequently grasped between 20 cm outside the bathtub rim and 20cm inside the bathtub rim during entry and exit. Several factors may contribute to this finding. First, participants may select a grasp location to minimize forward COM excursion during the grasping phase, grasping closer to their COM, and reducing the time between balance disturbance and hand position [31]. Second, closer grasp locations may require lower muscular effort [32]. Third, during a balance loss scenario, reaction time may be shorter for a closer grasp location, allowing more time for generating stabilizing forces. Finally, a closer grasp location may reflect the volume of visual field information stored for use during balance recovery reactions [19,33].

Considering these factors, our findings can be used to drive efforts to develop a universal grab bar configuration to support the bathing habits of most adults. Several existing codes and standards recommend a vertical grab bar for bathtub exit [7,8,30]. In our study, vertical grasp location on a VRT grab bar during bathtub entry and exit was moderately correlated with height, with participants grasping within 65% - 90% of their total body height, across EXIT conditions. Extrapolated across a range of heights from a 5th percentile female (142.45 cm) to a 95th percentile male (185.68 cm) [34], a minimum graspable area, including 10% tolerance, between 84 and 184 cm above the floor could be suggested for a grab bar placed at the entrance to a bathtub to support entry and exit. With the 41 cm rim height of the bathtub in this study, these dimensions translate to a graspable area between 43 and 143 cm above the bathtub rim. Positioning this vertical grab bar within 5 cm of the horizontal center of the bathtub rim will support the expected horizontal position of most users. For a grab bar along the back wall of the bathtub, participants of this study grasped vertically between 20% and 85% of their body height, which maps to a vertical graspable range of 25 to 156 cm above the floor (0 to 115 cm above the bathtub rim). Accommodating users of different heights may best be accomplished using a diagonal grab bar to span the vertical grasp range while allowing the user to select a preferred horizontal location. Higher grasp locations may be preferred to support other bathing tasks, such as washing the hair [35], while lower grasp locations further away from the control end of the bathtub may be appropriate for a bather who uses a bath seat or prefers to bathe seated at the bottom of the bathtub. We observed that participants prefer to grasp within a narrow horizontal range. Therefore, it may be valuable to consider the preferred grasp height of the user when considering the horizontal placement of ancillary items in the bathtub, such as a bath seat, soap dish, or towel rack, to allow continuous support along the varying heights of a diagonal grab bar.

There are cases where the suggested grab bar locations may not cover all use cases. In addition to evaluating grasp location during bathing tasks such as washing the feet or leaning over to test the water temperature, further work involving children may clarify whether the lower limits suggested are appropriate. Additionally, we only included participants who self-identified as healthy and able to bathe independently in this study; users with specific needs not covered by the suggested grab bar configurations, such as those with mobility challenges or who use mobility devices, may benefit from a more targeted or complex configuration of grab bars. For example, a horizontal grab bar may be preferred over a vertical grab bar by older adults [3,11] during bathtub entry and exit, STS from the bathtub floor, and balance recovery. In a study by Morales et al [36], older adults and users of mobility devices reported that using a vertical grab bar for bathing transfers felt less safe than a horizontal grab bar, while some users or participants refused to attempt to use the VRT grab bar to perform a bathing transfer, or reported that it felt uncomfortable or too physically challenging. Older adults and people who use mobility devices may place greater loads on a grab bar during a bathing transfer. Higher vertical

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loads may cause slipping on a vertical grab bar if they exceed the hand-grab bar friction generated through grip strength. Additionally, horizontal grab bars may allow the "push off" strategy, described previously, which may be more comfortable or require less physical effort than the "pull up" strategy required when using a higher grasp height on a vertical grab bar. Finally, upper extremity mobility, such as limited wrist or shoulder range of motion, may contribute to perceived comfort, effectiveness, or safety when using some grab bar configurations. Further work evaluating the use of grab bars during different bathing tasks with users of different mobility levels or assistive device requirements will inform optimal grab bar placement for other bathing subtasks and mobility levels.

Limitations

This study had several limitations. First, to reduce the data collection burden, participants differed between EXIT and STS tasks. However, direct comparisons were not made between the 2 tasks. To maintain a safe data collection environment, we did not include a reactive grasping perturbation condition for older adults. While we did not observe an age effect for any outcome, age-related decreases in joint power [37,38] may amplify the decrease in grasp height we observed between nonperturbation and perturbation trials. We did not evaluate the shoulder range of motion, which has been demonstrated to decrease with age, and which may have influenced grasp height [24]. Third, we did not evaluate whole-body kinematics or kinetics in this study. Further exploration of this data may improve understanding of how preferred grasp location affects balance control and joint moments during bathing tasks. Fourth, we did not include children in our study population. While nearly 100% of children older than 12 years, and 25% of children aged 6 - 11 years fall within the height range selected for our suggested universal configuration [34], further research could clarify whether the suggested configuration would also support children. It is possible that habitual higher grasps, used to reach grasping points on playground equipment, the hand of a caregiver, or to access handrails or surfaces, may affect overall grasping strategy and height in children. Fifth, it is unclear whether adaptation in reach-to-grasp strategies would impact grasp location. In a home bathroom, grasp location during habitual use and balance loss may converge. However, in an unfamiliar bathroom, such as in a hotel, grab bar positioning should consider both the proactive and reactive grasping locations observed in this study.

Conclusions

In this study, we aimed to evaluate the grasp location of healthy adults during a bathtub exit task and a STS task. Preferred and reactive grasp locations were summarized to make suggestions for a universal grab bar configuration to support users of different heights. Based on experimental results, a 1-meter vertical grab bar in line with the bathtub rim will effectively support proactive grab bar use during bathing transfers, as well as reactive use during balance loss, for most Canadians. For STS from a bath seat, a diagonal grab bar will accommodate the change in grasp height between the STS and stand-to-sit phases of the task.

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Conflicts of Interest

None declared.

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Abbreviations

COM: center-of-mass
HH: high horizontal
I45: incline 45°
I60: incline 60°
LH: low horizontal
OA-HIP: older adult, hand-in- place group
SH: standard horizontal
SLS: sodium lauryl sulfate
STS: sit-to-stand
VRT: vertical
YA-HIP: younger adult, hand-in-place group
YA-RTG: younger adult, reach-to-grasp group

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Evaluating R2Play, A Novel Multidomain Return-to-Play Assessment Tool for Concussion: Mixed Methods Feasibility and Face Validity Study

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Abstract

Background: Return-to-play guidelines for concussion recommend a multimodal approach to assess recovery, symptoms, exertion tolerance, and cognition. However, existing assessments do not reflect the speed or complexity of multidomain skill integration in sport. We developed *R2Play*, a dynamic multidomain return-to-play assessment tool, and previously established proof of concept by demonstrating design objectives alignment.

Objective: We aim to (1) assess the feasibility of *R2Play* according to usability, reliability, practicality, and safety; (2) examine physical exertion levels during *R2Play* as a preliminary marker of face validity; and (3) understand clinician and youth perspectives on the feasibility, face validity, potential value, and challenges associated with *R2Play*.

Methods: A convergent parallel mixed methods design was used. Rehabilitation clinicians were paired with youth cleared to return-to-play postconcussion to complete *R2Play* together and provide feedback through semistructured interviews. Feasibility was assessed on predefined criteria for usability (clinician ratings on System Usability Scale), practicality (assessment duration), reliability (technical issues), and safety (adverse events). Face validity was evaluated with a target of youth achieving ≥80% of age-predicted maximal heart rate or rating of perceived exertion ≥7/10. Interviews explored perspectives on feasibility and face validity, analyzed using content analysis. Quantitative and qualitative results were merged via joint display to identify areas of convergence, divergence, and complementarity.

Results: Participants included 10 youth (ages 13 - 20 y) with a history of concussion and 5 clinicians (n=2 physiotherapists, n=2 occupational therapists, and n=1 kinesiologist). Success criteria were met or approached for all feasibility domains. Clinician-rated usability was good-to-excellent (System Usability Scale=84.00±6.02), and youth reported that instructions were easy to learn. There were no catastrophic technical or user errors interrupting assessments. Configuration was completed in 5.74 (SD 1.09) minutes, and assessments took 26.50±6.02 minutes. There were no safety or symptom exacerbation incidents requiring assessment modification. *R2Play* elicited vigorous intensity physical exertion (peak heart rate=90.10±5.78% age-predicted maximal heart rate, peak rating of perceived exertion=5.50±1.72), with target exertion criteria met for 9/10 youth. Clinician and youth feedback confirmed that *R2Play* reflects elements of sport across physical, cognitive, and perceptual domains, making it a valuable tool for assessing readiness to return-to-play and informing rehabilitation planning for unresolved issues. Mixed

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methods meta-inferences provided enhanced insights regarding how to improve the usability, practicality, safety, and face validity of *R2Play*.

Conclusions: Findings support the potential feasibility and face validity of *R2Play*, a multidomain assessment tool for youth with concussion, demonstrating excellent usability, vigorous physical exertion demands, and promising feedback regarding its potential to fill gaps in the return-to-play process among this initial sample from a single site. Future work is underway to establish the cross-site feasibility of *R2Play* and evaluate its content validity by establishing the physical, cognitive, and perceptual loading of assessment levels.

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KEYWORDS

concussion; pediatrics; return to sport; dual task; feasibility, mixed methods

Introduction

Background

Concussion is a significant public health concern, which impacts more than 10% of Canadian school-aged children each year [1,2]. Sport is a leading cause, accounting for 30% - 40% of concussions among Canadian youth [3-5]. In Ontario, Canada, Rowan's Law (Bill 193) guides concussion safety practices, including a mandate for medical clearance of youth returning to sport after concussion [6]. Similar policies exist in all US states [7] and are recommended across Canadian provinces [8,9]. Yet, evaluating concussion recovery and readiness for return-to-play (return-to-play) is challenging, as there is no single objective test and limited evidence-based standards to support decision-making [10-12]. Evidence suggests that current approaches are inadequate, as injury risk remains significantly elevated in the year following return-to-play postconcussion, indicating potential ongoing neurological dysfunction [13,14]. Many athletes also report feeling anxiety or fear upon return-to-play, highlighting the importance of psychological readiness [15,16]. Better tools are clearly needed to measure complete biopsychosocial recovery and guide safe return-to-play after concussion.

Multidomain Concussion Assessment

Emerging research shows that novel assessment paradigms simultaneously targeting multiple domains of function (eg, cognitive and motor performance) can help uncover lingering subclinical neurophysiological changes after concussion [12,17]. Dual task tests involving concurrent motor (eg, walking) and cognitive (eg, backward spelling) tasks elicit subtle neuromuscular and attentional impairments among individuals with concussion that persist beyond traditional single-domain measures for several months after injury and are linked to subsequent injury risk [17-21]. Deficits include changes in gait speed or stability, cognitive accuracy, and reaction time, which are quantified in dual task costs by the magnitude of performance decrements upon introduction of a second task [17,22-24]. These performance "costs" become more pronounced as cognitive task complexity increases [25]. It is thus problematic that standard dual task tests do not reflect the speed or complexity of skill integration in sport, which involves multiplanar movement and spontaneous decision-making in response to dynamic stimuli, within an unpredictable environment [26,27]. Emerging digital approaches such as virtual reality offer promising potential for creating more realistic testing scenarios but face challenges in clinical translation (eg, cost or availability, personalization, or scoring complexity) and have yet to be adapted for return-to-play (see the review by DuPlessis et al [26] of existing multidomain assessments). Thus, ecologically relevant and clinically feasible multidomain assessments that mimic the complex demands of sport may help guide rehabilitation and safe return-to-play following concussion [26].

R2Play Assessment Tool

Our team developed *R2Play*, a multidomain return-to-play assessment tool for youth with concussion, designed to help simulate the complex demands of sport within clinical settings [28]. *R2Play* was developed through a user-centered design approach involving clinicians, sport coaches, youth athletes, and families with lived experience of concussion. Through this process, *R2Play* was established as a system of low-cost tablets displaying numbers and letters that youth run between to connect an alphanumeric "trail" (1-A-2-B-3-C…) through levels with layered challenges to perception, cognition, and exertion. Heart rate (HR), perceived exertion, and concussion symptoms are monitored throughout *R2Play*, with performance measured via level completion times, errors, and multitask cost scores reflecting performance changes between levels with the addition of new challenges. Using low-cost and widely accessible technology, *R2Play* aims to provide a clinically feasible return-to-play assessment with greater ecological relevance through integration of physical skills (multiplanar exertion), cognition (complex decision-making), and psychosocial stress (performance pressure) within a dynamic, changing environment. A complete description of the *R2Play* development process and initial prototype can be found in DuPlessis et al [28]

Feasibility testing is an important step in complex intervention development that can help improve design, strengthen evaluation methods, and facilitate implementation [29,30]. For technology-based rehabilitation innovations, progressive small-scale studies involving end users are recommended to help identify and proactively address usability and feasibility issues before broader-scaled evaluation [31]. We conducted initial proof-of-concept testing for *R2Play* (version 1) with 5 clinicians and 10 youth sport participants without recent concussion history, demonstrating alignment with system design objectives, including excellent usability, moderate intensity physical exertion demands, and promising qualitative feedback

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regarding its potential value in clinical practice [32]. Based on this preliminary work, minor changes were made to improve *R2Play* (eg, enhancing the usability of interface screens, refining level structure, and shortening the assessment). In the present study, we sought to test the revised *R2Play* system (version 2) among youth previously cleared to return-to-play, a critical step to enable larger validation studies among youth recovering from concussion.

Purpose and Objectives

The purpose of this study was to evaluate the feasibility and face validity of *R2Play* (version 2) among youth with concussion history and prior clearance to return-to-play. We conceptualized face validity as the extent to which *R2Play* feels like sport, a valuable early indicator of how well it reflects multidomain demands of sport and the extent to which it may apply to real-world sport environments (ie, ecological validity) [28,33]. Specific objectives were:

1. Assess the feasibility of *R2Play* in terms of usability, reliability, practicality, and safety according to the a priori success criteria described in Table 1.
2. Examine physical exertion levels during *R2Play* as a marker of face validity, with the target of youth achieving ≥80% of age-predicted maximal heart rate (HR_{max}) or rating of perceived exertion (RPE) ≥7/10.
3. Understand clinician and youth perspectives on the feasibility, face validity, potential value, and challenges associated with *R2Play*.

Iterative design and testing are essential to ensure success in large-scale validation and implementation of health technologies [31]. Addressing these aims is thus intended to help optimize the design of *R2Play*, increasing the likelihood of achieving favorable outcomes in larger-scale psychometric validation, efficacy, and implementation trials.

Table . Quantitative feasibility domains and success criteria. Data sources for each domain can be found in Multimedia Appendix 1.

Domain	Definition	Success criteria
Usability	Does the *R2Play* system allow clinicians and youth to complete the assessment effectively, efficiently, and to their satisfaction?	• Mean SUS[a] score ≥80 • 90% of assessments completed without catastrophic user error[b]
Reliability	Does the *R2Play* system perform appropriately to administer the assessment without error?	• 90% of assessments completed without catastrophic technical error[b]
Implementation and practicality	Can *R2Play* be learned and administered in a timely and consistent manner?	• All clinicians achieve training task completion scores >15 (75%) during a 1-hour virtual training session. • Assessment configuration completed in ≤5 minutes for 90% of sessions • Active assessment completed in 20 - 30 minutes for 90% of sessions
Safety	Can *R2Play* be administered safely to youth being cleared for return-to-play postconcussion?	• No *R2Play*-related safety incidents requiring medical attention • No *R2Play* assessment sessions requiring cessation or modification due to concerning exacerbation of concussion-related symptoms

[a]SUS: System Usability Scale.

[b]See definition in Textbox 1.

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Textbox 1. Definitions and severity grading of technical errors and usability issues.

Event definitions

- Technical errors: instances in which the system malfunctions or does not perform appropriately as expected (eg, unresponsive tablet, incorrect content displayed on tablet, wrong screen shown within clinician interface, and buttons within interface not functioning properly).
- Usability issues: aspects of the system or a user's (clinician or youth) interaction with the system that make it difficult for them to independently complete an assessment task effectively and efficiently (eg, pressing the wrong button to achieve the desired goal or not understanding level instructions).

Event severity

- Recoverable: system or interface enters a state that the users did not intend, but they can quickly recover and continue the assessment without intervention from the research team.
- Unrecoverable: system or interface enters a state that the users did not intend, and they cannot recover without intervention from the research team. The research team resolves the issue quickly without significantly interrupting the assessment session.
- Catastrophic: assessment session is terminated and must be entirely restarted or significantly interrupted in a way that requires substantial intervention from the research team and causes a delay in continuing the assessment.

Methods

Design

This study followed a convergent parallel mixed methods design in which quantitative and qualitative data were collected simultaneously, analyzed separately, and merged upon interpretation with equal priority [34]. Specifically, we leveraged a descriptive observational design [35] for quantitative evaluation and used qualitative description [36] to explore participant perspectives. From a pragmatist perspective, this approach sought to obtain a comprehensive understanding of research questions through triangulation across methods and datasets [37]. It aimed to address not only whether *R2Play* could work, but also how and why it may work, with the goal of gathering data and feedback to optimize this novel assessment approach [38]. Broadly, we operationalized feasibility according to domains described by Bowen et al [39], which are reflected in both quantitative and qualitative components. The GRAMMS (Good Reporting of a Mixed Methods Study) checklist (Checklist 1) was used to guide study design and dissemination [40].

Participants

Identical samples were used for quantitative and qualitative strands [41]. Ten youth previously cleared to return-to-play after concussions were each paired with 1 of 5 trained clinicians to complete *R2Play* together. These sample sizes reflect the exploratory nature of the quantitative objectives and align with recommendations for qualitative interview studies [42]. In our proof-of-concept work, qualitative data saturation was reached with the same sample sizes and study design [32].

Youth inclusion criteria were age 10 - 25 years (consistent with WHO definition of "young person" [43]), as younger children require unique developmentally appropriate assessments [12]; experience with return-to-play process after concussion within the previous 5 years (any mechanism of injury); clinician clearance for unrestricted RTP (per current standard of practice [12]); normal or corrected to normal vision and hearing; fluent in English. Youth were excluded if they had any pre-existing conditions that could impede safe participation (eg, musculoskeletal injury or neurological or cardiovascular condition) or a developmental or learning disability that interfered with their ability to do physical activities, hear noises, follow instructions, or communicate.

Clinicians were required to have ≥1 year of experience working with youth, experience working with concussion or another acquired brain injury population, English fluency, and ability to commit to study requirements (6 h total over 4 separate days).

Recruitment

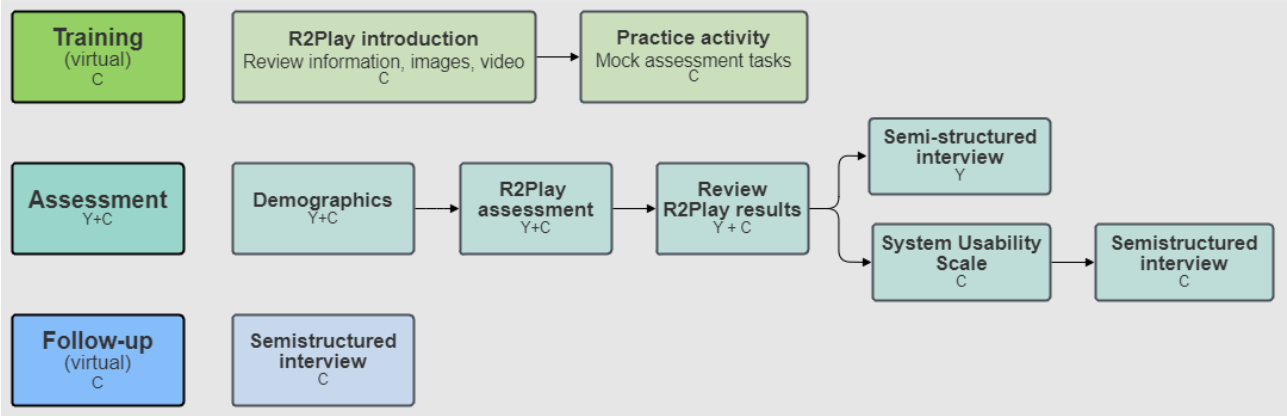
Convenience sampling was used, in which youth were recruited internally through the Holland Bloorview Kids Rehabilitation Hospital (HBKRH) concussion services. Youth who accessed clinic services were either referred to this study by a care team member or contacted directly by the research team following discharge if they had consented to participate in the HBKRH research notification program. Additional youth were identified via snowball sampling, word of mouth, and institutional advertisements at HBKRH. Clinicians were recruited from the local community via social media, professional networks, and word of mouth. Diversity was sought in representation across disciplines and practice settings (ie, private vs public, acute vs chronic).

Protocol

Figure 1 summarizes this study's protocol. Clinicians first attended a 1-hour virtual training session to learn to administer *R2Play*. Training was led by the primary author (JS) and involved a brief presentation, demonstration of the system interface, and practicing key tasks in facilitating *R2Play* (Checklist 2). Following training, clinicians were paired with a youth participant to complete *R2Play* together in person at HBKRH. After finishing the assessment, the clinician and youth participants reviewed results together with a research team member and then completed separate semistructured interviews to provide feedback. To enable practice and reflection, clinicians were asked to complete 2 assessment sessions with different youth. Within 1 week after their second session, clinicians completed an in-depth follow-up interview (30 - 60 min) to reflect further on their experience and perspective, considering both *R2Play* sessions.

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Figure 1. Study protocol. C: clinician participant; Y: youth participant.



Data Collection Measures

Demographics

Youth completed a brief demographic form collecting their age, sex, gender, sport participation (weekly hours), number of diagnosed concussions, and time to return-to-play. Clinicians were asked to report their age, gender, discipline, years of experience, practice setting, and client age range.

Clinician Training Task Activity

A standardized checklist (Checklist 2) was used by the training facilitator (JS) to record completion of 10 key tasks during the training practice activity. Task completion was scored as completed with ease (2), completed with help (1), or not completed (0) [28]. Total completion score was calculated by summing individual task scores (maximum score of 20).

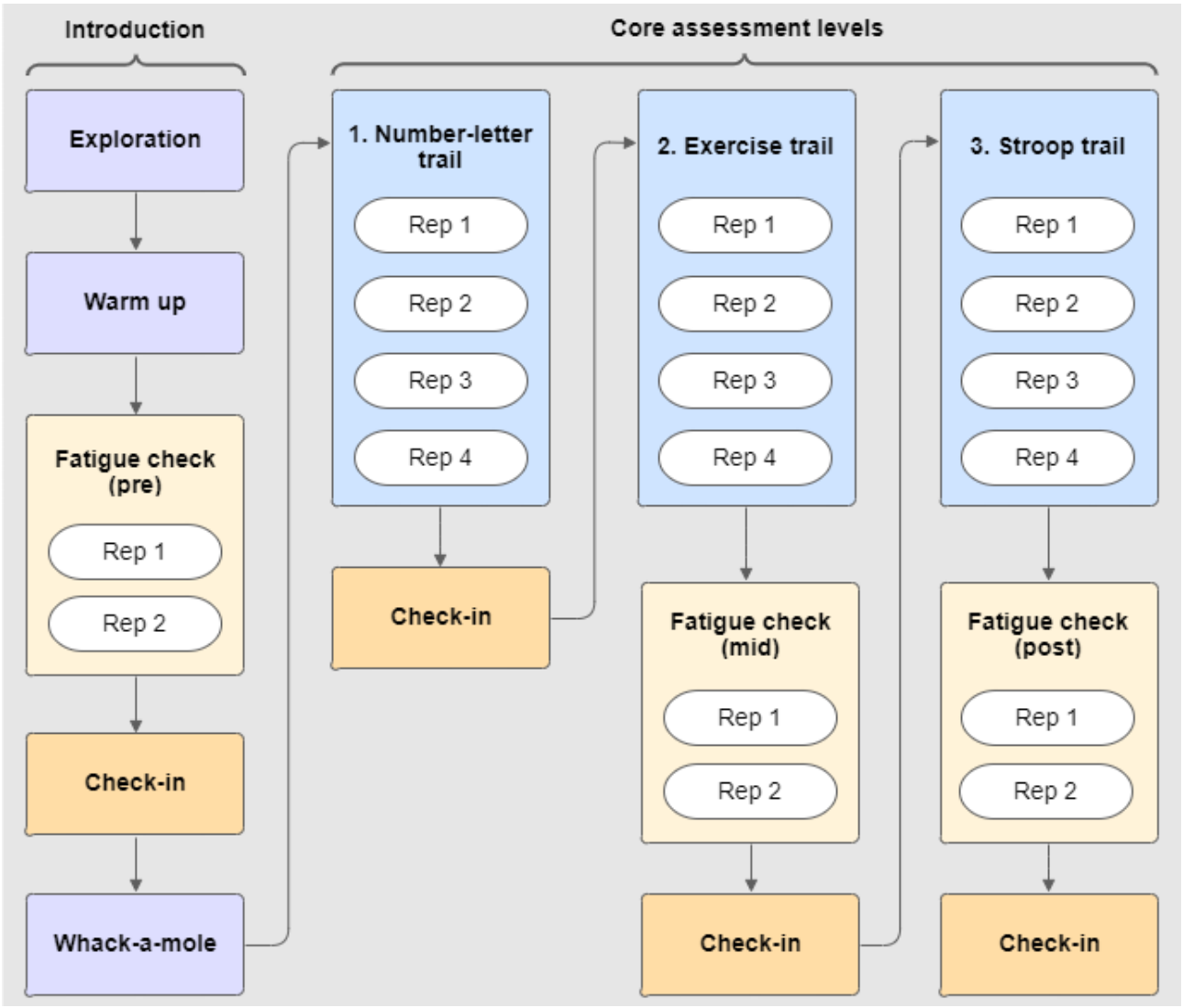
R2Play Assessment

Protocol

An overview of the *R2Play* assessment (version 2) can be found in Figure 2. Briefly, the assessment consisted of an introduction phase with 3 activities to orient participants to the *R2Play* system and task, followed by 3 core assessment levels (number-letter, exertion, and Stroop) with varied physical and cognitive demand complexity. Between these core levels, there were 3 fatigue checks to capture any changes in sprint completion time. A description of each assessment activity can be found in Figure 3. Each core level consisted of 4 repetitions: 2 standard condition repetitions and 2 repetitions that introduced layered perceptual challenge conditions (Figure 4) [44]. Level instructions were explained to youth using 4 training methods within the *R2Play* interface: (1) verbal instructions; (2) introducing trail sounds; (3) video demonstration of the level, and (4) tracing activity to practice the number-letter pattern. Brief check-ins were conducted after each level, in which participants rated their perceived exertion and changes in concussion symptoms (see measures below). HR was also monitored throughout the entire assessment and streamed live in the clinician interface.

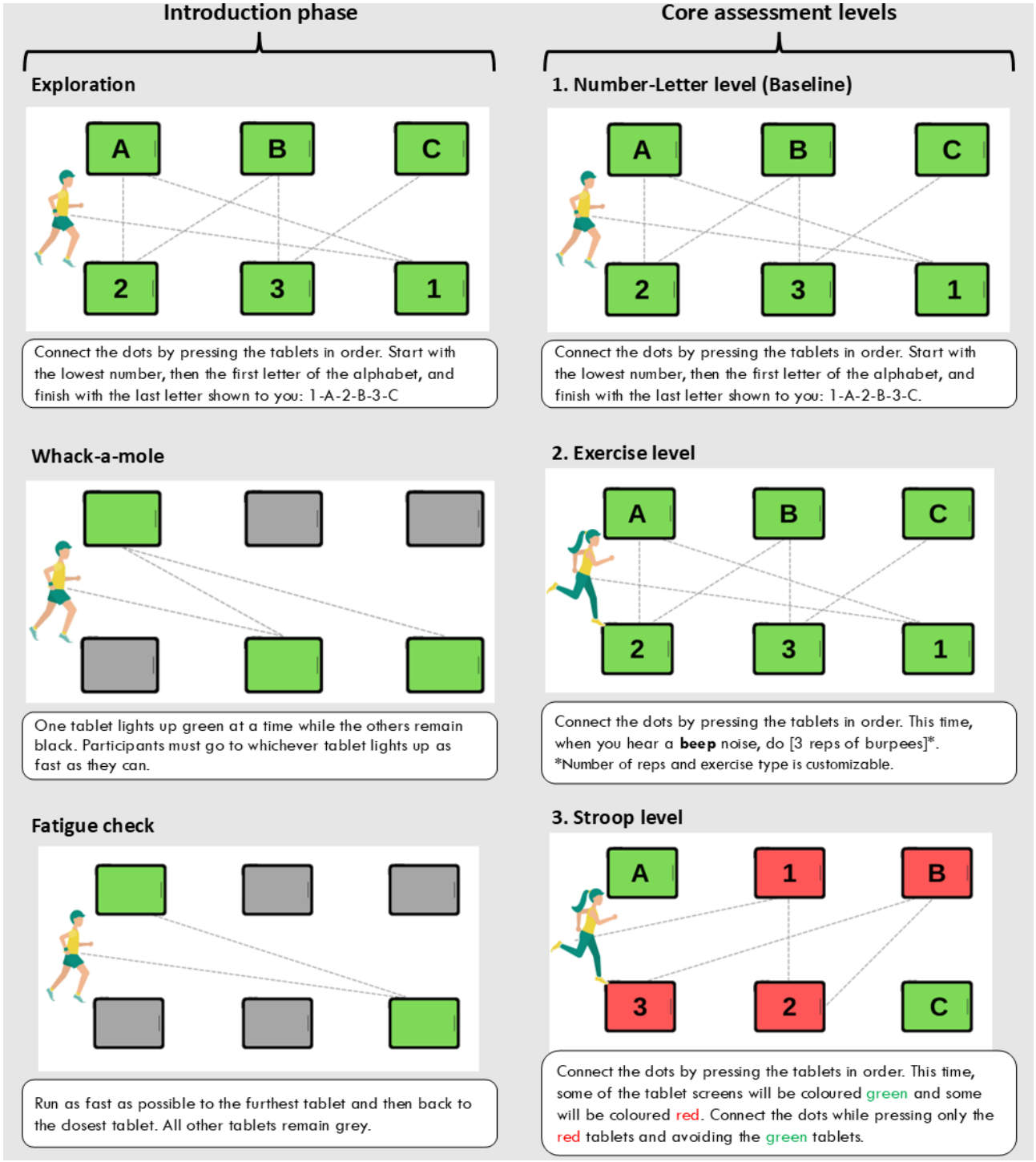
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Figure 2. *R2Play* (version 2) assessment protocol. The introductory phase helps orient participants to the *R2Play* system and learn the assessment task. The core assessment levels make up the backbone of assessment scoring. Rep: repetition.



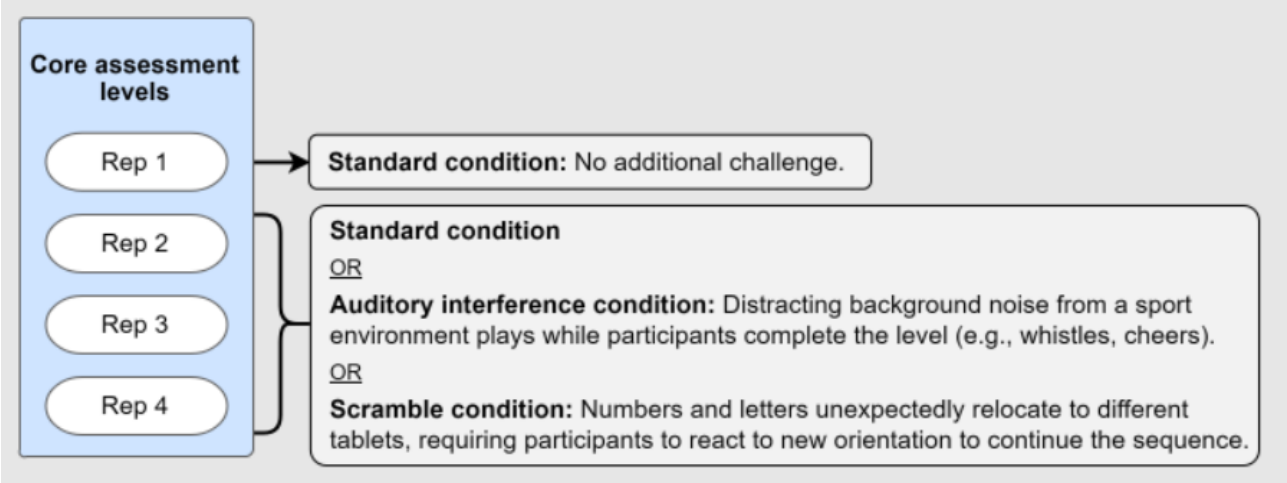
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Figure 3. *R2Play* (version 2) assessment level descriptions. For the core assessment levels, 1 repetition comprised 2 cycles of the same 6-character sequence (1-A-2-B-3-C), for a total of 12 tablet selections. Trail sequences were programmed to have running distance between correct tablet taps standardized to 45 m (±1%) for all number-letter and exercise level repetitions and 30 m (±1%) for all Stroop level repetitions (due to green tablet omissions). Across all levels, the distance traveled per correct tablet selection was approximately 7.5 m. Rep: repetition.



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Figure 4. Repetition conditions for the core *R2Play* assessment levels. Within each level, the first repetition is the standard condition. Repetitions 2 - 4 are a randomized order of another standard condition, the auditory inference condition, and the scramble condition. Rep: repetition.



Scoring

The *R2Play* assessment is scored via level completion times, errors (ie, incorrect tablet selections), and HR. Completion time is calculated in seconds and measured relative to the number of tablet selections in the level (ie, seconds/tablet). Based on these metrics, multidomain cost scores are calculated that reflect performance changes between levels and conditions as new challenges are added. Cost scores are expressed as the percentage change in score between a baseline and more challenging level or condition (calculations detailed in Multimedia Appendix 2).

Heart Rate

Youth wore a Polar H10 chest strap monitor (Polar Electro) to capture their HR throughout *R2Play*. Average and peak HR (beats per minute) were calculated for each participant and level.

Rating of Perceived Exertion

Youth reported their RPE during check-ins immediately after each *R2Play* level using the 10-point children's OMNI scale, a validated tool for measuring RPE among exercising youth [44].

Concussion-Related Symptom Evaluations

Post-Concussion Symptom Inventory

Before and after *R2Play*, youth completed the 26-item adolescent Post-Concussion Symptom Inventory (PCSI) [45] to assess the presence and severity of concussion-related symptoms across physical, cognitive, emotional, and sleep or fatigue domains. Symptoms were rated on a 6-point Likert scale from "not a problem" (0) to "severe problem" (6). Overall PCSI symptom score was calculated by summing all rated symptoms (maximum of 156).

Symptom Check-In

After each *R2Play* level, youth completed a brief check-in to assess symptom changes, with the following response options: no symptoms (0), some symptoms but did not get worse (1), symptoms got worse (2), symptoms so much worse I had to stop (3).

System Usability Scale

Immediately after finishing each *R2Play* assessment, clinicians completed the System Usability Scale (SUS), a validated measure of subjective usability [46]. The SUS contains 10 items rated on a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). Item responses are each assigned a score contribution from 0 - 4, which are summed and multiplied by 2.5 to produce a total SUS score of 100. A total SUS score of 68 is considered average, 68 - 80 is good, and ≥80 excellent [47].

Assessment Session Recordings

Screen recordings of the *R2Play* clinician software interface and video recordings of the entire assessment sessions were captured to provide insight regarding participant interactions with the system and to enable further investigation of technical or usability issues.

Field Notes

A structured template was used by research team members during all *R2Play* assessment sessions to record field notes capturing any technical errors, usability issues, or support required by participants.

Semistructured Interviews

Interviews explored participants' experiences with *R2Play* and perspectives on its feasibility, face validity, potential value, and challenges. Youth were asked to reflect on the acceptability of *R2Play*, usability, demand (ie, perceived value), practicality (eg, ability to learn rules), and face validity (ie, whether *R2Play* felt like playing sports). Clinician postsession interviews focused on initial reactions to *R2Play* in terms of usability, training requirements, and perceived value. Clinician follow-up interviews were structured around multiple domains of feasibility (acceptability, usability, demand, implementation, practicality, adaptability, expansion, and safety) [39] and face validity. Interview guides can be found in Multimedia Appendix 3. All interviews were audio recorded, transcribed verbatim, and checked for accuracy.

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Analysis

Quantitative

Feasibility (objective 1) was evaluated based on predefined criteria for usability, reliability, practicality, and safety (Table 1). These domains were chosen from Bowen et al [39] and other literature [31,48] to address the most pertinent uncertainties at this stage, with the success criteria set based on proof-of-concept results where possible [32,49,50]. Assessment duration and exertion data were ascertained from automated system logs and analyzed using Microsoft Excel (Microsoft Corp) and R statistical software (R Foundation). Quantitative feasibility data were summarized using descriptive statistics and 95% CIs where appropriate.

Observational analysis of video and screen recordings was performed using a standardized data extraction sheet to identify technical and usability issues (Multimedia Appendix 4). Two authors (JS and AL) independently reviewed recording footage from 2 *R2Play* sessions and met to compare findings and resolve discrepancies. Each researcher then reviewed 4 more session recordings independently. Once all sessions were reviewed, the researchers met again to discuss and confirm identified events, collaboratively resolving any uncertainties. Field notes were referenced to provide additional context about identified events. Finally, both researchers worked together to group similar events and tally their occurrences. Identified issues were discussed with the project engineer to determine causes and implement solutions.

Physical exertion (objective 2) was evaluated with the target of youth achieving a vigorous intensity level at any point during the assessment (≥80% HR_{max} or RPE ≥7) as a marker of face validity [49]. These thresholds align with clinical exercise testing guidelines and exertion testing protocols for concussion [50,51]. Exertion data were plotted and visually inspected to identify trends across assessment levels. There was no missing data across all quantitative analyses.

Qualitative

Interview transcripts exploring participant perspectives (objective 3) were analyzed separately for youth and clinicians via qualitative content analysis using the feasibility and face validity domains as a framework for analysis [52]. A total of 2 transcripts were collaboratively coded by 2 authors for clinician postsession and follow-up interviews (JS and EK), and youth interviews (JS and DD). Codes were initially derived inductively from the data, without applying any theoretical framework and using the participants' own words wherever possible. Preliminary clinician and youth codebooks were then transferred to NVivo qualitative analysis software (Lumivero) and flexibly applied to the remaining transcripts by the lead author (JS), allowing for the addition of new codes to capture unique concepts. Once all transcripts were coded, reviewers organized the codes into categories that specifically addressed the feasibility and face validity domains. Strategies to enhance rigor included collaboratively coding initial transcripts, verifying emergent codes with another reviewer, discussing categories within the research team, and retaining an audit trail of analysis [53,54].

Mixed Methods Integration

Quantitative and qualitative strands were integrated at the levels of design, methods, reporting, and interpretation [34,55]. Within this convergent design, strands were initially linked by identical sampling of the same participants (ie, connecting) [41,55]. Strand-specific data for feasibility and face validity were analyzed separately, with results reported narratively using a weaving approach [55]. Strands were merged via joint display to identify areas of convergence, divergence, and complementarity [55,56]. Data was triangulated across sources (eg, SUS, video and screen recordings, interviews, and field notes) and samples (ie, clinicians and youth) to aid interpretation and enhance credibility [57]. Multimedia Appendix 3 provides a joint display of integrated data highlighting the specific quantitative and qualitative data addressing study aims. We used the decision tree from Younas and Durante [58] and guidance from Aschbrenner et al [59] to select appropriate joint displays based on our design, mixing purpose, and integration techniques. Joint displays were constructed according to essential elements recommended by Guetterman et al [56]

Ethical Considerations

Ethics approval was obtained from HBKRH (REB #20 - 099) and the University of Toronto (REB #40694). All participants provided voluntary informed written consent. Efforts were undertaken to maintain privacy and confidentiality of participant data and identities. Participants received compensation in the form of gift cards.

Results

Overview

Five clinicians and 10 youth (ages 13 - 20 y) with concussion history participated (Tables 2 and 3). Quantitative and qualitative results for each feasibility domain and face validity are presented within the subsections below, each followed by a brief description of key findings from mixed methods integration (ie, meta-inferences) presented via joint displays.

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Table . Clinician participant characteristics.

Clinicians (C)	Age range (years)	Sex	Clinical discipline	Practice setting	Experience (years)	Days between study sessions
C1	30 - 35	F	Physiotherapy	Private	5 - 10	16
C2	25 - 30	F	Kinesiology	Public and private	3 - 5	4
C3	25 - 30	F	Occupational therapy	Private	3 - 5	3
C4	25 - 30	F	Physiotherapy	Public and private	0 - 3	71
C5	30 - 35	F	Occupational therapy	Private	5 - 10	28

Table . Youth participant characteristics.

Youth (Y)	Age (years)	Sex	Gender	Sports played (hours per week)	Number of concussions reported	Time since last concussion (months)	Approximate time to return-to-play (days) for latest concussion
Y1	14	M[a]	Boy or man	Hockey, soccer, and volleyball (19 total)	6	2	Unknown
Y2	16	F[b]	Girl or woman	Softball (5-6), ultimate frisbee (4), running (1-2), and swimming (2-3)	1	20	30
Y3	19	F	Girl or woman	Snowboarding (0 - 10) and Muay Thai (4-12)	2	59	120
Y4	16	F	Girl or woman	Basketball and volleyball (6 total)	2	36	30
Y5	14	M	Boy or man	Hockey (6), baseball (3), and snowboarding (8)	2	26	14
Y6	16	F	Girl or woman	Hockey (4-5) and gymnastics (2)	3	54	120
Y7	13	F	Girl or woman	Soccer (6), hockey (6), and badminton (10)	5	6	150
Y8	15	M	Boy or man	Hockey (4), snowboarding (6), swimming, golf, and tennis	1	50	21
Y9	13	F	Girl or woman	Volleyball (4)	1	2	7
Y10	20	F	Girl or woman	Soccer (8)	2	60	60

[a]M: male.

[b]F: female.

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Feasibility

Usability

SUS

Mean total SUS score across all sessions was 83.75 (SD 4.45; 95% CI 80.99 - 86.51), surpassing the success target of 80. Usability ratings remained relatively stable from clinicians' first (SUS=83.50±2.85; 95% CI 81.00 - 86.00) to second sessions (SUS=84.00±6.02; 95% CI 78.72 - 89.28). An SUS score >80 places *R2Play* within the 90 - 95 percentile range of usability, corresponding to "good-to-excellent" usability [60]. Across both sessions, items rated least favorably were "I felt very confident using the system" (mean 3.90, SD 0.74) and "I needed to learn a lot of things before I could get going with this system" (mean 2.50, SD 0.97; reverse weighting).

Usability Issues From Observational Analysis

Usability issues identified in the video and screen recording analysis are shown in Table 4. Overall, fewer usability issues were documented for clinicians' second assessment sessions (n=16) compared to their first (n=23), and a higher proportion of issues were recoverable in their second sessions (53% vs 17%). No usability issues met the definition of catastrophic (Textbox 1).

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Table . Usability issues identified from observational analysis of video and screen recordings.

Severity[a]	Frequency	Description
First assessment session (n=23; 17% recoverable)		
Catastrophic	0	N/A[b]
Unrecoverable (n=19)[c]		
	8	The researcher intervened to provide direction because the clinician did not deliver the appropriate level's instructions
	4	The clinician needed help from the researcher to navigate the software interface
	4	The youth required an explanation of the instructions from the researcher
	2	The clinician asked for clarification from the researcher about the level's instructions
	1	The youth false-started (moved before the start cue)
Recoverable (n=4)[c]		
	3	The youth required further explanation of instructions from the clinician while completing a level
	1	The clinician had difficulty navigating the software interface but was able to recover independently
Second assessment session (n=15; 53% recoverable)		
Catastrophic	0	N/A[b]
Unrecoverable (n=7)[c]		
	2	The clinician needed help from a researcher to navigate the software interface
	2	The clinician asked for clarification from the researcher about the level's instructions
	1	The youth false-started (moved before the start cue)
	1	The clinician did not provide appropriate level instructions
	1	The clinician asked for clarification about check-in response options
Recoverable (n=8)[c]		
	3	The clinician had difficulty navigating the software interface but was able to recover independently
	3	The youth required further explanation of instructions from the clinician while completing a level
	2	The tablet needed to be readjusted

[a]Severity definitions can be found in Textbox 1. Briefly, unrecoverable errors required intervention from the research team, while recoverable errors could be resolved by the clinician or the youth participant themselves.

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[b]N/A: not applicable.

[c]Subtotal.

Qualitative Interview Findings (Clinicians)

Usability Overview

Clinicians found *R2Play* highly usable, describing the interface as "well designed," "intuitive," and "easy to use." They noted it became easier with practice, and they felt more comfortable in their second session despite the time between sessions (3 - 71 d). Confidence in using *R2Play* was primarily limited by a lack of familiarity with the assessment protocol and level instructions.

Usable Aspects

On-screen prompts and automation made it particularly easy for clinicians to navigate the interface: "I think the way it is set up… kind of just the next thing is automatic, I think makes sense from a usability standpoint" (C5). They also appreciated that all components of the assessment were "embedded" within the interface (eg, PCSI) so they did not need to manage additional applications or supplies. Other usable aspects included the multimodal level training screens, time-stamped observation notes, and "cheat sheet" handout resources.

Usability Challenges

Clinicians found that following the overall flow of the *R2Play* assessment protocol and delivering level instructions was most challenging. For example, one clinician said, "It took me a little while to get used to the protocol. I'd get confused as to what I was getting the athlete to do sometimes… just getting your head wrapped around the flow and how to direct the athlete and work through the different stages" (C1). Some clinicians also reported difficulty navigating results screens and explaining the cost scores to youth.

Usability Suggestions

To support consistent delivery of level instructions, a standardized script embedded within the interface was recommended. Areas for increased automation, prompts, and guidance within the interface were also highlighted (eg, level training screens). Knowledge mobilization tools such as lay summaries, visuals, and interpretation guidelines were recommended to help communicate cost score results to youth and families.

Qualitative Interview Findings (Youth)

Rules and Instructions

Most youth found the instructions easy to learn and follow. Some reported initial confusion about aspects of the task, for example, the need to complete 2 cycles of the 6-character sequence, but they gained familiarity through repetition of tasks across assessment levels. Video and audio demonstrations were seen as particularly helpful for learning instructions. For earlier stages of concussion recovery, more visuals and further simplification of instructions were recommended.

Tablet Button System

Youth described the tablet buttons as easy to use, despite some concerns regarding their stability and sensitivity. For example, before becoming familiar with the system, youth reported initial apprehension about tapping the tablets without toppling them, or being unsure how much force was needed to register a tablet selection. One participant noted that her long fingernails were a potential usability issue as they made it difficult to select tablets while running.

Reliability

Technical Errors

A total of 7 technical errors were recorded and managed by the research team without data loss. There was 1 catastrophic error in which multiple tablets lost connection to the system mid-assessment, significantly interrupting active assessment time (Table 5). One unrecoverable error occurred in which the HR monitor disconnected, requiring researcher intervention. Recoverable errors included unregistered tablet selections (n=3) and buttons within the clinician interface not functioning properly (n=2).

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Table . Duration of configuration and active assessment for *R2Play* sessions. Configuration time includes assessment initiation, customization, and baseline measures collection. Clinicians were not required to perform system set-up in this study (ie, arranging tablets or connecting the system). Active assessment is the time during which a participant is completing *R2Play* levels.

Session	Configuration, (minutes)	Active assessment, (minutes)	Total, (minutes)
First assessment session			
C1	12.75[a]	32.19[ab]	44.94
C2	4.89	27.03	31.92
C3	5.07	31.43[a]	36.50
C4	3.80	21.41	25.22
C5	7.90[a]	30.44	38.34
Mean (SD; 95% CI)	6.88[a] (3.61; 3.71 - 10.05)	28.50 (4.43; 24.62 - 32.38)	35.38 (7.36; 28.93 - 41.83)
Second assessment session			
C1	6.94[a]	27.03	32.97
C2	4.29	24.96	29.24
C3	5.02	30.95	35.97
C4	6.99[a]	27.84	34.84
C5	6.44[a]	21.75	28.19
Mean (SD; 95% CI)	5.74 (1.09; 4.78 - 6.69)[a]	26.50 (3.42; 23.50 - 29.51)	32.24 (3.41; 29.25 - 35.23)
All sessions			
Mean (SD; 95% CI)	6.31 (2.59; 4.04 - 8.58)[a]	27.94 (4.06; 24.38 - 31.50)	34.40 (5.66; 29.29 - 39.21)

[a]Target feasibility success criteria were not met (Table 1).

[b]Active assessment interrupted by technical error (loss of system connection).

Qualitative Interview Findings (Clinicians and Youth)

Overall, *R2Play* was seen to run smoothly with minimal technical issues. Technical errors observed by clinicians and youth included unregistered or delayed tablet selections and unresponsive tablets. Clinicians also identified minor issues within the interface, including training videos and audio clips not functioning properly.

Implementation and Practicality

Clinician Training Task Completion

All clinicians achieved a training task completion score ≥18/20 (90%) and were able to fully or partially complete all training tasks. The most common task in which all clinician participants required assistance was “train a new client on a given level of the *R2Play* assessment” (n=5 received partial points). While they were all able to deliver basic level instructions, points were deducted due to missed details (eg, not explaining repetition conditions), or ineffective use of multimodal training methods (video demo, trace-it-out, and trail sounds). The second most common task requiring help was “report and explain a specified cost score from an *R2Play* assessment to a client” (n=2 received partial points).

Assessment Duration

Table 5 presents the duration of assessment configuration and active assessment [1] Overall, the target of 20 - 30 minutes of active assessment time was met for 8/10 (80%) sessions, while the target of ≤5 minutes of configuration time was only met for 5/10 (50%) sessions. Total *R2Play* duration was slightly lower for clinicians’ second sessions (mean 32.24, SD 3.41 min) compared to their first (mean 35.38, SD 7.36 min).

Qualitative Interview Findings (Clinicians)

Time

Clinicians spoke about the need to balance the desire for prolonged exertion against the practicality of assessment length. They appreciated measuring performance over a longer interval, in contrast to existing tests: “Sometimes our tests are only like 10 minutes, and they could clear it... So, I think the fact that it’s a bit longer of an assessment and you’re measuring over time is really helpful” (C3). However, the time required for set-up, configuration, assessment, and results review was seen as a potential barrier to clinical implementation. An hour-long appointment was thought to be required for *R2Play*, which was seen as a challenge in some practice structures, though some clinicians felt that the comprehensive nature of *R2Play* made it appropriate as a stand-alone final return-to-play clearance discharge assessment.

Space and Set-Up

Physical space was described as a barrier to conducting functional assessments such as *R2Play* in clinical environments. Setting up *R2Play* was seen as a potential challenge due to the equipment components and standardized positioning, which could amplify time constraints. Quick and easy set-up was thus

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important to clinicians, who also recommended designated assessment spaces and support staff to assist with set-up. Rehabilitation hospitals, university clinics, and specialty programs were seen as appropriate settings with suitable space and staffing to support *R2Play*.

Cost

Some clinicians thought the cost of *R2Play* could be prohibitive for individual providers and small organizations. They described a need to demonstrate the value of *R2Play* relative to existing tools to justify its cost and suggested discounted bundle packages for purchasing equipment, software, and training to improve affordability.

Safety

Adverse Events

While no adverse events occurred during *R2Play* sessions, potential safety concerns were noted in four sessions, including participants slipping on the floor while running (n=3) or lunging beyond the tablet trail and narrowly avoiding collision with other equipment (n=2).

Concussion-Related Symptoms

Median PCSI symptom score decreased from 10.5 (IQR 5 - 14, range 5 - 17) to 6 (IQR 5 - 12, range 1 - 29) from pre- to post-*R2Play* assessment. Most (9/10) participants reported either "no symptoms" or "some symptoms but did not get worse" for all postlevel symptom check-ins, indicating no change in symptoms throughout *R2Play*. One participant (Y1) reported "symptoms got worse" (mild headache) but was able to continue. No sessions were stopped or modified due to worsening symptoms. Full PCSI and symptom check-in data can be found in Multimedia Appendix 5.

Qualitative Interview Findings (Clinicians)

Overview

Clinicians thought *R2Play* would be very safe if used with the right individuals, at an appropriate stage of recovery. They provided 3 broad categories of recommendations to ensure safety.

Preparticipation Screening and Warm-Up

Some clinicians recommended prerequisite criteria or assessments that youth should clear before attempting *R2Play*. This included minimal symptom burden, aerobic exercise tolerance, and appropriate vestibular function (eg, vestibular or ocular-motor screening). For example, 1 clinician discussed how *R2Play* could build on prior exercise testing:

> *Something like a Buffalo concussion [treadmill] test would be good to do [before R2Play]… it would be helpful if you knew they could exert themselves to a certain point and have minimal symptoms, let's layer in complexity now with R2Play and that might make it safer* [C3]

Given the physical demands of *R2Play*, musculoskeletal screening and thorough physical warm-ups were also recommended.

Monitoring Tolerance

Clinicians emphasized the importance of frequent check-ins during *R2Play* to monitor changes in symptoms and HR. One clinician suggested standardized stopping criteria: "If there are certain criteria, like if their symptoms jump this much, if their HR jumped this much, if there are things in there that more uniformly a clinician would be stopping it, I don't think it's unsafe" (C3). Adequate rest breaks and opportunities to pause or stop testing were also seen as important to ensure comfort for youth who may be deconditioned or symptomatic postconcussion.

Controlled Testing Environment

Clinicians affirmed the need to consider the testing environment to reduce risk for injury. Specifically, ensuring an open space without tripping hazards, an appropriate floor surface to prevent slips, and appropriate footwear.

Qualitative Interview Findings (Youth)

Youth reported feeling very safe while completing *R2Play*. They appreciated frequent check-ins and breaks, providing opportunities for rest and the option to stop if needed, which were recognized as important for youth recovering from a concussion. Some youth initially felt nervous due to the novelty or complexity of *R2Play*, which gradually subsided after the first few tasks, underscoring the importance of the introduction phase before core assessment levels. As youth became more comfortable, they also felt their performance improved: "I was anxious when coming in, but I think after the first set of stuff, I was pretty comfortable just because it was easy to grasp and follow … I felt like there was a very notable link between my anxiety going down and performance going up" (Y6). Three youth mentioned slipping and sliding on the floor as a potential safety risk or performance impediment.

Acceptability

Qualitative Interview Findings (Clinicians)

Comprehensive Assessment

Clinicians described *R2Play* as a comprehensive assessment because it simultaneously addresses multiple factors in being ready for return-to-play after concussion and involves integration across domains of function. They appreciated how it provides a practical method to create more dynamic testing environments that better reflect the demands of sport:

> *It brings together all the necessary elements that we need to look at to make a really good, informed decision for readiness. So, what it does differently is it has all the input from different domains of function and things that will influence performance, which is something that isn't included in current testing and standardized protocols.* [C1]

Enjoyable and Engaging

Clinicians felt that *R2Play* would be enjoyable for most youth athletes who are not symptomatic. Specific aspects that they highlighted as making it particularly enjoyable for youth were its interactivity, gamification, challenge, competitiveness, and introduction of new challenges without becoming repetitive.

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Nevertheless, clinicians suggested that enjoyment could vary, as youth who lack confidence or are not psychologically ready for return-to-play may be hesitant to engage in *R2Play* due to fear of symptoms or reinjury. One clinician discussed how *R2Play* could help build rapport with clients through interactive activity:

> *I honestly think it's helpful to build rapport with your client… there's lots of opportunities to cheer them on or provide reassurance or encouragement… compared to like the Buffalo Concussion Test, which I think is very helpful, but I either chat with them while they're on the treadmill, but then they're also trying to focus, and then I'm just asking them questions every minute… so in terms of client rapport, there's not a lot of time or aspect for that. So, I thought this one did that, which was fun.* [C3]

Customizability

Clinicians appreciated built-in options for customizing the *R2Play* assessment, such as the number of tablet selections in the trail and adapting the system layout to different clinical spaces. Some expressed a desire for more customizability related to the height of tablet targets and the ability to skip, repeat, or combine levels based on areas most relevant for each client:

> *One thing that could be helpful… something a bit more customizable to layer in certain features. So, if you really wanted to challenge somebody, or if they're playing an even higher level of sport, and just having the option to like, put the auditory on the whole time and do the Stroop and do the scramble… just to have more options, I guess, or more freedom to use your clinical judgment.* [C3]

Qualitative Interview Findings (Youth)

Comprehensive and Realistic

Youth described *R2Play* as a comprehensive test of readiness for return-to-play that was "more realistic to going back to sports" (Y1). They found it a good reflection of elements required for return-to-play, with over two-thirds of youth specifically mentioning combined physical and cognitive demands as an aspect they especially liked about it. For example, "I like that it's exercise, but you also have to think at the same time, because that's definitely a big part of [RTP]. I think that was good to put those two things together." (Y3).

Enjoyable and Engaging

Youth described *R2Play* as more enjoyable than other assessments in their recovery. They appreciated the "active," "engaging," and "interactive" nature of *R2Play,* which they framed in contrast to more passive traditional assessments such as walking, treadmill tests, and questionnaires: "[This was] definitely a lot more active. When I was doing [my recovery], I think it was a lot of just walking, like I never got actually out of breath… this one was a lot more fun, a lot more interactive and engaging." (Y8). The gamification of *R2Play* and involvement of technology (ie, tablets) were seen as particularly appropriate for young people. Task variety and the introduction of new challenges throughout *R2Play* were also highlighted as elements that increased engagement and enjoyment.

Demand

Qualitative Interview Findings (Clinicians)

Limitations With Existing Approaches to Return-to-Play

Clinician interviews highlighted gaps in current approaches to the return-to-play process, including a lack of standardized criteria for determining readiness and limitations with existing assessments. They described a lack of consistency in RTP clearance, whereby organizations or providers devise their own protocols, leading to subjective decision-making largely based on intuition. Elements of readiness to RTP that clinicians felt were not sufficiently addressed by existing assessments included multiplanar movement, multidomain integration (ie, thinking while exercising), and sensory sensitivity (eg, noise). They emphasized that these components are not considered until athletes progress to sport-specific training in which the clinician is typically not present:

> *The change of direction, acceleration, deceleration, turning movements, quick pivots, those things are where you'll start to see challenge, certainly in a sport situation, and aren't usually incorporated until the athlete is on the field or with their team in an environment that you're not able to evaluate other than just asking them how they did.* [C1]

Assessing Sport Tolerance

Clinicians discussed how *R2Play* could help assess clients' tolerance to sport-like activity within a controlled setting before returning to unpredictable sport environments. For this purpose, clinicians would consider the athlete's response to dynamic exertion and any symptom changes throughout *R2Play* as an indicator of readiness for return-to-play:

> *If [a person's] symptoms are exacerbating when they're doing this task, that's a pretty good indicator that maybe they're not ready to be doing something at that high intensity or that length of time.* [C5]

Using Cost Scores to Assess Multidomain Skill Integration

Clinicians appreciated the cost score approach to assessing multidomain skill integration and emphasized the importance of interpreting them within the context of the individual's overall condition and their own clinical judgment. They also saw value in observing youths' movement during testing to help contextualize cost score results in relation to the performance requirements of their specific sport or activity. Further research was emphasized to support clinical use of cost scores, including understanding psychometric properties (validity and reliability), creating normative datasets, establishing clinically significant cutoffs, and developing knowledge mobilization tools to support interpretation.

Results Can Inform Tailored Return-to-Play Guidance

Based on cost score results and potential symptom exacerbation during testing, clinicians felt that *R2Play* could help identify individual areas of weakness and inform personalized guidance to address any unresolved consequences of injury. For example,

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"If I'm noticing that when there is auditory noise or there is a scramble, it's a huge discrepancy, then they're probably not ready to go into an environment where they have to make a lot of cognitive decisions on a quick basis. So maybe they're not ready for passing drills that involve someone else coming from a different direction, or they're not ready to go into a busy gym yet." (C4).

Qualitative Interview Findings (Youth)

Limitations With Existing Approaches to Return-to-Play

Similar to clinicians, the youth discussed limitations with existing approaches to the return-to-play process based on their experiences. Though the confidence they reported at the time of RTP varied, most youth expressed concerns about the tests and exercises they did during their recovery. Many described the process as focusing on either physical or cognitive aspects, without adequate attention to both domains and their integration. One youth discussed how testing physical-cognitive integration could have helped in their recovery:

> *I wish something like this had been around when I was trying to return to sport because things like reaction time and all that stuff and my ability to think while moving around was not something that was really ever assessed… it would have made the process a lot smoother.* [Y6]

Value of R2Play for Assessing Return-to-Play Readiness

Youth discussed the value of *R2Play* for assessing tolerance to sport-like exertion. This included monitoring symptoms, HR, or any "slow-down" in their performance to enable clearer return-to-play decisions and determine appropriate exertion levels based on their progress. Some youth felt this opportunity to test their abilities within a controlled setting could have improved confidence in RTP: "I think [doing *R2Play*] would have decreased a lot of my anxiety going back and a lot of the uncertainty of like, how am I going to react? I had no clue." (Y6).

Timing of R2Play Assessment

Given its complexity and demands, youth felt that *R2Play* would not be appropriate for early stages of recovery. Rather, they envisioned it toward the end of recovery as a final step before returning to full sport participation:

> *I feel like [R2Play] could be used during the end… when the patient is almost 100%, they could do the testing just to see if there's any setbacks with exercise or anything* [Y5]

Integrated Mixed Methods Feasibility Findings

To address our intended mixing purposes of comparing (triangulation across datasets), expanding (elucidating broader understandings), and enhancing (increase meaningfulness of interpretations), we constructed a side-by-side comparison joint display (Table 6) to illustrate integrated mixed methods findings (meta-inferences) within the feasibility domains of interest [58,59].

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Table . Side-side comparison joint display of mixed methods integration findings for feasibility domains.

Number	Domain	Quantitative evidence[a]	Qualitative evidence[a]	Meta-Inference[a]
1	Usability	• SUS:[b] mean SUS score was 83.75 (SD 4.45), within the 90 - 95 percentile range of usability and corresponding to a grade of "A" for "good-to-excellent" usability. • Usability issues: there were no catastrophic usability issues and few (n=7) unrecoverable usability issues in clinicians' second assessment session.	• Usability overview (C[c]): clinicians found *R2Play* highly usable and described it as "well designed," "intuitive," and "easy to use." • Tablet button system (Y[d]): Youth found the tablet buttons easy to use. "I think kids [are] a lot more used to using tablets… I didn't have any trouble [using the system]." [C2] • Rules and instructions (Y): most youth reported the rules of *R2Play* were easy to learn and follow. "It was easy [to learn the rules] … it's pretty simple, like you figure it out… it's pretty easy to pick up." [Y1]	Concordance: *R2Play* is highly usable for both clinicians and youth. The interface is easy for clinicians to navigate, and youth can easily understand the instructions and complete required tasks using the tablet button system.
2	Usability	• SUS: items rated least favorably were "I felt very confident using the system" (mean 3.90, SD 0.74) and "I needed to learn a lot of things before I could get going with the system" (mean 2.50, SD 0.97)	• Usability challenges (C): clinician confidence was limited by a lack of familiarity with the *R2Play* protocol and instructions. "I don't think it was anything difficult. I think it was more, just familiarity… just not intuitively knowing what comes next." (C5)	Expansion: lack of familiarity with the *R2Play* protocol, rather than navigating the interface, reduced clinician confidence and perceived usability.
3	Usability and practicality	• Usability issues: there were fewer usability issues in clinicians' second assessment session (n=16) compared to their first (n=23), and a greater proportion of issues were recoverable (53% vs 17%). • Assessment duration: total *R2Play* duration was lower for clinicians' second sessions (mean 32.24, SD 3.41 min) compared to their first (mean 35.38, SD 7.36 min).	• Easy to use and learn (C): *R2Play* was easier, and clinicians felt more confident in their second session. "I feel like my familiarity with the system was a lot better this time... it was much more seamless." [C4] • With more familiarity in their second session, clinicians were better able to guide participants through *R2Play*. "The more familiar you are with it, the faster you're going to get it up and running and the faster you'll be able to let the patient know and understand what they're doing." [C1]	Expansion: *R2Play* becomes easier to use and faster to administer with practice due to greater familiarity with navigating the interface and delivering level instructions.

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Number	Domain	Quantitative evidence[a]	Qualitative evidence[a]	Meta-Inference[a]
4	Usability and practicality	• Training task activity: training tasks in which clinicians needed the most help were (1) Train a client on a level of the *R2Play* assessment (n=5); and (2) Report and explain a specified cost score from an *R2Play* assessment to a client (n=2).	• Usability challenges (C): aspects of *R2Play* that were challenging for clinicians included explaining level instructions and assessment results. "The main [challenge] was delivering the tests exactly and just knowing what kind of things to emphasize so the participant was able to understand what we're asking." [C2] "I still kind of fumbled with the results screens, the cost scores and stuff, I think that's where I was still kind of second-guessing." [C3]	Concordance: clinicians need support to follow the overall *R2Play* protocol, deliver instructions in a standardized manner, and interpret and explain cost score results in a way that is understandable and meaningful to youth and families.
5	Practicality	• Assessment duration: the target of 20 - 30 minutes active assessment time was met for 8/10 (80%) sessions, including all clinicians' second sessions.	• Time (C): the time required for set-up, configuration, assessment, and results review was seen by clinicians as a potential barrier to clinical implementation of *R2Play*. "I think one of the biggest challenges will be the length of it… for it to seamlessly integrate into current practice, I think it might be long" [C1]	Discordance: target duration was met for most sessions, though clinicians had concerns about the length of *R2Play*, suggesting a need to reconsider the targets and further explore practicality.
6	Safety	• Adverse events: there were no adverse events recorded across all sessions. • Concussion symptoms**:** total PCSI symptom score decreased from pre- to post-*R2Play*, and no *R2Play* sessions were stopped or modified due to worsening symptoms.	• Safety (C): clinicians thought *R2Play* would be very safe if used with the right individuals at an appropriate stage of recovery. "It's very safe, you are in a controlled environment, you have that heart rate monitor on them, you are checking on their symptoms… if there are any concerns, you're in that controlled environment to manage that." (C2) • Safety (Y): youth reported feeling very safe while completing *R2Play*. "I felt very comfortable and very safe." [Y10]	Concordance: *R2Play* appears safe with appropriate precautions in place. Among youth previously cleared to return-to-play after concussion, *R2Play* does not appear to cause symptom exacerbation.
7	Safety			

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Number	Domain	Quantitative evidence[a]	Qualitative evidence[a]	Meta-Inference[a]
		• Adverse events: near misses were recorded for (1) participant slipping while running (n=3) and (2) participant lunging beyond the tablet trail and narrowly avoiding other equipment (n=2).	• Controlled testing environment (C): clinicians highlighted the testing environment as important to limit hazards for slips and trips. "The only thing I noticed from the last one was just the slippery floors, so that's something [to be] mindful of." [C2] • Safety (Y). 3 youth mentioned slipping as a potential safety risk.	Concordance: testing environment is an important safety consideration for *R2Play*, including floor surface and other potential hazards.

[a]Text before the colon indicates quantitative data source (column 3), qualitative category or subcategory (column 4), or meta-inference labeling (column 5).

[b]SUS: System Usability Scale.

[c]C: clinician.

[d]Y: youth.

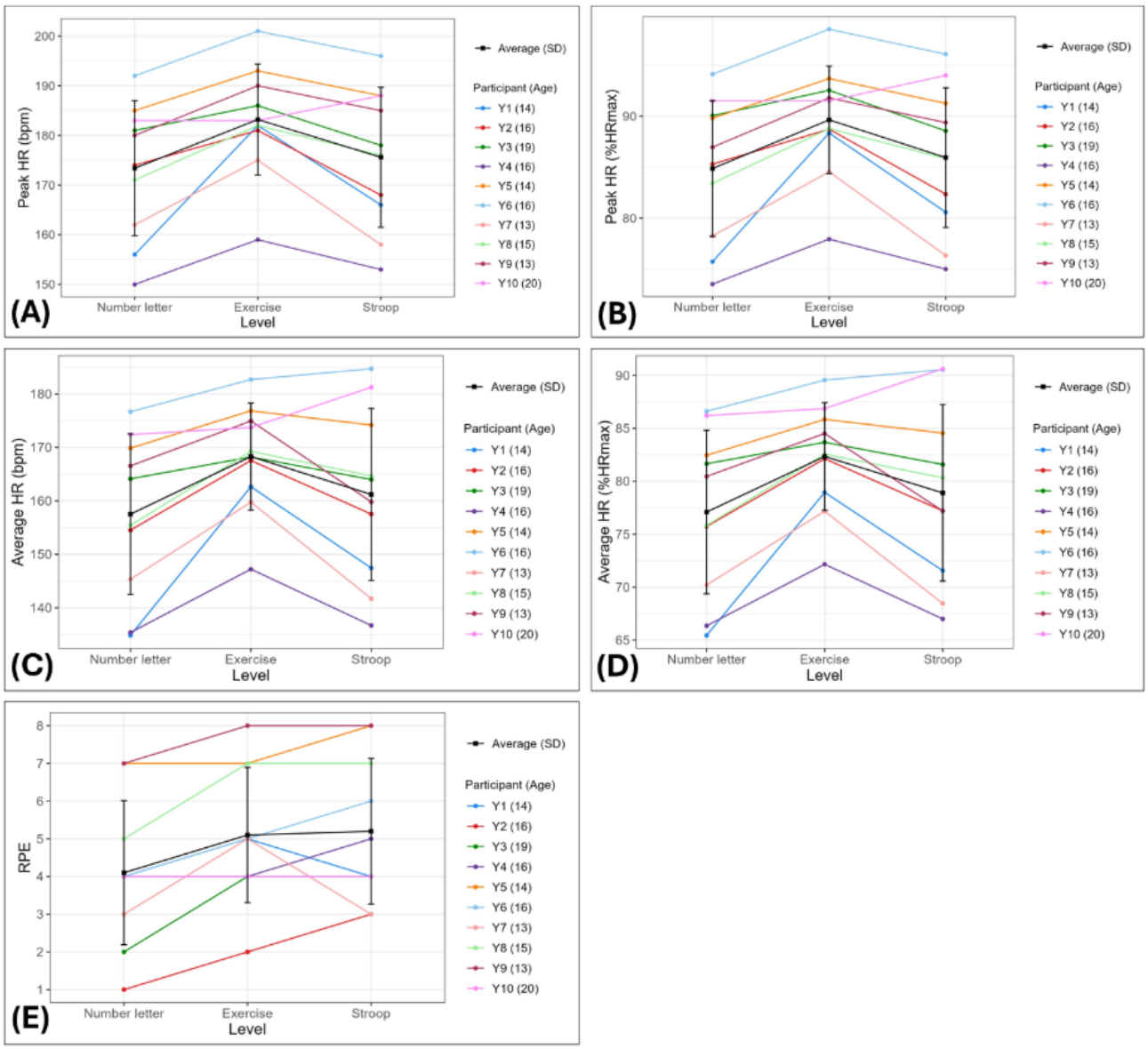
Face Validity

Physical Exertion

Figure 5 presents HR and RPE data for each participant across *R2Play* levels. All participants achieved vigorous intensity physical exertion levels (peak HR=78% - 99% HR_{max}, panel B). Target exertion criteria (≥80% HR_{max} or RPE ≥7) were met for 9/10 participants. As expected, HR was generally highest in the exercise level, while RPE was elevated in the exercise and Stroop levels compared to the baseline number letter level.

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Figure 5. HR and RPE for each participant across core *R2Play* assessment levels. HR is expressed as the peak raw HR measurement (A), peak percentage of age-predicted maximal HR (B), average HR (C), and average percentage of age-predicted maximal HR (D) across all repetitions within each level. RPE (E) was captured retrospectively during breaks between levels. HR: heart rate; $\%HR_{max}$: percentage of age-predicted maximal heart rate; RPE: rating of perceived exertion; Y: youth participant.



Qualitative Interview Findings (Clinicians)

Represented Elements of Sport

Overview

Clinician feedback regarding elements of sport represented in *R2Play* is presented with sample quotes in Table 7 and summarized in the subsections below.

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Table . Clinician feedback regarding elements of sport represented in *R2Play*.

Domain category and subcategory	Sample quote
Physical	
Maximal exertion	"Getting that really fast acceleration… where they're basically running full tilt, is helpful because a lot of times when you're putting people through a return-to-play, you're getting them on a bike and telling them to cycle at a certain amount, they're not hitting that 80% - 90% of heart rate max, and sometimes it's at those higher levels that you start to see some symptoms." [C4]
Sustained exertion	"The thing I liked about [*R2Play*] was that it was long enough that you have to be *working*, exerting your body for a longer period of time, which is more indicative of sport… sometimes our tests are only like 10 minutes long and they could clear it… So, I think the fact that it's a bit longer of an assessment and you're measuring over time is really helpful." [C3]
Multiplanar movement	"It's really the only one that I'm familiar with that allows as much functional movement… more of the sport-specific movements that you'd be expecting them to have to be capable of… like change of direction, acceleration, deceleration, a lot of the turning movements, the quick pivots" [C1]
Quick movements	"You were just also assessing like the ability to click the [tablets] at a certain speed. So, I kind of just made note like if they were able to make those fast movements." [C2]
Cognitive	
Reaction time	"I do think it's good at getting… like quick, reactionary kind of stuff which I think is sometimes missing with return-to-play assessments." [C3]
Divided attention	"You're seeing like, how well they can tolerate like a sudden change in the environment and just getting distracted and then coming back to it." [C2]
Spontaneous decision-making	"It forces the participant to be reactive rather than just be able to kind of go through like an obstacle course or something that they know exactly what's going to happen." [C4]
Multitasking	"I think the multitasking part is quite effective… It's the first one that I've done that has the multitasking element." [C4]
Perceptual	
Visual stimulation	"And then the visual stimuli. If you are, let's say at a hockey game, and there's the bright lights… any arena where there are lights or changes, you can see that [from *R2Play*] and you can make note of like, what kind of triggers are there." [C2]
Background noise	"…those background noises… a lot of athletes, when they do return to play, the audio is like a major thing as well, especially someone with concussion with noise sensitivity." [C2]

Physical Domain

Clinicians emphasized high exertional load, multiplanar movement, and quick motor responses as physical aspects of sport reflected in *R2Play*. They appreciated how it elicited maximal and sustained exertion, which were seen as important aspects of sport missing in current protocols. Dynamic multiplanar movement was also seen as unique compared to other assessments that are often "just in a straight line" (C5), with clinicians specifically mentioning rapid acceleration, direction changes, turning or pivoting, and lateral footwork.

Cognitive Domain

Clinicians described cognitive elements of *R2Play* as uniquely sport-like compared to existing assessments. Specific cognitive skills they discussed included selected and divided attention, decision-making, multitasking, and quick reactions. Responding to spontaneous changes in the environment (ie, scramble condition) was highlighted as especially relevant to sport and informative for return-to-play assessment.

Perceptual Domain

Clinicians primarily discussed visual and auditory stimulation as perceptual elements of sport reflected in *R2Play*, specifically mentioning the background noise condition as an aspect that contributed to face validity.

Missing Elements of Sport

Elements of sport that clinicians thought were missing from *R2Play* were sport-specific skills, navigating other competitors

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(ie, collision avoidance), communicating with teammates or coaches, visually tracking objects (ie, smooth pursuits), and hand-eye coordination.

Suggestions to Improve Face Validity

Clinicians offered the following suggestions to enhance face validity of *R2Play*: incorporating sport-specific skills (eg, stick handling or dribbling between tablets) and surfaces (eg, testing on grass, turf, or court), having the athlete visually track and respond to an external stimulus while completing *R2Play* (eg, catching a ball), varying the heights of tablet targets to match sport-specific movement patterns, and displaying participants' scores between levels to increase performance pressure.

Qualitative Interview Findings (Youth)

Physical Domain

Youth discussed how dynamic movement during *R2Play* made it feel more like sport than other tests: "It's moving around [as] opposed to walking and balancing on one foot, like I don't normally balance on one foot when I'm playing a sport, I'm running around and I'm doing stuff and that's kind of like me pressing the tablets" (Y8). They highlighted that agility skills used during *R2Play* reminded them of sport, including stopping and starting, pivoting, lunging, and quick direction changes. The cardiovascular demand of *R2Play*, involving short bursts of exertion followed by brief breaks, was also likened to sport.

Cognitive Domain

The "thinking" elements of *R2Play* made it feel more "realistic" for youth compared to other physical tests they had performed. Specific cognitive aspects that youth discussed were planning and monitoring plans, thinking and reacting quickly, and selected and divided attention. The scramble condition was highlighted as particularly relevant to sport-like thinking skills:

> *When the scramble happens, having to look around and reassess constantly where everything is as things change… having to move around and quickly shift what you're going to do and make a different plan without much warning… you gotta keep moving, but you also have to keep planning. That felt pretty sport-like.* [Y1]

Perceptual and Socioemotional Domains

Fewer youth discussed the perceptual and socioemotional aspects of *R2Play*, though some mentioned visual scanning, background noise, head movement, and competitiveness.

Integrated Mixed Methods Face Validity Findings

To address our mixing purposes of comparing, expanding, and enhancing, we constructed a cross-case comparison joint display [58,59] (Figure 6) linking youth participants' physiological exertion (ie, HR), perceived exertion (RPE), and qualitative feedback. To better understand the relationship between these data sources and how well *R2Play* elicits a "sport-like" level of exertion, we stratified the joint display by whether participants met predefined exertion targets for HR and RPE (see Methods).

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Figure 6. Cross-case comparison joint display of mixed methods integration for exertion data. Green text indicates the exertion target was met. Red text indicates the exertion target was not met. HR: heart rate; %HR_{max}: percentage of age-predicted maximal heart rate; Q: question; RPE: rating of perceived exertion; Y: youth participant.

	Participant (Age)	Peak Heart Rate Raw (%HR_{max})	Peak RPE	Qualitative Data *(Q12: How hard did it feel like you were working?)*
Met exertion targets for both HR and RPE	Y5 (14)	193 (94%)	8	"Probably about a 7.5 out of 10."
	Y8 (15)	182 (89%)	7	"I'd say [*R2Play*] is like a seven compared to like a ten, if ten is me complete out of breath in hockey."
	Y9 (13)	190 (92%)	8	"Like in the middle"
Met exertion target for either HR or RPE	Y1 (14)	182 (88%)	5	*Qualitative data not available*
	Y2 (16)	181 (89%)	3	*Qualitative data not available*
	Y3 (19)	186 (93%)	4	"Four, maybe?"
	Y6 (16)	201 (99%)	6	"I was breathing sort of hard… but it wasn't crazy hard. It wasn't like, oh my gosh, I can't do this anymore, which was good because nobody wants to feel like that."
	Y7 (13)	175 (85%)	5	"I was working pretty hard. I told her I was not tired at the end, but it was because I got to sit down, I wasn't tired. But when I was doing it, my brain was at maybe a 90%."
	Y10 (20)	188 (94%)	4	"I felt like I was working hard. I think if I didn't take some longer breaks, I would have been a lot more tired. I didn't feel overly tired, it was a good level. I think I ranked it like four or five."
HR and RPE target not met	Y4 (16)	159 (78%)	5	"On a scale of 1-10, maybe like 6 or 7."
Meta-inference: *Discordance.* Regardless of whether they met exertion targets, youth participants' peak RPE and retrospective qualitative feedback often did not match the level of exertion reflected in their peak HR. Qualitative feedback suggested that rest breaks between levels may have impacted participants' RPE reports, indicating a need to reconsider the RPE collection approach.				

Discussion

Overview

This study established initial feasibility and face validity of *R2Play*, a novel multidomain return-to-play assessment tool for concussion, at a single center through a mixed-methods approach involving a small sample of clinicians and youth with concussion history (Multimedia Appendix 6). Overall, most success criteria were met across all feasibility domains, with excellent usability (SUS=84.00±6.02), vigorous intensity exertion (peak HR=78% - 99% HR_{max}), and no adverse events. Usability and technical issues were identified and addressed through iterative design changes, some of which are highlighted below. Clinicians and youth feedback indicated that *R2Play* reflects elements of sport across physical, cognitive, and perceptual domains, making it a potentially valuable tool for assessing readiness to return-to-play and informing rehabilitation treatment planning postconcussion.

Feasibility

The mixed-methods approach and end user involvement in this study were particularly beneficial for understanding the usability and practicality of *R2Play*. Concordance across data sources indicated that *R2Play* is highly usable for both clinicians and youth (Table 6; meta-inference #1), which aligns with our proof-of-concept study findings [32]. This is critical given the importance of ease of use for successful adoption of rehabilitation technologies [61,62]. Importantly, we found that clinicians' confidence in using *R2Play* was primarily limited by being unfamiliar with the assessment protocol and that support was needed to follow the protocol, deliver standardized instructions, and interpret and explain cost score results (meta-inference #2 and 4). These challenges have been

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addressed through upgrades to the clinician interface (map of assessment flow and standardized instruction scripts) and developing more extensive training resources. They also highlight an opportunity for participatory design and cocreation of knowledge mobilization materials to help clinicians communicate about *R2Play* in a manner that is meaningful for youth and families [63-65]. Consistent with broader usability literature [66,67], *R2Play* appeared to be used in an easier and faster manner with practice (meta-inference #3), reflecting calls to provide users with multiple opportunities to test a prototype [68]. Future work must consider changes in usability and *R2Play* results upon repeat administration (ie, test-retest reliability) due to familiarization with this novel approach. Overall, these findings reflect the value of mixed methods designs involving users in testing early prototypes of technology-based rehabilitation interventions and may be useful for other teams applying similar approaches [69].

The lack of adverse events and minimal symptom exacerbation during *R2Play* supports its safety, corroborated by youth and clinician feedback confirming their comfort with the protocol (meta-inference #6). Safety recommendations from clinicians, including preparticipation screening and monitoring tolerance, align with best practices for clinical exercise testing and postconcussion exertion assessment [50,51,70,71]. This feedback has informed an *R2Play* safety plan involving contraindication screening, standardized stopping criteria, and symptom management procedures. The absence of symptom provocation across most of this sample of recovered youth suggests that task requirements are appropriate and tolerable for youth beyond return-to-play clearance, providing a useful reference for future evaluation among youth with more recent concussion history. Importantly, 1 participant reported an increase in headache that may indicate incomplete physiological recovery [12,51], underscoring the potential for *R2Play* to detect unresolved changes that may be missed by traditional practices. Of note, this participant had a history of multiple concussions and was only 2 months postinjury at the time of testing. Further work is required to understand the safety of this approach among youth at the time of assessment for return-to-play clearance and establish the sensitivity of *R2Play* for detecting symptom exacerbation associated with ongoing concussion-related neurophysiological disturbances that may only manifest in complex testing environments involving integration across functional domains [72-74].

Qualitative feedback regarding acceptability and demand highlighted opportunities for *R2Play* to address gaps in the return-to-play process. Variability in operationalizing recovery and RTP noted by clinicians is well documented [11,75-77], reflecting fundamental challenges in this field [10,12]. Importantly, clinicians and youth expressed concerns about whether existing assessment and rehabilitation methods fully address the multidimensional aspects of return-to-play readiness, emphasizing the integration of physical and cognitive function as an element not adequately considered in practice, despite its ubiquity in sport [78] and growing attention in research [17,79]. The comprehensive nature of *R2Play* and its multidomain demands were thus appreciated by clinicians who viewed it as a potentially useful tool to assess tolerance to sport-like activity within a controlled setting before youth return to sport. As noted by clinicians, this assessment approach could involve monitoring physiological (HR) and symptom responses and capturing observations about movement quality and performance during prolonged dynamic exertion. Similarly, youth also saw *R2Play* as potentially useful to provide a clearer picture of readiness to return-to-play during advanced stages of recovery, which could help alleviate the anxiety and fear that are common when returning to sport [15,16]. In sum, clinicians and youth with concussion experience see value in novel multidomain assessments such as *R2Play* to help determine readiness for higher-risk sport activities (stages 4 - 6 in the return-to-play protocol) [12] and to better capture the biopsychosocial factors that may contribute to reinjury [18,80] and limit psychological readiness to return-to-play [16,81]. These findings may be useful for other teams developing novel multidomain concussion assessments.

In this study and initial proof-of-concept work [32], some clinicians spontaneously identified the cost of *R2Play* as a potential implementation barrier. As cost estimates were not disclosed, these concerns may reflect preconceptions about technology, given the integration of multiple devices in *R2Play*. Nevertheless, cost is indeed an important factor that likely limits uptake of existing multidomain assessments, which often use sophisticated technologies to enhance ecological validity or enable scoring (eg, virtual reality and motion capture) [26]. Accessible pricing and equipment were therefore a priority in designing *R2Play* [28]. Equipment costs for the current *R2Play* prototype total approximately CAD $4250 (approximately US $3000) and are expected to decrease with further engineering refinement. This is markedly lower than many traditional neurocognitive testing batteries that face challenges in adoption due to high fees for software licensing, subscription, or interpretation [82]. Economic analyses are needed to establish the value of novel return-to-play tools such as *R2Play* by comparing the costs of assessment (in material and time) against potential savings in reducing reinjury and improving outcomes [83]. Commercialization models involving industry partnership could also help ensure sustainable pathways for widespread scalability of these tools.

Physical Exertion and Face Validity

In this small sample of youth previously recovered from concussion, *R2Play* elicited vigorous intensity physical exertion (peak HR=78% - 99% HR_{max}), with target exertion criteria met for 9/10 participants. This indicates that exertional demands are sufficient for assessing exercise tolerance, an important indicator of physiological recovery and readiness to return-to-play [51,84]. As expected, HR was highest in the exercise level, consistent with the physical demands. Interestingly, RPE was similar between the exercise and Stroop levels despite different physical demands. Possible explanations include (1) participants did not distinguish between physical exertion and cognitive effort in RPE ratings [85], (2) cognitive effort from the Stroop task caused higher perceptions of physical exertion [86], or (3) fatigue across the assessment led to higher-than-expected RPE during the final (Stroop) level [87]. Future work addressing these questions will obtain separate ratings of physical and

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cognitive effort (now built into the system) and explore perceptions of level demands using targeted interview questions.

Mixed method integration (Figure 6) revealed discordance wherein RPE and qualitative feedback often did not match participants' peak HR. Here, we draw on mixed methods literature to address these discordant findings [88,89]. One approach is to seek explanations from existing research [90]. An exercise physiology lens may help understand the discrepancy between physiological (objective) and perceived (subjective) exertion responses. As *R2Play* involves short (~30 - 60 s) intervals of high intensity exercise, it is possible that the brevity of these bouts and frequent breaks could limit perceptions of effort, despite substantially elevating HR. There is indeed evidence of RPE decoupling from HR during interval training, attributed to positive feelings of relief, achievement, and enjoyment [91,92]. This is particularly relevant because the youth described *R2Play* as enjoyable. Another strategy to manage discordance is comprehensive case analysis [88], a form of reconciliation (reanalysis) [89] that involves identifying patterns in individual case-level data. We speculate that sport history may influence participants' effort perceptions such that those who are accustomed to explosive activities similar to *R2Play* (eg, hockey or soccer) may report lower effort perception. Given our limited sample size, initiation [89] of future work is warranted to explore this hypothesis by asking participants how the exertional demands of *R2Play* compare to their sports. Finally, an exclusion approach questions the validity of conflicting data [89]. In this case, temporal differences may have affected data quality. While HR was measured as participants actively completed *R2Play* levels, RPE and qualitative feedback were captured retrospectively while participants were at rest, during breaks, and upon assessment completion, respectively. Indeed, 2 participants mentioned that breaks affected their effort perception. In future work, care should be taken to ensure that RPE ratings pertain to active level completion.

Limitations and Future Directions

This study lays the foundation for future work toward the goal of establishing *R2Play* as a clinically feasible, ecologically valid, and objective return-to-play assessment. Importantly, youth in this sample were previously cleared to RTP up to 5 years before enrollment, and clinicians did not administer *R2Play* in the context of real clinical decision-making for return-to-play clearance. While this work provided useful insights for the current stage of development, future validation studies should be conducted at the time of RTP clearance to determine the value of *R2Play* in supporting clinical decision-making (eg, increasing clinician confidence) and improving outcomes such as athletes' psychological readiness to return-to-play and risk of reinjury. Additionally, youths' concussion histories were established via self-report, without capturing how they received return-to-play clearance or what criteria were used to establish clearance. This information should be collected in future studies to contextualize participants' *R2Play* results and symptom responses in relation to best practice guidelines and the established return-to-play strategy [12].

Future work is needed to validate the level structure, scoring, and ecological relevance of *R2Play*. This requires understanding the physiological, neurocognitive, and psychosocial task demands, which may be best accomplished through mixed-methods approaches that combine objective measurement with participant feedback [93]. Here, "sport-like" elements were primarily established through self-reported perceptions that may not translate to actual performance validity in real-world sport contexts. In addition to HR monitoring used here to capture physiological demands, objective measures of biomechanics (eg, accelerometry) and cognitive load (eg, electroencephalogram and functional near-infrared spectroscopy) could help assess whether movement and cognitive demands in *R2Play* reflect those in different sport environments. Validating a complex assessment such as *R2Play* is a complicated undertaking that is anticipated to span multiple years with ongoing iteration. This preliminary study was performed with a small convenience sample at a single site, supported by the original system design team, which limits generalizability. The primary author who conducted clinician training was also involved in data collection and interviews, which could influence participant responses (observer expectancy bias). Furthermore, we only considered a subset of relevant feasibility domains, some of which were only explored qualitatively. Future work will consider other aspects of feasibility (eg, implementation fidelity, adaptability, and integration) [39] across care settings, with quantitative progression criteria [59]. To address these questions, a larger multicenter pilot study is now underway evaluating the cross-site feasibility of *R2Play* and establishing its content validity by determining the physical, cognitive, and perceptual loading of the assessment leveling structure [94].

Conclusions

Findings from this preliminary single-center study support the potential feasibility and face validity of *R2Play*, a new multidomain assessment tool for youth with concussion, demonstrating excellent usability, vigorous physical exertion demands, and promising feedback regarding its potential to fill gaps in the return-to-play process. Implementation considerations and mitigation strategies were identified related to time, cost, space, and equipment set-up. A multicenter study is underway to assess cross-site feasibility of *R2Play* and evaluate its content validity by establishing the physical, cognitive, and perceptual loading of assessment levels [94].

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Data Availability

Data will be made available upon reasonable request to the corresponding author and in line with ethical standards of practice and institutional data transfer agreements.

Conflicts of Interest

SM is the Editor-in-Chief of *JMIR Rehabilitation and Assistive Technologies*.

Multimedia Appendix 1
Joint display of integrated data collection.
[DOCX File, 20 KB - rehab_v12i1e78486_app1.docx]

Multimedia Appendix 2
R2Play cost scores.
[DOCX File, 16 KB - rehab_v12i1e78486_app2.docx]

Multimedia Appendix 3
Semistructured interview guides.
[DOCX File, 22 KB - rehab_v12i1e78486_app3.docx]

Multimedia Appendix 4
Observational analysis data extraction sheet.
[DOCX File, 19 KB - rehab_v12i1e78486_app4.docx]

Multimedia Appendix 5
PCSI and symptom check-in results. PCSI: postconcussion Symptom Inventory.
[DOCX File, 16 KB - rehab_v12i1e78486_app5.docx]

Multimedia Appendix 6
Visual abstract.
[PNG File, 428 KB - rehab_v12i1e78486_app6.png]

Checklist 1
GRAMMS checklist.
[DOCX File, 15 KB - rehab_v12i1e78486_app7.docx]

Checklist 2
Clinician training practice task checklist.
[DOCX File, 19 KB - rehab_v12i1e78486_app8.docx]

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Original Paper

Home-Based Augmented Reality Exercise For People With Parkinson Disease: Qualitative Acceptability Study

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Abstract

Background: The rising prevalence of Parkinson disease and the growing demand on the health care system underscore the need for accessible and innovative care solutions, such as Reality Digital Therapeutics (Reality DTx)—an augmented reality neurorehabilitation program that delivers remotely prescribed gait and balance exercises for people with Parkinson disease to perform at home.

Objective: At a preimplementation stage, this qualitative study aimed to explore the acceptability of Reality DTx.

Methods: An exploratory qualitative study design was used. We conducted semistructured interviews, guided by the theoretical framework of acceptability, with 22 people with Parkinson disease who used Reality DTx at home for 6 weeks as part of a feasibility trial. We conducted a reflexive thematic analysis using an inductive, semantic approach informed by critical realism.

Results: The results of the reflexive thematic analysis are described in 3 themes and 9 subthemes. The 3 themes are “there was considerable interindividual variation,” “the intervention is complementary to supervised physical therapy,” and “adherence in the long term is crucial.” Participants reported variable perceptions of effectiveness and variable experiences of effort to complete the Reality DTx program. They viewed Reality DTx as a valuable complement to supervised physical therapy and emphasized the indispensable role of the physical therapist for external control of long-term exercise adherence and for meaningful feedback on motor performance, as well as the desire for social connection. Flexibility in time and location was mentioned as a very important program characteristic, supporting long-term exercise adherence. Suggestions for improvement included enhanced visibility of progression in scores, increased variation in games, and the integration of competitive elements.

Conclusions: Remotely prescribed, gamified, augmented reality exercises at home, complementary to supervised physical therapy, are acceptable to people with Parkinson disease. The findings inform future Reality DTx development and implementation from the perspective of people with Parkinson disease, which should be weighted with the perspectives of other stakeholders such as clinicians and other key decision-makers.

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KEYWORDS

Parkinson disease; augmented reality; home-based rehabilitation; acceptability; physical therapy; neurorehabilitation

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Introduction

Background

Parkinson disease is a neurodegenerative disease characterized by nonmotor symptoms, such as apathy and cognitive deficits, and motor symptoms, of which gait and balance impairments are already present early in the course of the disease, affecting everyday mobility and increasing the risk of falls [1,2]. The number of people with Parkinson disease is expected to exceed 13 million globally by 2040 [3]. This rise, along with the growing demand on the health care system, highlights the need to enhance access to treatment and improve the health care system's efficiency. One way to improve accessibility for people with Parkinson disease is through technology-supported, home-based care [4-6]. This also accommodates the challenges people with Parkinson disease often face with rehabilitation, such as motor symptom fluctuations, lack of time, and poor accessibility to exercise locations or lack of transportation [7-9].

This study describes the acceptability of a particular digital therapeutic innovation for home-based care, namely Reality Digital Therapeutics (Reality DTx), an augmented reality (AR) neurorehabilitation program with gamified AR exercises specifically designed for people with Parkinson disease to train their gait and balance at home. With AR glasses, the real world is augmented with spatially aware digital objects, so-called holograms, while the real world remains visible through transparent see-through lenses. Besides providing gait and balance exercises, Reality DTx aims to increase therapy adherence by making rehabilitation accessible at home, available at any time, and enjoyable through gamification [10,11]. Our recent feasibility trial showed that, for people with Parkinson disease with modified Hoehn and Yahr (H&Y) disease severity 2 to 2.5, Reality DTx is feasible for home use, with a high adherence (ie, participants performed 104% of the prescribed exercise sessions and 88% of the prescribed exercise minutes over 6 weeks) [11]. It was further found to be safe, usable, and progressive but achievable (ie, increasing difficulty while maintaining high performance), and it showed promise to improve aspects of gait, balance, and fall risk [11]. This study, as part of the feasibility trial, explores the acceptability of Reality DTx for gait and balance exercises at home from the perspective of people with Parkinson disease.

Implementation of technological innovations in health care often fails [12,13]. One of the reasons is that the users' motivations, values, and norms lead to resistance or rejection of the technology, or that technological adaptations over time do not meet users' needs [12,13]. Therefore, early engagement of and regular evaluations with key stakeholders are crucial. In the case of Reality DTx, these key stakeholders include the innovation recipients (people with Parkinson disease), the innovation deliverers (the therapists), and the key decision-makers (physical therapy clinic owners, policy makers, and health care insurers) [14]. The acceptability of innovation among key users is one of the critical outcome measures to assess during development and implementation [15,16], yet an evaluation of acceptability is often lacking in technology health care research [6,12,13,17].

This study attempts to address this limitation by focusing on the acceptability of Reality DTx for gamified gait and balance exercises at home among people with Parkinson disease, the innovation recipients. They participated in the very first feasibility trial with AR gait and balance exercises at home [10,11]. The stage at which this study is conducted can thus be considered a preimplementation stage [15,18,19]. Acceptability is defined in line with the theoretical framework of acceptability (TFA) of health care interventions, which states that acceptability is "a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention" [16]. The TFA implies that acceptability should not solely be evaluated through commonly used measures of observed behavior, such as dropout and adherence rates, but must also include users' knowledge and experiences with the health care intervention, as behavioral measures may not fully explain why participants' withdrawal or adherence rates are low or high.

To illustrate this, 2 systematic reviews showed that home-based technology-enhanced interventions often used adherence logbooks or closed-ended satisfaction questionnaires to assess acceptability, with few studies exploring subjective user experiences underlying these numbers through qualitative evaluations [20,21]. The UK Medical Research Council guidance for the development and evaluation of complex interventions advocates for such qualitative or mixed methods process evaluations [22]. A qualitative process evaluation may help to identify intervention components, intervention outcomes, contextual factors, and their interactions. These links, so-called mechanisms of change, could provide insights into how interventions achieve their partially context-dependent effects. The Reality DTx program demonstrated feasibility and effectiveness in a research setting [11], but this may not translate to daily clinical practice due to contextual differences. In clinical practice, therapists, instead of researchers, provide personalized exercise prescriptions tailored to rehabilitation goals, which potentially enhances the experience for people with Parkinson disease. A qualitative evaluation could uncover the subjective mechanisms driving the high adherence and progressive-but-achievable character of the program shown in our feasibility trial [11]. Despite the growing number of studies on technology-based interventions for people with Parkinson disease, qualitative assessment of acceptability in this field is still limited, while the examples provided here highlight its relevance [23,24].

Objectives

The aim of this qualitative study was to explore acceptability through in-depth direct experiences of people with Parkinson disease who received the 6-week Reality DTx gamified gait and balance program at home as part of our feasibility trial [10,11], complementary to more indirect quantitative acceptability indicators such as adherence and dropout rates. At this preimplementation stage, these direct responses of people with Parkinson disease could provide valuable insights into the mechanisms of change (eg, factors that motivate participants to train with Reality DTx) in the context of digitally supported independent exercise at home [6,16,18,22]. Therefore, this study

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adopted a qualitative approach using semistructured interviews. The perceptions and experiences of people with Parkinson disease will be discussed in relation to the current literature on technology-enhanced interventions. Recommendations for future development of Reality DTx and challenges for implementation are outlined. In a wider context, the study will provide insights into the experiences of people with Parkinson disease with technology-based rehabilitation at home that may stretch beyond the particular use case of Reality DTx in people with Parkinson disease.

Methods

Ethical Considerations

Ethics approval was obtained from the accredited Medical Research Ethics Committees United, the Netherlands (R22.076, NL82441.100.22). Participants provided written informed consent obtained by LESH, DJG, or EMH before participating in the feasibility study. The study was conducted and reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) [25]. Consent has been obtained from all identifiable individuals included in this manuscript.

Study Design

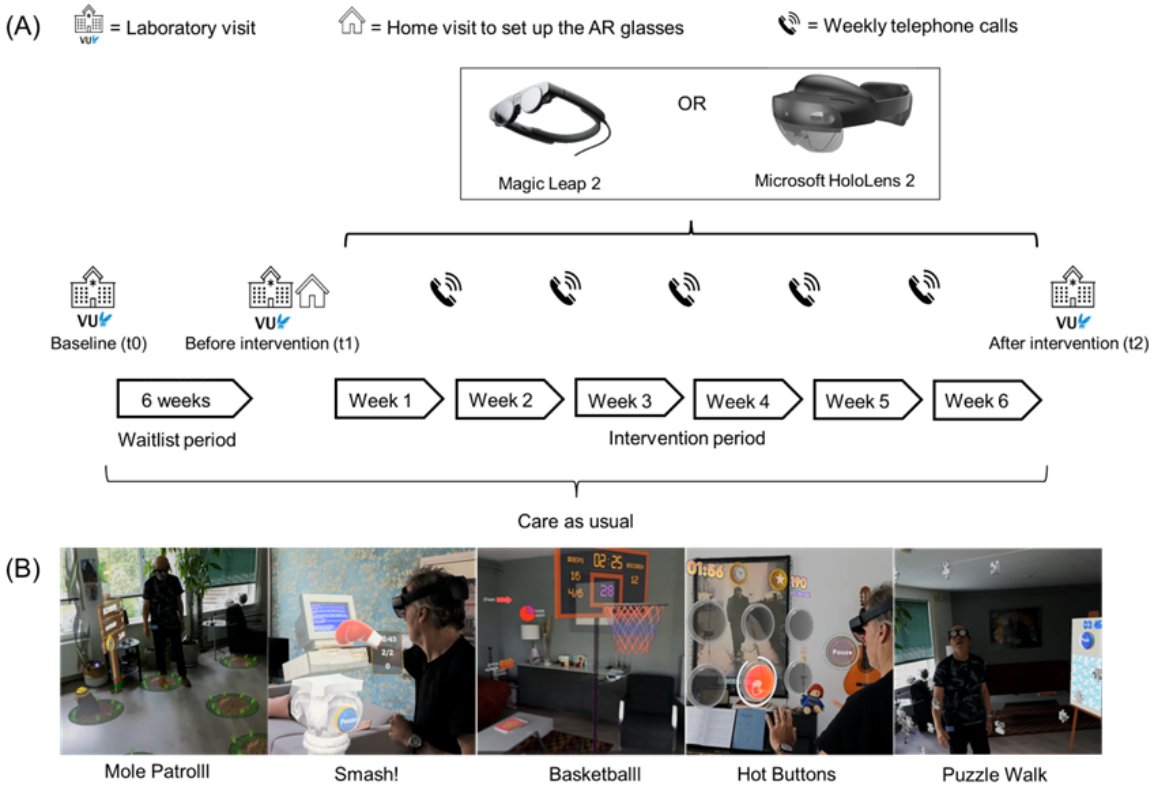
This exploratory qualitative study was guided by a critical realist epistemology, seeking to understand how participants experienced the Reality DTx exercise program in ways that reflect aspects of their lived reality, using semistructured interviews. This study was part of a larger feasibility study that evaluated the feasibility and potential efficacy of Reality DTx [10,11].

The Reality DTx Program

The Reality DTx neurorehabilitation program is a class I CE-marked medical software app for AR glasses for home-based gait and balance exercises (Figure 1A). Following clinical guidelines [26-28], participants were instructed to use Reality DTx 6 weeks at home for at least 30 minutes per day and 5 days a week. Participants completed the 5 complementary AR exercises (every 3-min game was prescribed twice; Figure 1B), either in a single session or in so-called “exercise snacks” divided over the day. Among these 5 AR exercises, Mole Patrolll is a goal-directed walking exercise that targets gait initiation, dynamic balance, turning, stopping, and strength (in squat mode). The user is challenged to stomp on appearing moles before they disappear. Smash! is a boxing exercise that targets gait, dynamic balance, weight shifting, and turning. The user walks between 2 plinths and smashes as many items as possible from each. Hot buttons is a dynamic reaching exercise that targets functional reaching, reaction time, and dynamic balance. The user must press as many buttons as possible (1×3, 2×3, or 3×3 configurations) before they disappear. Basketball is a sit-to-stand exercise that targets dynamic balance and lower-limb muscle strength. The user completes sit-to-stand movements or squats and throws basketballs into the hoop. Puzzle walk is a goal-directed walking exercise that targets gait, dynamic balance, turning, stopping, and functional reaching. The user collects puzzle pieces at various heights and places them on the easel as fast as possible. The exercises increase in difficulty by reducing the appearance duration of items (eg, moles and buttons) or by increasing the number of items or required movements, such as the smash items on the pillars, puzzle pieces, or the number of sit-to-stands or squats. Alongside usual care, researchers trained the participants in using Reality DTx and prescribed and supervised the program through weekly calls to personalize the program’s frequency, difficulty, type of AR exercise, and/or duration using shared decision-making and with input from adherence and performance measures from the web portal [11]. Participants received feedback on game performance in the form of in-game and postgame scores and encouraging commentary from the AR glasses (the additional file in the study by Hardeman et al [10] provide more details on these scores and the AR exercises).

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Figure 1. (A) Overview of the procedure of the waitlist-controlled feasibility trial, reprinted from the study by Hardeman et al [11]. (B) Images of the 5 Reality DTx exercises (from left to right): Mole Patrolll, Smash!, Basketball, Hot Buttons and Puzzle Walk.



Participants

Participants were recruited through convenience sampling, mainly via presentations at various Parkinson community groups hosted by the Dutch Parkinson Association in the west of the Netherlands, but also via physicians in our network and via the website of the Dutch Parkinson Association. Participants contacted the researchers voluntarily if they were interested.They were eligible to participate in the feasibility trial if they were diagnosed with Parkinson disease according to the UK Parkinson's Disease Brain Bank criteria (H&Y 2-4) and if they experienced bothersome gait and/or balance impairments, based on self-report. Participants were excluded if they comply with the following criteria: (1) a sign of inability to comply with protocol, (2) additional neurological diseases and/or orthopedic problems seriously interfering with gait and balance function, (3) insufficient physical capacity or cognitive and/or communicative inability to understand instructions and participate in the tests (as observed by the researchers), (4) visual or hearing impairments (after corrective aids), (5) severe visual hallucinations or illusions, (6) an inability to walk independently for 30 minutes, and (7) no stable dosages of dopaminergic medication. There were no additional criteria, nor a minimum treatment dose, to be eligible to participate in the semistructured interviews. There were no restrictions to usual care. Eligibility criteria were checked through telephone screening before enrollment and again during the baseline (t0) laboratory assessment of the feasibility trial by researchers LESH, EMH, and DJG (further details on eligibility screening are given in the study by Hardeman et al [10]). Three laboratory assessments were conducted at t0, before intervention (t1), and after intervention (t2) to evaluate feasibility in terms of safety, adherence and user experience, and potential efficacy with key clinical gait and balance tests and a targeted walking-related fall risk assessment, performed by the researchers (Figure 1 [11]). All participants of the feasibility trial were characterized at t0 by collecting demographics; the Montreal Cognitive Assessment, the Movement Disorder Society—Unified Parkinson's Disease Rating Scale (MDS-UDPRS), and the Physical Activity Scale for the Elderly. Following t2, all participants were invited to be interviewed. 92% (22/24) of the participants who started the Reality DTx program were interviewed. Two (8%) participants were not interviewed because they dropped out of the study in the first and fourth weeks of the intervention period due to too many technological issues with the AR glasses and due to medical circumstances unrelated to the study, respectively [11].

Procedure

The interviews were conducted after the postintervention gait and balance laboratory assessments of the feasibility trial. At the time of the interview, participants had not yet received personal feedback on their results of the gait and balance and targeted walking-related fall risk assessments (Figure 1). The interviews took place in a quiet, private room at the Vrije universiteit Amsterdam on the assessment day or, based on the participants' preference, via telephone on another day. Because some participants experienced difficulty in finding the right words to express themselves, 4 of the 8 partners present during the interview assisted in clarifying their views. These explanations were only used as such and were not included as primary data in the analysis.

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The interview guide was carefully constructed with standardized topics and questions but allowed the researchers to spontaneously react to the participants' responses with unscripted follow-up questions, as prescribed by reflexive thematic coding to ensure in-depth exploration [29]. The interview guide was partly based on the TFA [16], which consists of 7 acceptability indicators identified through an extensive literature search of health care interventions. These indicators include affective attitude, perceived effectiveness, intervention coherence, self-efficacy, opportunity costs, burden, and ethicality. We followed the operationalization of the TFA indicators by Gerards et al [30], specified in Table 1. Besides the TFA indicators, the interview guide included the following topics: (1) program-specific factors, such as the type of AR exercises, frequency, intensity, and duration; (2) context-specific factors, such as exercise at home and remote supervision; (3) the usability of Reality DTx software and the AR glasses (Microsoft HoloLens 2 and Magic Leap 2); and (4) the future potential of Reality DTx in health care (Table 1). The interview guide was created by LESH and reviewed with MR and Strolll Limited (the manufacturer of Reality DTx) before and after pilot testing. The initial draft interview guide was updated with questions on willingness to continue the exercise program after trial, usability, commercial potential, and intended users. Researchers LESH and DJG conducted, respectively, 82% (n=18) and 18% (n=4) of the 22 interviews. The interviews were held from March to July 2023, were audio recorded and were transcribed verbatim by LESH. They lasted 57 (SD 14) minutes on average.

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Table 1. Topics, subtopics, and operationalization of the semistructured interview guide.

Topics and subtopics	Operationalization
Theoretical acceptability framework	
Affective attitude	• "How did you feel about the Reality DTx[a] training?"
Perceived effectiveness	• "To what extent did you experience effects from the training?"
Intervention coherence	• "Can you explain to me, in your own words, what the goal of the training was?"
Self-efficacy	• "How did you do in the training?"
Opportunity costs	• "To what extent did you have to give up on other activities to participate in the training?"
Burden	• "What did you think of the difficulty of the training (in general, not per game)?"
Ethicality	• "To what extent did the training fit your views on home-based gait-and-balance exercise?"
FITT[b] principles	
Frequency of the training	• "What did you think of the frequency of the training (ie, 5 days a week)?[c]"
Intensity of the training	• "What did you think of the intensity of the training?[c]" • "Do you think your physical fitness has increased?"
Type of AR[d] exercises	• "What did you think of the type of training (eg, gait and balance, type of exercises)?" "What game did you like the most?" "What game did you like the least?"
Duration of the training	• "What did you think of the duration of the training program as a whole (ie, 6 weeks)?[c]" • "Would you have wanted to keep the device for longer?"
Duration of 1 session	• "What did you think of the duration of one training session (ie, 30 minutes)?[c]"
Context-specific factors	
Training individually	• "What did you think about training individually?"
Training at home	• "What did you think about training at home?"
Scoring system	• "What did you think about the scoring system that was used during training?"
Remote supervision	• "What did you think about remote supervision?"
Usability	
Weight of the glasses	• "What did you think about the weight of the AR glasses?"
Field of view	• "What did you think about the visibility of the holograms in the games?"
Controlling the holograms	• "What did you think about controlling the holograms or buttons with your hands? If you could chose, how would you like to control/select the buttons/holograms?"
Wearer comfort	• "How long do you think you could wear the AR glasses before it becomes uncomfortable? (...hour(s) ...min)"
AR glasses	• "What were your expectations about training with Reality DTx and how do you feel about them now?" • "What did you think about the AR glasses?" • "What would you change about the AR glasses?"
Experiences during the last week of training [e]	

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Topics and subtopics	Operationalization
Adverse events	• "Did you experience any difficulties in terms of eye sight during the Reality DTx training? That is, were all letters and holograms clearly visible and readable?" • "Did you experience any of the following problems this week: eye strain, dizziness, headache, something else, which is: ...?" • "Did you fall/nearly fall during the training this week?"
Technical issues	• "Did you experience any technical difficulties this week?"
Overall feeling of safety	• "Did you feel unsafe at any point during the Reality DTx training?"
Overall usefulness	• "On a scale from 0 to 10, how useful did you find the training?"
Overall user-friendliness	• "On a scale from 0 to 10, how user friendly did you find the glasses/the Reality DTx app?"
Future perspective	
Suggestions for improvements	• "Do you have any suggestions for improving the Reality DTx training program?"
Monthly subscription	• "If you would need to pay a monthly prescription for Reality DTx (which includes the AR glasses, the application, and technical support), what would you pay?"
Intended users	• "What type of people do you think will benefit most from Reality DTx?"
Future implementation in health care	• "How would you feel if, in the future, Reality DTx would replace part of your supervised physical-therapy sessions with remotely prescribed home-based sessions resulting in less frequent in-clinic sessions, for example, once every 3 weeks instead of once a week?"

[a]Reality DTx: Reality Digital Therapeutics.

[b]FITT: frequency, intensity, type, and time.

[c]Participants were provided with multiple-choice answer options, such as "too infrequent—too often," "too light—too hard" and "too easy—too hard," to guide their responses. However, they were encouraged to explain their answers.

[d]AR: augmented reality.

[e]Data related to this topic were collected during the weekly telephone calls and used in the data analysis of the number of adverse events and the number of technical issues reported in the study by Hardeman et al [11].

Analysis

We applied a reflexive thematic analysis as described by Braun and Clarke [31-33] in 6 phases, as presented in Table 2. We used an inductive, semantic approach that is, coding and theme development were directed by the content of the data and explicitly reflected the data. We aimed to remain close to what participants said while ensuring clarity and comprehension in naming and describing themes and subthemes. To ensure a critical realist approach, that is, to acknowledge the researcher's role in the analytic process, while simultaneously ensuring that we remained close to the participants' lived experiences, the research team maintained detailed reflexive memos. In this way, we could critically examine and document biases, assumptions, and the evolution of our themes. In addition, regular team triangulation sessions were held to enhance analytic rigor and to ensure that our interpretation remained grounded in the data (Table 2; phases 2-5). Transcripts and themes were analyzed and discussed in Dutch using Atlas.ti software (version 20; Lumivero). Themes and selected quotations were translated into English by LESH. Logs of the data analysis steps were kept.

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Table 2. Description of the reflexive thematic analysis followed, including a description of the triangulation process, corresponding to the 6 phases [31-33].

Phase[a]	Description of the reflexive thematic analysis process as described by Braun and Clarke [31-33][a]	Description of the reflexive thematic analysis data analysis process of this study
1. Familiarizing with data	Transcribing data (if necessary), reading and rereading the data, and noting down initial ideas	Data were transcribed by LESH. LESH and EvB familiarized themselves with the data.
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire dataset and collating data relevant to each code	Initial open codes of 4 transcripts were generated and thoroughly discussed and revised by LESH and EvB. Initial codes were collated in categories by LESH in a mind map that was presented, thoroughly discussed, and revised during multiple triangulation sessions between LESH, EvB, MvG, and EMH, while LESH open-coded the remaining data.
3. Searching for themes	Collating codes into potential themes and gathering all data relevant to each potential theme	Potential themes and subthemes, resulting from categories of open codes, were discussed in the first 5 triangulation sessions with the authors EvB, MvG and EMH and further refined by LESH.
4. Reviewing themes	Checking if the themes work in relation to the coded extracts (level 1) and the entire dataset (level 2) and generating a thematic "map" of the analysis	An initial thematic map was generated by LESH. Initial themes and subthemes were discussed in relation to the coded extracts, in relation to each other, and in relation to the entire dataset during the subsequent 4 triangulation sessions with the authors mentioned earlier.
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme and the overall story the analysis tells and generating clear definitions and names for each theme	Following the initial thematic map, the overall story was drafted and discussed between the authors mentioned earlier in the subsequent 4 triangulation sessions. Themes and subthemes were further defined and named until agreement was reached.
6. Producing the report	The final opportunity for analysis: selection of vivid, compelling extract examples; final analysis of selected extracts; relating back of the analysis to the research question and literature; and producing a scholarly report of the analysis	The drafted overall story was further refined, and corresponding selected extracts were replaced if they did not represent the theme or subtheme accurately.

[a]Adapted from the study by Braun and Clarke [31].

Researcher Positionality

The analysis was conducted from a reflexive thematic analysis approach, informed by a critical realist orientation, while acknowledging that data interpretation is also shaped by the researchers' disciplinary backgrounds and professional experience. While interpretation inevitably involved the researcher's perspective, every effort was made to remain true to the participants' own meanings and experiences, acknowledging the potential influence of the researcher's subjectivity throughout the analytic process. The lead analyst (LESH) is a PhD candidate with a background in clinical psychology and neuropsychology who worked as a psychologist in rehabilitation. Her clinical experience contributed to a close reading of how participants described cognitive and emotional processes in everyday contexts. The analysis was supervised by EvB, a clinical epidemiologist and applied sciences lecturer with previous training and experience in qualitative interview methods. Their complementary perspectives, informed by neuropsychology and physical therapy, helped to frame the data in relation to rehabilitation goals, patient engagement, and perceived barriers. Triangulation sessions were held between LESH and EvB to support reflexivity and analytic consistency and were enriched by input from EMH and MvG, who brought in human movement science expertise. EMH is a PhD candidate and human movement scientist, and MvG is a PhD candidate specializing in fall prevention in the older adults as part of the In Balance trial [34], with experience in qualitative analysis. LESH, DJG, and EMH and author MR are part of the same research team at the Vrije Universiteit Amsterdam, with author JN involved as an external PhD cosupervisor of LESH. EvB and MvG are not part of the same team. Some of the participants had participated in previous trials and thus had a connection with researchers LESH, EMH, and DJG. LESH and EMH worked closely with all participants as part of the data collection of the Reality DTx feasibility trial, whereas DJG was only involved in the final stages of the data collection of the trial.

Results

Study Sample

The study included 22 people with Parkinson disease, 7 women (32%) and 15 (68%) men, with a mean age of 66 (range 51-82) years. The time since diagnosis was on average 8 (range 1-20) years, and participants were classified with a modified H&Y of 2 (14/22, 64%) or 2.5 (8/22, 36%). An overview of participant characteristics to characterize the sample is provided in Table 3. Medication remained stable over the waitlist and intervention period. For further participant characteristics, please refer to our feasibility results [11].

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Table 3. Demographics and clinical characteristics of the sample assessed during baseline measurements (t0) of the feasibility study.

Participant number	Sex	Age (y)	Time since diagnosis (y)	Modified H&Y[a]	MoCA[b] score	Total MDS-UPDRS[c] score	PASE[d] score
1	Male	72	1	2	26	34	182.3
2	Male	74	6	2	18	78	49.0
3	Female	60	2	2	27	39	238.9
4	Male	51	7	2.5	28	46	180.8
5[e]	Female	60	20	2.5	29	62	71.1
6	Female	68	8	2	28	59	40.0
7	Male	73	11	2	19	76	68.2
8	Female	56	1	2	29	70	93.0
9	Male	74	12	2.5	22	78	96.6
10	Male	59	6	2	25	53	89.9
11	Male	51	2	2	28	50	95.0
12	Male	65	6	2	27	68	211.8
13	Male	53	14	2	29	50	80.6
14	Female	57	13	2.5	28	78	78.7
15[e]	Female	66	11	2.5	30	67	180.0
16	Male	82	8	2.5	30	73	134.4
17	Male	74	5	2	29	78	160.6
18	Male	63	6	2	29	76	97.7
19	Male	78	4	2	26	68	171.0
20	Male	68	10	2.5	28	79	76.1
21	Male	71	15	2	30	51	151.4
22	Female	74	7	2.5	23	73	118.7

[a]Modified H&Y: the Modified Hoehn and Yahr Scale (ranging 1-5; following progression in symptoms).

[b]MoCA: Montreal Cognitive Assessment (total score is 30; a score of ≥26 is considered normal [35]).

[c]MDS-UPDRS: Movement Disorder Society-unified Parkinson's Disease Rating Scale (ranging 0-272, higher total scores indicate more severe overall symptom severity).

[d]PASE: Physical Activity Scale for the Elderly (higher scores indicate higher physical activity levels).

[e]Participants who dropped out of the study due to medical circumstances unrelated to the study in weeks 4 and 6.

Context

The sample can be further characterized according to a number of reported experiences, which is important for the interpretation of the findings. First, participants expressed a notable sense of responsibility to contribute to scientific research, which motivated them to adhere to the prescribed program to the best of their ability:

> *Because I had said "yes" once, I also wanted to follow through. To serve you as best as I can, I want to fulfil my commitment to the best of my ability.* [Participant 19]

Second, as reflected in the individual Physical Activity Scale for the Elderly and Montreal Cognitive Assessment scores (Table 3), participants showed variability in physical and cognitive abilities, with some being more physically active than others. This variability was also present in their expressions, for example:

> *And by then I have walked outside for four hours, half an hour in that sense, is more than easily met every day.* [Participant 19]

These participants who were relatively physically active were often more engaged in work or had busy retirement schedules:

> *Well, I was glad I had two days off every week, because honestly, having to train five out of seven days really kept me accountable, so to speak. But since I work full time and often trained in the evenings, it was like, okay, okay, let's just get it done. I think if there hadn't been any pressure, I might have skipped it more often.* [Participant 3]

Other participants had more severe physical or cognitive symptoms that interfered with their performance:

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> *Well, first of all, he [partner] tells me: "Stand up straight, stretch your leg." If he didn't, I would forget. He helps me remember, so alone, I wouldn't get anywhere.*

In general, participants realized that their Parkinson symptoms would deteriorate over time rather than that they would improve, independent of their commitment to exercise in general:

> *Initially, I noticed a very positive effect. But lately, I feel like I'm just deteriorating because of the Parkinson.* [Participant 5]

Third, some participants expressed more experience and affinity with technology than others:

> *Since COVID, we've gotten used to doing everything remotely, so that works pretty well, although I do struggle sometimes because, you know, I'm not exactly a computer genius.* [Participant 19]

> *I know I'm very enthusiastic about these kinds of things, especially because it involves technology because I want to provide feedback from the user's perspective to help improve it.* [Participant 18]

Qualitative Findings

Overview

The results of the reflexive thematic analysis are described in 3 themes: "there was considerable interindividual variation," "the program is complementary to supervised physical therapy," and "adherence in the long term is crucial," and 9 subthemes (Textbox 1).

Textbox 1. Themes and subthemes resulting from the reflexive thematic analysis.

There was considerable interindividual variation

- Variation in perceived effectiveness
- Variation in experienced effort

The program is complementary to supervised physical therapy

- Supervision by the physical therapist
- Social connection
- Different treatment modalities within physical therapy

Adherence in the long term is crucial

- Flexibility
- Better visibility of progression in scores
- More variation in games
- The addition of a competitive element

There Was Considerable Interindividual Variation

There was considerable interindividual variation in perceived effectiveness and experienced effort.

Variation in Perceived Effectiveness

Participants identified various effects of the program. Examples included improvements in aspects of gait and balance—the program goals—as well as other improvements, such as increased endurance, decreased muscle rigidity, and increased confidence in their own body.

On one hand, some of the participants perceived specific improvements during gameplay:

> *Well, with turning, I would practice turning left or right since that's my difficult side, with the boxing game. So I consciously focused on turning right, and I noticed it started to improve pretty quickly.* [Participant 13]

On the other hand, others described benefits that transferred to daily life activities, such as playing tennis:

> *Well, I was able to move more easily on the court again. I wasn't constantly stuck or too late to get to the ball. Thoughts like: "Be careful or you'll fall," were much less present. I moved more easily with less freezing.* [Participant 20]

> *Yes, yes, I walk to the supermarket. I used to have to stop two or three times to catch my breath. But the last few times, I didn't need to, I stopped once and continued.* [Participant 6]

Furthermore, some participants reported that the exercises required them to concentrate more, either on the task at hand or on the movement:

> *Other people too—people who want to move, not just their bodies but also their brain. Using their brains more, improving concentration—it's good for that too...* [Participant 6]

Furthermore, some participants felt more cognitively alert or more physically active after the exercise sessions, although this distinction was not always clearly expressed:

> *Normally, you do things on autopilot. As a Parkinson patient, you have to think about it. After a training session, it's physical, but it also feels like it wakes you up somehow...* [Participant 12]

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Participants who did not perceive direct effects, characterized by relatively high levels of physical activity as described in the earlier context, offered several explanations. They suggested that their already high levels of physical activity may have diminished the potential gains of the intervention, that their gait and balance deficits were still relatively mild, that symptom decline over time masked the program effects, or that the duration of the intervention was too short to produce noticeable changes. Despite the absence of perceived effects, they expressed a strong belief that physical activity is inherently beneficial when diagnosed with Parkinson disease:

> *I also do physical therapy fitness, which is endurance already. I think it makes a difference depending on what stage of Parkinson's you're in and how active you can still be. If you don't do much and then try these exercises, you'll probably notice a difference. But if you're already doing a lot, you might not see immediate effects. Still, I feel it's worthwhile—I don't feel like I'm wasting my time.* [Participant 3]

Some of these participants believed that the program was more suitable for people with Parkinson disease with more severe symptoms:

> *But as you go along, you notice that it really does something for you. If it could be developed into a fully functional system, I think it would have a lot of added value, especially for Parkinson patients with more severe problems. I don't think I'm quite at that point yet.* [Participant 12]

The belief that physical activity is inherently beneficial when diagnosed with Parkinson disease aligns with the observation that some participants were not able to recite the program goal—to improve gait and balance—communicated at the start of the intervention. Instead, participants considered increasing physical activity as their primary program goal:

> *I initially struggled with it, but I believe the idea was to get people with Parkinson moving. You can prescribe exercises, and they'll do them once, but the challenge is to do them more often. That's why, having something that keeps you accountable—without it, it fades away.* [Participant 16]

Variation in Experienced Effort

Participants experienced the program as demanding for various reasons. Participants who were relatively physically active with busy work or retirement schedules, as described in the context earlier, experienced difficulty in integrating the program into their daily or weekly routines. They experienced considerable training load:

> *I must admit, I found it challenging to fit it into my schedule. That's why I say it was demanding. After a whole day of activities, sitting down at 5 p.m, I didn't always feel like doing an hour of training.* [Participant 19]

On the contrary, other participants expressed the desire to train more frequently than 5 times per week.

Participants with relatively lower activity levels and more severe physical or cognitive symptoms, as described in the context earlier (Table 3), experienced the program as more physically demanding:

> *I could do the training and complete it, but afterwards, I'd be really tired. I had to sit or lie down to regain energy.* [Participant 6]

Other remarks with regard to the experienced intensity of the program were that the exercise intensity was partially determined by the level of effort put into the exercises:

> *And that's the big issue with this product—how enthusiastic will someone play the games? If I just play a game casually, it doesn't have the same effect as when I tell myself: let's go for it, I know it's good for me and let's challenge myself to keep improving each time.* [Participant 18]

The Program Is Complementary to Supervised Physical Therapy

Overview

During the interview, participants were presented with a hypothetical future scenario in which traditional supervised physical therapy would be replaced by a hybrid model that combines supervised physical therapy with the remotely prescribed Reality DTx gait and balance program at home. In this scenario, participants were given an example that illustrated this change, which would reduce the number of clinic visits and increase remotely prescribed exercise hours at home (Table 1 provides the scripted scenario). The discussion of this scenario resulted in the perspective that the program could complement, but not replace, supervised physical therapy sessions to a greater or lesser extent:

> *I personally think it doesn't replace the physical therapist. I see it as an added value, an extra way of training...* [Participant 8]
>
> *Look, I do stability exercises, but I also do core exercises and such. So this can't replace that, but you can certainly integrate some of your movements into it.* [Participant 12]

This perspective was shaped by several underlying factors, outlined in the subsequent sections in 3 subthemes: "supervision by the physical therapist," "social connection," and "different treatment modalities within physical therapy."

As described earlier, some participants believed physical activity is inherently beneficial for Parkinson disease, even without perceived effects. In addition, they emphasized the importance of long-term adherence for effectiveness:

> *And the question is whether it sticks. I don't think the chances are very high. At least, my personal theory is that it could help for a while, but I would have to keep doing these kinds of exercises.* [Participant 20]

On that note, participants emphasized the need for external control to sustain long-term adherence to the program. In the context of this study, researchers fulfilled this role by remotely prescribing and adjusting AR exercises in a shared

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decision-making process with participants through weekly calls to discuss their adherence, performance, and progress. These calls were perceived positively:

> *Well, you could modify the games and you asked whether everything was okay—I appreciated that.* [Participant 9]

Supervision by the Physical Therapist

In a future clinical scenario in which the program complements supervised physical therapy, some participants explicitly tasked the physical therapist with the remote supervision of adherence:

> *Look, if you go to the physical therapist, you'll be exposed if you haven't been practicing, so to speak.... You might need to provide some kind of access to the physical therapist for that.* [Participant 8]

Apart from adherence supervision, participants valued the physical therapist for providing real-time feedback on movement quality:

> *Yes, absolutely, it's important that when you do it over a longer period, the physical therapist also looks at how you move and corrects you if you're not doing it properly.* [Participant 19]

Participants emphasized the importance of executing the correct movement, but the level of trust in technology's ability to elicit the correct movement varied. Some participants believed that the technology did elicit the correct movement:

> *So you have to stretch your arm far enough. So you make sure that you're far enough from the pilar to punch. If you're too close, it doesn't work. The system's requirements for the punch naturally lead you to a properly extended arm movement, so that's beneficial for the exercise.* [Participant 17]

Whereas others were uncertain whether the technology had supported them sufficiently in executing the movements correctly at home:

> *You do perform the movement, but at the physical therapist, I try to make the movement so it's really correct. With Hot Buttons, you don't really know if you're performing the movement optimally.* [Participant 11]

In line with the experienced uncertainty about the correctness of movements, the encouraging commentary provided by the AR glasses as a form of feedback was not perceived positively because it was not related to their actual performance:

> *Well, I want to be complimented because I actually did it really quickly, you know? Not because the software developer programmed a compliment every five minutes so that everyone gets the same "yay" and confetti, whether they're fast or slow....* [Participant 8]

Social Connection

Some participants considered the AR program as complementary to rather than a full replacement of supervised physical therapy sessions because of the social aspect of group-based physical therapy. Many participants engaged in group-based physical therapy, supervised by their physical therapist. Participants described group-based physical therapy as a socially enriching activity, emphasizing connection with peers:

> *It could never replace it for me, especially the Parkinson-specific aspects of physical therapy. I mean, you can use equipment at any gym—that's not the point. But talking about Parkinson and how to deal with it, how to turn over in bed, how to get on a bike properly—those very specific things can't be replaced.* [Participant 21]

Group-based physical therapy was also identified as a motivator to exercise:

> *It's a pretty lonely game—a game you play on your own. The actual motivation, in my opinion, is having a connection with others. That is more appealing to me.* [Participant 17]

Different Treatment Modalities Within Physical Therapy

Finally, some participants considered the AR program as complementary to rather than a full replacement of, supervised physical therapy sessions because physical therapists offer different treatment modalities that they deemed important. Examples are strength training, fall prevention exercises, and hands-on therapy:

> *Well, I go to physical therapy twice a week, and I'm in a group where I do many other things, so to speak. One day a week is for endurance, and the other day is for Parkinson exercises with the group—memory training, fall prevention, all kinds of things.* [Participant 8]

Adherence in the Long Term Is Crucial

Flexibility

If participants were asked to reflect on continuing with Reality DTx after study completion, they reported that the flexibility of the program was a very important aspect. Participants agreed that the program was particularly flexible, which supports exercise adherence in the long term. Several aspects of the program's flexibility were highlighted, such as the speed of setting up the program, the efficient use of time of an exercise session, and the possibility to exercise each day, at the most convenient time, for example, when Parkinson symptoms were least disruptive, without having to travel. The perceptions of flexibility fit nicely with the daily fluctuations in symptoms that participants described:

> *An advantage is that it doesn't matter much at what time you do it specifically. You can decide for yourself, now I feel good, let's do it now because it is least inconvenient.* [Participant 18]

A couple of improvements for long-term adherence to the program were suggested, outlined in the following subthemes: "better visibility of progression in scores," "more variation in games," and "the addition of a competitive element."

Better Visibility of Progression in Scores

An important improvement relates to the scoring system. The score was presented at the end of each game; however, without

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comparison to previous scores (ie, only a podium of personal best scores was presented as a reference). Participants perceived the score as a very important motivator. They expressed the desire to see their scores improve, to become better at a game:

> *You need to find motivation somewhere. You can try to be faster because you want to score more points. Even though you know it's only about the movement, you still want to get as many balls in the net as possible. That's just human nature.* [Participant 17]

> *Yes, but I do think, one of the motivations for me was being able to improve myself through the game. You don't really win, but it's still a kind of victory over yourself. You think, "Yes, it's higher, I did it!"* [Participant 3]

With the score as an important motivator, participants indicated the importance of having a clear overview of their scores and a sufficient understanding of how to improve them. They wished to track their progression over time.

Participants also discussed the desire to feel challenged, which was also primarily related to the possibility improving scores:

> *Well, I think when you reach a higher level, it becomes harder to beat your record. That's a bit demotivating because maybe you do better with 24 puzzle pieces instead of 12, but you don't see it. I find that disappointing.* [Participant 3]

On a final note, technical issues encountered during the study sometimes hindered participants from continuing an exercise session, which negatively impacted the ability to improve their scores. Looking ahead, the stability of the technology was identified as an important area for improvement.

More Variation in Games

To adhere to the program in the long term, participants indicated a desire for a broader selection of games to prevent boredom:

> *But I think if there's a continuous stream of new content, it keeps things fresh....* [Participant 12]

More variety within a game was also mentioned as a way to increase the level of challenge of a game. Suggestions to increase the level of challenge or for new games were to incorporate a cognitive element or to increase the variety of movements or stimuli. The level of challenge was one of the primary factors influencing participants' selection of the most enjoyable game. Another factor was the recognizability of games related to sports they had played in the past, such as tennis:

> *Well, the boxing game, the turning—it's part of the exercise, turning and turning. So it's an exercise too, but at some point, you get a bit fed up with it.* [Participant 16]

The Addition of a Competitive Element

Although participants felt that the program could not replace the sense of connection that group-based physical therapy provides, they suggested implementing a competitive element into the program. Some suggested including a virtual ranking with other users, and others suggested incorporating a multiplayer option in the same (virtual) environment:

> *I've wondered if digital games or digital challenges could motivate you. I mean, like what I do with my physical therapy group—a few men who cheer each other on with great enthusiasm. That might be motivating....* [Participant 17]

Discussion

Principal Findings

This qualitative study aimed to explore the acceptability of Reality DTx, a home-based gamified gait and balance exercise program for people with Parkinson disease. The findings reveal considerable interindividual variation in perceived effectiveness and experienced effort, which corresponded to differences in physical activity, physical ability, and cognitive ability observed in our sample (Table 3). Still, participants consistently expressed a strong belief that physical activity is inherently beneficial when having Parkinson disease. They recognized the added value of the Reality DTx program as a complement to supervised physical therapy sessions. Participants also expressed that Reality DTx cannot fully replace supervised physical therapy sessions because of their desire for external control of the clinician to encourage long-term adherence and provide meaningful feedback on movement quality, as well as their desire for social connection inherent to group-based physical therapy and other treatment modalities offered by the physical therapist not being part of Reality DTx. An important element that was valued by the participants was the flexibility of the program, supporting long-term exercise adherence. The program was considered flexible in both time (eg, exercising when convenient in terms of symptom fluctuations and daily routines) and place (eg, exercising in your living environment rather than in a clinic, without having to travel). Participants suggested that adherence in the longer term would benefit from better visibility of progression in scores, more variation in games, and the addition of a competitive element.

The Indispensable Role of the Clinician

It is important to interpret our findings within the context of the research setting, where researchers remotely prescribed and supervised the Reality DTx program [11]. This deviates from real-world scenarios, where clinicians will typically do this, probably taking a hybrid therapy approach combining remotely prescribed independent exercise at home with supervised physical therapy in the clinic (which aligns with "care as usual" in this study design). The absence of expert supervision in this study might have affected participants' ability to envision the suggested partial replacement of supervised therapy sessions by Reality DTx sessions at home, which would result in a reduction of clinic visits—a future scenario that might be inevitable in light of diminishing accessibility to health care [3-6]. The importance of expert supervision was supported by reported needs for external control to encourage long-term adherence and to provide meaningful feedback on movement quality and a better understanding of the program and exercise goals, all known as important elements of (remote) physical therapy [17,20,27,36-39]. Certainly, the clinician—and by extension the clinical relationship—is indispensable in the future use case of remotely prescribed and supervised Reality DTx.

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Patients and clinicians describe this relationship as one initially built on face-to-face interaction that encompasses a level of trust, positive regard, and knowledge of the patient and illness [40].

We acknowledged the value of this relationship in a follow-up clinical trial where the Reality DTx program starts supervised in the clinic, building a relationship between patient, therapist, and technology, before continuing to exercise independently at home, complementary to usual care. Exercises are remotely prescribed and supervised by the clinician [41]. Technology could support the clinical relationship even further by providing meaningful feedback on movement quality to both the patient and the clinician (enhancing knowledge of performance [40] and patient self-efficacy in terms of the TFA [16]), which also aids motor learning [42]. For example, feedback on movement quality could be generated with motor parameters derived from the AR data during gameplay, such as step length [43-45]. These AR-based motor parameters and other variables, such as physical activity levels and disease severity, could also be used to support the clinician in intervention personalization in terms of optimal training dosage, challenge, and difficulty progression [46,47]. Given the value of the clinical relationship, the clinician should play an active role in this process [31,33].

Other Promoters of Long-Term Exercise Adherence

Besides remote supervision of adherence and meaningful feedback on movement quality, the flexibility of the program was an important acknowledged characteristic of the program to support long-term exercise adherence. The possibility to exercise at home could potentially increase the number of exercise hours, as it overcomes often-reported barriers such as travel time to the clinic and fluctuations in motor symptoms that affect motor performance during exercise [48]. Furthermore, social connection to peers, experienced as a missing element by some participants, has consistently been recognized as a key motivator for long-term exercise adherence in previous Parkinson disease research [21,24,36-38]. Moreover, the finding aligns with the psychological need for relatedness as one of the underlying factors of the well-established self-determination theory of intrinsic motivation [49]. On the contrary, group-therapy has also been reported as confrontational, that is, to be confronted with motor disabilities of oneself or peers [36,38]. In that regard, home-based exercise such as Reality DTx might be a suitable alternative. An element of competition, which could be added to the Reality DTx software, could provide a sense of relatedness if desired.

Putting Reported Experiences in Perspective

Although participants did not envision a partial replacement of supervised physical therapy sessions, the allocation of Parkinson care to the home environment might be inevitable in light of the growing demand and diminishing capacity of the health care system. Hybrid and technology-enhanced interventions, such as Reality DTx, are needed to lower the burden on health care professionals and to foster self-management of people with Parkinson disease [3-6]. However, the implementation of technology-enhanced interventions such as Reality DTx is rather complex because of multiple dynamically and unpredictably interacting domains, such as the domains of the innovation recipients, innovation deliverers, and key decision-makers [12,13,50]. As for the domain of the practice owners, as key decision-makers, concerns related to technology-enhanced interventions have been raised, such as a lack of logistic support setting up the technology and increased administrative workload and costs [24]. With regard to the wider system of key decision-makers, financial and regulatory bodies may not support technology-enhanced interventions [12]. Motivations, values, and norms of the involved stakeholders at each domain and across domains should be carefully weighted to explore and reduce or “run with” complexity [13,50]. This qualitative study will provide these other stakeholders with the perspective of the innovation recipients, people with Parkinson disease. We have informed our public-private partner, Strolll Limited, about the research findings (including the items from Table 1 that were not reported in this paper, such as usability) for further development of Reality DTx.

Strengths, Limitations, and Future Research

To the best of our knowledge, this is the first study into AR home-based exercise for people with Parkinson disease that adopts a qualitative approach and explores the direct subjective experiences of people with Parkinson disease. This is a strength, because these direct experiences complement the more indirect measures of acceptability of the feasibility trial [10,11], such as adherence rates, and provide insights into the mechanisms of change of Reality DTx for gait and balance exercises at home. For example, external control of the intervention by a clinician to encourage long-term adherence and provide meaningful movement and game performance feedback, and the flexibility of the program, appear to be important mechanisms of change in maintaining the relatively high adherence rates and improving motor performance.

Another strength of this study is the early involvement of the intervention recipients in this preimplementation phase [6,18]. The needs of people with Parkinson disease reflected in the findings will inform future Reality DTx development and implementation. In addition, the findings will also inform the intervention deliverers, that is, the clinicians, as we aim to explore the acceptability among clinicians and the appropriateness of the program as part of clinical practice in the pragmatic clinical trial mentioned earlier [41]. The trustworthiness of this study was warranted with extensive triangulation with internal and external researchers who brought various perspectives to the table and reflected extensively on how these perspectives affect data analysis [51]. Furthermore, the steps of the reflexive thematic analysis were followed in an iterative and rigorous manner, reviewing open coding and themes and subthemes, and data analysis steps were recorded and reported. The elaborate description of our sample and context aids the understanding of the transferability of the results. These methodological study strengths notwithstanding, there were also a number of methodological limitations to point out. First, one researcher (LESH) in the triangulation was also involved in the feasibility trial and conducted most of the interviews. Ideally, to increase the trustworthiness of the findings, an independent interviewer could be considered in the future [30,51]. Second, the intervention was conducted in a research setting, which is not only a different context but also

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one that may have introduced a number of limitations, such as a gratitude bias (ie, people with Parkinson disease may have felt compelled to adhere to the exercise program out of a sense of duty to the research, see our remarks in the Results section context), recruitment bias (ie, recruited participants might have been more interested in technology so-called early adopters [52] compared to the general population of people with Parkinson disease, see our remarks in the Results section context) and responder bias (ie, 2 participants who dropped out of the feasibility study were not interviewed, potentially missing valuable insights or opposing perspectives that could challenge the study's findings).

These biases and the broadening of recruitment strategies in terms of clinical characteristics, such as symptom severity (modified H&Y 2-2.5 in this trial), should be addressed in future research to improve the generalizability of acceptability results. For example, purposive sampling of people with Parkinson disease with various user characteristics (eg, different levels of affinity with technology) may reduce recruitment bias related to early adopters. Furthermore, symptom severity and physical activity level are suggested to affect the intervention's acceptability in terms of perceived effectiveness and experienced effort (burden, in terms of the TFA [16]) and should be addressed in further development of the intervention to improve acceptability and explore clinical implications. A potential clinical implication of these findings, in particular, could be that the intervention is more appropriate and easier adopted by people with Parkinson disease with lower physical activity levels, as suggested in a previous study [53]. Acceptability could be improved for people with Parkinson disease with various physical activity levels and disease severities through adjustable intensity levels and personalization based on AR motor parameters [43,45-47]. The impact of individual differences in clinical (eg, physical activity level and symptom severity) and user (eg, affinity with technology) characteristics on the acceptability and adoption of the intervention should be explored in future effectiveness-implementation trials [22].

Conclusions

People with Parkinson disease (H&Y 2-2.5) considered Reality DTx acceptable as an exercise program complementary to supervised physical therapy. Mechanisms of change for maintaining high adherence rates and a progressive-but-achievable intervention and for improving motor performance were identified and included external control of the intervention by a clinician, meaningful movement and game performance feedback, and the flexibility of the program. Individual differences in physical activity levels and disease severity may further explain acceptability in terms of perceived effectiveness and experienced effort. In light of the growing demands on health care, replacing supervised physical therapy sessions in the clinic with remotely prescribed therapy at home might be inevitable. In anticipation of this transformation, Reality DTx could better fit the needs of people with Parkinson disease and support long-term adherence to exercise by improving real-time movement feedback, by enhancing the visibility of progression in scores, by increasing variation in games, and by incorporating a competitive element into the game. Additional qualitative, in-depth research and weighting of interests, values, and norms among stakeholders in the wider system of users is needed to arrive at an encompassing evaluation of the acceptability of Reality DTx or related interventions.

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Authors' Contributions

LESH was responsible for conceptualization, investigation, data analysis, writing—original draft, and writing—review and editing. EvB was responsible for methodology, data analysis, supervision, and writing—review and editing. EMH was responsible for data analysis—triangulation, investigation and writing—review and editing. MvG was responsible for data analysis—triangulation and writing—review and editing. DJG was responsible for conceptualization, investigation, supervision, and writing—review and editing. JN was responsible for conceptualization, supervision, and writing—review and editing. MR was responsible for conceptualization, funding acquisition, supervision, and writing—review and editing.

Conflicts of Interest

MR is a scientific advisor with share options for Strolll Ltd., a digital therapeutics company building AR software for physical rehabilitation, for one day a week ancillary to his main positions as associate professor Technology in Motion at Vrije Universiteit Amsterdam and Senior Scientist at Maastricht University. To prevent any potential bias, MR has not been part of data analysis. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Abbreviations

AR: augmented reality
COREQ: Consolidated Criteria for Reporting Qualitative Research
H&Y: Hoehn and Yahr
Reality DTx: Reality Digital Therapeutics
t0: baseline
t1: before intervention
t2: after intervention
TFA: theoretical framework of acceptability

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Effects of Technology-Assisted Rehabilitation After Spinal Cord Injury: Pilot Randomized Controlled Crossover Trial

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Abstract

Background: Technology-assisted and robotic rehabilitation methods are increasingly used in neurorehabilitation. Still, scarce evidence exists on their effects on upper extremity functioning after spinal cord injury, especially at the chronic stage.

Objective: The present study aims to evaluate the effects of a 6-week intervention focusing on technology-assisted upper extremity rehabilitation in adults 1-8 years after incomplete cervical spinal cord injury.

Methods: In this pilot randomized controlled crossover trial, 20 participants (10 men, 34 - 73 y of age) were recruited by mail and randomized into 2 sequences (AB: n=10 and BA: n=10). All participants received a 6-week rehabilitation intervention in Period 1 or Period 2, with a 4-week washout period in between. The intervention was delivered 3 times a week for 6 weeks (18 sessions) by occupational therapists specialized in spinal cord injuries. Each 1-hour therapy session included a minimum of 30 minutes of technology-assisted upper extremity rehabilitation using interactive and task-specific AMADEO, DIEGO, or PABLO devices. Other occupational therapy activities were allowed to complete the 1-hour therapy session. The effects of the 6-week rehabilitation intervention were compared with 6 weeks of no intervention, and the analyses were based on paired data. Each participant served as their own control. Hand and arm function were evaluated using the Action Research Arm Test, the American Spinal Injury Association–Upper Extremity Motor Score (ASIA-UEMS), grip strength, pinch strength, and the Spinal Cord Independence Measure–Self Report. Rehabilitation goal attainment was evaluated by the Goal Attainment Scale. Face-to-face assessments were conducted at baseline, after Period 1, after Period 2, and at 6 months, except for the Goal Attainment Scale, which was used at the beginning and immediately after the rehabilitation intervention.

Results: The effects of the rehabilitation intervention compared to no intervention were statistically insignificant, except for the ASIA-UEMS (median change 1, IQR 0 - 2 point versus 0, IQR −2 to 0 point) in participants in sequence BA (n=7) who received the rehabilitation intervention during Period 2 (*P*=.04). The rehabilitation intervention showed good feasibility and tolerability in adults with incomplete cervical spinal cord injury. Of 20 participants (median age 62, IQR 58 - 66 y), 19 enrolled in the study, and 17 completed at least 80% of the rehabilitation sessions. Fourteen out of 16 participants included in the final analysis attained their rehabilitation goals. The goals were mainly focusing on “fine hand use” and “hand and arm use” related to self-care and domestic life.

Conclusions: Results of this pilot study suggest that technology-assisted upper extremity rehabilitation provided by occupational therapists is safe and has potential for broader clinical use in adults with incomplete cervical spinal cord injury. The rehabilitation intervention showed good feasibility and positive outcomes in rehabilitation goal attainment. This study was left unpowered, and the results need to be confirmed in a larger randomized controlled trial.

Trial Registration: ClinicalTrials.gov NCT04760470; https://clinicaltrials.gov/study/NCT04760470

(JMIR Rehabil Assist Technol 2025;12:e78091) doi:10.2196/78091

KEYWORDS

crossover design; goal attainment scaling; international classification of functioning, disability and health; randomized controlled trial; spinal cord injury; technology-assisted; rehabilitation; robotic; upper extremity

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Introduction

Spinal cord injuries (SCIs) remain a significant global health concern with high incidence, prevalence, and years lived with disability [1]. In Finland, approximately 500 new cases occur annually [2]. Cervical SCIs are particularly severe, often leading to incomplete or complete tetraplegia. The extent of loss in motor function in the upper extremities depends on the level and completeness of the cervical injury, with higher and more complete injury causing more profound impairments [3].

The loss of upper extremity function is especially debilitating when affecting the ability to perform essential activities related to self-care, domestic life, work, and mobility. Consequently, recovery of upper extremity function has been identified as the highest priority in adults with tetraplegia following SCI [4-6]. Therefore, there is a crucial need for effective rehabilitation methods to restore and improve these essential functions.

The use of technology-assisted and robotic rehabilitation methods is increasing, supplementing conventional neurorehabilitation approaches [7-10]. The primary goal of these methods is to facilitate adaptive plasticity and strengthen intact motor pathways through intensive, repetitive functional training [9,11]. They also facilitate relearning of lost motor skills through the repetition of precise, high-quality movements and activate and strengthen affected muscles.

Robotic rehabilitation shows promise in improving hand and arm function in individuals with stroke [10,12] and SCI [11,13]. Yet, there is scarce evidence, mostly case series, of the effects of technology-assisted upper extremity rehabilitation in individuals with SCI [9,11,14-16]. Only a few pilot randomized controlled trials (RCTs) have evaluated the effects of robotic rehabilitation on hand and arm functions [17-21] and self-reported independence in daily activities [17,18] among individuals with incomplete cervical SCI. Sample sizes have been small, focusing on acute and subacute rehabilitation, and the differences between the groups have been mainly statistically insignificant. We aimed to gain new evidence on the effects of technology-assisted upper extremity rehabilitation in the long term after cervical SCI.

Several studies have recently tested and explored technology-assisted rehabilitation methods in diverse patient populations with chronic health conditions such as Parkinson disease and dementia [22], after stroke [23-25], and in critically ill patients in intensive care units [26], showing good feasibility, usability, and preliminary effects. This study aimed to evaluate the effects of a 6-week intervention focusing on technology-assisted upper extremity rehabilitation in adults with incomplete cervical SCI.

Methods

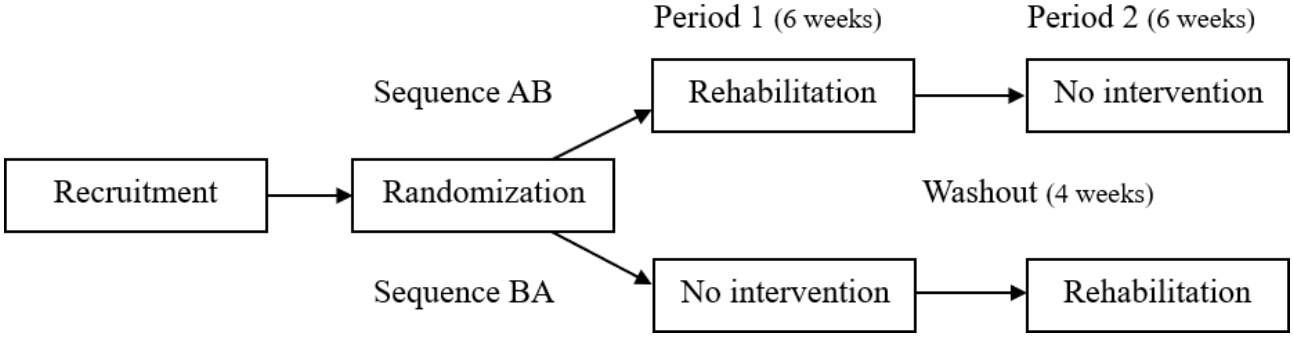
Study Design

This pilot randomized controlled crossover trial (NCT04760470) was conducted following the Consolidated Standards of Reporting Trials extension to crossover trials [27]. The trial duration was 16 weeks, including two 6-week periods (Period 1 and Period 2) and a 4-week washout period in between. The site of intervention, Validia Rehabilitation Center in Helsinki, Finland, is specialized in subacute and later-stage rehabilitation of individuals with SCI.

Participants were randomized into sequence AB or BA in a 1:1 ratio. The sequences were generated prior to the trial using a block design and placed in sealed envelopes in the block size of 6. After the baseline assessment and final eligibility, the sequence-blinded assessor (JP) contacted the rehabilitation site to give the participant's contact information to the occupational therapist providing the 6-week rehabilitation intervention. The occupational therapist conducted the randomization and then contacted the participant to give further instructions and scheduled 18 therapy sessions. By this way, the randomized sequence was known only to the participants and supervising occupational therapists.

All participants received the intervention. In Period 1, half of the participants (n=10), randomized into sequence AB, received a 6-week rehabilitation intervention, while the other half (n=10), randomized into sequence BA, continued with no intervention. In Period 2, the roles were switched (Figure 1). None of the participants received other physical rehabilitation (physio- or occupational therapy) during the trial.

Figure 1. Illustration of this 2-sequence, 2-period randomized controlled crossover trial adapted from Lim et al (2021) [28].



A crossover design was chosen because of a limited number of trial candidates and their diverse functional abilities, which are typical for individuals with SCI. The design allowed us to compare the treatment effects of a 6-week intervention focusing on technology-assisted upper extremity rehabilitation to no intervention in each participant [28]. Moreover, within-participant comparison reduced the effects of covariates. The target group of the study represented adults with chronic and stable stages of SCI, minimizing the possible period effect.

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The carryover effect was possible because of the nature of rehabilitation.

Participants

The target population was recognized from the patient registry of the SCI outpatient clinic of the Helsinki University Hospital by a clinician (JA). Candidates' neurological level of injury was classified according to the International Standards for Neurological Classification of SCI [29]. Inclusion criteria were 18 - 75 years of age, clinically diagnosed with incomplete cervical SCI (American Spinal Injury Association Impairment Scale [AIS] grades C-D), and 1 - 10 years since injury.

Individuals with health conditions that could prevent intensive rehabilitation or bias results were excluded by the clinician (JA). Other exclusion criteria were screened during the inquiry calls (SH and JP) and at the baseline assessment by an experienced physiotherapist (JP). Exclusion criteria were injuries preventing training, poor tolerance for intensive rehabilitation, severe instability or severely limited range of motion in upper extremity joints, severe spasticity in upper extremity muscles, cognitive inability to understand the goal and instructions during rehabilitation, concurrent participation in another study or technology-assisted upper extremity rehabilitation, and unlikeliness to complete the intervention and participation until 6-month follow-up.

The patient registry was screened in February 2021, July 2022, and February 2023. In November 2021, due to slow progress in recruitment, the inclusion criterion concerning the time since injury was extended from 1 - 5 to 1 - 10 years. Altogether, 148 candidates were invited to participate in the study via 6 separate mailings over a 26-month period between February 2021 and April 2023. In addition, information about the study was published in a national SCI patient journal to motivate eligible candidates. One to 2 reminders were sent for candidates without response.

Ethical Considerations

The technology-assisted upper extremity rehabilitation in subjects with incomplete cervical SCI study was approved by the Ethics Committee of Helsinki University Hospital (669/2020). Written informed consent was obtained from all participants prior to inclusion, and the principles of the Declaration of Helsinki were followed. Participation was voluntary and no compensation was provided. All data were handled confidentially and stored separately from any personal contact information.

Rehabilitation Intervention

The 6-week intervention focusing on technology-assisted upper extremity rehabilitation was delivered by occupational therapists experienced in treating patients with SCI. The intervention was provided face-to-face, 3 times a week for 6 weeks (18 sessions) in a private outpatient clinic specialized in neurorehabilitation. Each 1-hour therapy session included a minimum of 30 minutes of technology-assisted upper extremity rehabilitation with interactive and task-specific rehabilitation devices AMADEO, DIEGO, and PABLO from Tyromotion GmbH (Graz, Austria) utilizing direct biofeedback and gamification. These 3 devices were chosen as they are specially designed for upper extremity rehabilitation, easy to use, and available at the rehabilitation site involved. The occupational therapists were also familiar with these devices for a longer period of time.

The rehabilitation intervention with progressive intention was personalized on each participant's individual needs and capabilities. AMADEO allowed training unilateral grasping movements and finger extension passively, actively, and assist-as-needed. DIEGO allowed training unilateral and bilateral arm and shoulder movements in 3D space with intelligent weight relief. PABLO included 3 options for hand and arm rehabilitation. PABLO Multiboard allowed training bilaterally postural control, elbow flexion and extension, as well as upper extremity mobilization in different directions. PABLO Multiball allowed to train wrist movements in all directions, and PABLO Handsensor allowed to train various finger grips and grasp, as well as upper extremity movements in 3 motion axes. Devices were selected individually for each participant based on their functional abilities and rehabilitation goals. Besides the minimum of 30 minutes of technology-assisted rehabilitation, occupational therapists were asked to include other relevant therapy activities based on each participant's personal rehabilitation goals to complete the 1-hour therapy session. There was no need for content changes during the trial.

Outcome Measures

Data from all but one outcome (the Goal Attainment Scale [GAS]) was collected face-to-face at baseline, after Period 1, after Period 2, and at 6 months. The effects of rehabilitation intervention on participants in sequence AB were assessed between the baseline and "after Period 1" assessments and on participants in sequence BA between "after Period 1" and "after Period 2" assessments. All outcome assessments (except for the GAS) were conducted by the same sequence-blinded assessor (JP), who was trained for the outcome measures and had no role in implementing the rehabilitation intervention. Measuring points were scheduled in advance based on the baseline assessment. Assessments were conducted at the site of rehabilitation intervention between April 2021 and August 2024. For compliance evaluation, the content of each therapy session was recorded case by case on a study-specific form by the supervising occupational therapist.

Action Research Arm Test (ARAT) was used to evaluate the ability of upper extremity to grasp and transfer objects. It was originally developed for individuals with stroke [30] but also used among individuals with SCI [13,20,21]. The outcome consists of 19 items in 4 subscales including grasp (6 items, 0 - 18 points), grip (4 items, 0-12 points), pinch (6 items, 0-18 points), and gross movement (3 items, 0-9 points). Each item is scored from 0 to 3 (0, no movement; 1, movement task is partially performed; 2, movement task is completed but takes abnormally long; and 3, movement is performed normally), total score ranging from 0 to 57. Higher scores mean better performance [31]. The total score can be further divided into 3 disability categories (0 - 4, severe; 5 - 51, moderate; and 52 - 57, mild disability) [32]. The intrarater reliability of ARAT has been found high in individuals with stroke (intraclass correlation coefficient >0.98) [31] and (intraclass correlation

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coefficient >0.99) [30]. The minimal detectable change in individuals with stroke is suggested to be 5.7 points [33]. Average ARAT total score from right and left upper extremities was used for analysis.

American Spinal Injury Association–Upper Extremity Motor Score (ASIA-UEMS) was used to measure upper extremity muscle strength. It is held as a standardized method to evaluate upper extremity function and classify SCIs [34]. Muscle strength of 5 upper extremity key muscles (elbow flexors and extensors, wrist extensors, finger flexors, and abductors) is tested manually with scaling from 0 to 5 (0, total paresis; 5, normal active movement, complete range of motion against gravity and high resistance in functional position), total score ranging from 0 to 25 per side [35]. Grip strength was measured with the Jamar dynamometer and pinch strength with the Pinch meter. The highest value from 3 attempts of grip and pinch in 3 common positions (2-point, 3-point, and lateral pinch) was recorded. The minimal detectable change for grip strength after stroke is 2.7 - 4.7 kg [36].

Functional independence was assessed with the Spinal Cord Independence Measure–Self Report (SCIM-SR) [37]. SCIM-SR is a frequently used patient-reported outcome measure that has shown adequate psychometric properties to assess functioning in daily activities of individuals with SCI [38]. It consists of 17 items in 3 subscales, including self-care (6 items, 0 - 20 points), respiration and sphincter management (4 items, 0 - 40), and mobility (9 items, 0 - 40). Item scores range from 0 - 3 to 0 - 15, the total score being 0 - 100. Higher score equals better performance and independence [39]. The minimal detectable change for SCIM-SR total score is 5.3 and for self-care subscore is 1.5 [40].

GAS is a widely used person-centered and collaborative approach to set personally meaningful goals and evaluate the effectiveness of a rehabilitation intervention [41-43]. The idea is to set a realistic rehabilitation goal using the SMART (Specific, Measurable, Attainable, Realistic, and Timed) principles and then form a personalized 5-point scale, ranging from −2 to +2, to quantify progress toward defined rehabilitation goal [44]. Zero represents the expected level of performance after rehabilitation, +1 represents somewhat more than expected, and +2 represents much more than expected. Respectively, −1 refers to somewhat less than expected and −2 refers to much less than expected (the initial level before the rehabilitation) [42,45-48].

Each participant set their personal rehabilitation goals together with the supervising occupational therapist at the beginning of the rehabilitation intervention. GAS was then used only once after the intervention to evaluate the immediate effects of rehabilitation. The use of GAS and scaling of personal rehabilitation goals made it possible to compare rehabilitation goal attainment among the participants. In cases of multiple goals, the raw scores (−2 to +2) were summed up and then interpreted with a readymade table of *T* scores ranging from 18 to 82. *T* score is dependent on the number of goals. A *T* score of 50 indicates that the expected target level has been attained, a score >50 refers to more than expected, and a score <50 refers to less than expected. Finally, the rehabilitation goals were linked to the International Classification of Functioning, Disability and Health to see which chapters and categories of functioning and disability were meaningful for the participants with incomplete cervical SCI, aiming to improve their hand and arm function [49,50].

Feasibility of the rehabilitation intervention was defined as >60% of participants enrolled with at least 80% of sessions completed and by the compliance of technology-assisted rehabilitation.

Statistical Analysis

Analyses were performed using the IBM SPSS version 29.0 for Windows (SPPS Inc, Chicago, IL). Because of the small sample size and after visual inspection, nonparametric tests were used. Baseline differences between sequences AB and BA were examined with Fisher Exact and Fisher–Freeman–Halton Exact tests for categorical variables and with Mann-Whitney *U* test for continuous variables. Descriptive statistics were presented in numbers and relative frequencies and as medians and interquartile ranges (IQR) calculated as Tukey's Hinges.

The effects of rehabilitation intervention on hand and arm function were compared to effects of no intervention based on paired data. Each participant served as their own control following the crossover design [28]. This within-participant difference between rehabilitation and no intervention was tested using repeated measures of the Wilcoxon signed-rank test. Effects of rehabilitation were tested between baseline and "after Period 1" assessments for sequence AB and between "after Period 1" and "after Period 2" assessments for sequence BA. The threshold for significance was set at $P<.05$.

Sufficient sample size for ARAT was determined using the *t* test calculator of the University of California San Francisco, Clinical & Translational Science Institute. As validation studies for ARAT in individuals with SCI were missing, the earlier findings among individuals with chronic stroke were considered. A mean change of 6.1 (SD 5.2) was used as reference (0.8 power, $P\leq.05$) [33]. The calculations suggested 13+13 participants. Individuals with SCI commonly have paresis in both upper extremities. Presuming the drop-out rate of 20%, and to account for the more conservative nature of nonparametric testing, the aim was to recruit 30+30 participants.

Results

Participants

A total of 148 eligible candidates were recognized from the patient registry and invited by mail to participate (Figure 2). Finally, 20 participants, with a median age of 62 years (IQR 58 - 66), were recruited and randomized into sequences AB (n=10) and BA (n=10). Nine participants in sequence AB and 8 participants in sequence BA received intended rehabilitation intervention. Participant 10 (in sequence BA) withdrew from the study prior to the trial, believing not to benefit from the rehabilitation intervention. Participants 18 (AB) and 19 (BA) withdrew during the rehabilitation intervention due to personal reasons unrelated to the intervention. Participant 17 (BA) was unavailable for the last 2 assessments because of a health issue. This resulted in a final analysis sample of 16 participants (9

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men and 7 women), with a median age of 63 (IQR 54 - 66) years. Differences between participants (n=16) and drop-outs (n=4) in age (63, IQR 54 - 66 versus 62, IQR 62 - 62 years), sex (male 9/16 vs 1/4), and years since injury (3, IQR 2 - 7 versus 5, IQR 2 - 7) were not statistically significant.

All 20 participants (10 men, 34 - 73 y of age; 1 - 8 y since SCI) had incomplete cervical SCI graded as AIS D, most of which were caused by a disease (Table 1; Table S1 in Multimedia Appendix 1). The majority of participants had mild upper extremity disability [32] and were able to walk.

Nineteen participants out of 20 (95%) enrolled in the study, and 17 out of 19 (89%) completed at least 80% of the therapy sessions. The number of completed therapy sessions among 16 participants who completed the study was a median of 17 (IQR 17-18) out of 18. Two participants missed 2 sessions, and 8 participants missed 1 session (Table 2). One participant felt pain in the right upper extremity during the rehabilitation intervention. No other side effects nor adverse events were reported.

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Figure 2. Participant recruitment and retention for the technology-assisted upper extremity rehabilitation in subjects with incomplete cervical spinal cord injury (T-ARSCI) study.

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Table . Baseline characteristics of 20 participants with incomplete cervical SCI[a] in total and by sequences in the technology-assisted upper extremity rehabilitation in subjects with incomplete cervical spinal cord injury (T-ARSCI) study.

Variable	Total (N=20)[b]	Sequence AB (n=10)[b]	Sequence BA (n=10)[b]	*P* value
Male, n (%)	10 (50)	10 (50)	10 (50)	>.99[c]
Age (y)	62 (58 - 66)	62 (55 - 66)	62 (61 - 65)	.65[d]
Age at injury onset (y)	58 (53 - 61)	56 (53 - 62)	59 (55 - 60)	.60[d]
Time since injury (y)	3 (2–7)	3 (3–7)	3 (2–7)	.65[d]
Etiology of SCI, n (%)				>.99[c]
Disease	15 (75)	7 (70)	8 (80)	
Trauma	5 (25)	3 (30)	2 (20)	
Level and grade of SCI[e], n (%)				.13[f]
C2 AIS D	5 (25)	2 (20)	3 (30)	
C3 AIS D	4 (20)	3 (30)	1 (10)	
C4 AIS D	5 (25)	1 (10)	4 (40)	
C5 AIS D	3 (15)	3 (30)	0	
C6 AIS D	2 (10)	—	2 (20)	
C8 AIS D	1 (5)	1 (10)	—	
Mobility outdoors 10 - 100 m, n (%)				>.99[f]
No devices	12 (60)	6 (60)	6 (60)	
Cane	2 (10)	1 (10)	1 (10)	
Crutches	3 (15)	1 (10)	2 (20)	
Manual wheelchair	1 (5)	1 (10)	—	
Electric wheelchair	2 (10)	1 (10)	1 (10)	
ARAT[h] total score				
Right	52 (48 - 54)	52 (47 - 54)	52 (48 - 56)	.70[d]
Left	50 (46 - 54)	50 (45 - 54)	50 (47 - 57)	.57[d]
ASIA-UEMS[i]				
Total score	47 (44 - 48)	46 (42 - 48)	48 (46 - 50)	.30[d]
Right	24 (23 - 25)	24 (23 - 25)	24 (23 - 25)	.94[d]
Left	24 (21 - 25)	22 (20 - 25)	24 (23 - 25)	.24[d]
Grip strength (kg)				
Right	29 (24 - 36)	33 (25 - 35)	25 (16 - 36)	.26[d]
Left	26 (16 - 32)	25 (15 - 34)	26 (16 - 30)	.79[d]
Pinch strength (kg)				
2-Point right	4 (4–6)	5 (4–6)	4 (4–6)	.43[d]
2-Point left	4 (2–4)	4 (2–5)	4 (2–4)	.49[d]
3-Point right	6 (5–7)	6 (6–7)	6 (5–6)	.29[d]
3-Point left	5 (4–6)	5 (4–6)	5 (4–5)	.44[d]
Lateral right	7 (6–8)	7 (6–9)	7 (6–8)	.38[d]

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Variable	Total (N=20)[b]	Sequence AB (n=10)[b]	Sequence BA (n=10)[b]	*P* value
Lateral left	6 (4–8)	6 (4–8)	6 (4–8)	.73[d]
SCIM-SR[j]				
Total score	90 (78 - 98)	88 (71 - 98)	97 (80 - 99)	.57[d]
Self-care subscore	18 (16 - 20)	17 (14 - 20)	19 (18 - 20)	.26[d]

[a]SCI: spinal cord injury.

[b]Reported as median (IQR) unless stated otherwise. IQR=(25th percentile–75th percentile) by Tukey Hinges.

[c]Fisher exact test (2-sided) *P* value for group difference.

[d]Mann-Whitney *U* test asymptotic significance (2-tailed) *P* value for group difference.

[e]According to the International Standards for Neurological Classification of Spinal Cord Injury, expressed by level of injury (C2-C8) and by the American Spinal Injury Association Impairment Scale (AIS, grades A-E, A: complete/no motor, no sensory, no sacral sparing, E: normal/motor and sensory function are normal).

[f]Fisher–Freeman–Halton exact test (2-sided) *P* value for group difference.

[g]Not applicable

[h]ARAT: Action Research Arm Test; total score 0 - 57.

[i]ASIA-UEMS: American Spinal Injury Association–Upper Extremity Motor Score; total score 0 - 50 (max. 25 per side).

[j]SCIM-SR: Spinal Cord Independence Measure—Self Report; total score 0 - 100, self-care subscore 0 - 20.

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Table . Personal rehabilitation goals and their attainment by GAS[a] and the change in ARAT[b] total score before and after the rehabilitation intervention in 16 participants with incomplete cervical spinal cord injury in the T-ARSCI[c] study.

ID	Rehabilitation goal (ICF code[d])	GAS *T* score[e]	ARAT right[f]	ARAT left[f]	Sessions[g]
1	• It is easier for me to carry and handle a coffee cup (d430, d440)	60	–4	–6	18
2	• I can make better use of my left hand when playing the piano (d440, d920)	40	0[h]	0[h]	17
3	• I can crochet longer with a thick crochet hook (d445, b740, d920) • I can crochet a dishcloth with a thin crochet hook (d440, d920) • The pain in my upper limbs has relieved (b280)	59	+1	+1	16
4	• It is easier for me to take a bank card out of my pocket with the right hand (d440)	50	+2	0[h]	17
5	• It is easier for me to take the cutlery out of the dishwasher (d440, d640)	50	+1[h]	+3	16
6	• It is easier for me to button my shirt (d440, d540)	50	0	–3	17
7	• Pain no longer interferes with my sleep (b280, b134) • I have less pain in my hands (b280)	44	+3	+1	18
8	• I can push a stroller with both hands (d445)	50	0[h]	0	17
9	• It is easier for me to button my jeans (d440, d540)	60	+3	0	17
11	• I can zip up a jacket with both hands (d440, d540)	50	0	+12	17

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ID	Rehabilitation goal (ICF code[d])	GAS *T* score[e]	ARAT right[f]	ARAT left[f]	Sessions[g]
12	• I can lift the dishes up into the cupboard (d430, d640)	50	+2	+2	17
13	• I can touch my hair at the back of my head (d445)	60	0	–2	17
14	• The pain when doing something disturbs me only half of the time (b280, b160) • I can write the diary for up to five minutes at a time (d170, b740)	69	+3[h]	+3[h]	18
15	• I can use (squeeze and hold) a steel strapping dispenser with both hands for 11 straps (d445, d430, d740) • I don't need to think about my hands even when they are more spastic (b160)	50	+2	0	18
16	• I can button a flannel shirt with six buttons with both hands in less than 2 min (d440, d540) • I can knead a liter of bun dough until it is ready for baking. (d445, b740, d630)	62	+2	–3	18
20	• I have better activity in my right hand (d445)	60	0	+5	18

[a]GAS: Goal Attainment Scale.

[b]ARAT: Action Research Arm Test

[c]T-ARSCI: technology-assisted upper extremity rehabilitation in subjects with incomplete cervical spinal cord injury.

[d]International Classification of Functioning, Disability and Health: b134, Sleep functions; b160, Thought functions; b280, Sensation of pain; b740, Muscle endurance functions; d170, Writing; d430, Lifting and carrying objects; d440, Fine hand use; d445, Hand and arm use; d540, Dressing; d630, Preparing meals; d640, Doing housework; d920, Recreation and leisure.

[e]Goal Attainment Scale *T* score: 50 indicates that the expected level has been attained; >50, more than expected; <50, less than expected.

[f]Difference before and after the rehabilitation intervention: difference between the baseline and "after period 1" assessments for sequence AB and difference between "after Period 1" and "after Period 2" assessments for sequence BA. Positive score indicates better performance in Action Research Arm Test.

[g]Total number of therapy sessions during the 6-week rehabilitation intervention (max 18).

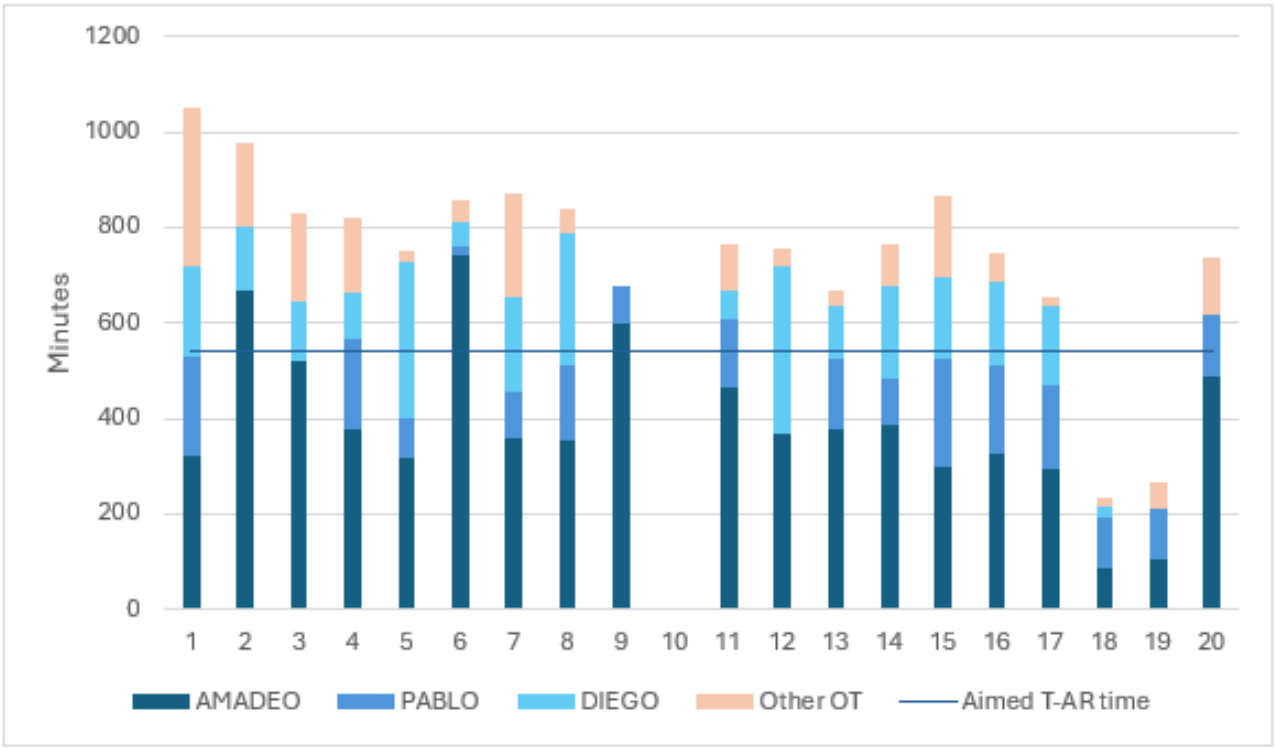
[h]Ceiling effect.

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Implementation of the Rehabilitation Intervention

The aimed minimum of 30 minutes of technology-assisted rehabilitation per session exceeded in all analyzed cases (n=16), the median time being 40 (IQR 38 44) minutes per session. AMADEO was the most frequently used device (62% of the total technology-assisted rehabilitation time; Figure 3).

Figure 3. The total time of technology-assisted upper extremity rehabilitation (T-AR) and other occupational therapy (OT) in minutes during the 6-week rehabilitation intervention in 20 participants with incomplete cervical spinal cord injury in the T-ARSCI study. T-ARSCI: technology-assisted upper extremity rehabilitation in subjects with incomplete cervical spinal cord injury.



Other occupational therapy methods during 1-hour rehabilitation session included stimulation of skin sensation; manual therapy (including fascia manipulation); upper extremity strength training with dumbbells, gym equipment, and other equipment, for example, Reha-Slide Duo (shoulder, elbow, and wrist coordination exercises) and Myro (interactive sensor-based surface); overall relaxation with physioacoustic chair; stretching; spasticity inhibition; paraffin treatment for pain and spasticity management; kinetic taping of fingers; task-oriented functional training; and interview along with goal setting and evaluation.

Effects of the Rehabilitation Intervention

The effects of the rehabilitation intervention compared to no intervention were not statistically significant, except for the ASIA-UEMS in participants in sequence BA receiving the rehabilitation intervention during Period 2 (Tables S2 and S3 in Multimedia Appendix 1). Median ASIA-UEMS sum score change was 0 (−2 to 0) during no intervention and 1 (0 - 2) during rehabilitation intervention (P=.04).

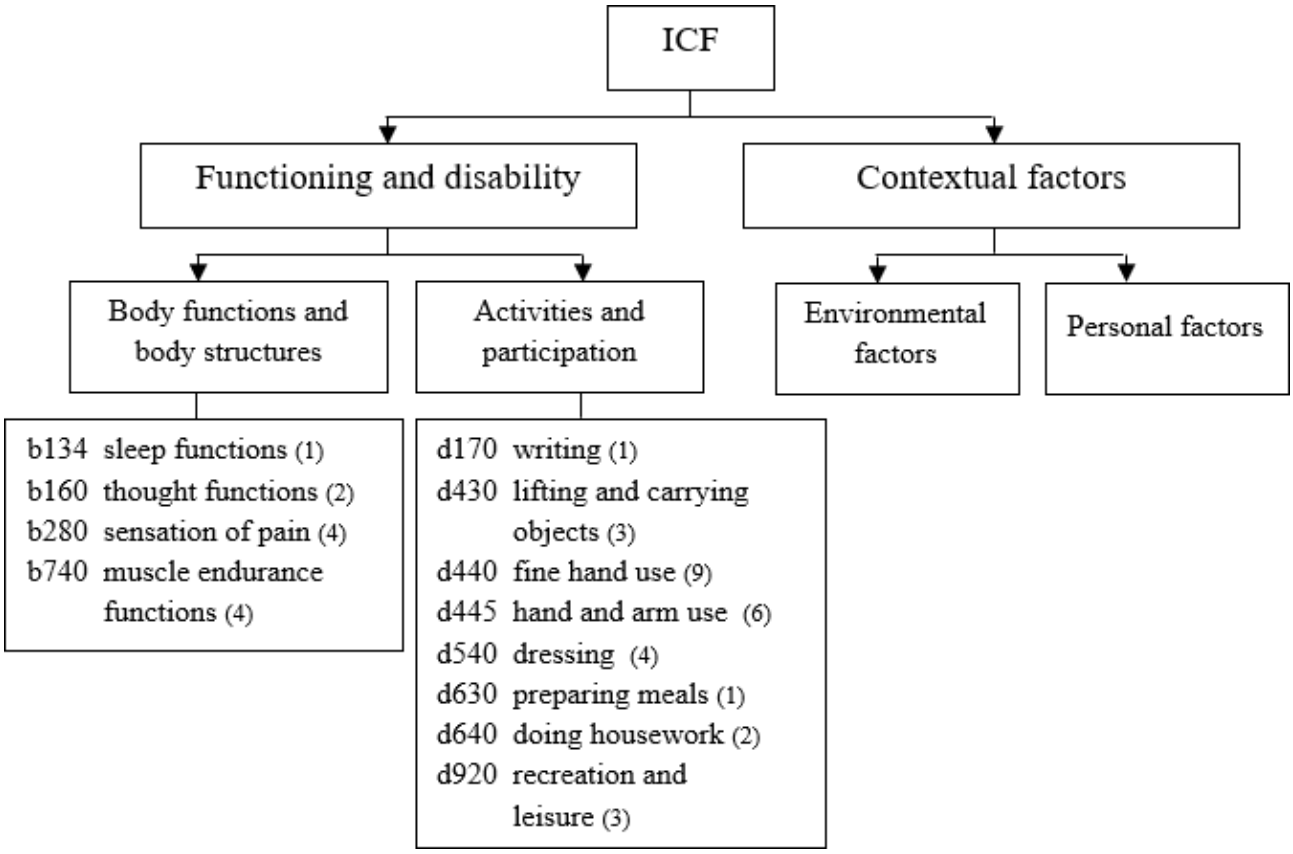
Overall, the outcomes varied individually, showing both positive and negative changes before and after the rehabilitation intervention. For example, the average ARAT improved in 4 out of 9 participants in sequence AB and in 6 out of 7 participants in sequence BA (Figure S1 in Multimedia Appendix 1). The greatest improvements in ARAT were observed in the Pinch subscale, as it also showed the most deficits at baseline.

Personal rehabilitation goals were set prior to the rehabilitation intervention, scaled by GAS, and assessed once after the intervention to evaluate the immediate effects of rehabilitation. Goal attainment during the 6-week rehabilitation intervention was mostly successful (Table 2). Fourteen out of 16 participants attained their goals, the median GAS T score being 50 (IQR 50 - 60).

More than two-thirds of rehabilitation goals were linked to “Activities and Participation” and the rest to “Body Functions and Body Structures” components of the International Classification of Functioning, Disability and Health [45] (Figure 4). “Fine hand use” and “hand and arm use” related to self-care and domestic life were the most targeted categories.

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Figure 4. Focus of rehabilitation goals in 16 participants with incomplete cervical spinal cord injury in the T-ARSCI study linked to the International Classification of Functioning, Disability and Health (ICF). Number in parentheses after the ICF category (eg, d170 writing) refers to the number of observed goals. T-ARSCI: technology-assisted upper extremity rehabilitation in subjects with incomplete cervical spinal cord injury.



Discussion

Principal Findings

The effects of rehabilitation intervention did not differ from the effects of no intervention, except the improvement in upper extremity muscle strength (ASIA-UEMS) in participants randomized into sequence BA. According to GAS, most participants attained their rehabilitation goals focusing on “fine hand use” and “hand and arm use.” Rehabilitation intervention showed good feasibility, compliance, and tolerability in adults with incomplete cervical SCI.

Previous studies have given support for technology-assisted rehabilitation in populations with SCI, highlighting the potential of these technologies to support upper extremity recovery [13,17-19,51,52]. For instance, individuals 2 - 8 years after a traumatic cervical SCI at level C4-C6 (AIS grades A-D) benefited from the technology-assisted rehabilitation using wrist robot according to robotic kinematics, although there were no changes in muscle strength of the trained arm [52].

The GAS indicated that a 6-week intervention focusing on technology-assisted upper extremity rehabilitation can address personalized rehabilitation goals effectively. Most goals, such as better handling of a coffee cup, buttoning of the jeans, and ability to prepare meals, were achieved. This aligns with the earlier findings arguing that fine hand use and hand and arm use categories are among the highest priorities among individuals with SCI [53]. Moreover, the intervention was well-tolerated, with only 1 reported side effect (muscle pain) and good compliance among participants. This supports the practicality of incorporating technology-assisted devices into clinical settings, particularly when tailored to individual needs and supervised by specialized occupational therapists.

The variation in within-participant changes during the study may reflect normal fluctuations over time rather than a direct effect of the rehabilitation. In addition, discrepancies between the outcomes and goal attainment by GAS were evident. For future effective studies, it is crucial to reach a bigger sample size, perhaps also a longer period than 6 weeks of intervention. It may also be considered to choose conventional RCT design instead of crossover, despite the diversity of the SCI population and the limited number of study candidates. There are also other spinal cord–specific upper extremity outcomes with proven psychometrics, such as the Graded Redefined Assessment of Strength, Sensation and Prehension [54], to be considered. Although some improvements in hand and arm function were observed over time in both sequences, we could not attribute these changes to the 6-week rehabilitation intervention.

Strengths and Limitations

This study has both strengths and limitations. Although the crossover design is known to be valuable for small sample sizes and to minimize variability by allowing each participant to serve as their own control, this study was left underpowered. Aimed sample size of 30+30 was not achieved due to challenges in recruitment, including delays caused by the COVID-19 pandemic. The small sample size increases the risk for a type II error, potentially obscuring statistically significant effects.

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Also, the outcome measures may have lacked the sensitivity to detect subtle changes. For example, 8 participants scored the maximum in ASIA-UEMS already at baseline. Also, the ARAT and the SCIM-SR showed a ceiling effect in this population. Participants were not blinded, which could have biased the outcomes after rehabilitation intervention in favor of higher self-perceived independence by SCIM-SR and better goal attainment by GAS. Finally, improvements observed after rehabilitation in the long term suggest a possible carryover effect.

One strength of the study was randomization that diminished selection bias and ensured balance between the 2 sequences. Another strength was that occupational therapists providing rehabilitation intervention were specialized in neurorehabilitation and SCIs, as well as familiar with the technological devices used. They had no role in recruitment or outcome assessments. Moreover, the sequence-blinded assessor had no role in implementing the rehabilitation intervention. The use of a sequence-blinded assessor ensured the reliability of outcome assessments.

The personalized rehabilitation intervention guided by the SMART goals ensured that the rehabilitation was both meaningful and directly applicable to the participants' daily life. Furthermore, the intervention demonstrated high feasibility and tolerability, as evidenced by good compliance rates and the absence of major adverse events, supporting its potential for broader clinical implementation.

Conclusions

Results of this pilot crossover RCT suggest that technology-assisted upper extremity rehabilitation provided by occupational therapists is safe and has potential for broader clinical use in adults with incomplete cervical SCI with mild disability in hand and arm function. Rehabilitation intervention showed good feasibility and positive outcomes, especially in functional goal attainment. However, strong evidence about the effects of the rehabilitation intervention on upper extremity muscle strength was not discovered.

As for future insight, we believe that technology-assisted rehabilitation holds potential to complement neurorehabilitation and may further improve hand and arm function in this population. With a larger RCT, it is possible to refine modern rehabilitation methods to improve hand and arm function and support greater independence in daily life for individuals with SCI.

Acknowledgments

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

JP, KK, JA, and SH conceived and designed the study. JA was responsible for screening the study candidates and for the invitations. SH and JP received inquiry calls and interviewed the candidates for eligibility. JP collected the data. MMK conducted the statistical analysis supported by biostatistician Paula Reiterä and was responsible for writing and editing of the paper. SH interpreted the content of the therapy sessions and analyzed the compliance of the rehabilitation intervention. All authors were involved in data interpretation, critical revision, and final approval of the paper. SH was responsible for obtaining project funding and takes responsibility for the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material, including participant characteristics, within-participant difference in hand and arm function, and Averaged Action Research Arm Test (ARAT) scores.
[DOCX File, 48 KB - rehab_v12i1e78091_app1.docx]

Checklist 1
CONSORT-eHEALTH V1.6.1.
[PDF File, 1047 KB - rehab_v12i1e78091_app2.pdf]

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Abbreviations

AIS: American Spinal Injury Association Impairment Scale
ARAT: Action Research Arm Test
ASIA-UEMS: American Spinal Injury Association–Upper Extremity Motor Score
GAS: Goal Attainment Scale
RCT: randomized controlled trial
SCI: spinal cord injury
SCIM-SR: Spinal Cord Independence Measure–Self Report
SMART: Specific, Measurable, Attainable, Realistic, and Timed
T-ARSCI: technology-assisted upper extremity rehabilitation in subjects with incomplete cervical spinal cord injury

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Multiparametric MRI Assessment of Morpho-Functional Muscle Changes Following a 6-Month FES-Cycling Training Program: Pilot Study in People With a Complete Spinal Cord Injury

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Abstract

Background: Spinal cord injuries (SCIs) cause debilitating secondary conditions such as severe muscle deterioration, cardiovascular, and metabolic dysfunctions, significantly impacting patients' quality of life. Functional electrical stimulation (FES) combined with cycling exercise (FES-cycling) has shown promise in improving muscle function and health in individuals with SCI.

Objective: This pilot study aimed to investigate the potential role of multiparametric magnetic resonance imaging (MRI) to assess muscle health during and after an FES-cycling rehabilitation program.

Methods: Four male participants with chronic SCI underwent a 6-month FES-cycling training program, consisting of two 30-minute sessions per week. MRI scans were performed at baseline (T_0), after 3 months (T_1), at the end of the training (T_2), and 1-month posttraining (T_3). The MRI protocol included T_1-weighted imaging for volume quantification, Dixon imaging for fat fraction, multi-echo spin echo for T_2 relaxation times, and diffusion tensor imaging to assess diffusion parameters.

Results: Muscle hypertrophy was observed, with an average increase in muscle volume of 22.3% at T_1 and 36.7% at T_2 compared with baseline. One month posttraining, muscle volume remained 23.2% higher than baseline. Fat fraction decreased from 11.1% at T_0 to 9.1% at T_2, with a rebound to 10.9% at T_3. T_2 relaxation times showed a reduction even though this was not consistent among participants. Diffusion tensor imaging parameters revealed subtle changes in muscle tissue microstructure, with a decrease in fractional anisotropy mainly associated to an increase of radial diffusivity.

Conclusions: Although preliminary, this study provides evidence that 6 months of low-intensity FES-bike training can increase muscle volume and decrease fat infiltration in individuals with SCI. The study demonstrates that the use of a multiparametric MRI provides comprehensive insights into both macroscopic and microscopic changes within muscle tissues, supporting its integration into clinical practice for assessing the efficacy of rehabilitation interventions.

Trial Registration: ClinicalTrials.gov NCT06321172; https://clinicaltrials.gov/study/NCT06321172

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KEYWORDS

functional electrical stimulation; FES; cycling; exercise; physical activity; spinal cord injury; multiparametric MRI; skeletal muscle; rehabilitation; magnetic resonance imaging; muscle; muscular; musculoskeletal; spine; MRI; mpMRI; image; imaging

Introduction

Spinal cord injury (SCI) refers to a damage of the spinal cord due to traumatic or nontraumatic events affecting globally over 15 million people [1]. SCIs cause debilitating and life threating secondary conditions that leads to critical health complications, such as severe muscle deterioration, weakness, cardiovascular, and metabolic dysfunctions [1-3], significantly impacting patients' quality of life. Due to the unloading following an SCI, skeletal muscle (SM) undergoes numerous adaptations, including rapid and profound atrophy, intramuscular fat accumulation, impaired muscular glucose metabolism and decreased force generation and muscle performance [4].

Therefore, to counteract detrimental effects of SCI on SM health, rehabilitation plays a crucial role with promising positive effects [4-7]. So far, several activity-based interventions have been widely applied in SCI and among them transcranial magnetic stimulation, functional electrical stimulation (FES), and robotic-assisted treadmill training are effective in improving function in individuals with SCI [5].

FES consists in the application of low-energy electrical stimuli to peripheral nerves, to promote muscle contractions which ultimately results in functional movements [8]. Specifically, FES-cycling training, which exploits the use of FES to induce the pedaling movement has shown promising results in enhancing muscle health and function in individuals with SCI [4,9] Previous studies demonstrated improvements in muscle mass, strength, and overall metabolic profile following FES-based training. The effects of FES-cycling training on muscle health after SCI are multifaceted and include muscle atrophy attenuation or reversal [10-12], increased muscle cross-sectional area (CSA) [13-15], increased muscle size [10], improved body composition, plasma glucose, and SM glucose uptake [16-18], increased power output, peak isometric strength, knee extensor torque [13,19,20], and increased motor function scores [19].

Currently, in this field, traditional noninvasive assessment methods for SM health fall short in providing comprehensive insights into muscle morphology and function. In particular, the use of MRI (magnetic resonance imaging) is limited to basic protocols, typically consisting of T_1-weighted sequences, primarily focused on the quantification of muscle volume and CSA [13,15,19,21-24] thus not fully exploiting the strength and versatility of noninvasive MRI techniques in capturing other crucial aspects such as fat infiltration, tissue inflammation, and microstructural changes.

Multiparametric MRI (mpMRI) addresses these limitations by integrating various imaging sequences, including T_1-weighted (T_1w), quantitative T_2 (qT_2), diffusion-weighted imaging (DWI), and Dixon techniques [25,26], offering a detailed quantitative evaluation of muscle properties and enabling a thorough assessment of muscle health.

MpMRI provides several advantages over traditional MRI to evaluate SM. It allows for the quantification of fat and water content within muscles, which is crucial for understanding the extent of fat infiltration, a common issue in individuals with SCI. In addition, parameters such as T_2 relaxation times and diffusion related parameters provide information on muscle edema, inflammation, and microstructural properties, essential for a comprehensive assessment of SM tissue [27]. This more advanced approach thus holds significant potential for monitoring the SM changes due to rehabilitation interventions like FES-cycling training.

This pilot study aims to leverage the capabilities of mpMRI to assess the morphological and functional changes and their evolution in SM of individuals with complete SCI following FES-cycling training. This study is part of a wider one evaluating the effects of FES-cycling training on multi-factorial aspects, such as osteoporosis, pedaling performance, spasticity and perceived well-being of patients [28].

By providing a detailed evaluation of muscle health, this study seeks to explore the feasibility of the use of mpMRI to enhance our understanding of the impact of FES-cycling training on muscle tissue and promote its implementation as a valuable tool to assess rehabilitation effects on SM in individuals with complete SCI.

Methods

Participants

A total of 4 male participants with complete SCI, aged 30 (SD 8) years, were recruited from the Istituto di Ricovero e Cura a Carattere Scientifico Eugenio Medea. The inclusion criteria required participants to have a complete SCI (more than 6 month and less than 5 years after the lesion; American Spinal Injury Association Impairment Scale of A or B; lesion level ≤ T_3), an age between 18 and 65 years old, and the ability to engage in the FES-cycling training program.

At baseline (T_0) demographic and clinical data were collected from each participant, including age, height, BMI, time since injury, lesion level (American Spinal Injury Association Impairment Scale), previous experience with FES and trike or cycling after the injury, current pharmacological therapy. Furthermore, spasticity was assessed using the Modified Ashworth Scale (MAS) and no severe levels were found at T_0 for all participants (MAS score for each participant <2).

Functional Electrical Stimulation–Cycling Training Program

The participants underwent a 6-month FES-cycling training program performed using a recumbent trike (ICE VTX, 2017), adapted for participants with reduced mobility, combined with two 4-channels current-controlled stimulators (RehaMove3 and Hasomed GmbH) [29]. The training program included 2 weekly sessions, each lasting 30 minutes of stimulation, over 6 months.

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Each session consisted of 6 sets of 3 - 6 minutes of duration at a cycling rate between 30 and 50 revolutions per minute, with brief rest periods in between. The cadence for each pilot was chosen to allow independent pedaling throughout the set duration [28]. Throughout the training sessions, continuous monitoring of heart rate (HR) was conducted with the only purpose of ensuring participant safety, allowing for the immediate cessation of exercise if HR exceeded safe thresholds. This was achieved using the Polar H10 chest strap, which captures HR data at a sampling rate of 1 Hz. HR during training sessions ranged from a minimum average HR of 75 bpm to a maximum average HR of 113 bpm.

The stimulators delivered biphasic square pulses with a maximum current amplitude of 130 mA, a frequency of 40 Hz and a pulse width that ranged between 400 and 500 µs. The stimulation targeted 4 muscle groups per leg such as quadriceps, hamstrings, gluteal muscles, and calf muscles.

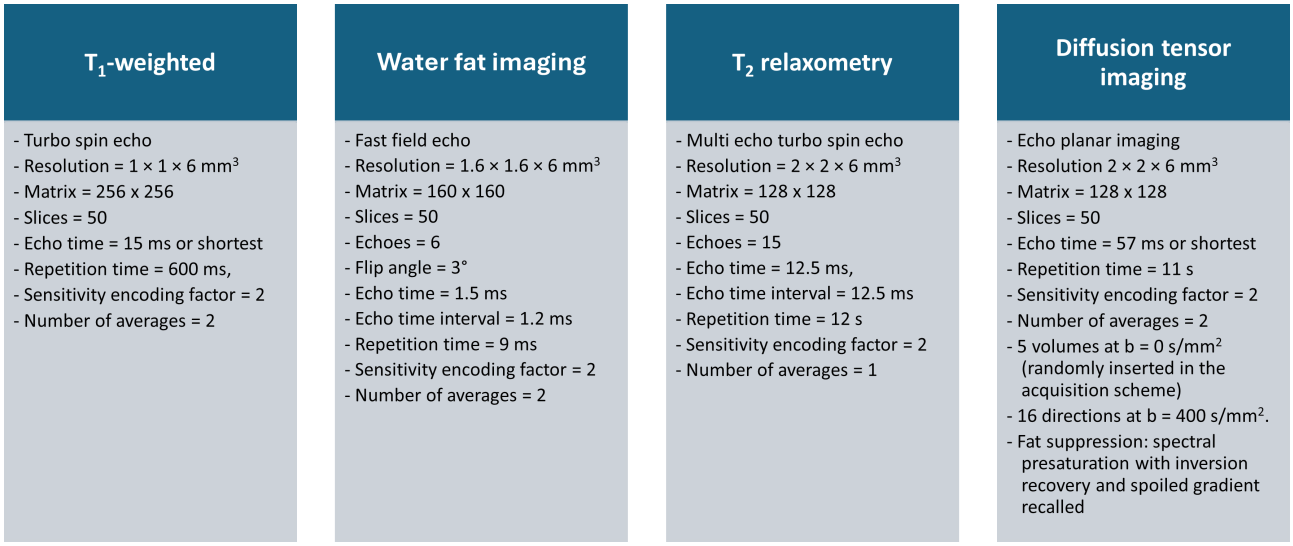
Magnetic Resonance Imaging Acquisitions

MRI scans were performed at 4 time points, at the beginning of the study (T_0, n=4), after 3 months of training (T_1, n=4), at the end of the training (T_2, n=4), and 1-month posttraining deconditioning (T_3, n=3). One of the 4 participants was scanned only up to T_2, since he did not interrupt the training program. The longitudinal MRI assessment was designed to track the SM alterations that occur throughout the training period. In addition, this timeline allows us to assess the impact of short-term deconditioning, which can frequently arise in real-life situations, such as during vacation intervals.

A 3T Achieva dStream MRI scanner (Philips) was used for imaging. The participant was positioned on the examination table, feet facing the scanner ("feet-first" orientation), with the pelvis slightly shifted to align the thigh being scanned closer to the midline. Positioning cushions were used to improve comfort, stabilize the limb and keep the legs separated. Finally, the multichannel Philips dStream Torso coil is placed over the targeted thigh and secured with velcro straps.

The MRI protocol included a T_1w turbo spin echo (TSE) sequence for volume quantification, a 6-point Fast Field Echo m-Dixon Quant sequence for fat fraction quantification, 15-echo multi-echo turbo spin echo (multi-TSE) sequence for T_2 relaxation time quantification, and a single shell diffusion tensor imaging (DTI; 16 directions at b=400 s/mm²; 5 b=0 s/mm^2 volumes acquired also in opposite phase encoding direction) for the diffusion parameters assessment. Regarding the anatomical region covered in the magnetic resonance (MR) images, the scans encompassed thigh volume in a 30 cm range along the head-to-feet axis, starting from the midpoint of the femoral head. Further details regarding the acquisition protocols are displayed in Figure 1.

Figure 1. Multiparametric magnetic resonance imaging protocol used for assessing muscle volume, fat fraction, T_2 relaxation times, and diffusion parameters. All sequences were acquired according to the axial plane placed perpendicular to the femur and with the upper part of the field of view placed in the middle of the head of the femur. All sequences share the same field of view (size 256 × 256 × 300 mm^3), regardless of their acquisition matrix and reconstructed voxel size.



Magnetic Resonance Imaging Analysis

As shown in Figure 2, to derive muscle volume and CSA, regions of interest (ROIs) were delineated on T_1w images for specific thigh muscles, including the vastus lareralis, vastus medialis, vastus intermedius, rectus femoris, sartorius, gracilis, adductor magnus, semimembranosus, semitendinosus, biceps femoris caput longum, biceps femoris caput breve, and adductor longus. The semiautomated segmentation was performed using the Deep Anatomical Federated Network [30], which combines automated and manual refinement processes. Volumes for individual muscles and the overall average were computed using 3DSlicer software. The largest CSA (CSA-max) was obtained selecting the slice exhibiting the maximum muscle area.

For the quantitative analysis of MRI derived parameters, the same ROIs used for the evaluation of volume and CSA, ranging from the beginning of the semimembranosus to the last available slice of the rectus femoris were used. Consistency was maintained in the ROIs across all longitudinal scans for each participant as shown in Figure 3.

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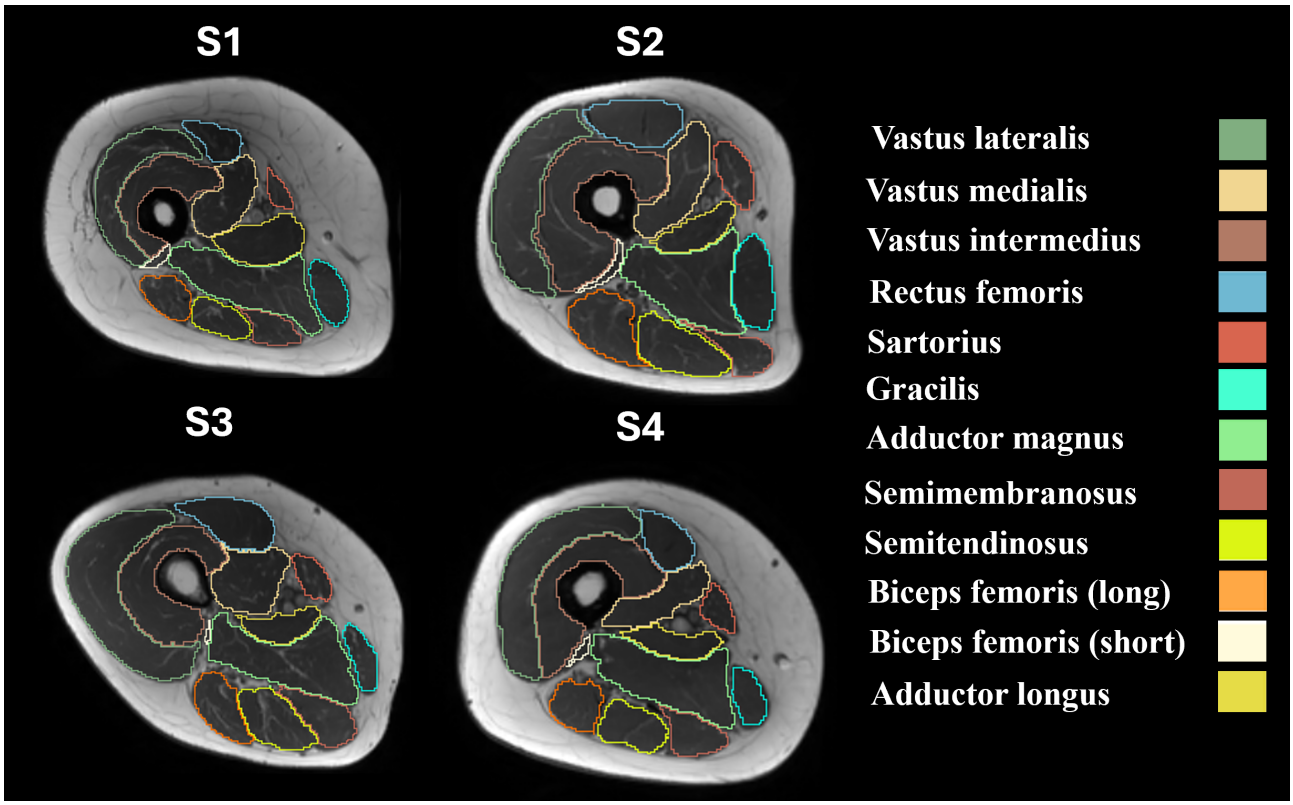
The parameters derived from the MR images were calculated by averaging their values across the 12 distinct ROIs defined before. The corresponding coefficients of variation were also calculated to characterize the intrinsic variability of each parameter for each time point and each participant (Multimedia Appendix 1).

Fat fraction (FF) was estimated from the mDixon sequence [31] using the Quant model implemented in the scanner which improves the classical bicompartmental exponential model by including a 7-peak fat modeling and T_2* correction to produce FF maps.

T_2 relaxation times were estimated from the multi-TSE images using the extended phase graph approach [32], which models spin behavior and predicts MR signals at various time points, accounting for T_1 and T_2 relaxation processes. Specifically, an open-source toolkit for water T_2 mapping was used [33]. The algorithm was applied to the multi-TSE acquisition after generating a dictionary containing 200 linearly spaced values for water T_2 (range 5 - 80 ms), 50 values for the B1 factor (range 50% - 120%), and 101 values for the FF (range 0% - 100%). The fat T_2 was assumed constant at 151 ms. Maps derived from the extended phase graph method, constrained by the external proton-density-weighted fat fraction, were produced.

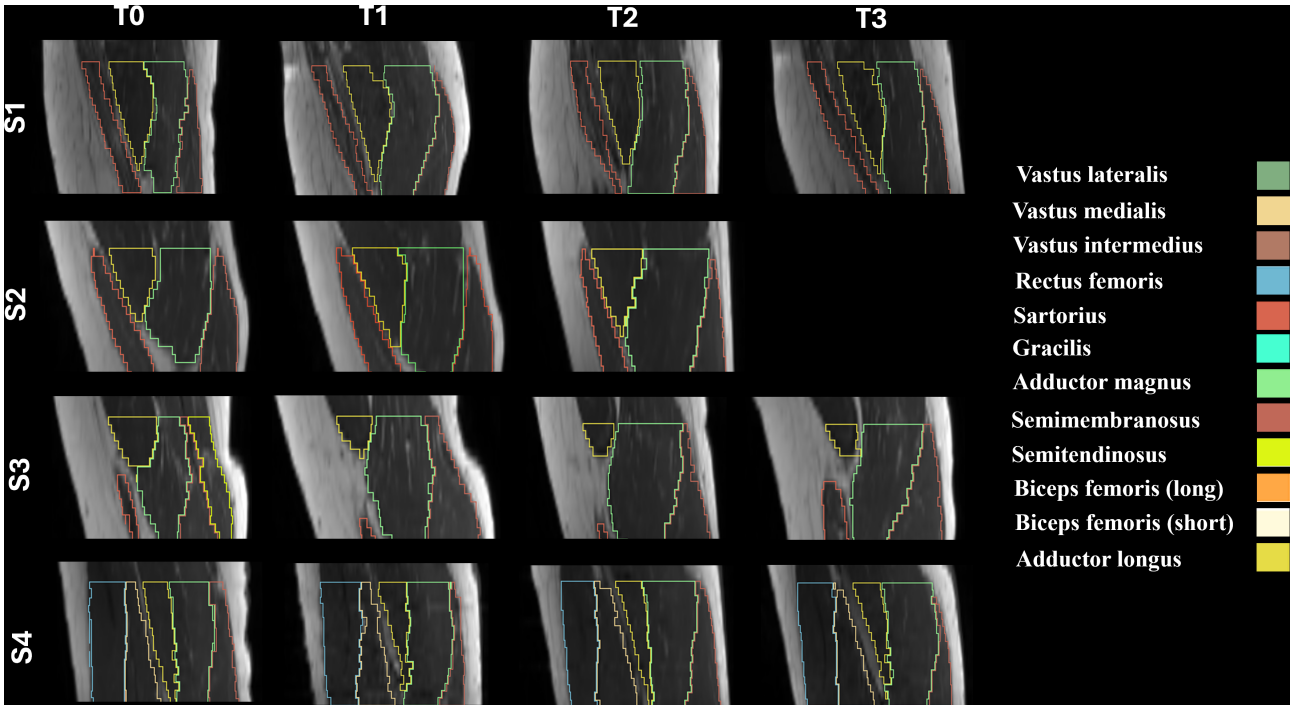
DTI parameters, including fractional anisotropy (FA), mean diffusivity (MD), radial diffusivity (RD), and axial diffusivity (AD), were calculated using the MRtrix3 package [34]. Images were denoised with a method based on random matrix theory [35] and the Gibbs ringing artefacts were removed using the method of local subvoxel-shifts [36]. To mitigate susceptibility artifacts, b_0 images were collected with the reversed phase-encode directions, resulting in pairs of images with distortions going in opposite directions. From these pairs the susceptibility-induced off-resonance field was estimated using a method similar to that described in [37] as implemented in FMRIB Software Library [38]. Afterwards, images were corrected for eddy current-induced distortions and participant movements registering each volume in the data set to the reference b_0 volume. Finally, the diffusion tensor was fitted to the log-signal using an iterative weighted least-squares with weights based on the empirical signal intensities (2 iterations were be performed) [39].

Figure 2. Representative axial magnetic resonance imaging cross-sections of the thigh for 4 participants (S1 to S4), with segmented anatomical regions representing individual muscles. Each muscle is outlined in a specific color corresponding to the legend on the right. Muscles include the vastus lateralis, vastus medialis, vastus intermedius, rectus femoris, sartorius, gracilis, adductor magnus, semimembranosus, semitendinosus, biceps femoris (long and short heads), and adductor longus.



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Figure 3. Extension of thigh muscle regions of interest across 4 participants (S1 - S4) in a representative sagittal plane for each time point (T_0-T_3). Each muscle is outlined with a distinct color. The regions of interest boundaries were consistently defined from the beginning of the semimembranosus to the last available slice of the rectus femoris, ensuring reproducibility across participants and time points. Magnetic resonance imaging scans covered a 30 cm range along the head-to-feet axis from the midpoint of the femoral head.



Statistical Analysis

Considering the small sample size, a descriptive statistical analysis was performed using R Statistical Software (v4.1.2, R Foundation for Statistical Computing) [40,40]. In particular, changes in muscle volume, CSA, FF, T_2 relaxation times, and DTI parameters across the 4 time points were described reporting medians and median absolute deviations (MAD).

Ethical Considerations

All participants provided written informed consent before enrollment. The research protocol was approved by the ethics committee of Istituto di Ricovero e Cura a Carattere Scientifico Medea (N. 14/22 CE, approved on February 17, 2022) and the protocol was registered on ClinicalTrials.gov (NCT06321172).

Results

Participants

Table 1 provides clinical and demographic characteristics of participants in the pilot study. All participants completed the training program with a compliance greater than 78%, performing a minimum of 40 sessions over the 52 foreseen.

Table . Clinical and demographic characteristics of participants.

Participant	Age (years)	Distance from lesion (years)	Type of lesion (ASIA[a])	Height (cm)	BMI at T_0	Previous experience with FES[b]	Previous experience with cycling or trike	Drug therapy
S1	23	2.0	T10-11 (A)	178	25.2	No	No	—[c]
S2	29	1.1	T3 (A)	173	20.7	Yes	No	Oxybutyn, lansoprazole, D-base
S3	41	3.8	T5 (A)	175	24.5	Yes	Yes	—
S4	27	1.8	T12 (B)	191	21.9	Yes	Yes	Baclofen, lyrica

[a]ASIA: American Spinal Injury Association Impairment Scale.

[b]FES: functional electrical stimulation.

[c]Not applicable.

Muscle Volume and Cross-Sectional Area

As shown in Figure 4, analysis of the MR images revealed relevant changes in muscle volume and CSA-max over the 24-week FES-bike training program. At T_1 (after 3 months of training), participants showed an average increase in muscle volume of 23% compared with baseline (T_0). This growth

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continued through T_2 (after 6 months of training), with an overall increase of 37% in muscle volume. One month after the training (T_3), a slight reduction was observed, yet the muscle volume remained 23% higher than at baseline. Similarly, as displayed in Figure 5, CSA-max increased by 27% at T_1 and 37% at T_2, with a decrease to 16% above baseline at T_3. It is noteworthy that the observed trend was consistent in all the 4 participants involved in this study as shown in Figures 3 and 4.

Figure 4. Changes in normalized muscle volume over the 6-month functional electrical stimulation–cycling training and 1-month posttraining. The left panel shows 3D-reconstructed volume renderings for an example volunteer at each time point (**T_0, T_1, T_2, and T_3**), illustrating the changes in muscle size. The right panel presents box plots of normalized muscle volume measurements for all participants at each time point.

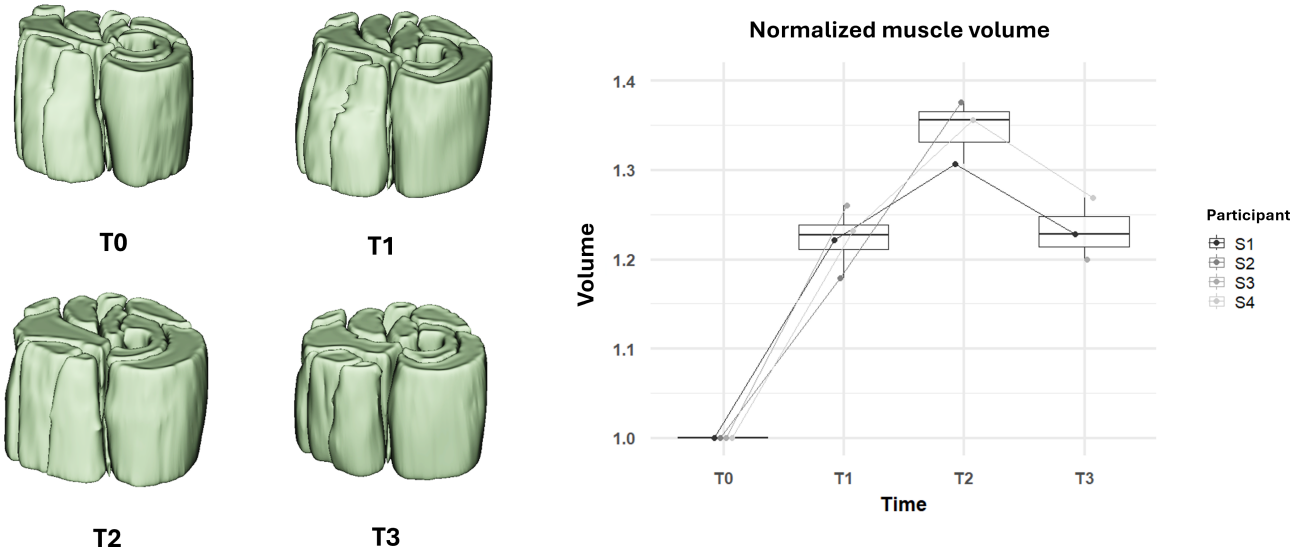
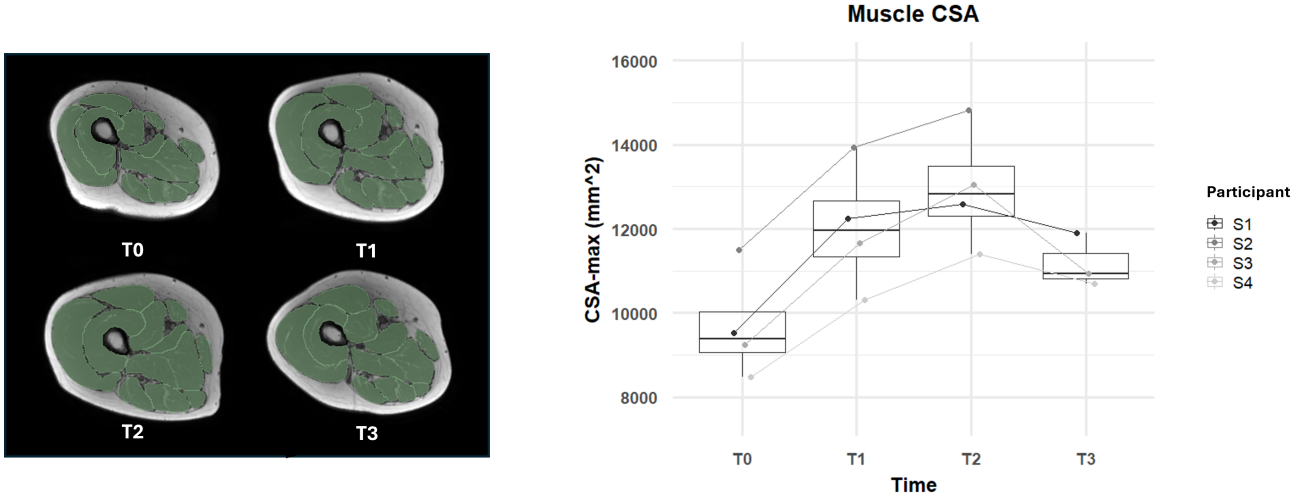


Figure 5. Changes in a muscle's largest cross-sectional area (CSA) over the 6-month functional electrical stimulation–cycling training program and 1-month posttraining. The right panel shows box plots of cross-sectional area measurements for all participants at each time point (**T_0, T_1, T_2, and T_3**). The left panel illustrates the magnetic resonance imaging cross-sectional images of the thigh muscles for an example volunteer at each time point, highlighting the visual changes in muscle size.



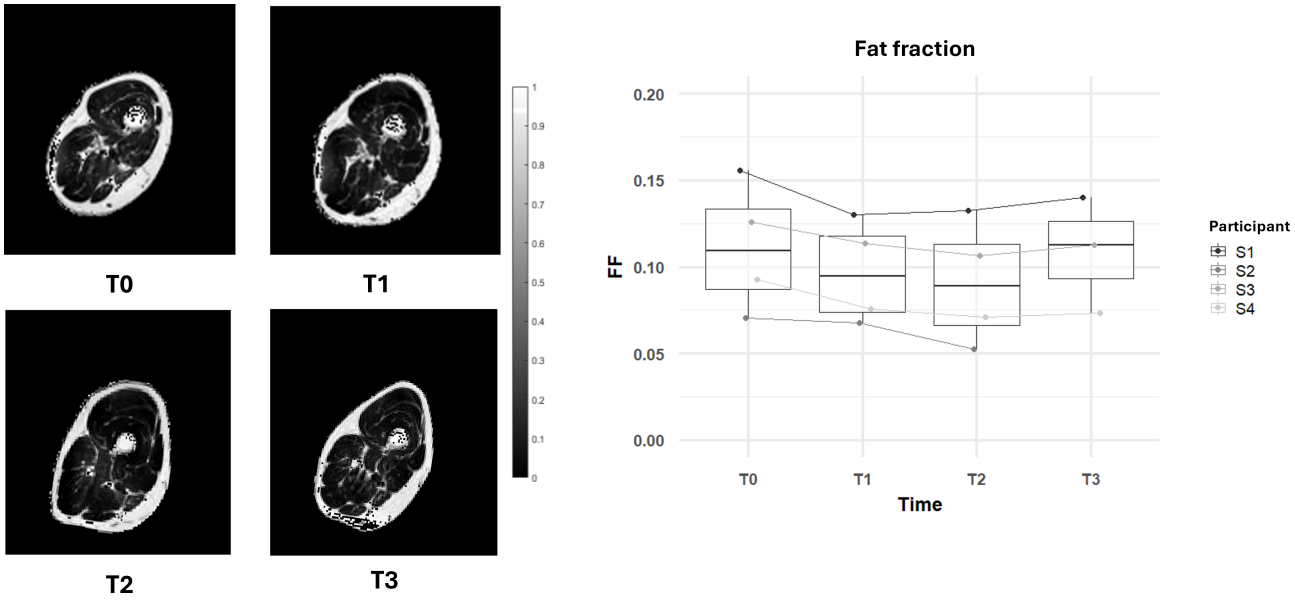
Fat Fraction

As shown in Figure 6, the FF in the muscle tissue showed a notable decrease from T_0 to T_2. The baseline measurements indicated a median FF of 10.9% (MAD=4%). By T_1, the FF decreased to 9.4% (MAD=3%), representing a reduction of 13%. By T_2, this reduction continued to 8.9% (MAD=4%), representing a total reduction of approximately 19%. The FF reduction was consistent in all the 4 participants.

At T_3, a rebound effect was observed, with FF measurements showing an increase to 11.3% (MAD=4%), a 3% higher than the baseline. Even in this case the trend was consistent in all the participants.

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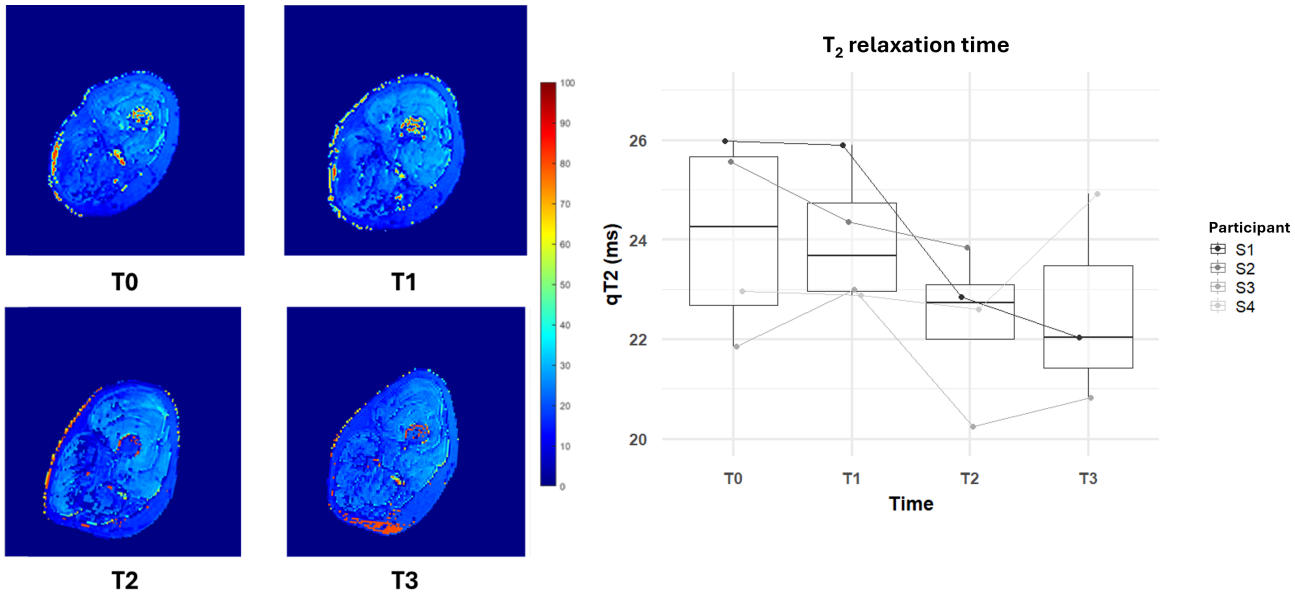
Figure 6. Changes in muscle fat fraction over the 6-month functional electrical stimulation–cycling training and 1-month posttraining. The right panel shows box plots of fat fraction measurements for all participants at each time point (**T_0, T_1, T_2, and T_3**). The left panel displays magnetic resonance imaging cross-sectional images of the thigh muscles for an example volunteer at each time point, illustrating the reduction in fat infiltration.



T_2 Relaxation Time

As shown in Figure 7, qT_2 times demonstrated a decreasing trend over the course of the training. Starting at a median of 24.3 ms (MAD=2.2 ms) at T_0, the qT_2 reduced to 23.7 ms (MAD=1.1 ms) by T_1, reflecting a decrease of 2%. By T_2, the qT_2 relaxation time further reduced to 22.7 ms (MAD=0.9 ms), reflecting a total decrease of approximately 6%. At T_3, the qT_2 relaxation time slightly reduced to 22.0 ms (MAD=1.8 ms) and it was still lower than the initial value of about 9%. As to qT_2, there was a high variability, and the trend was not consistent among participants. Just at T_2, 4 out of 4 participants showed a reduction in qT_2 as shown in Figure 7.

Figure 7. Changes in T_2 relaxation times over the 6-month functional electrical stimulation–cycling training and 1-month posttraining. The right panel shows box plots of T_2 relaxation times for all participants at each time point (**T_0, T_1, T_2, and T_3**). The left panel displays T_2 relaxation maps of the thigh muscles for an example volunteer at each time point.



Diffusion Tensor Imaging Parameters

As shown in Figure 8, DTI parameters revealed subtle but meaningful changes in muscle tissue microstructure.

Specifically, FA showed a decrease from 0.271 (MAD=0.03) at T_0 to 0.249 (MAD=0.02) at T_1, a reduction of approximately 8%. By T_2, FA slightly increased to 0.258 (MAD=0.02), maintaining an overall reduction from baseline. At T_3, FA increased further to 0.261 (MAD=0.017), still showing a net decrease of 4% with respect to baseline. The FA reduction was consistent in all the participants at T_1 and T_2.

Regarding the MD, it showed minimal variation, starting at 0.00159 mm²/s (MAD=0.00008 mm²/s) at T_0, increasing to

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0.00160 mm²/s (MAD =0.00004 mm²/s) at T_1 and decreasing to 0.00157 mm²/s (MAD=0.00003 mm²/s) by T_2, representing a total change of about 1%. By T_3, MD values were at 0.00160 mm²/s (MAD=0.00003 mm²/s), showing an increase of 1% from baseline. There was no consistency among partcipants regarding any relevant trend.

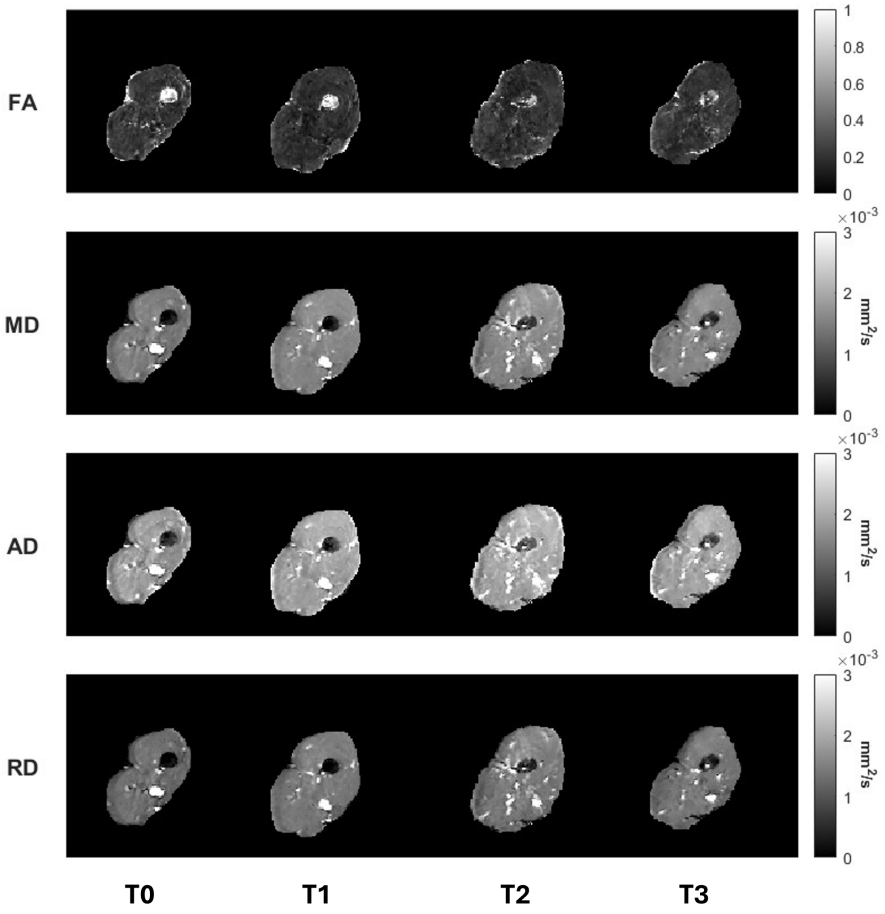
As to RD, it started at 0.00135 mm²/s (MAD=0.00008 mm²/s) at T_0, slightly increasing to 0.00138 mm²/s (MAD=0.00002 mm²/s) at T_1, an increase of 2%. By T_2, RD slightly decreased to 0.00136 mm²/s (MAD=0.00004 mm²/s), whereas at T_3, RD values still persisted to 0.00136 mm²/s (MA=0.00006 mm^2/s). At T_1, 3 out of 4 participants exhibited the RD raise.

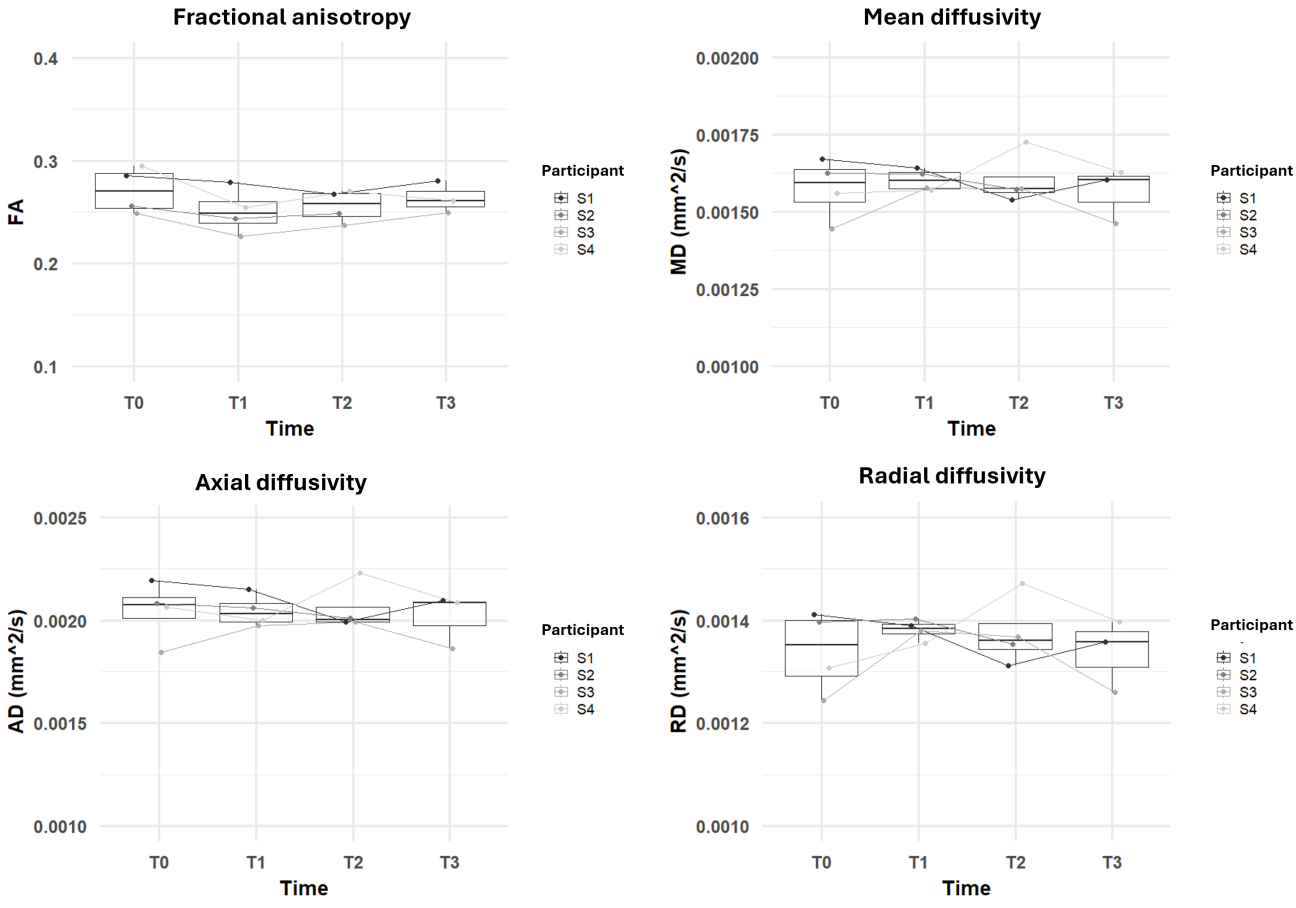
Finally, considering the AD, it began at 0.00207 mm²/s (MAD=0.00010 mm²/s) at T_0, decreasing to 0.00203 mm²/s (MAD=0.00006 mm²/s) at T_1. By T_2, AD further decreased to 0.00200 mm²/s (MAD=0.00001 mm²/s), representing a total decrease of 4%. At T_3, AD values were at 0.00209 mm²/s (MAD=0.00001 mm²/s), showing an increase of 1% from baseline. Even in this case, 3 out of 4 participants have shown a decrease in AD at T_1.

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Figure 8. Changes in diffusion tensor imaging parameters over the 6-month functional electrical stimulation–cycling training and 1-month posttraining. The top panel displays axial magnetic resonance imaging images for fractional anisotropy, mean diffusivity, radial diffusivity, and axial diffusivity of 1 example volunteers at each time point (T_0, T_1, T_2, and T_3). The bottom panel shows box plots of these diffusion tensor imaging parameters for all participants over time.

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Discussion

Principal Findings

This pilot study aimed at evaluating the feasibility of the use of mpMRI to assess the effects of 6-month FES-cycling training on muscle health in individuals with complete SCI. The use of mpMRI to evaluate SM has emerged as a novel approach recently, providing comprehensive insights into both macroscopic and microscopic changes within muscle tissues [25-27].

This advanced approach is promising for evaluating the effects of FES-cycling training on muscle tissue, moving beyond traditional metrics based essentially on the assessment of muscle volume and strength to explore changes in muscle composition and microstructural environment.

Advanced Magnetic Resonance Imaging Insights

The relevant growth in muscle volume, and similarly the CSA increase, documented in this study highlight the capability of FES-cycling training to counteract muscle atrophy. These findings are in line with previous research that demonstrates the benefits of FES in improving muscle mass. In particular, FES-cycling training was reported to be effective in increasing CSA up to 12% in individuals with complete SCI [13-15] and more strongly electrically-stimulated resistance training, focused mainly on muscle strength and hypertrophy, have reported a 20% - 72% increase of muscle size after 8 - 16 week intervention at chronic timepoints [21,22,41].

A reduction in the FF, as observed in the study in all the participants from T_0 to T_2, generally indicates a decrease in intramuscular fat content. This is often associated with improved muscle quality and a shift toward more lean muscle mass. In the context of FES-cycling training, this reduction likely reflects the beneficial effects of increased physical activity and muscle contractions on reducing fat infiltration in the muscles [42-44], which is commonly increased in conditions of muscle disuse or atrophy [45] such as SCI. However, previous findings on the effects of FES training on muscle fat in individuals with SCI are contrasted. Some earlier studies have failed to find any relevant change in intramuscular fat [22,46], whereas others reported up to 53% decrease [15]. It should be noted that all previous studies evaluated fat infiltration using T_1w images in a “semiquantitative” approach, thus they did not fully exploit the capability of MRI to quantify fat infiltration using water-fat imaging techniques based on advanced Dixon techniques as proposed in our work.

Our results, although based on a limited number of participants and exhibiting significant variability, displayed a reduction in muscle water T_2 relaxation times more consistently after 6 months of training. This reduction is typically linked to decreased muscle inflammation and fluid content, usually indicating healthier muscle conditions. More broadly, the qT_2 of muscle water serves as an indicator of disease activity in SM [47]. Changes in qT_2 are nonspecific and can result from various mechanisms, including inflammation, necrosis, muscular dystrophy, acute denervation, or conditions causing intracellular or extracellular edema, or a combination of both. In rehabilitation contexts, particularly following interventions like FES-cycling training, a reduction in qT_2 may indicate positive responses to the physical activity imposed by the training regimen.

In this pilot study, we observed subtle yet meaningful changes in DTI parameters that allow us to speculate on potential modifications occurring in muscle tissue microstructure. Specifically, FA decreased from T_0 to T_1, and although it slightly increased at T_2 and T_3, it still showed a net decrease from baseline. RD increased at T_1 and T_2 before returning to baseline levels at T_3. In contrast, AD decrease at T_1 and T_2, whereas MD showed minimal variations remaining relatively stable over the study period. These changes in DTI parameters may be related to alterations in the microstructural properties of muscle tissue following the FES-cycling training. Diffusion MRI has been widely used to assess the diffusivity of water molecules in tissue and the use of DTI was proposed to indirectly infer microstructural changes of muscle tissue [48,49]. Galbán et al [48] associated the first, second, and third eigenvalues to the diffusive transport along the long axis of a muscle fiber, within the endomysium perpendicular to the long axes of the muscle fibers, and within the cross-section of a muscle fiber, respectively. Furthermore, Hata et al [49] have associated changes in FA, AD, and RD to inflammation, regeneration and remodeling phase in a preclinical model of muscle injury. Interestingly, DTI parameters such as FA and RD have been found to be sensitive tools for monitoring muscle fiber size and can be useful in assessing muscle atrophy with some limitations in measuring muscle hypertrophy [50,51]. Furthermore, FA and RD parameters were associated with muscle fiber composition, with higher FA values (and lower RD values) indicating a higher proportion of type I fiber in muscle tissue [52]. Specifically, the decrease in FA observed in our study, primarily due to increased RD and reduced AD, may be associated with a change in muscle fiber diameters and a reconversion of fibers type, which are common responses to FES-training [53]. While it is important to acknowledge that DTI is one of the simplest methods for modeling diffusion MRI signals and that more complex modeling techniques have recently been developed for assessing SM using diffusion MRI [54-56], there remains room to speculate on interesting aspects of SM microstructure.

Clinical and Research Implications

The findings from this study highlight the potential of mpMRI as a monitoring tool in rehabilitation settings. By providing a detailed assessment of muscle health, mpMRI can help clinicians develop more targeted and effective rehabilitation strategies. It also offers a method to supervise and adjust treatments based on individual responses, potentially leading to better outcomes and more personalized care strategies.

Furthermore, the application of mpMRI enables the exploration of the underlying mechanisms through which physical rehabilitation interventions, such as FES-cycling training, exert their effects. Understanding these mechanisms can guide the development of new interventions that target specific aspects of muscle health and function.

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Limitations and Future Directions

The limitations of this pilot study, including its small sample size and the absence of a control group, suggest caution in generalizing the findings. Future research should aim to confirm these results through larger-scale studies with diverse populations and control conditions.

The study exclusively involved male volunteers, as female participants were unavailable during the project's s timeframe. This gender-specific enrollment, also considering the small sample size, aligns with the statistically higher occurrence of spinal cord injuries in men, which is threefold that of women, as detailed in the research by Lu et al [57]. While acknowledging this as a potential limitation, we maintain confidence in the validity of our findings. It is reasonable to expect that the observed trends in muscle parameter variations would be consistent across genders. However, it is important to note that the magnitude of changes, particularly in muscle mass, can differ in women, reflecting the distinct physiological characteristics between the sexes.

A further limitation of this study is also represented by the lack of longitudinal clinical data that, considering also the small sample size, cannot allow a reliable evaluation of relationships between MRI parameters and participant-specific characteristics (clinical, demographic etc). To strengthen the impact of the proposed approach on SM health in a rehabilitative context, larger cohort studies, including the collection of longitudinal parameters to describe patients' characteristics, are needed.

In this study, the final timepoint, occurring one month posttraining, allowed us to evaluate the impact of deconditioning over a brief interval. This interval is representative of a potential pause in the training program, such as 1 that might occur during everyday life, for instance, a brief vacation break. Indeed, our aim was to understand the short-term reversibility of training effects and their implications for maintaining physical conditioning in real-world scenarios. It would be interesting to include an additional late MRI scan to monitor the progression of muscle atrophy and know the time required to return to baseline values. This additional data point could provide valuable insights into the recovery dynamics and inform future therapeutic strategies.

Finally, forthcoming studies should incorporate molecular and histological analyses to investigate changes at the cellular level, including muscle fiber type transitions, capillary density, and protein expression related to muscle hypertrophy and atrophy.

Conclusions

In conclusion, this study underscores the use of mpMRI in advancing our understanding of the physiological impacts of rehabilitation interventions on muscle health in individuals with SCI. The detailed insights provided by mpMRI suggest its integration into clinical practice to assess the efficacy of interventions like FES-cycling training. By advancing our understanding of the physiological impacts of FES-cycling training, this research paves the way for more effective and personalized rehabilitation protocols, ultimately improving the quality of life for individuals with SCI.

Acknowledgments

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Conflicts of Interest

AP is cofounder and shareholder of 2 startups, Agade srl and AllyArm srl, which are active in the field of exoskeletons for industrial and biomedical applications, respectively. All other coauthors have no conflicts of interest.

Multimedia Appendix 1
Supplementary table
[DOCX File, 20 KB - rehab_v12i1e64825_app1.docx]

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Abbreviations

AD: axial diffusivity
CSA: cross-sectional area
CSA-max: largest cross-sectional area
DTI: diffusion tensor imaging
DWI: diffusion-weighted imaging
FA: fractional anisotropy
FES: functional electrical stimulation
FF: fat fraction
HR: heart rate
MAD: median absolute deviation
MAS: Modified Ashworth Scale
MD: mean diffusivity
mpMRI: multiparametric magnetic resonance imaging
MR: magnetic resonance
MRI: magnetic resonance imaging
Multi-TSE: multi-echo turbo spin echo
qT_2: quantitative T_2
RD: radial diffusivity
ROI: region of interest
SCI: spinal cord injury
SM: skeletal muscle
T_1w: T_1-weighted
TSE: turbo spin echo

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Use of ChatGPT for Urinary Symptom Management Among People With Spinal Cord Injury or Disease: Qualitative Study

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Abstract

Background: Individuals with spinal cord injury or disease (SCI/D) experience disproportionately high rates of recurrent urinary tract infections, which are often complicated by atypical symptoms and delayed diagnoses. Patient-centered tools, like the Urinary Symptom Questionnaires for Neurogenic Bladder (USQNB), have been developed to support symptom assessment yet remain underused. Generative artificial intelligence tools such as ChatGPT may offer a more usable approach to improving symptom management by providing real-time, tailored health information directly to patients.

Objective: This study explores the role of ChatGPT (version 3.5) in supporting urinary symptom management for individuals with SCI/D, focusing on its perceived accuracy, usefulness, and impact on health care engagement and self-management practices.

Methods: A total of 30 individuals with SCI/D were recruited through advocacy groups and health care networks. Using realistic, scenario-based testing derived from validated tools for symptom management with SCI/D, such as the USQNB, participants interacted with ChatGPT to seek advice for urinary symptoms. Follow-up interviews were conducted remotely to assess individuals' experiences using ChatGPT for urinary symptom management. Data were analyzed using inductive content analysis, with themes refined iteratively through a consensus-based process.

Results: People with SCI/D reported high levels of trust in ChatGPT's recommendations, with all 30 participants agreeing or strongly agreeing with the advice provided. ChatGPT's responses were perceived as clear and comparable to professional medical advice. Participants mentioned concerns about the lack of sources and integration with patient-specific data. ChatGPT influenced individuals' decision-making by supporting symptom assessment and guiding participants on when to seek professional care or pursue self-management strategies.

Conclusions: ChatGPT is a promising tool for symptom assessment and managing chronic conditions such as urinary symptoms in individuals with SCI/D. While ChatGPT enhances accessibility to health information, further research is needed to improve its transparency and integration with personalized health data to be a more usable tool in making informed health decisions.

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KEYWORDS

ChatGPT; urinary symptom management; spinal cord injury; trust in artificial intelligence

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Introduction

Background: Recurrent Urinary Tract Infections for Individuals With Spinal Cord Injury or Disease

Each year, urinary tract infections (UTIs) impact approximately 150 million people worldwide [1]. UTIs represent a substantial burden on health care systems due to frequent emergency department visits and the complexities of managing recurrent cases. Among individuals with spinal cord injury or disease (SCI/D), including multiple sclerosis and spina bifida, the burden of UTIs is more pronounced, with nearly 60% experiencing recurrent UTIs each year—a rate 30 times higher than that of the general population [2,3]. Recurrent UTIs are the leading cause of hospital readmissions for individuals with SCI/D, underscoring the challenges in both symptom management and timely diagnosis [4,5].

Challenges in Symptom Recognition and Treatment

The disproportionately high prevalence of UTIs in SCI/D populations is linked to neurogenic bladder dysfunction, a condition often requiring catheterization—either intermittent or indwelling—that significantly increases susceptibility to bacterial colonization and infection [6,7]. Unlike the general population, individuals with SCI/D frequently exhibit atypical UTI symptoms such as fatigue, cloudy or malodorous urine, and abdominal discomfort [8,9]. The atypical symptomatology complicates UTI recognition and delays diagnosis, contributing to further health risks and reduced quality of life [10,11].

This combination of persistent bacteria in the urine and atypical infection symptoms makes it challenging to determine when antibiotic treatment is needed, potentially leading to both delayed treatment of serious infections and unnecessary antibiotic use for benign bacteriuria. Misdiagnoses often lead to unnecessary antibiotic prescriptions, increasing the risk of antimicrobial resistance and placing additional strain on the health care system [12,13]. Addressing these symptom presentation challenges requires reliable, standardized tools that empower individuals with SCI/D to accurately identify and manage their symptoms.

Limitations in the Use of Validated Symptom Assessment Tools

The Urinary Symptom Questionnaires for Neurogenic Bladder (USQNB) is a validated set of instruments designed to capture nuanced symptom profiles across different bladder management methods, including intermittent catheterization, indwelling catheters, and independent voiding [14-17]. While the USQNB tool demonstrates strong alignment with patient-reported outcomes and provides a robust framework for clinical use, its application remains inconsistent in practice [5,15]. Many individuals with SCI/D instead rely on less reliable resources such as general internet searches or anecdotal advice, which can lack accuracy and relevance [18,19].

Validated tools like the USQNB exist to support symptom assessment, yet their limited adoption highlights the need for more accessible solutions that can provide immediate personalized guidance. Despite the availability of validated tools, like the USQNB, individuals with SCI/D often turn to general internet searches or anecdotal advice for symptom assessment. Digital platforms (eg, internet) are an increasingly common source of health information to support symptom assessment, with over 70% of users reporting online searches for health-related content [20,21]. Digital platforms offer accessibility and immediacy but are criticized for propagating misinformation, leading to anxiety, ineffective self-management, and delays in seeking professional care [22,23]. ChatGPT, along with other large language models, has been increasingly integrated into health information seeking and chronic care contexts, offering decision-making support and patient engagement across a range of conditions [24-26].

Opportunities and Risks of Digital Tools

ChatGPT has demonstrated potential utility in health care settings, including clinical decision support, patient education, and symptom interpretation [27,28]. Recent qualitative work shows that patients are already using ChatGPT to interpret symptoms and guide care-seeking behavior while also raising concerns about reproducibility and source credibility [29]. While early studies have shown promising results in general medical applications, ChatGPT's effectiveness for specific populations with complex health care needs, such as individuals with SCI/D, remains unexplored. ChatGPT's ability to process natural language and provide contextual responses could be especially valuable for individuals with SCI/D who often face challenges in interpreting their unique symptoms.

The Role of ChatGPT in SCI/D Symptom Management

For individuals with SCI/D, ChatGPT's ability to provide immediate tailored responses could help address barriers to timely health care access, such as mobility limitations and the need for specialized expertise [12,13]. However, ChatGPT's usefulness depends on patients' perceptions of accuracy and relevance, as well as its integration with existing health care practices. Other studies have shown that chatbot-based tools are acceptable and potentially beneficial for individuals with complex or stigmatized conditions, including those with limited access to traditional care [30]. Recent work has also examined generative artificial intelligence (AI) errors in health care settings, including a preliminary classification system that categorized errors by input and output stages, identifying omission errors as the most common in both patient-facing and clinical documentation large language model applications [31]. Understanding how individuals with SCI/D perceive and use ChatGPT is critical for evaluating its potential as a reliable tool for managing urinary symptoms.

This study aims to explore the use and perceptions of ChatGPT for urinary symptom management among individuals with SCI/D, addressing the following objectives:

- Identify the types of urinary symptom–related information users seek through ChatGPT
- Evaluate the perceived accuracy, usefulness, and limitations of ChatGPT's responses
- Examine how ChatGPT-derived information is integrated with existing health resources and professional medical

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recommendations, using valid and reliable patient-centered, patient-reported outcomes (USQNB)
- Assess the impact of ChatGPT use on self-management practices and health care engagement

By addressing these objectives, this research seeks to advance the understanding of AI's role in supporting individuals with complex health care needs.

Methods

Overview

The 2-phase study approach examined the use and perceptions of ChatGPT for urinary symptom management among individuals with SCI/D.

- Phase 1 consisted of scenario-based testing in which participants interacted with ChatGPT (version 3.5) using scenarios based on validated patient-reported outcome tools, specifically the USQNB for intermittent and indwelling catheter users.
- Phase 2 consisted of follow-up interviews to assess participants' experiences using ChatGPT for urinary symptom management advice.

Ethical Considerations

The MedStar Health Research Institute Institutional Review Board approved this study (IRB #00007397). Participants received a US $50 check as compensation following completion of the interview.

Interview Guide Creation

The semistructured interview guide was developed using the two USQNB instruments for intermittent and indwelling catheter users, both are validated instruments with established reliability [15-17]. The USQNB comprises distinct instruments for different bladder management methods (intermittent catheters, indwelling catheters, and independent voiding, which was not included in this study) specific to individuals with neurogenic lower urinary tract dysfunction. These tools were adapted to capture a range of patient-reported experiences. The scenario-based testing involved:

- providing demographics, health information–seeking behaviors, and technology comfort level;
- sharing experiences with urinary symptoms and UTIs, including specific instances of seeking or considering medical attention for a possible UTI;
- interacting with ChatGPT for urinary symptom management scenarios; and
- completing a follow-up survey on trust and agreement with ChatGPT.

The interview guide included questions on participants' agreement with ChatGPT's symptom management recommendations, comfort level using AI technology for health care decisions, perceived limitations and concerns, typical approaches to health care decision-making, and preferences for receiving medical advice.

Data Collection

Participants were purposively sampled from advocacy groups, social media platforms, and the MedStar National Rehabilitation Hospital outpatient network [32]. The National Rehabilitation Hospital serves over 400,000 patients annually and maintains a database of more than 300 individuals with spinal cord injury or neurogenic bladder dysfunction. Participants were selected based on the following inclusion criteria:

- Diagnosed with SCI, multiple sclerosis, or spina bifida
- Experienced recurrent urinary symptoms requiring management (intermittent or indwelling catheter)
- Ability and willingness to participate in remote scenario-based testing

Eligible participants were contacted through direct outreach, leveraging partnerships with advocacy organizations and clinical referrals. Recruitment materials emphasized the minimal risks involved and highlighted the importance of participant contributions to advancing research on AI-driven health care solutions.

Participants interacted with ChatGPT using scenarios that simulated real-world symptom management challenges for individuals with SCI/D. These scenarios were based on validated patient-reported outcome tools for bladder management, specifically the USQNB [15-17]. Follow-up interviews were conducted to capture participants' perceptions of ChatGPT's usability, accuracy, and value in managing their symptoms. After the interviews, participants completed a 5-item survey that included rating their level of agreement with ChatGPT's responses.

The scenario-based testing was conducted remotely using Microsoft Teams (version 2406), which expanded the geographic reach and provided flexibility by eliminating commute time. Before testing began, each participant provided verbal consent. Follow-up interviews lasted approximately 30-60 minutes and were recorded for transcription and analysis. The average interview duration was 34.0 (SD 15.9, range 8-67) minutes, for a total of 17 hours and 9 minutes. The interviewer (AKR) encouraged participants to elaborate on their experiences, particularly focusing on their interactions with ChatGPT and how it influenced their symptom management decisions.

Data Analysis

Interview transcripts were cleaned and deidentified. Two researchers (IN, DNB) organized the data in Microsoft Excel (version 2406), with columns for each interview question and respective responses from all 30 interviewees.

The research team conducted an inductive content analysis [33] of the interview data. Two researchers (BZH, AKR) developed a codebook iteratively with four emerging themes: experiences with ChatGPT, decision-making influence, health and technology use, and symptom management.

Three researchers (BZH, IN, DNB) independently coded interview questions for each of the four main codes. Researchers met periodically and resolved discrepancies through consensus-based discussions. During discussions, the team

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iteratively refined code definitions and identified emerging subthemes.

To ensure rigor, the team used peer debriefing and maintained an audit trail of research decisions [32,34]. The final analysis involved identifying patterns within and across themes, synthesizing findings to address our research questions about experiences using ChatGPT for urinary symptom management advice and its influence on health care engagement decisions.

Results

Participants

A total of 30 individuals with SCI/D participated in this study. Table 1 summarizes participant characteristics, including demographics and clinical details.

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Table . Study participant characteristics.[a]

	Participants (N=30)
Gender, n (%)	
Male	20 (67)
Female	10 (33)
Age (years)	
Range	31-75
Mean (SD)	53.9 (14.0)
Race/ethnicity, n (%)	
White	27 (90)
Black or African American	2 (7)
Asian	1 (3)
Location, n (%)	
Suburban	20 (67)
Urban	7 (23)
Rural	3 (10)
Primary conditions, n (%)	
Spinal cord injury	20 (67)
Multiple sclerosis	8 (27)
Spina bifida	2 (7)
Catheter use, n (%)	
Indwelling catheter	8 (27)
Intermittent catheter	22 (73)
Annual household income (US $), n (%)	
≥$150,000	11 (37)
$100,000-$149,999	2 (7)
$75,000-$99,999	3 (10)
$50,000-$74,999	8 (27)
$25,000-$49,999	4 (13)
<$25,000	2 (7)
Technology use, n (%)	
Comfortable or extremely comfortable	29 (97)
Medium comfortability	1 (3)
Technologies used, n (%)[b]	
Google	22 (73)
Amazon Alexa	10 (33)
Siri	5 (17)
ChatGPT	4 (13)

[a]The percentages do not add up to 100 in some categories due to rounding.

[b]Participants could select multiple options for this question.

Themes

Overview

Our team identified four emerging themes:

- Symptom management: how participants experience, interpret, and respond to urinary symptoms in their daily lives, including their physical manifestations, functional impacts, and coping strategies

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- Experiences with ChatGPT: how participants evaluate and perceive ChatGPT's reliability, capabilities, and limitations for urinary symptom management, including their assessment of its accuracy and comparisons to other information sources
- Decision-making influence: how participants use ChatGPT to inform choices about symptom assessment, self-management strategies, and timing of professional medical care engagement
- Health and technology use: how participants typically access health information and engage with technology in their daily lives, including their comfort level with digital tools and preferred sources for medical advice

Symptom Management

Table 2 shows three key management considerations: daily life impacts, symptom characteristics, and management approaches. A total of 5 participants reported fatigue, 6 reported pain, and 4 reported having a fever; 5 noted emotional impacts, and 3 described social limitations. Among 29 participants discussing symptoms, 7 reported cloudy urine, 5 reported malodorous urine, and 5 reported dark urine. A total of 6 participants experienced increased frequency, and 4 reported leakages. Of 28 participants describing management strategies, 15 increased water intake and 18 used supplements. A total of 5 participants used medications, and 4 described equipment management techniques.

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Table . Thematic analysis of ChatGPT use by individuals with spinal cord injury or disease (SCI/D) for urinary symptom management.

Theme and component	Definition	Exemplary quote
Urinary symptom management		
Daily life impact	How urinary symptoms affect daily activities	• "It depends on the severity; catheter clogging can prevent me from leaving the house, discomfort and pain, and restriction on going out in public." (P20) • "Sickness, nausea, smelly urine, affects how I interact with people often - the main issue is I try not to get close to people due to smelly urine." (P26)
Symptom characteristics	Frequently experienced urinary symptoms	• "If these symptoms occur individually: abdominal pain, dizziness, decreased urine volume, worse smelling volume, darker urine, increase in fatigue, loss of appetite, feeling unwell, altered sleeping patterns, muscle aches, increased positional pain, nausea, change in bowel patterns, abdominal discomfort or bloating, irritability or mental slowing. If multiple occur together, I may call the doctor. I typically wait until it gets bad." (P18)
Management approaches	Methods used for self-management	• "I've taken everything from cranberry pills to...garlic pills. I've read all these different things where people find certain diets to help less. Sugars, less starches, cause starches turn into sugars, more proteins, increased fluid intake...I've tried all of the above." (P7)
Experiences with ChatGPT		
Information accuracy assessment	How participants evaluate ChatGPT's reliability and alignment with professional medical guidance	• "I don't think it was the best…It could be more beneficial if it knew more about my medical record…if it could connect with my chart." (P22)
Information source comparison	How participants compare ChatGPT to other health information sources	• "Yes, as long it's correct and there is some background that it's coming from a reliable source" (P25) • "First I would use my web portals, because that's trained doctors and nurses" (P18)
Decision-making influence		

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Theme and component	Definition	Exemplary quote
Symptom evaluation	How participants assess specific health symptoms and their severity	• "I have muscle aches, I feel unwell, and I have abdominal discomfort" (P3) • "ChatGPT, I'm experiencing cloudiness, dark color, urine leakage, and increased odor in my urine. Should I seek medical advice?" (P14)
Guidance seeking	How participants use ChatGPT's recommendations for health care decisions	• "How long should these symptoms persist before I seek treatment: back pain, fever, abdominal bloating, overall fatigue, increased frequency, urgency, odor, and cloudiness?" (P6) • "The incontinence Is not excessive, but more than usual. It doesn't smell and is cloudy each time I cath. Are there certain solutions I can try myself before I seek antibiotics?" (P27)
Patterns in health information seeking and technology use		
Health information sourcing	Primary methods for obtaining health advice	• "I go to my general practitioner or research on Web MD-type places." (P12) • "Doctors, PubMed, family and friends that are physicians" (P20)
Technology engagement	Level of technology use for health information	• "Comfortable but not 100% with technology." (P29)

Experiences With ChatGPT

Table 2 presents two perspectives on information evaluation: accuracy assessment and source comparison. Of the 30 participants, 13 strongly agreed and 17 agreed with ChatGPT's advice, and 5 participants noted alignment with professional medical guidance. For example, one participant shared, "It seems to be on target with what the professionals tell me." ChatGPT provided suggestions such as "monitor symptoms for 48 hours before seeking care" or "increase fluid intake to alleviate mild urinary symptoms," which participants often described as clear and actionable.

Some participants, however, indicated that ChatGPT's advice lacked the specificity they needed. Suggestions like "Seek medical advice if symptoms persist beyond 72 hours" were perceived as too general, particularly when participants expected advice tailored to their individual health histories.

Decision-Making Influence

Table 2 shows two health care engagement patterns: symptom evaluation and care guidance. A total of 29 participants described ChatGPT's influence on health care decisions, 17 assessed their urine characteristics, 6 inquired about pain, and 5 noted urination pattern changes. One participant exemplified typical queries: "I'm experiencing cloudiness, dark color, urine leakage, and increased odor in my urine, should I seek medical advice?"

Among the 28 participants seeking care guidance, 12 used ChatGPT to determine when to seek professional help, 9 sought self-management guidance, and 7 requested urgent care advice.

Health and Technology Use

Table 2 presents two information access patterns: health information sourcing and technology engagement. Of the 30 participants, 27 consulted doctors for health advice, with 5 mentioning specialists specifically. A total of 15 used internet resources, and 4 consulted family members with medical backgrounds. Of the 30 participants, 29 reported regular technology use. Most described high comfort levels, though age-related challenges were noted; for instance, one participant explained, "[Th]is a learning experience for an older guy."

Discussion

Patient Trust and the Promise of Generative AI

This study provides novel insights into how individuals with SCI/D perceive and use ChatGPT (version 3.5) for managing urinary symptoms. Our findings demonstrate both promising applications and important limitations of AI-driven health information tools in supporting chronic condition management.

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These findings align with a recent generative AI study reporting that 42% of errors in patient-facing language models were omissions, with 25% of the errors having high clinical significance [31]. These results also echo prior studies highlighting ChatGPT's potential in chronic care, mental health, and patient education while also raising concerns about reproducibility and trustworthiness [26,30]. The high level of trust in ChatGPT reported by participants is consistent with emerging literature on AI acceptance in health care settings [27]. However, this trust must be considered within the broader challenges faced by individuals with SCI/D in interpreting urinary symptoms, especially given the atypical presentation of UTIs and difficulties in symptom interpretation highlighted by previous research [8,9].

ChatGPT's Role in Supporting Symptom Interpretation

Our findings regarding symptom assessment patterns are particularly noteworthy when considered alongside existing literature on UTI management in SCI/D populations. Participants frequently sought guidance on assessing urine characteristics, pain, and urination pattern changes—symptoms that often present atypically in this population [3]. These behaviors align with other qualitative studies in which patients used ChatGPT to make sense of ambiguous symptoms and to guide decisions about care seeking [29]. These findings suggest ChatGPT may serve as a valuable tool in helping individuals interpret their symptoms, potentially addressing the gap between symptom onset and clinical intervention that has been identified as a significant challenge in UTI management [4,5]

The role of ChatGPT in health care decision-making emerged as a key theme, with 28 participants using it to guide care-seeking behaviors. This finding is significant given the high rates of emergency department visits and hospital readmissions for UTIs among individuals with SCI/D [2]. ChatGPT's ability to provide immediate, tailored feedback may help address the uncertainty in distinguishing between asymptomatic bacteriuria and true UTIs—a distinction that has proven challenging even in clinical settings [35].

Limitations of ChatGPT in Personalized Care

However, participants' concerns about ChatGPT's lack of integration with personal health records echo broader challenges in health information technology adoption. This limitation is particularly relevant given the importance of standardized assessment tools, like the USQNB [14], and the need for contextualized symptom evaluation in neurogenic bladder management. Future development of AI-driven health tools should prioritize integration with validated assessment instruments and personal health data to enhance their utility in chronic condition management.

Study Limitations and Opportunities for Future AI-Driven Care

The study revealed that while participants maintain strong relationships with health care providers, they value ChatGPT as a complementary resource. This mirrors findings from studies in perinatal mental health, where patients describe chatbots as supportive and scalable companions between formal care encounters [30]. Such tools may help bridge the gap between professional care visits, potentially reducing delays in symptom recognition and treatment initiation that have been associated with poorer outcomes in this population [12].

There are some study limitations. First, our sample was limited to individuals with SCI/D who had extensive experience managing urinary symptoms and were predominantly White (27/30) and technologically proficient (29/30 comfortable with technology). Despite recruitment efforts through multiple platforms, including advocacy groups, social media, and clinical networks, the study sample lacked racial and ethnic diversity. Thus, findings may not be generalizable to newly diagnosed patients or those with less experience in symptom management. Additionally, while the remote scenario-based testing format enhanced accessibility, it limited our ability to observe contextual factors influencing real-world use. Future research should prioritize the recruitment of racially, ethnically, and socioeconomically diverse participants, including individuals newly navigating urinary symptom management. In addition, future research should examine how AI tools, like ChatGPT, can be better integrated with validated condition-specific instruments such as the USQNB to enhance clinical relevance and accuracy. Longitudinal studies are also needed to assess whether AI use improves symptom recognition, self-management behaviors, care-seeking decisions, and clinical outcomes over time. These directions will help clarify the role of generative AI in improving access, quality, and safety of care for individuals with SCI/D and other populations managing chronic conditions.

This study provides important insights into the potential role of AI chatbots like ChatGPT in supporting urinary symptom management for individuals with SCI/D. While participants found value in using ChatGPT to verify their knowledge and potentially gain additional information, it is clear that these tools should complement rather than replace existing health management strategies and professional medical care. As AI continues to evolve, careful consideration must be given to how it can be optimally integrated into chronic disease management to enhance patient care while maintaining appropriate safeguards and supporting established clinical relationships.

Conclusion

Individuals with SCI/D generally find ChatGPT to be a trustworthy and valuable tool for managing urinary symptoms while still relying on their personal experience and professional medical advice for decision-making. As AI technology continues to advance, it has the potential to serve as a complementary tool in chronic condition management. Generative AI tools should consider attention to personalization, integration with existing health care systems, and ethical considerations to be highly usable for individuals managing chronic conditions like SCI/D.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
SCI/D: spinal cord injury or disease
USQNB: Urinary Symptom Questionnaires for Neurogenic Bladder
UTI: urinary tract infection

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Mobile-Based Digital Rehabilitation Program for Patients After Anterior Cervical Discectomy and Fusion: Prospective Cohort Study

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Abstract

Background: Anterior cervical discectomy and fusion (ACDF) is a common treatment for degenerative cervical spine disease, yet its frequent postoperative follow-up places substantial demands on both patients and health care systems. A digital program integrating computer-vision–guided exercise, wearable posture monitoring, and cognitive behavioral therapy (CBT) could provide remote monitoring and rehabilitation to alleviate this burden.

Objective: This study aims to evaluate the clinical effectiveness and compliance of a 12-week digital rehabilitation program after ACDF compared with conventional in-person therapy.

Methods: In this prospective cohort study, 336 postoperative patients self-selected either a 12-week mobile-based program incorporating computer-vision–guided exercises, wearable posture sensors, and cognitive behavioral therapy (n=270), or in-person rehabilitation group (IRG, n=66) involving weekly therapist-supervised sessions and paper-based home exercises. Digital users were stratified into a digital rehabilitation completion group (DCG, n=192) and a digital rehabilitation noncompletion group (DNG, n=78). All participants were recruited at a single tertiary hospital and returned to the clinic for outcome assessments at 0, 12, and 24 weeks postoperatively. Outcomes—primarily pain (visual analog scale [VAS]) and disability (neck disability index [NDI]), as well as 36-item short form survey mental component summary (SF-36 MCS), 3-plane cervical range of motion (ROM), muscle endurance, and patient satisfaction—were recorded at 0, 12, and 24 weeks postoperatively. All statistical analyses were performed using SPSS (version 29.0; IBM Corporation). Results were reported as means, SDs, and 95% CIs.

Results: Both the DCG (n=192, who completed all digital sessions) and IRG (who completed 12 weeks of weekly in-person sessions and home exercises) demonstrated significant improvements in pain and disability at weeks 12 and 24, with no significant differences between groups (P>.05). At Week 12, VAS decreased by −2.5 (95% CI −3.0 to −2.0) in the DCG and −2.8 (−3.7 to −1.9) in the IRG; NDI decreased by −6.8 (−10.3 to −3.3) and −8.1 (−14.3 to −1.9), respectively. At Week 24, VAS and NDI reductions reached −4.0 (−4.5 to −3.5) and −13.3 (−17.4 to −9.2) in the DCG, and −4.1 (−5.0 to −3.2) and −14.2 (−21.3 to −7.1) in the IRG. In contrast, the DNG showed minimal improvements: VAS changes were −0.8 (−1.6 to 0.0) at week 12 and −1.3 (−2.1 to −0.5) at week 24; NDI changes were −2.2 (−8.2 to 3.8) and −6.4 (−13.0 to 0.2), respectively (P<.05 compared to DCG and IRG).

Conclusions: The digital rehab program led to comparable improvements in pain, function, and mental health as conventional in-person rehab. Higher adherence was linked to better outcomes, supporting digital rehab as an effective, patient-centered approach after ACDF.

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KEYWORDS

anterior cervical discectomy and fusion; digital rehabilitation; computer vision; remote rehabilitation; wearable sensors; postoperative rehabilitation

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Introduction

Background

With the rapid global aging of the population, degenerative cervical spine disease has become a major public health challenge affecting older adults. Approximately 85% of individuals above 60 years old show radiographic evidence of cervical degeneration, and the number of people living with neck pain reached 203 million—an increase of 77.3% since 1990—placing neck pain among the leading contributors to musculoskeletal disability [1]. Also, the global age-standardized prevalence of neck pain is 27 per 1000 in 2019, causing substantial health care expenditure and productivity loss [2].

For degenerative cervical spine disease accompanied by spinal cord or nerve root compression, anterior cervical discectomy and fusion (ACDF) remains the surgical gold standard [3]. However, shorter inpatient stays indicate that most functional recovery occurs after discharge, and traditional outpatient physiotherapy often lacks continuous monitoring, real-time feedback, and psychological support [4]. It is further revealed that postoperative patients and their caregivers widely seek support to close these postdischarge guidance gaps [4].

Digital rehabilitation has the potential to address these shortcomings and provide remote, real-time, and individualized exercise guidance. In previous studies involving chronic low back pain, AI-assisted tele-rehabilitation significantly reduced pain and improved function within 4 - 8 weeks [5,6], while systematic reviews confirmed that digital health interventions lessen neck and back pain and enhance quality of life [7,8]. Other studies further indicate that spine-surgery patients using digital platforms experience lower rates of postoperative emergency visits and readmissions, highlighting their potential in postoperative care [9].

However, evidence for digital rehabilitation specifically designed for ACDF postoperative patients remains limited [9]. Thus, this study evaluates the effectiveness and safety of an AI-driven digital rehabilitation program in promoting functional recovery and improving compliance following ACDF, thereby providing evidence-based postoperative digital rehabilitation strategies.

Objective

This study aims to evaluate the clinical efficacy of a digital rehabilitation program that combines computer-vision–guided exercise coaching, real-time inertial-sensor monitoring, and cognitive behavioral interventions for patients recovering from ACDF. By systematically comparing neck-pain intensity, quality of life, and functional recovery before and after the intervention, we will assess the program's effectiveness in relieving symptoms, enhancing quality of life, and promoting functional recovery.

Methods

Study Design

This single-centered, prospective cohort study was carried out at Peking Union Medical College Hospital to compare a 12-week digital rehabilitation program with standard in-person physiotherapy after ACDF [10-15]. A total of 336 eligible patients were enrolled.

Postoperatively, participants selected their rehabilitation modality based on personal preference and logistical convenience, forming the digital rehabilitation group and the in-person rehabilitation group (IRG). Within the digital rehabilitation group, compliance criteria further divided patients into a digital rehabilitation completion group (DCG) and a digital rehabilitation noncompletion group (DNG).

All groups followed an identical evidence-based rehabilitation protocol. Digital groups (DCG and DNG) used the healbone rehabilitation system (HRS), a remote rehabilitation platform developed by Jiakangzhongzhi Technology Co, paired with inertial measurement unit (IMU) wearables, completing three 30-minute sessions per week. IRG attended one 45-minute, in-person session with a physical therapist each week and performed the remaining exercises independently at home using a printed manual. Pain, functional status, health-related quality of life, and cervical range of motion were assessed at baseline (Week 0), Week 12, and Week 24, whereas patient satisfaction was measured only at Week 24.

Inclusion and Exclusion Criteria

All participants were recruited at Peking Union Medical College Hospital. Two licensed physicians enrolled postoperative ACDF candidates according to the inclusion and exclusion criteria. Each participant received detailed information about the study's objectives, procedures, and potential risks. Enrollment proceeded only after written informed consent was obtained. The inclusion and exclusion criteria were as follows:

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Textbox 1. Inclusion and exclusion criteria for participant selection.

Inclusion criteria:

1. Less than 70 years old.
2. Signed informed consent.
3. Diagnosis of cervical pathology Grade III or IV.
4. Experiencing cervical spine disease for longer than 2 months.
5. ≤3 segments requiring cervical fusion.

Exclusion criteria

1. Severe spinal canal stenosis.
2. Presence of diseases preventing exercise.
3. History of cervical or other spinal surgeries.
4. History of spinal infection or tumors.

Blinding

Because of the distinct modes of intervention, conventional double‐blinding was not feasible. To minimize bias, we implemented several safeguards. Follow-up assessments were conducted by clinicians blinded to group allocation. Group identifiers were replaced with coded labels during data analysis, and data analysis was completed without knowledge of group allocation.

Intervention

The digital and in-person groups followed an identical rehabilitation protocol, designed by licensed physicians and physical therapists with reference to clinical guidelines. The program included cervical range-of-motion exercises, cervical-muscle strengthening exercises, scapular-stability exercises, and functional exercises. Full details are provided in Multimedia Appendix 1. All patients underwent follow-up assessments at baseline, Week 12, and Week 24.

Digital Rehabilitation Group

Participants used a mobile rehabilitation app paired with wearable IMU sensors for training and monitoring. They were instructed to complete 3 30-minute sessions per week for 12 weeks, totaling 36 sessions according to clinical protocols [16-18]. The app comprises three modules: (1) computer-vision exercise coaching, (2) cognitive behavioral therapy (CBT), and (3) posture monitoring. Figures 1 and 2 depict the implementation of these modules.

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Figure 1. Computer vision–guided exercise and cognitive behavioral therapy modules. During each session, the front-facing cellphone camera works with a computer-vision-based software application to capture head-and-neck angles in real time for guided exercises. The cognitive behavioral therapy (CBT) module allows patients to access lessons and complete interactive homework assignments.



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Figure 2. Patient monitoring module and software module. The posture-monitoring module uses a 9-axis inertial measurement unit (IMU) paired with a notification alert system. Patients wear the IMU during daily activities; when abnormal cervical posture is detected, the system sends a warning message, encouraging proper postoperative posture.



In-Person Rehabilitation Group

Participants attended one 45-minute, therapist-supervised session per week and received a printed home-exercise booklet identical to the digital protocol for self-directed practice in between visits. Two licensed physical therapists delivering the sessions completed 3 training workshops (≥1 hour each) before the beginning of this study to ensure protocol fidelity.

Computer-Vision Exercise Coaching

Before discharge from the hospital, participants installed the training app on their smartphones and logged in with their registered accounts. Patients then followed the software app, which provided tutorials on how to complete each exercise. The cell phone's front-facing camera captured cervical angles in real time, and the software provided verbal and auditory feedback to patients when they were completing their exercises in real time [19-22]. Each session lasted about 30 minutes, 3 times per week, for a total of 36 sessions over 12 weeks according to clinical guidelines [23-27].

Cognitive Behavioral Therapy (CBT)

The digital rehabilitation app delivers eight micro-lessons designed to reduce postoperative chronic pain and psychological stress. Each lesson lasts 15 - 20 minutes and is completed once per week during the first 8 weeks of training. Licensed therapists created the curriculum with reference to clinical protocols. The lessons progress through the following topics:

- Pain education: explaining that pain is not always proportional to tissue damage
- Cognitive restructuring: recognizing and correcting negative thought patterns
- Daily routine planning: helping patients establish balanced activity and rest schedules
- Sleep management: addressing postoperative insomnia or poor sleep quality
- Stress regulation: mitigating anxiety, fear, and feelings of helplessness
- Goal maintenance: reinforcing intrinsic motivation for long-term recovery.

After completing each lesson, patients complete an interactive homework assignment and write an electronic diary. Licensed therapists review submissions online each week and provide feedback within 24 hours, thereby fostering patients' self-management skills.

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Posture Monitoring

Patients in the digital rehabilitation group were instructed to wear a 9-axis IMU on the forehead for real-time tracking of cervical flexion and rotation. The device had to be worn for more than 4 hours per day during waking activities. If forward flexion exceeded or axial rotation surpassed a preset range, the app sent an alert. Each day, the software generated a posture-monitoring report and uploaded it to the cloud for therapist review. If no data were received for 48 hours, the system issued an automatic reminder to the patient, followed by a therapist phone check-in to improve engagement [28-31].

Completion Criteria

Within the digital rehabilitation arm, patients were classified as either the DCG or the DNG according to the following criteria:

Exercise compliance: all 36 scheduled sessions had to be completed. Each session required every prescribed exercise to be completed.

CBT compliance: all 8 CBT micro-lessons had to be viewed, with the associated homework submitted.

Posture-monitoring compliance: the IMU had to be worn for ≥4 hours per day, on ≥70% of the total days for the 12-week digital program [32-34].

Every DCG patient completed the full set of 36 sessions and met the CBT and posture-monitoring requirements. By contrast, most DNG participants discontinued the program early and did not meet completion criteria.

Outcome Measures

Primary Outcomes

Primary outcomes included pain intensity, assessed with a visual analog scale (VAS), and neck-specific disability, assessed with the neck disability index (NDI). These measures are well validated in cervical spine disease populations [35]. We measured both outcomes at 0, 12, and 24 weeks postoperatively to capture the longitudinal course of pain relief and functional recovery.

Secondary Outcomes

Psychological Health

Psychological health was assessed with the mental component summary (MCS) of the 36-item short form survey (SF-36) [36]. Higher MCS values indicate better mental well-being. Participants complete the SF-36 at 0, 12, and 24 weeks after surgery, allowing us to track the trajectory of postoperative psychological adjustment alongside physical recovery.

Objective Kinematics

Cervical mobility was quantified as active range of motion (ROM) in 3 anatomical planes—flexion, extension, lateral bending, and axial rotation—using a handheld digital inclinometer. After a standardized warm-up, each participant performs 3 maximal pain-free movements per plane; the mean of the 3 trials is recorded at 0, 12, and 24 weeks to document changes in kinematics over time.

Muscle Endurance

Cervical flexor and extensor endurance was measured with standardized supine and prone hold tests as described by Harris et al [37]. For the flexor assessment, the participant was in a supine position, lifted their heads upwards, and maintained this posture until they felt fatigued. The duration of the test was measured in seconds. For the extensor assessment, positioned in a prone posture, participants suspended their necks in the air with a weight attached (2 kg for males, 1 kg for females) and maintained the neck parallel to the ground until they felt fatigued. The assessments were performed 3 times, and the mean of the 3 trials is recorded at 0, 12, and 24 weeks, providing an objective measure of muscular performance during rehabilitation.

Patient Experience

Overall patient experience was evaluated once, at 24 weeks, using the Chinese Patient Satisfaction Questionnaire–Revised (PSQ-R) [38]. Each item is rated on a 5-point Likert scale, with higher scores indicating greater satisfaction. Administering the PSQ-R after the full intervention period captures patients' comprehensive impressions of care quality and rehabilitation effectiveness.

Statistical Analysis

All statistical analyses were performed using SPSS software (version 29.0; IBM Corp). Descriptive statistics for baseline characteristics were reported as mean (SD) for continuous variables or number (%) for categorical variables. Between-group comparisons for continuous variables were conducted using independent-sample 2-tailed *t* tests under the assumption of normality. Categorical variables were compared using χ^2 tests. Primary outcomes (VAS and NDI) and secondary outcomes (SF-36 MCS, cervical ROM, muscle endurance) were assessed at baseline (0 week), 12 weeks, and 24 weeks postoperatively. Results were presented as means, SDs, and 95% CIs. Pairwise group comparisons between the DCG, DNG, and IRG were conducted at each time point using independent-sample 2-tailed *t* tests. A *P* value less than .05 was considered statistically significant.

Ethical Considerations

This study was supported by CAMS Innovation Fund for Medical Sciences (CIFMS; Grant No. 2023-I2M-C&T-B-002) and the National High-Level Hospital Clinical Research Funding (Grant No. 2022-PUMCH-A-123). The protocol adhered to the principles of the Declaration of Helsinki and was reviewed and approved by the Ethics Committee of Peking Union Medical College Hospital, Chinese Academy of Medical Sciences (approval No. I-25PJ0581). Written informed consent was obtained from all participants prior to enrollment. All personal data were coded and deidentified to ensure participant privacy and data security. No financial or other compensation was offered to participants.

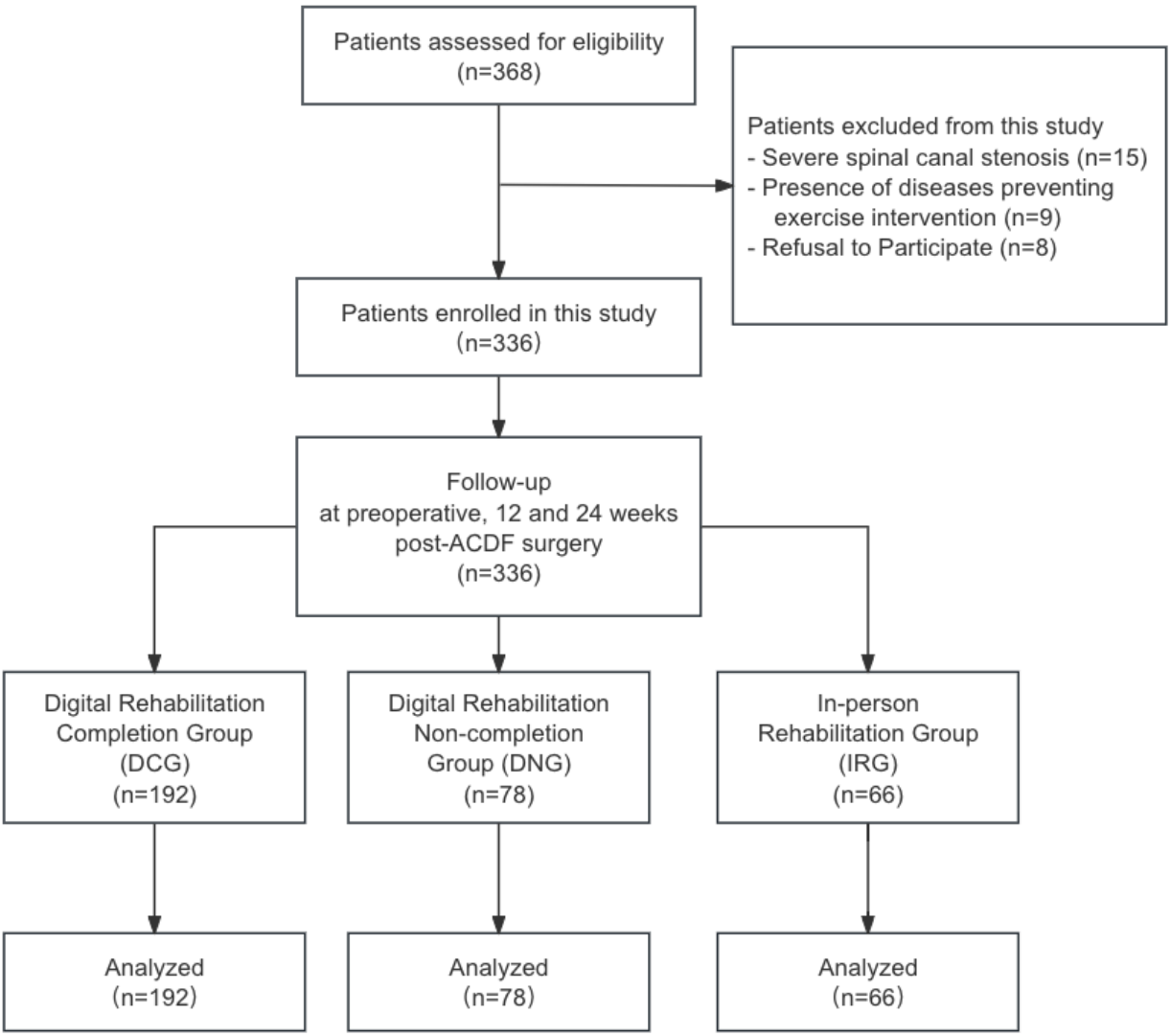
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Results

Participant Characteristics

Between January and December 2023, we screened 368 candidates for the study. Fifteen were excluded because of severe spinal-canal stenosis, 9 because of comorbid conditions that limited exercise, and 8 declined participation. The remaining 336 patients met all criteria and completed the baseline assessment (Figure 3). All were followed longitudinally and allocated to one of 3 cohorts according to actual rehabilitation uptake: 192 in the DCG, 78 in the DNG, and 66 in the IRG.

Figure 3. Experimental protocol.



Baseline demographic and neurological profiles were well matched. Mean age was 54.3 (10.1) years in the DCG, 54.1 (9.7) years in the DNG, and 53.4 (9.5) years in the IRG. Women accounted for 50%, 52%, and 51% of each group, respectively. On preoperative neurological examination, the prevalence of unilateral radicular pain was similar (56%, 59%, and 57%, respectively), as was bilateral radicular pain (13%, 14%, and 15%). Rates of muscle weakness (57%, 55%, and 56%), sensory deficit (43%, 45%, and 44%), and a positive upper-limb traction test (80%, 77%, and 78%) also showed no meaningful differences. These findings confirm baseline comparability among the 3 groups (Table 1).

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Table . Baseline patient characteristics for the 3 groups.

Description	DCG[a] (n=192)	DNG[b] (n=78)	IRG[c] (n=66)
Age (years), mean (SD)	54.3 (10.1)	54.1 (9.7)	53.4 (9.5)
Patient sex, n (%)			
Male	96 (50)	37 (48)	32 (49)
Female	96 (50)	41 (52)	34 (51)
Neurological examination, n (%)			
Unilateral nerve root pain	107 (56)	46 (59)	38 (57)
Bilateral nerve root pain	25 (13)	11 (14)	10 (15)
Motor dysfunction	109 (57)	43 (55)	37 (56)
Sensory disturbance	82 (43)	35 (45)	29 (44)
Upper limb tension test	154 (80)	60 (77)	52 (78)

[a]DCG: digital rehabilitation completion group.

[b]DNG: digital rehabilitation noncompletion group.

[c]IRG: in-person rehabilitation group.

Primary Outcomes

Pain Intensity (Visual Analog Scale [VAS])

At 12 weeks postoperation, mean VAS scores changed by −2.5 points in the DCG (95% CI −3.0 to −2.0) and by −2.9 points in the IRG (95% CI −3.8 to −2.0). In contrast, the DNG showed only a −0.8 point change (95% CI −1.6 to 0.0). By 24 weeks, the pain had decreased in both completion groups, −4.0 points in the DCG (95% CI −4.5 to −3.5) and −4.1 points in the IRG (95% CI −5.0 to −3.2). The difference between these 2 groups was not significant (P=.82), yet both outperformed the DNG, which changed by just −1.3 points (95% CI −2.1 to −0.5) (Table 2).

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Table . Pain and functional outcomes.

Outcomes and groups	Baseline (0-wk)	*P* value[a]	12-wk, mean (SD)	Δ12-wk[b] (95% CI)	*P* value[a]	24-wk, mean (SD)	Δ24-wk[c] (95% CI)	*P* value[a]
VAS (0 - 10)								
DCG[d]	6.1 (3.1)	DCG[d]/IRG[e]: .83	3.6 (1.3)	–2.5 (–3.0 to –2.0)	DCG[d]/IRG[e]: .56	2.1 (2.2)	–4.0 (–4.5 to –3.5)	DCG[d]/IRG[e]: .46
DNG[f]	6.2 (2.9)	DCG[d]/DNG[f]: .80	5.4 (2.1)	–0.8 (–1.6 to 0.0)	DCG[d]/DNG[f]: <.001	4.9 (2.2)	–1.3 (–2.1 to –0.5)	DCG[d]/DNG[f]: <.001
IRG[e]	6.0 (3.3)	IRG[e]/DNG[f]: .70	3.2 (1.9)	–2.8 (–3.7 to –1.9)	IRG[e]/DNG[f]: <.001	1.9 (1.8)	–4.1 (–5.0 to –3.2)	IRG[e]/DNG[f]: <.001
NDI (0 - 100)								
DCG[d]	38.2 (22.1)	DCG[d]/IRG[e]: .95	31.4 (11.3)	–6.8 (–10.3 to –3.3)	DCG[d]/IRG[e]: .54	24.9 (18.2)	–13.3 (–17.4 to –9.2)	DCG[d]/IRG[e]: .80
DNG[f]	37.5 (22.3)	DCG[d]/DNG[f]: .81	35.3 (14.6)	–2.2 (–8.2 to 3.8)	DCG[d]/DNG[f]: .04	31.1 (19.1)	–6.4 (–13.0 to 0.2)	DCG[d]/DNG[f]: .02
IRG[e]	38.4 (21.8)	IRG[e]/DNG[f]: .80	30.3 (13.1)	–8.1 (–14.3 to –1.9)	IRG[e]/DNG[f]: .03	24.2 (19.3)	–14.2 (–21.3 to –7.1)	IRG[e]/DNG[f]: .03
SF-36 MCS								
DCG[d]	37.3 (23.8)	DCG[d]/IRG[e]: .84	46.3 (25.8)	9.0 (4-14)	DCG[d]/IRG[e]: <.001	58.7 (14.9)	+21.4 (17.4 to 25.4)	DCG[d]/IRG[e]: <.001
DNG[f]	36.8 (23.9)	DCG[d]/DNG[f]: .88	37.9 (23.4)	+1.1 (–6.4 to 8.6)	DCG[d]/DNG[f]: .001	44.6 (18.7)	+7.8 (–1.0 to 14.6)	DCG[d]/DNG[f]: <.001
IRG[e]	36.6 (24.2)	IRG[e]/DNG[f]: .96	41.7 (24.4)	+5.1 (–3.3 to 13.5)	IRG[e]/DNG[f]: .34	49.5 (16.4)	+12.9 (5.8 to 20.0)	IRG[e]/DNG[f]: .09

[a]*P* value: the significance level was set at *P*<.05

[b]Δ12wk: difference of change between baseline and the 12th week's outcome

[c]Δ24wk: difference of change between baseline and the 24th week's outcome

[d]DCG: digital rehabilitation completion group.

[e]IRG: in-person rehabilitation group.

[f]DNG: digital rehabilitation noncompletion group.

Neck-Specific Disability (Neck Disability Index [NDI])

At the 12-week assessment, NDI scores changed by −6.8 points in the DCG (95% CI −10.3 to −3.3) and by −8.1 points in the IRG (95% CI −14.3 to −1.9), whereas the DNG changed by only −2.2 points. By week 24, the changes were even greater, −13.3 points in the DCG (95% CI −17.4 to −9.2) and −14.2 points in the IRG (95% CI −21.3 to −7.1). These two groups did not differ significantly (*P*=.46), but both had greater changes than DNG's −6.4 points (95% CI −13.0 to 0.2) (Table 2).

Secondary Outcomes

Psychological Health (SF-36 Mental Component Summary [MCS])

At Week 12, the DCG showed a 9-point rise in MCS (95% CI 4.0 - 14.0), whereas the IIRG improved by 5.1 points (95% CI –3.3 to 13.5). The DNG gained only 1.1 points (95% CI –6.4 to 8.6). By Week 24, the DCG's benefit widened to 21.4 points (95% CI 17.4 - 25.4), significantly surpassing the IRG's 12.9-point increase (95% CI 5.8 - 20.0; between-group *P*<.05) and the DNG's 7.8-point change (95% CI –1.0 to 14.6; between-group *P*<.05) (Table 2).

Cervical Range of Motion (ROM)

Sagittal Plane (Flexion–Extension)

At postoperative 0 week, sagittal plane ROM was similar across groups with no statistically significant differences. At 12 weeks, sagittal ROM improved from 78.7° to 94.4° in the DCG, from 77.3° to 83.4° in the DNG, and from 77.9° to 93.2° in the IRG. The corresponding gains were 15.7° (95% CI 14.1-17.3), 6.1° (95% CI 3.6-8.6), and 15.3° (95% CI 12.7-17.9), respectively. By Week 24, DCG and IRG further improved to 102.4° and 104.5°, while DNG reached 89.2°. Between-group differences were statistically significant for DCG versus DNG and IRG versus DNG at both time points (*P*<.001).

Coronal Plane (Lateral Bending)

At postoperative 0 weeks, coronal plane ROM was similar across groups with no statistically significant differences. Coronal ROM increased from 56.7° to 69.8° in DCG, 57.4° to 63.8° in DNG, and 55.9° to 68.2° in IRG at 12 weeks, with corresponding gains of 13.1°, 6.4°, and 12.3°. By Week 24, DCG reached 76.1°, IRG 77.5°, and DNG 67.2°, with continued

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between-group significance favoring DCG and IRG over DNG (P<.001) (Table 3).

Table . Cervical spine range-of-motion and neck-muscle endurance outcomes.

Outcomes and groups	Baseline	*P* value[a]	12-week, mean (SD)	Δ12-week[b] (95% CI)	*P* value[a]	24-week, mean (SD)	Δ24-week[c] (95% CI)	*P* value[a]
Sagittal ROM[d] (°)								
DCG[e]	78.7 (6.1)	DCG[e]/IRG[f]: .32	94.4 (9.4)	15.7 (14.1-17.3)	DCG[e]/IRG[f]: .36	102.4 (8.4)	23.7 (22.3-25.3)	DCG[e]/IRG[f]: .11
DNG[g]	77.3 (6.4)	DCG[e]/DNG[g]: .10	83.4 (9.1)	6.1 (3.6-8.6)	DCG[e]/DNG[g]: <.001	89.2 (12.7)	11.9 (8.7-15.1)	DCG[e]/DNG[g]: <.001
IRG[f]	77.9 (5.5)	IRG[f]/DNG[g]: .54	93.2 (9.3)	15.3 (12.7-17.9)	IRG[f]/DNG[g]: <.001	104.5 (9.6)	26.6 (23.9-29.3)	IRG[f]/DNG[g]: <.001
Coronal ROM (°)								
DCG[e]	56.7 (6.5)	DCG[e]/IRG[f]: .38	69.8 (7.1)	13.1 (11.7-14.5)	DCG[e]/IRG[f]: .36	76.1 (4.3)	19.4 (18.3-20.5)	DCG[e]/IRG[f]: .21
DNG[g]	57.4 (7.1)	DCG[e]/DNG[g]: .45	63.8 (5.9)	6.4 (4.3-8.5)	DCG[e]/DNG[g]: <.001	67.2 (5.3)	9.8 (7.8-11.8)	DCG[e]/DNG[g]: <.001
IRG[f]	55.9 (6.3)	IRG[f]/DNG[g]: .18	68.2 (6.7)	12.3 (10.1-14.5)	IRG[f]/DNG[g]: <.001	77.5 (8.6)	21.6 (19-24.2)	IRG[f]/DNG[g]: <.001
Horizontal ROM (°)								
DCG[e]	108.5 (5.3)	DCG[e]/IRG[f]: .22	123.2 (9.5)	14.7 (13.2-16.2)	DCG[e]/IRG[f]: .10	128.2 (12.4)	19.7 (17.8-21.6)	DCG[e]/IRG[f]: .34
DNG[g]	109.7 (5.9)	DCG[e]/DNG[g]: .12	115.4 (12.2)	5.7 (2.7-8.7)	DCG[e]/DNG[g]: <.001	118.9 (15.3)	9.2 (5.5-12.9)	DCG[e]/DNG[g]: <.001
IRG[f]	109.4 (5.0)	IRG[f]/DNG[g]: .74	126.3 (14.1)	16.9 (13.3-20.5)	IRG[f]/DNG[g]: <.001	130.1 (14.3)	20.7 (17-24.4)	IRG[f]/DNG[g]: <.001
Ventral endurance								
DCG[e]	43.4 (9.3)	DCG[e]/IRG[f]: .52	48.1 (5.1)	4.7 (3.2-6.2)	DCG[e]/IRG[f]: .08	55.2(4.2)	11.8 (10.4-13.2)	DCG[e]/IRG[f]: .62
DNG[g]	42.4 (8.8)	DCG[e]/DNG[g]: .41	45.3 (5.0)	2.9 (0.6-5.2)	DCG[e]/DNG[g]: <.001	48.4 (3.8)	6.0 (3.9-8.1)	DCG[e]/DNG[g]: <.001
IRG[f]	44.2 (8.4)	IRG[f]/DNG[g]: .21	49.5 (5.8)	5.3 (2.8-7.8)	IRG[f]/DNG[g]: <.001	55.6 (6.1)	11.4 (8.9-13.9)	IRG[f]/DNG[g]: <.001
Dorsal endurance (s)								
DCG[e]	75.8 (3.9)	DCG[e]/IRG[f]: .48	85.2 (4.2)	9.4 (8.6-10.2)	DCG[e]/IRG[f]: .71	90.6 (6.3)	14.8 (13.7 to 15.9)	DCG[e]/IRG[f]: .75
DNG[g]	76.8 (6.3)	DCG[e]/DNG[g]: .20	79.4 (6.9)	2.6 (0.5-4.7)	DCG[e]/DNG[g]: <.001	80.4 (6.7)	3.6 (1.5 to 5.7)	DCG[e]/DNG[g]: <.001
IRG[f]	75.2 (6.6)	IRG[f]/DNG[g]: .14	84.8 (8.4)	9.6 (7-12.2)	IRG[f]/DNG[g]: <.001	90.3 (6.7)	15.1 (12.8-17.4)	IRG[f]/DNG[g]: <.001

[a]*P* value: the significance level was set at P<.05.

[b]Δ12 week: difference of change between baseline and the 12th week's outcome.

[c]Δ24 week: difference of change between baseline and the 24th week's outcome.

[d]ROM: range of motion.

[e]DCG: digital rehabilitation completion group.

[f]IRG: in-person rehabilitation group.

[g]DNG: digital rehabilitation noncompletion group.

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Horizontal Plane (Axial Rotation)

At postoperative 0 week, horizontal plane ROM was similar across groups with no statistically significant differences. Horizontal ROM improved from 108.5° to 123.2° in DCG, 109.7° to 115.4° in DNG, and 109.4° to 126.3° in IRG by week 12, and further to 128.2° (DCG), 118.9° (DNG), and 130.1° (IRG) by Week 24. Between-group comparisons at both time points showed significant advantages for DCG and IRG over DNG (P<.001) (Table 3).

Cervical Flexor and Extensor Endurance

Ventral Endurance (Deep Flexor Muscles)

At baseline, deep-flexor endurance was similar across groups: DCG 43.4 (9.3)s, DNG 42.4 (8.8)s, and IRG 44.2 (8.4)s (all P>.40). By Week 12, endurance improved to 48.1 (5.1)s in the DCG, 45.3 (5.0)s in the DNG, and 49.5 (5.8)s in the IRG. The increases from baseline were 4.7s (95% CI 3.2-6.2), 2.9 (95% CI 0.6-5.2), and 5.3 (95% CI 2.8-7.8), respectively. Between-group comparisons showed significant differences between DCG and DNG (P<.001) and IRG and DNG (P<.001), but not between DCG and IRG (P=.08).

At Week 24, endurance further increased to 55.2 (4.2)s in the DCG and 55.6 (6.1)s in the IRG, compared to 48.4 (3.8)s in the DNG. Improvements were 11.8s (95% CI 10.4- 13.2), 11.4s (95% CI 8.9-13.9), and 6.0s (95% CI 3.9-8.1), respectively, with sustained significance for DCG versus DNG and IRG versus DNG (both P<.001) (Table 3).

Dorsal Endurance (Extensor Muscles)

At baseline, extensor endurance was also comparable: DCG 75.8 (3.9)s, DNG 76.8 (6.3)s, IRG 75.2 (6.6)s (P >.10). At Week 12, the values increased to 85.2 (4.2)s (DCG), 79.4s (6.9)s (DNG), and 84.8s (8.4)s (IRG), with corresponding gains of 9.4, 2.6, and 9.6.

At Week 24, endurance rose to 90.6 (6.3)s (DCG), 80.4 (6.7)s (DNG), and 90.3 (6.7)s (IRG). The improvements from baseline were 14.8s (95% CI 13.7-15.9s), 3.6s (95% CI 1.5-5.7s), and 15.1s (95% CI 12.8-17.4s), respectively. DCG and IRG both significantly outperformed DNG (P<.001), while DCG and IRG remained comparable (P=.75) (Table 3).

Patient Satisfaction (PSQ-R)

At Week 24, patient-reported satisfaction was high and comparable between the DCG and the IRG: DCG, 95.7 (6.1) (95% CI 94.8 - 96.6) versus IRG, 95.9 (6.5) (95% CI 94.3 - 97.5); P=.83. The DNG averaged 84.3 (7.9) (95% CI 82.5 - 86.1). Satisfaction in the DNG was lower than in the DCG (P<.001) and IRG (P<.001), reaching statistical significance (Table 4).

Table . Patient satisfaction at 24 weeks (PSQ-R).

Group	24-week, mean (SD)	95% CI	P value[a]
DCG[b] (n=192)	95.7 (6.1)	94.8 - 96.6	DCG[b]/IRG[c]: .83
DNG[d] (n=78)	84.3 (12.9)	82.5 - 86.1	DCG[b]/DNG[d]: <.001
IRG[c] (n=66)	95.9 (6.5)	94.3 - 97.5	IRG[c]/DNG: <.001

[a]P value: the significance level was set at P<.05.

[b]DCG: digital rehabilitation completion group.

[c]IRG: in-person rehabilitation group.

[d]DNG: digital rehabilitation noncompletion group.

Discussion

Principal Findings

We enrolled 336 patients who underwent ACDF and compared 3 rehabilitation strategies—a complete digital program, conventional in-person physiotherapy, and an incomplete digital program—at 12 and 24 weeks. Patients who finished the digital program (DCG) achieved pain (VAS) and neck-specific disability (NDI) reductions comparable to those in the in-person group (IRG) and superior to those in the digital group who did not complete the program (DNG). Changes in 3-plane cervical range of motion and in flexor/extensor muscle endurance were greater in both DCG and IRG than in the DNG. The DCG also reported the largest improvement in mental health (SF-36 MCS). Patient satisfaction remained high and similar between the DCG and IRG groups, whereas inadequate compliance in DNG substantially weakened treatment benefits.

Digital Rehabilitation for Functional Recovery

This study validated the effectiveness of a digital rehabilitation program in facilitating functional recovery following ACDF surgery. At 24 weeks postsurgery, the DCG demonstrated superior improvements in cervical spine mobility across sagittal, coronal, and horizontal planes compared to the DNG, with a range of motion improved reaching 23.7 degrees, 19.4 degrees, and 19.7 degrees for DCG versus 11.9 degrees, 9.8 degrees, and 9.2 degrees for DNG, respectively. Moreover, significant improvements in neck muscle endurance were observed in the DCG, for anterior and posterior muscle groups at 11.8 seconds and 14.8 seconds, respectively, compared to 6 seconds and 3.6 seconds in the DNG. A notable reduction in the NDI of 13.3 for DCG and 6.4 for DNG was also documented, further showing the digital rehabilitation program's effect in promoting cervical spine functional recovery.

This study highlighted the effectiveness of combining computer vision-guided exercises with sensor-based monitoring to deliver precise rehabilitation guidance postsurgery. The computer vision-guided approach allowed the physician to monitor

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whether patients completed the exercises correctly and detected when there was difficulty performing an exercise. By providing precise and real-time feedback via computer vision, the digital program allows the physician to monitor the patient remotely and to adjust the intensity of the exercise, ensuring that patients are engaged in suitable exercises, therefore improving the effectiveness of the rehabilitation process. The wearable sensor further monitored patient behavior to correct postures, which could facilitate recovery. These findings are consistent with previous studies that showed digital rehabilitation is comparable to traditional rehabilitation methods in terms of effectiveness [39]. This is further supported by DCG and IRG demonstrating similar outcomes, both superior to DNG, showcasing the potential of technology-enhanced programs to offer more customized and flexible patient management solutions [40].

Cognitive Behavioral Therapy for Pain Management

Additionally, this study evaluated the impact of integrating CBT into a digital rehabilitation program to improve pain management and psychological health. The usage of a digital platform for CBT delivery allowed the patients to have continuous access to pain management content and strategies, irrespective of physical location or mobility restrictions. The digital program taught patients how to manage postsurgical pain and educated patients to focus on breathing exercises and guided exercises to decrease pain. The results showed that a notable reduction in the VAS pain score of 4.1 for DCG by the 24th week, compared to 1.3 for the DNG. This finding is consistent with previous studies that demonstrated CBT techniques, such as cognitive restructuring and coping strategy enhancement, significantly reduce pain intensity and distress associated with pain conditions [36]. This is consistent with the gate control theory of pain, which proposes that when non-nociceptive input predominates, such as tactile stimulation or other sensory modalities, the perception of pain is reduced [40]. Moreover, the emphasis on behavior modification strategies, encouraging active engagement in exercise and social activities, resonates with previous work that found lifestyle modifications play a vital role in mitigating the influence of pain on daily functioning and overall quality of life [41]. These findings demonstrate the importance of the cognitive-behavioral component of pain management.

Improved Patient Satisfaction

This study's findings showed that patients in the DCG reported high satisfaction scores comparable to those in the IRG, with scores of 95.7 and 95.9, respectively. In contrast, the DNG reported a significantly lower satisfaction score of 84.3 points. The higher patient satisfaction observed in both the DCG and IRG for cervical spine rehabilitation post-ACDF was potentially caused by several key factors. The digital rehabilitation program tailored the rehabilitation plans to individual needs and introduced the convenience of undergoing therapy at home, the ease of access, and personalization potentially improved patient satisfaction. This is supported by previous studies that highlighted digital health programs in promoting patient engagement and satisfaction by leveraging the convenience and flexibility of technology-based solutions [42].

Moreover, the interactive software used in the digital rehabilitation program made rehabilitation exercises more engaging and interactive, similar to gameplay. The incorporation of interactive experiences within the digital rehabilitation program introduces patient satisfaction in the rehabilitation process, a factor that not only aids in maintaining high levels of patient compliance but also enriches the psychological well-being of patients undergoing treatment [43,44]. This finding is similar to previous research, which asserts that the interactive components of digital health programs contribute to positive patient experiences and outcomes [45]. These elements together contribute to the overall increase in patient satisfaction.

Mental Health

The SF-36 MCS results highlight the impact of the rehabilitation types on mental health post-ACDF cervical spine rehabilitation. Over the 24 weeks, the DCG and IRG saw significant mental health improvements, with scores rising of 21.4 and 12.9 points, respectively. The DNG showed a moderate improvement of 7.8 points. This is consistent with previous studies that showed digital rehabilitation platforms, particularly those incorporating cognitive-behavioral strategies, have a significant positive impact on mental health [46]. The improved mental health score could be due to the comprehensive approach of these systems. Particularly in digital rehabilitation, the inclusion of CBT provides essential psychological support, directly contributing to mental health improvements. Also, software increases the patient education frequency, which could have a more profound impact on the patient's mental health improvement. This is in contrast with the standard of care patient education, which solely focused on postoperative wound care and joint function training, which did not address the mental well-being of the patient.

Clinical Implications of Digital Rehabilitation

Our study shows that patients who completed the 12-week digital rehabilitation program experienced pain relief, functional gains, and improvements in three-plane cervical range of motion and muscle endurance that matched those achieved through conventional, clinic-based therapy at both 12 and 24 weeks after ACDF. In addition, the digital group reported better mental health scores and higher satisfaction, whereas participants with poor adherence realized only modest improvements. These findings reinforce earlier telerehabilitation research indicating that smartphone- and wearable-based interventions can equal in-person physiotherapy in clinical effectiveness while offering greater accessibility and adherence [5,47].

The platform we evaluated combines computer-vision motion analysis, inertial-sensor posture monitoring, and brief CBT modules within a single mobile app. This training-and-feedback loop provides patients with real-time corrective cues and allows licensed clinicians to remotely review performance data and provide feedback to the patients. The CBT component addresses postoperative mood and motivation, thereby supporting sustained engagement [48]. High satisfaction and completion rates in the DRG further attest to the platform's ability to keep users actively involved [6,49].

From a health services perspective, digital rehabilitation offers several advantages. First, clinicians can monitor recovery more

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frequently without requiring patients to make repeated clinic visits, reducing travel time and associated costs. Second, continuous data captured by the software enables providers to identify early signs of nonadherence or postoperative psychological distress and intervene promptly. Finally, because its underlying technologies are disease-agnostic, a similar framework can be applied to other musculoskeletal diseases, providing a scalable template for modernizing postoperative rehabilitation care.

Limitations

This investigation was conducted at a single, high-volume tertiary medical center, which may limit geographic and institutional generalizability; however, the center's standardized surgical pathways and comprehensive follow-up enhance internal validity and provide a benchmark for future multicenter studies. Second, rehabilitation modality was determined by participant preference rather than random allocation, introducing the possibility of selection bias. Third, although patients who underwent multilevel fusion were excluded to ensure surgical homogeneity, the resulting cohort offers a clear view of single-level ACDF recovery and establishes a foundation for subsequent work in more complex cases. These considerations suggest that in the future, randomized and multicenter clinical trials can extend the present findings to broader patient populations and surgical scenarios.

Conclusions

This investigation demonstrates that a 12-week digital rehabilitation program delivers postoperative pain relief and functional recovery comparable to conventional, clinic-based therapy following ACDF. Beyond matching these core outcomes, the digital pathway confers additional advantages in psychological well-being and maintains high levels of patient-reported satisfaction. By combining computer-vision–guided exercise, wearable sensor monitoring, and embedded cognitive-behavioral support, the platform enables effective remote rehabilitation for ACDF patients. High compliance translates directly into greater clinical benefit, underscoring engagement as a pivotal determinant of success in remote care models. These findings support digital rehabilitation as a clinically effective, resource-efficient, and patient-centered option for postoperative rehabilitation, with potential for broader applications in musculoskeletal care.

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Data Availability

Data is deposited in publicly available repositories (where available and appropriate).

Authors' Contributions

SL and XC performed data curation and validation. SL and DL conducted formal analysis. DL and CYL contributed to methodology and visualization. YC handled project administration. SC conceptualized the study and supervised writing—review and editing. SL wrote the original draft.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Digital rehabilitation program exercise protocol for patients after anterior cervical discectomy and fusion.
[DOCX File, 937 KB - rehab_v12i1e60717_app1.docx]

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Exploring Rehabilitation Patients' Perspectives on What Matters for the Adoption of Home-Based Rehabilitation Technology: Q-Methodology Study

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Abstract

Background: Rehabilitation technologies can support recovery and rehabilitation outside clinical settings. However, their adoption remains challenging. Factors such as ease of use, perceived benefits, and social influence play a role, but little is known about how rehabilitation patients perceive their relative importance.

Objective: This study aimed to systematically explore the viewpoints of rehabilitation patients regarding the adoption of home-based rehabilitation technology.

Methods: Between May and September 2024, this study examined the viewpoints of rehabilitation patients with acquired brain injury regarding the adoption of home-based rehabilitation technology using Q-methodology. A purposive sample of 21 participants ranked 34 opinion statements based on perceived importance and explained their choices during follow-up interviews. By-person factor analysis identified common patterns in how participants ranked the statements. These patterns, referred to as factors or viewpoints, were further interpreted using qualitative interview data.

Results: Three viewpoints were identified, each highlighting different factors important for adopting home-based rehabilitation technology: (1) technology supporting rapid recovery, (2) technology supporting independence and self-control, and (3) technology as a supporting partner. Participants consistently emphasized the importance of regaining independence, receiving feedback during exercises, simple and easy-to-use designs, and approval from therapists, while positive reports in mainstream media, support from friends, and reducing travel to rehabilitation centers were considered less important.

Conclusions: The findings suggest that rehabilitation patients with acquired brain injury prioritize different factors when adopting home-based rehabilitation technology. While some factors are commonly valued, the diversity in patient viewpoints underscores the need for tailored, user-centered approaches in the design and implementation of these technologies. A one-size-fits-all approach would likely be ineffective in meeting their varying needs.

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KEYWORDS

home-setting; rehabilitation technology; Q-methodology; technology acceptance; acquired brain injury; patient views; home-based rehabilitation technology

Introduction

Rehabilitation technology is a rapidly growing field in both research and clinical practice [1,2]. These technologies encompass tools and devices designed to support individuals in improving or regaining physical, cognitive, psychological, or social functioning following injury or illness [3]. They offer several benefits, such as enabling home-based training [4,5], reducing the workload of health care professionals [6], and accelerating recovery through increased therapy intensity and patient engagement [4,5,7]. However, their adoption in home settings remains challenging, with abandonment rates reaching up to 80% [8,9].

The reasons for abandonment are multifaceted and often stem from a mismatch between users' needs and preferences and the available technology [10-14]. The technology may not always address users' needs, and as those needs evolve, initially suitable technologies may become inadequate [13]. This highlights the necessity of user-centered approaches in the development of home-based rehabilitation technology [10,11]. Incorporating

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users' perspectives throughout the development process is considered essential for improving usability and adoption rates.

The unified theory of acceptance and use of technology (UTAUT) [15] is a framework that can provide insights into users' perspectives regarding technology adoption. UTAUT synthesizes elements from 8 established models, including the theory of reasoned action [16], the theory of planned behavior [17], and the technology acceptance model [18]. While the 8 models individually explain 17% - 42% of the variance in technology acceptance, UTAUT accounts for up to 69% [15], making it a robust framework for understanding technology adoption behavior and informing design and implementation practices.

According to UTAUT, 3 main factors determine the intention to adopt technology: performance expectancy (the perceived benefits), effort expectancy (the ease of use), and social influence (the belief that significant others support its use). This intention, combined with facilitating conditions such as available resources, ultimately determines adoption behavior [15]. These factors may also be influenced by individual characteristics, such as age, sex, education level, and disease severity [15,19-23].

The relative importance of these adoption factors may differ between rehabilitation patients, as each follows a personalized treatment plan based on their specific impairments and goals [24]. Exploring this variation and identifying commonalities are therefore crucial for the effective design and implementation of home-based rehabilitation technology. This study aims to systematically explore the viewpoints of rehabilitation patients using the UTAUT framework and Q-methodology. Specifically, the focus is on rehabilitation patients with acquired brain injury (ABI). With an aging population, the number of patients with ABI requiring rehabilitation is expected to rise, while resources remain limited [25,26]. Home-based rehabilitation technology has the potential to counterbalance this trend, but only if it is successfully and widely adopted. By focusing on the viewpoints of rehabilitation patients with ABI, this study seeks to provide insights that can guide the development and implementation of home-based rehabilitation technology.

Methods

Study Design

A Q-methodology study (Q-study) was conducted. This is a mixed methods approach that enables the systematic examination of experiences and perspectives on a specific topic within a particular population. Participants rank statements on a sorting grid based on their perceived importance or level of agreement, followed by interviews in which they elaborate on their reasoning. The ranked statements are analyzed using by-person factor analysis to identify shared viewpoints, which are then interpreted alongside qualitative interview data to construct a narrative for each viewpoint [27].

Participants and Setting

The study was conducted at Rijndam, a rehabilitation center in Rotterdam, the Netherlands. Eligible participants were aged 18 years or older, diagnosed with ABI, had completed or were still undergoing inpatient or outpatient rehabilitation at Rijndam, and were proficient in Dutch. Prior experience with home-based rehabilitation technology was not required.

Health care professionals at the center informed patients about the study. Interested patients could either schedule an appointment directly or give permission for their health care provider to share their contact details with the first author (KEB), who then contacted them to schedule an appointment. Of the 22 patients who expressed interest, 1 was excluded due to a visual impairment. The final sample included 21 participants.

Participants were purposively selected to ensure maximum diversity of perspectives relevant to the study context. Theoretical saturation was monitored throughout recruitment. No substantially new opinions or opinion statements emerged in the final 3 interviews, indicating that the final sample was sufficient to capture the range of shared viewpoints present in this setting [28].

Statement Development

To explore the full range of possible views on the topic, the statements in a Q-study need to encompass the subject comprehensively [27]. In this study, the statements were developed without a strict definition of specific rehabilitation technology to allow for authentic responses based on participants' own interpretations. However, the scope was limited to technologies used for physical rehabilitation.

A structured approach was used to develop the statements. First, we conducted a review of peer-reviewed literature [10,19,20,29-36] on the acceptance and adoption of rehabilitation technologies, which resulted in 156 (overlapping) verbal statements. These were then organized according to the factors outlined in the UTAUT framework: performance expectancy, effort expectancy, social influence, facilitating conditions, and behavioral intention. Subsequently, the authors KEB, JMC, and SJK reviewed and refined the set of statements, reducing it to 34. Given that patients with ABI often experience cognitive and language impairments [37] and that too many statements could be overwhelming [27], extra care was taken to keep the statements concise while still covering the most important aspects. To ensure the language was accessible, the Dutch "Is het B1?" tool was used to check for B1-level phrasing. The statements were pilot-tested with 2 rehabilitation patients, who were invited to provide feedback on clarity and whether anything important was missing. Neither suggested any changes. Similarly, participants in the main study were asked whether any key points had been overlooked or if anything was unclear. No issues were raised. Table 1 presents the final set of statements.

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Table . Final set of statements and idealized Q-sort for the factors (viewpoints).

Statement		Factor or viewpoint		
		1A[a]	2B[b]	3C[c]
Performance expectancy				
	1. A faster recovery process	4[d]	1[d]	3[d]
	2. Reaching rehabilitation goals more quickly	4	0[d]	3
	3. Control over my own recovery process	0	4[d]	2
	4. The convenience of recovering at home	3	2	0[d]
	5. Flexibility to do exercises whenever I want	−1	4[d]	0
	6. Avoiding travel to the rehabilitation center	−2	−2	−1
	7. Being less dependent on others	1	1	2
Effort expectancy				
	8. Technology that is simple to use	0	0	1
	9. Technology that is quick and easy to understand	1[e]	0	−1
	10. Technology that is ready for immediate use	2	1	−1
	11. Being able to understand the technology without explanation	0	−1	−2
	12. Being able to independently use the technology	1	3[e]	1
	13. Setting up the technology within 5 minutes	2[d]	−1[e]	−2[e]
Social influence				
	14. Approval from my doctor or therapist	1	2	2
	15. Support from family	2[e]	−1	1
	16. Support from friends	−2	−2	−3
	17. Recommendations from peers	−2	−3	1[d]
	18. Positive experiences shared on social media	−4	−4	−4
	19. Positive coverage on television	−4	−4	−2
Facilitating conditions				
	20. Maintaining contact with peers	−3	−3	0[d]
	21. Progress monitored by a physician or therapist	3	2	4[e]
	22. Insight into my own progress	0[d]	3[e]	4[e]
	23. Direct feedback during exercises	3	1[e]	3

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Statement		Factor or viewpoint		
		1A[a]	2B[b]	3C[c]
	24. The ability to compare my progress with peers	−1[d]	−2[d]	1[d]
	25. Rewards for performing exercises well	−2	−2	0[d]
	26. Technology with different levels of difficulty	1	−1[d]	2
	27. Exercises presented in the form of games	−3[d]	0	0
	28. Availability of support for technical issues	0	1[d]	−1
	29. Cost reimbursement for the technology	0	0	−2[e]
	30. Guarantee of my safety	2	3	0[d]
	31. Guarantee of my privacy	−3[e]	2[e]	−4[e]
	32. Limited space required for the technology	−1	−1	−3[d]
Intention to use				
	33. Technology as a supplement to treatment at the rehabilitation center	−1	0	−1
	34. Technology as a partial replacement for treatment at the rehabilitation center	−1[d]	−3	−3

[a]Technology supporting rapid recovery.

[b]Technology supporting independence and self-control.

[c]Technology as a supporting partner.

[d]$P<.01$.

[e]$P<.05$

Data Collection

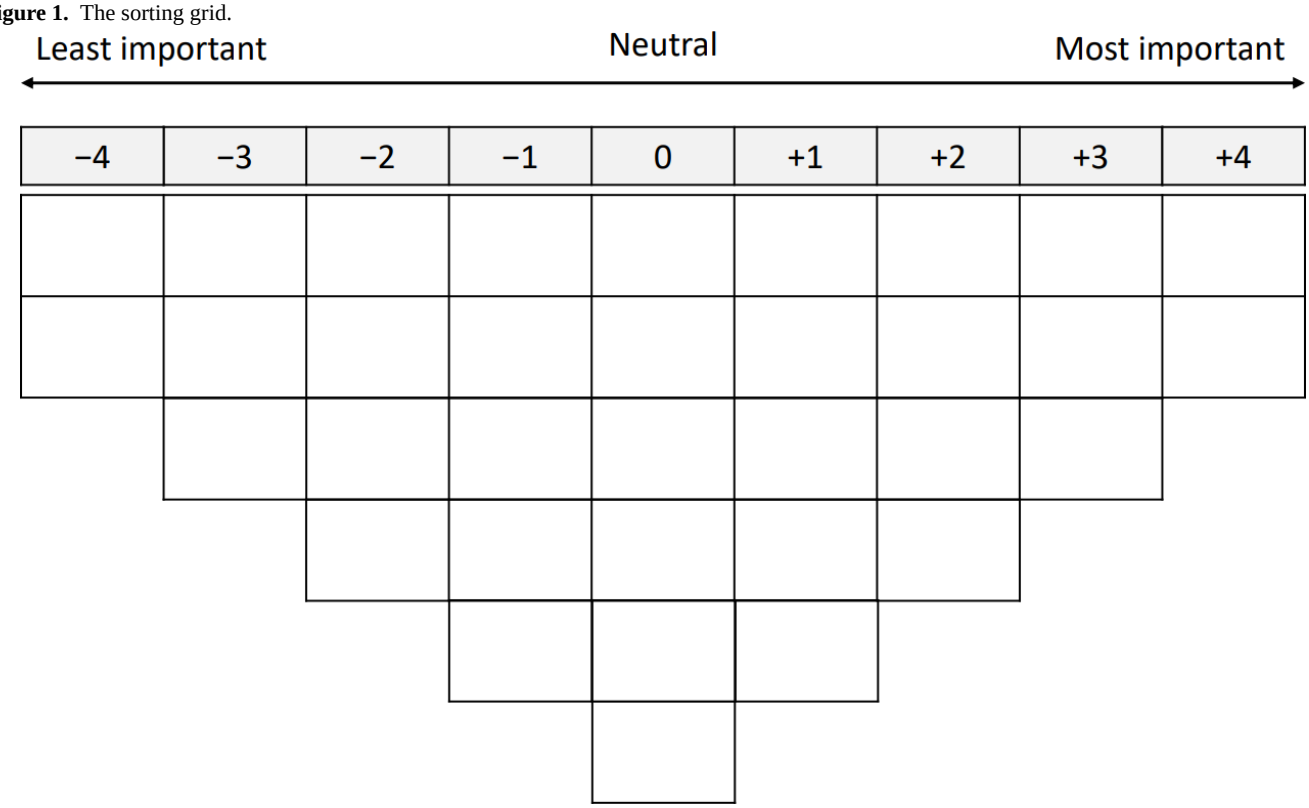
From May to September 2024, the first author (KEB) conducted individual Q-study interviews in person, in Dutch, lasting an average of 41 (SD 13) minutes. Interviews took place either at participants' homes or at the rehabilitation center, depending on their preference. With consent, interviews were audio-recorded to ensure accuracy and for reference purposes.

During the interview, participants were asked to sort the 34 statements into 3 initial piles: "important," "neutral," and "unimportant." Once sorted, the statements were ranked on a sorting grid with a forced-choice frequency distribution ranging from −4=least important to +4=most important (Figure 1). Participants began by selecting the 2 most important statements from the "important" pile and placing them in the +4 column. They then selected 3 slightly less important statements for the +3 column. This process continued until all statements from the "important" pile had been ranked. The same procedure was repeated for the "unimportant" pile, beginning with the −4 column and moving up. Finally, the "neutral" statements were placed in the remaining columns. This process resulted in a fully ranked set of statements, commonly referred to as a Q-sort [27].

After completing the ranking, participants were asked to explain their choices, with particular attention to the statements placed in the extreme columns (+4 and −4). These explanations provided qualitative data that helped contextualize the rankings. All participant comments during the ranking process and explanations were transcribed verbatim for analysis.

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Figure 1. The sorting grid.



Data Analysis

The rankings of the 21 participants were analyzed using by-person factor analysis to identify shared viewpoints on the acceptance of rehabilitation technology. The analysis was conducted using KADE software (version 1.3.1) [38]. Data clusters were identified through centroid factor analysis and varimax rotation, with each cluster representing a potential factor, which in turn represents a potential shared viewpoint among participants. Potential factors were evaluated using 3 criteria: the number of associated participants, applying a significance level of .05 (corresponding to a factor loading of ±0.34); a minimum of 2 participants per factor; and the Kaiser-Guttman criterion, which suggests retaining factors with eigenvalues of 1.0 or higher [27,39]. For each factor, the rankings of associated participants were combined by calculating weighted averages to create an "idealized Q-sort." These idealized Q-sorts illustrate how a typical participant with that viewpoint would rank the statements on the grid [27]. Qualitative data from the interviews were incorporated to contextualize and enhance the understanding of the shared viewpoints. No coding or categorization of the qualitative data was conducted prior to the quantitative analysis. After the quantitative analysis revealed the viewpoints, the qualitative data were categorized accordingly. The reporting of the study adhered to the checklist developed by Dieteren et al [40], ensuring transparency and methodological rigor.

Ethical Considerations

Ethics approval for this study was obtained from the internal review board of Erasmus School of Health Policy & Management, Erasmus University Rotterdam (ETH2324-0759), and all participants provided written informed consent to participate in the study. To support participant understanding, the consent form was written in Dutch at the B1 level and discussed with each patient prior to signing. All data collected were pseudonymized to protect participant privacy and confidentiality. The key linking participant identities to the data was stored separately on a password-protected file, with access restricted to the research team. Participants received a €20 (~23.5 USD) gift card as compensation for their participation.

Results

Overview

In total, 21 individuals participated in the study (Table 2). Only 2 of them had experience with home-based rehabilitation technology, specifically with an app, while the others had no prior experience. The analysis identified 3 factors that represent 3 shared viewpoints, collectively accounting for 54% of the variance. Data from 19 of the 21 participants were included, as 2 Q-sorts were confounded. Viewpoint 1 was supported by 9 participants, viewpoint 2 by 7 participants, and viewpoint 3 by 3 participants. The correlations between the viewpoints were moderate, with coefficients ranging from r=0.47 to r=0.59. The idealized Q-sort for the 3 viewpoints is presented in Table 1.

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Table . Characteristics of participants (N=21).

Characteristics	Values
Sex (female), n (%)	11 (52)
Age (years)	
Mean (SD)	54 (11)
Range	31 - 67
Marital status, n (%)	
Married	10 (47)
Living with a partner	4 (19)
Widowed	1 (5)
Single	6 (29)
Education, n (%)	
Secondary education	2 (10)
Vocational education	9 (43)
Higher education	10 (47)
Rehabilitation phase, n (%)	
Undergoing rehabilitation	14 (67)
Finished rehabilitation	7 (33)
Type of acquired brain injury, n (%)	
Stroke	20 (95)
Brain tumor	1 (5)
Type of impairment, n (%)	
Motor only (wheelchair dependent)	7 (33)
Motor only (not wheelchair dependent)	6 (29)
Motor, cognitive and language (wheelchair dependent)	3 (14)
Language only[a]	1 (5)
Cognitive and language only[a]	4 (19)

[a]Participants who previously experienced motor impairments but have recovered motor function.

Viewpoint 1: Technology Supporting Fast Recovery

In total, 9 participants held viewpoint 1. The majority were male participants (n=6), and 5 had attained higher education qualifications. Of these, 3 lived alone. Motor impairments requiring the use of a wheelchair were reported by 6 participants, and 3 of them also experienced language and cognitive difficulties. An additional 3 participants had motor impairments but did not require a wheelchair. All participants were engaged in rehabilitation.

Participants in this group believed that a faster recovery (statement 1, +4) and the quicker achievement of rehabilitation goals (statement 2, +4) were the most important factors when deciding to use rehabilitation technology at home. They expressed a strong desire to return to activities they had engaged in before their ABI: “I am a teacher and a sculptor. (…) and I need both of my hands for that. I’m hoping for a quick recovery. The sooner, the better” (Participant 11).

This focus on speed also influenced their preferences for technology that could support their recovery. Participants preferred devices that could be set up quickly, ideally within 5 minutes (statement 13, +2), and that were quick and easy to understand (statement 9, +1). They felt that complex or time-consuming setups could lead to frustration, reduced performance, and diminished motivation. Participant 14 explained:

> *If I have to think too much about something, my body doesn’t function as well. It’s either thinking or focusing on my body; I can’t do both at the same time. If the setup of the technology requires too much effort, it takes away from my movement, making it not worth using.*

Additionally, some participants emphasized the importance of simplicity, as they anticipated needing assistance from family members:

> *I can’t do much on my own, so anything I can manage by myself is a bonus. Otherwise, someone else has to*

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> *help me. My girlfriend is usually around, but she's not very good with this sort of thing, so it's helpful if the technology is simple, like having just one button.* [Participant 18]

Participants in this group placed significant value on family support (statement 15, +2), viewing it as essential for both practical help with using rehabilitation technology and emotional reassurance during decision-making. Participant 14 noted: "They influence my choices. It's reassuring to know that they support my decisions and back me up." Some participants mentioned that their family members sought additional information through the media to better understand their conditions and explore solutions. Participant 15 stated:

> *My family influences my decisions; they are important to me. They try to gain more knowledge through social media, but the information they find is often too limited and doesn't apply to my situation.*

Participants often regarded media coverage, whether from television (statement 19, −4) or social media (statement 18, −4), as unreliable and irrelevant to their recovery. They believed that recovery is unique to each individual, which also shaped their aversion to comparing progress with peers (statement 24, −1): "Everyone is unique, and every injury [referring to the aftermath of a stroke] is different, so there is no point in making comparisons" (Participant 19). This perspective also influenced their attitude toward game-like exercises (statement 27, −3), which they often associated with competition against peers. They found this unhelpful and preferred practical exercises: "There can be a competitive element, but it shouldn't be against someone else, as such comparisons are not meaningful" (Participant 21). Participant 14 added: "It's not something I need. While having some variety can be nice, I've gained much more from working hard and focusing on the practical exercises."

Participants in this group expressed minimal concern about safeguarding their privacy (statement 31, −3), believing their data would be secure: "I think it will be fine" (Participant 11). Additionally, they were open to using technology to replace certain aspects of their rehabilitation center–based treatment (statement 34, −1). This openness was primarily driven by concerns about the difficulties they might face when traveling to the center after transitioning to outpatient care: "I don't think it's impossible to come here, but it will be difficult since I'm in a wheelchair" (Participant 11).

Viewpoint 2: Technology Supporting Independence and Self-Control

In total, 7 participants aligned with this viewpoint, the majority of whom were female (n=4). Of these, 4 lived alone, and 4 had attained higher education qualifications. Previous motor impairments were reported by 4 participants, who now experienced only speech and memory difficulties. Motor impairments were still experienced by 3 participants: 1 required a wheelchair, while 2 did not. Of the 7 participants, 4 had completed rehabilitation, while 3 were still undergoing it.

This group highly valued their autonomy and independence during recovery. They prioritized the flexibility to choose when to exercise (statement 5, +4) and control over their recovery process (statement 3, +4). Their aversion to being told what to do made the ability to decide when to exercise particularly important:

> *I really dislike being told, "You have to do this now." That's why I don't go to physical therapy. For example, if I'm supposed to go on Tuesday at ten o'clock, I might not feel up to it or might be too tired to go.* [Participant 2]

For them, the autonomy to choose when and how to exercise was crucial for maintaining a sense of control:

> *It's about making my own decisions regarding my pace, whether I go fast or slow. Having the freedom to choose what I can do is important.* [Participant 3]

The emphasis on autonomy and independence also extended to their preferences for technology. They valued the ability to use it independently (statement 12, +3), as requiring assistance diminished their autonomy, reduced flexibility, and created an unwelcome burden for others: "It would be great not to rely on others to use it. This would also make things easier for the people around me" (Participant 8). Those living alone found technology that required assistance particularly inconvenient: "It doesn't seem very practical to have technology at home that can only be used with others. I live alone" (Participant 4). As participants emphasized the importance of using technology independently, they attached less value to technology with varying levels of difficulty (statement 26, −1): "There should be some adaptability in difficulty (...) but that's not the most important thing" (Participant 3).

To maintain their independence, participants emphasized the importance of gaining insight into their progress (statement 22, +3). They wanted to monitor their achievements and identify areas for improvement: "Insight into my own progress is important because it helps me understand where I need to improve or what I need to work on" (Participant 13). They also valued direct feedback during exercises (statement 23, +1) to ensure that tasks were performed correctly: "That seems useful to me, because otherwise, you don't gain anything from it" (Participant 7). Additionally, they stressed the need for technical support, such as a helpdesk (statement 28, +1), to resolve issues independently without relying on family or friends:

> *If something doesn't work and you can't fix it yourself, it is crucial to have someone available to help immediately. Otherwise, you might have to wait a couple of days until someone has time to help, which feels pointless.* [Participant 3]

Similar to viewpoint 1, participants in this group placed little emphasis on comparing their progress with peers (statement 24, −2), believing that recovery is unique to each individual: "I don't think it's important to compare, because everyone is different" (Participant 2). Their focus was primarily on their own recovery, rather than on that of others: "I don't really think about others in that regard. For me, it's about focusing on myself" (Participant 3).

In contrast to viewpoint 1, participants in this group placed less emphasis on achieving a faster recovery (statement 1, +1) or

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reaching rehabilitation goals quicker (statement 2, 0). They viewed recovery as a gradual process rather than something to rush: "A faster recovery process? No, I don't think it needs to be any quicker. It [recovery] is important, but it doesn't have to happen fast" (Participant 4). In addition, being able to set up technology within 5 minutes (statement 13, −1) was not a priority, as they appreciated the learning opportunity provided during the installation: "No, it doesn't matter if setting it up takes a little longer. While doing it, you're also learning and gaining a better understanding of how it [the technology] works" (Participant 3). Moreover, participants in this group placed significant emphasis on safeguarding their privacy (statement 31, +2), more so than those in viewpoint 1. Some were concerned about the potential misuse of their health data: "Of course, this is important because these medical details are relevant to insurance companies" (Participant 4). Others expressed a strong desire for confidentiality: "Not everyone needs to know what I have. My information should remain private" (Participant 3).

Viewpoint 3: Technology as a Supporting Partner

This viewpoint was held by 3 female participants, all of whom lived with others. Their educational backgrounds varied, including secondary education, vocational education, and higher education qualifications. Among them, 1 participant experienced language-related difficulties, while the other 2 experienced motor impairments requiring the use of a wheelchair. Of the 3 participants, 1 had completed rehabilitation, while the other 2 were still undergoing it.

Participants in this group emphasized the importance of receiving external insights to guide their recovery process. They valued gaining insight into their progress through technology (statement 22, +4), particularly because they found it difficult to recognize improvements on their own: "Sometimes, it's hard to see your progress on your own, so it would be helpful to have that insight" (Participant 12). This desire for insight was complemented by their preference for therapists to actively monitor their recovery (statement 21, +4). Participants highlighted the crucial role of therapists, as they could provide valuable guidance and intervene when necessary. Participant 20 explained: "This is important because therapists can intervene when needed." Participant 12 elaborated on how therapists could help set the appropriate difficulty level and ensure the recovery process stays on track:

> *For example, a therapist might recommend trying a higher level. While you can decide for yourself, they can also offer suggestions and ideas on what else to try. Having someone to guide you can be very helpful.*

The need for external guidance extended beyond professional support, as participants valued insights and encouragement from peers. They stressed the importance of maintaining peer contact (statement 20, 0) as well as receiving recommendations from peers (statement 17, +1). Participants saw peers as a source of practical advice and emotional support. Participant 16 shared: "You can learn from them; they have been through it too." Participant 12 expanded:

> *You can learn from one another. You might get tips, or someone might have figured something out that makes you think, "Oh, that's a good idea; I'll try that too." And while family and friends can offer support, connecting with fellow patients is also valuable, as they truly understand what you've been through.*

Peer contact also offered reassurance and positive feedback. Participant 12 recounted:

> *I just attended a meeting with people who have recovered well and can really express themselves. We were talking, and I said, "Wow, you speak so well!" They said the same to me, you know. It was really nice to hear.*

This emphasis on positive feedback fostered participants' interest in comparing their progress with others (statement 24, +1) and receiving rewards for their achievements (statement 25, 0): "It's nice to see and hear that you're doing well" (Participant 12).

Similar to participants with viewpoint 1, but unlike those with viewpoint 2, participants with viewpoint 3 emphasized the importance of a faster recovery (statement 1, +3) and the quicker achievement of rehabilitation goals (statement 2, +3). Participant 16 expressed: "Well, isn't that what we all want?" However, they also recognized the need for patience, as participant 20 explained: "I want to recover as quickly as possible, but the body also needs time to adjust." This nuance suggests that, while speed was a priority, it was not the most important factor influencing their decision to use technology at home. Participants with viewpoints 1 and 3 also shared a similar outlook on privacy, expressing minimal concern about safeguarding their personal information (statement 31, −4). They trusted that privacy measures were sufficient and felt that they had little to hide. Participant 20 commented: "I think that it will be fine. I also don't have much to hide." For those with viewpoint 3, this confidence extended to safety (statement 30, 0), as they believed the technology posed minimal risks.

In contrast to viewpoint 1, but aligning with viewpoint 2, participants with viewpoint 3 did not consider the ability to set up technology within 5 minutes (statement 13, −2) a priority. They expressed a relaxed attitude toward setup time, prioritizing functionality over speed. Participant 20 explained: "Five minutes? Why? There's plenty of time in a day." Participant 12 added, "Fifteen minutes would be fine with me as well. I want the technology to work properly."

Participants with viewpoint 3 placed less importance on the convenience of recovery at home (statement 4, 0), cost reimbursement (statement 29, −2), and the size of the technology (statement 32, −3) compared to those with viewpoints 1 and 2. They recognized that recovering at home could be convenient but argued that its relevance varies depending on the length of the rehabilitation period. They also stressed that being in the rehabilitation center is important for their recovery. In addition, they believed that the technology should be reasonably priced and of a manageable size. Participant 12 explained: "I do not consider costs when it comes to rehabilitation. That is not the priority; regaining my life is. However, it should still be affordable."

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The Consensus Among the 3 Viewpoints

Despite differences among the 3 viewpoints, participants agreed on several factors that are important to their decision to use rehabilitation technology at home. One point of consensus was the potential to reduce dependence on others (statement 7, +1, +1, +2). Many participants expressed frustration with relying on family members for everyday tasks and viewed rehabilitation technology as a way to regain autonomy. Participant 8 explained:

> *I really value my independence. For example, last weekend (...), I couldn't get a drink. I had to wait for my partner to bring it to me, which I don't want to keep doing. If the technology helps me practice these tasks, it would be great as it allows me to become less dependent.*

In addition, participants consistently emphasized the importance of certain features in rehabilitation technology. One key feature was direct feedback during exercises (statement 23, +3, +1, +3), which they believed was necessary for effective rehabilitation. Participant 11 noted: "Otherwise, you don't know if you're doing things correctly or incorrectly. I think that's really important in any learning process." Other important features emphasized by the participants included simplicity (statement 8, 0, 0, +1) and technology that could be understood quickly (statement 9, +1, 0, −1). Participants noted that difficulties in these areas might lead to frustration and reduce engagement. However, they did not consider being able to understand the technology without any explanation (statement 11, 0, −1, −2) to be essential. Some felt they could learn on their own, while others were comfortable receiving help or explanations from a therapist or family member.

Participants also agreed on several factors related to social influences. Approval from therapists (statement 14, +1, +2, +2) was considered very important, as therapists were seen as trusted advisers in decisions about home-based rehabilitation technology. In contrast, information from social media (statement 18, −4, −4, −4) and television (statement 19, −4, −4, −2) was deemed unimportant to their decision-making, either because participants used these platforms infrequently, questioned their reliability, or found them irrelevant. Likewise, support from friends (statement 16, −2, −2, −3) was not regarded as an important factor in deciding whether to use home-based rehabilitation technology.

Finally, participants agreed that reducing travel to the rehabilitation center (statement 6, −2, −2, −1) was not a major factor in their decision to use rehabilitation technology. Many lived close to the center, making travel a nonissue: "No, I live nearby, so it doesn't matter to me. I can even walk to the centre" (Participant 4). For those who lived farther away, tailored transport options, which are partly reimbursed by health insurers under certain conditions, minimized the challenge. Participant 2 shared: "I have tailored transport, so travelling to the centre isn't really an issue; it's all arranged for me."

Discussion

Principal Findings

This study identified three viewpoints on the adoption of rehabilitation technology for home use by rehabilitation patients with ABI: (1) technology supporting fast recovery, which prioritizes quick outcomes and ease of use; (2) technology supporting independence and self-control, which emphasizes autonomy and personal control; and (3) technology as a supporting partner, in which guidance and validation are highly valued. These findings highlight the diverse viewpoints of rehabilitation patients with ABI, suggesting that a tailored approach may be more effective than a one-size-fits-all approach.

Technology Supporting Fast Recovery

Participants with this viewpoint were predominantly male, cohabiting, and more severely impaired compared to those in other viewpoints. All were actively undergoing rehabilitation. They emphasized the importance of technology in achieving rapid recovery and meeting rehabilitation goals. This viewpoint seems to align with literature suggesting that male participants often prioritize results [15,23] and that individuals in the early stages of rehabilitation focus on the practical aspects of recovery [41]. Additionally, participants preferred devices that were easy to use and quick to set up, ideally within 5 minutes, to minimize frustration. This finding aligns with those of Lin et al [42] and Klaic and Galea [19], who noted that tasks with high cognitive load can lead to increased frustration and reduced performance. Features enabling progress comparisons or competitive, game-like formats were of little interest to participants in this group. This observation contrasts with previous studies [20,30,36]. However, those studies focused on individuals in the chronic phase of recovery, whereas participants in this group were actively undergoing rehabilitation and prioritized personal recovery and practical exercises. Moreover, participants emphasized the uniqueness of each recovery journey, which reduced the relevance of comparative metrics. This seems to align with Festinger's social comparison theory [43], which posits that individuals are less likely to compare themselves with others when there are substantial differences. Rehabilitation technology for this group should therefore focus on tracking individual milestones rather than comparative metrics. Family appeared to play an important role in decisions about adopting home-based rehabilitation technology. Participants noted that practical assistance (eg, help with setting up devices) and emotional support (eg, approval from family members) influenced their decision to adopt rehabilitation technology. This finding aligns with Schladen et al [44] and Nasr et al [36], who suggested that family involvement often plays a key role in decision-making. For this group, it is important that rehabilitation technology is designed to accommodate the needs of both users and their families and that family members are involved in the decision-making process when patients are presented with the option to use such technology.

Technology Supporting Independence and Self-Control

This viewpoint was predominantly expressed by female participants, most of whom were living alone. While most no

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longer experienced motor impairments and had completed rehabilitation, they continued to report cognitive and language difficulties. Autonomy and independence were viewed as important aspects of rehabilitation technology. This viewpoint seems to align with literature suggesting that female participants often adopt a process-oriented approach [15,23]. Additionally, the emphasis on autonomy and independence, as noted in previous studies [31,32,36], suggests that reliance on caregivers or professional support may act as a barrier to adopting rehabilitation technology in this group. Participants also highlighted the importance of gaining insight into their progress and receiving feedback during exercises. While feedback can motivate users [32,33,36], participants in this group primarily viewed it as a tool for improving performance. Participants further emphasized the importance of features such as access to a helpdesk and robust privacy safeguards, which is consistent with findings by Brouns et al [34]. These aspects should be prioritized in the design of rehabilitation technology for this group. Like the first viewpoint, participants placed limited value on comparing their progress with others. Instead, they emphasized the uniqueness of their recovery journeys. As a result, technology developed for this group may be most effective if it focuses on tracking individual progress and enables users to monitor it independently.

Technology as a Supporting Partner

This viewpoint was exclusively expressed by cohabiting female participants, who reported a range of impairments, with the majority still undergoing rehabilitation. Guidance and validation from external sources were considered important in their decision to adopt the technology. This viewpoint seems to align with existing literature, suggesting that female participants are more likely to adopt a process-oriented approach and tend to place greater emphasis on external opinions [15,23]. Furthermore, participants in this group emphasized the importance of tracking their own progress with technology, particularly as improvements are not always visible, a challenge also noted by Lavis et al [45]. Technology with clear progress-tracking features, such as charts or milestones, could help address this need. Additionally, therapist involvement was highlighted as crucial for the adoption of home-based rehabilitation technology, as participants noted the importance of receiving feedback, guidance, and help with adjusting difficulty levels. This aligns with prior research that underscores the value of therapist support in rehabilitation [19,30,33]. Moreover, participants valued staying connected with peers, receiving recommendations, comparing progress, and earning rewards. These preferences align with previous studies [34,35,45] and suggest that peer-focused communication features, comparative metrics, and reward systems could be beneficial for this group. Similar to the first viewpoint, participants in this group shared a desire for quicker recovery and goal achievement. However, they also acknowledged the importance of patience throughout the process. This indicates that, although fast recovery was valued, it was not the sole consideration in this group's decision to adopt home-based rehabilitation technology. Such reflections are consistent with prior studies [19,30,32,33]. Finally, although cost and size were noted as considerations [20,31,33,34], participants in this group expressed a willingness to invest in technology they perceived as helpful for their recovery.

The Consensus Among the Viewpoints

Participants agreed on several factors as important to their decision to adopt technology: reducing reliance on others, receiving immediate feedback, ensuring ease of use, and obtaining therapist approval. The emphasis on independence aligns with previous studies, which have identified it as a key rehabilitation outcome from the patient's perspective [46]. Immediate feedback during exercises was also considered important, consistent with earlier findings [20,32,36]. However, as this study did not explore the optimal format for delivering feedback, further investigation is warranted. Ease of use was also frequently cited as important [10,15,19,30-33,35], suggesting that ideal technology should be intuitive. However, participants in this study noted that the technology does not need to be entirely self-explanatory, as long as support is available, whether through written instructions, professionals, or family members. Moreover, therapist approval emerged as particularly important in the decision to adopt technology, reflecting previous research findings [36]. In contrast, participants showed disinterest in mainstream media (eg, social media and television) when deciding whether to adopt rehabilitation technology. This may be attributed to the generally older age of participants [47] or to the belief that each recovery journey is unique. Similarly, support from friends was mostly considered less important in the decision to adopt. Notably, avoiding travel to rehabilitation centers was not a priority for most participants. This differs from other studies [20,31,33,34], where it was seen as a major advantage. This contrast may be due to the fact that participants in this study lived nearby and that transportation costs are partially reimbursed by Dutch health insurers [48].

Implications

The findings of this study highlight the importance of a personalized, user-centered approach to the development and implementation of home-based rehabilitation technologies. Rehabilitation patients with ABI hold diverse viewpoints regarding the adoption of such technologies, underscoring the need for flexible and adaptable design. Actively involving patients in the development process can help ensure that these tools align with their expectations and support sustained engagement [10,11].

In terms of design, the findings suggest several practical implications. Across all viewpoints, participants emphasized the importance of intuitive interfaces and immediate feedback. However, the technology does not need to be fully self-explanatory, provided that support is available. Participants in viewpoint 1 seemed to prefer designs that prioritize simplicity and quick setup. Interfaces should therefore offer clear navigation and minimize the number of steps required. Social or peer-related features were considered less important and may be regarded as nonessential for participants with this viewpoint. For viewpoint 2, participants seemed to value designs that support independent use. This includes enabling self-paced interaction, personal goal setting, and individual progress tracking. As with viewpoint 1, social or peer-related features

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were not prioritized and may be considered nonessential. Participants in viewpoint 3 seemed to prefer designs that incorporate external guidance and validation. Features enabling therapist communication and peer support may therefore be particularly valuable for participants with this viewpoint. Additionally, features such as motivational feedback and rewards appear to be especially appropriate.

In terms of implementation, the findings also offer practical guidance. Motivations for using rehabilitation technologies varied among participants. While some focused on functional recovery, others prioritized maintaining autonomy or receiving consistent support. This variation highlights the need for tailored communication strategies that reflect individual goals and expectations. Moreover, therapists' approval played an important role in rehabilitation patients' decisions regarding adoption. As shown in this study and in the work of Nasr et al [36], patients often rely on therapists' guidance when deciding whether to use such tools. To guide rehabilitation patients effectively, therapists may benefit from training programs that build confidence and skills to recommend and evaluate these technologies.

Strengths and Limitations

A key strength of this study lies in the use of Q-methodology, which offers a structured yet flexible approach to exploring and comparing subjective viewpoints. This method is particularly well suited for including vulnerable populations, such as individuals with language or cognitive impairments [27,49-51], as it allows statements to be tailored to the target group and accommodates nonverbal communication. In this study, it enabled us to include rehabilitation patients with such impairments and to explore their viewpoints in depth. Given its strength in engaging vulnerable populations in research [49-51], we argue that Q-methodology could be used more frequently in rehabilitation research to help identify and understand the needs of vulnerable patient groups and to support more person-centered research.

However, several limitations should be considered when interpreting our findings. First, our analysis drew on the UTAUT framework [15] to interpret participants' views on technology adoption. While alternative behavioral models such as self-determination theory [52] or the health belief model [53] could have offered additional conceptual perspectives, we chose not to integrate them, as key constructs (eg, competence and perceived benefits) were already reflected in the data. This choice to focus only on the UTAUT framework may have limited the breadth—but not the depth—of the interpretation presented. Second, the study was conducted at a single rehabilitation center located in an urban area. As patient demographics and health care practices can vary across settings, future research should involve multiple centers, particularly in rural or less densely populated areas, to enhance the generalizability of findings. Third, the sample showed limited ethnic diversity, with only 1 participant each from Surinamese, German, and Croatian backgrounds. This may restrict the applicability of our findings to more ethnically diverse populations. Moreover, the majority of participants had experienced strokes, which may limit the relevance of the findings to individuals with other forms of ABI. Future studies should aim to include a broader range of injury types and participants from more diverse backgrounds to validate and expand upon our results. Finally, individuals with visual impairments were excluded from the study. Although it is possible to read the statements aloud, the second part of the method requires participants to physically sort a full set of written statements on a visual grid. This task relies heavily on visual-spatial processing. During piloting, participants with visual impairments experienced confusion and frustration. To prevent further distress and ensure methodological consistency, we decided to exclude individuals with significant visual impairments. This exclusion may have affected the representativeness of the sample, as their perspectives on technology adoption may differ in meaningful ways.

Conclusions

This study identified three viewpoints regarding the factors that rehabilitation patients with ABI consider important for the adoption of home-based rehabilitation technology: (1) technology supporting fast recovery, (2) technology supporting independence and self-control, and (3) technology as a supporting partner. These findings demonstrate that rehabilitation patients with ABI differ in both the design features they prioritize and the motivations that drive their use. As such, a one-size-fits-all approach to the development and implementation of home-based rehabilitation technology is unlikely to be effective.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

KEB, JMC, and SJK drafted the design for data collection and interpreted the data. KEB conducted the interviews and performed the analysis. KEB drafted the manuscript, and JMC, SJK, and GMR contributed equally to its refinement. All authors have read and approved the final version. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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List of abbreviations

ABI: acquired brain injury
Q-study: Q-methodology study
UTAUT: unified theory of acceptance and use of technology

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Sociotechnical Adaptation of Telerehabilitation in Rehabilitation Practice: Survey Among Rehabilitation Professionals

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Abstract

Background: Both rehabilitation practice and rehabilitation professionals' work have been transformed by the adoption of different technological solutions. Sociotechnical theory can be used to analyze the adoption of technologies in rehabilitation practice.

Objective: This study aimed to enhance the understanding of the sociotechnical perspective of telerehabilitation (TR) in rehabilitation practice, as well as the understanding of how sociotechnical frameworks can be used to examine the implementation of telerehabilitation in outpatient rehabilitation.

Methods: A survey of rehabilitation professionals (N=629) was conducted in a Finnish outpatient rehabilitation setting. Data from 5 open-ended questions were analyzed using inductive, deductive, and abductive qualitative content analysis. An analysis matrix formed from the Fit between Individuals, Tasks, and Technology (FITT) and the Fit between Individuals, Tasks, Technology, and Environment (FITTE) frameworks was used.

Results: Deductive analysis revealed that in individual-task fit, professionals' and clients' adequate skills, support for participation, and a positive attitude were essential. The task-technology fit highlighted the need for the professionals' familiarization, changes in methods and materials, and collaboration with clients and their close associates and networks. The individual-task fit revealed that professionals found TR tasks to be more complex than those in in-person practice and that TR increased professionals' perceived workload and clients' need for personal contact, especially during the familiarization phase. Our findings suggest that certain dimensions of the FITTE framework need to be specified in order to better understand the sociotechnical adaptation of TR.

Conclusions: We propose an extension to create the Fit between Individual, Task, Technology, Interactive Sociotechnical Environment, and Organizational and Sociopolitical Context (FITTIO) framework, which provides conceptual tools for making contextual interpretations of the adoption of TR in rehabilitation settings. This study increases understanding of the sociotechnical nature of TR, which can be used in the adoption of technological solutions in rehabilitation practice.

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KEYWORDS

rehabilitation professionals; sociotechnical adaptation; sociotechnical frameworks; telerehabilitation; outpatient rehabilitation

Introduction

In the past decades, the adoption of health IT, mobile devices and applications, a variety of web-based platforms and tools, and other digital health technologies has reshaped health care services and professionals' everyday work [1-3]. There are several different frameworks that can be used to analyze the adoption of technologies in health care, including sociotechnical theory [4]. According to Trist [5], sociotechnical systems theory posits that the main elements of social and technical systems are independent. However, they are also interdependent, as a change in one requires a change in the other. The theory seeks the optimal alignment between these 2 elements [5].

In the context of health care, Ammenwerth et al [6] developed the Fit between Individuals, Tasks, and Technology (FITT) framework. The framework demonstrates the conditions for optimal technology adoption in different health care settings [7-9]. This framework specifically focuses on the intertwined relationships between task, technology, and the individual [6]. The FITT framework has been widely applied and further developed. One research group found that the environment plays an important role in the adoption of technologies [10]. They

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extended the FITT framework with an environmental dimension, creating the Fit between Individuals, Tasks, Technology, and Environment (FITTE) framework. The environment dimension includes temporal and physical environments as well as organizational policies and procedures [10]. Environmental factors can explain why the adoption of a particular technology is successful in one environment and not functional in another [10-12]. Organizational, management, and leadership factors, as well as clients' everyday environments, should also be considered within the environmental context [11-14].

At present, research literature concerning the FITT and FITTE frameworks focuses mainly on specific professions such as nurses [6,10,11,14-16] and physicians [10,16-18]. Knowledge of the experiences of case managers, health coaches, social workers, and pharmacists is still quite limited [8,16,17,19]. Some studies have focused on a variety of health care professionals or other workers in health care [11,20-22]. Two studies also included technical staff [9,11]. There is little emphasis on physiotherapy [13] or other therapy professionals [12]. However, the use of telerehabilitation (TR) and factors related to its adoption differ between different professionals [23].

In this paper, we seek to pinpoint the technological and nontechnological factors influencing the adoption of TR in rehabilitation practice. Rehabilitation practice refers to services provided by professional therapists such as music therapists, neuropsychologists, physiotherapists, occupational therapists, and speech and language therapists. It encompasses a wide range of modalities depending on the therapist's training, the clients' needs, and the goals of therapy. Therapy can be short-term or long-term, depending on the complexity of the issues being addressed. Here, TR refers to the provision of numerous rehabilitation services through various achievements in information and communication technologies [24].

The goal of this study is twofold: (1) to describe the adaptation of TR in rehabilitation practice from a sociotechnical point of view and (2) to enhance the understanding of how sociotechnical frameworks can be used to examine the adoption of telerehabilitation in outpatient rehabilitation. The present study increases the understanding of the sociotechnical nature of TR, in terms of both technological and nontechnological factors, which can be used in the adoption of technological solutions in rehabilitation practice.

Methods

Study Setting

This substudy was conducted in Finland using a web-based survey. The first part of the study investigated and compared the uptake of TR in Finland among different rehabilitation professions during the COVID-19 pandemic [23]. The second part investigated different professional perspectives to provide insight into the extent to which there was consistency in experiences of adopting TR across different professionals [12].

Data Collection

The focus was on outpatient therapy for intensive medical rehabilitation clients in Finland. The target population comprised professionals who were providing outpatient therapy services in either the public or private sector in Finland during the first wave of the COVID-19 pandemic. A total of 629 professionals, including music therapists, neuropsychologists, physiotherapists, occupational therapists, and speech and language therapists, responded to the questionnaire.

The participants were recruited via email from the Kela directory, networks, and newsgroups of professional organizations, and social media. The questionnaire was anonymous. Responses to all questions were optional. The first page of the web-based questionnaire displayed the informed consent statement. Participants were required to indicate consent to proceed. The web-based survey and the participant recruitment process are illustrated in more detail elsewhere [23].

The questionnaire, designed specifically for this study, consisted of 24 questions regarding rehabilitation professionals' work and use of TR during the COVID-19 pandemic. Data were collected from May 7 to June 1, 2020. Data for this research consisted of responses to 5 open-ended questions (refer to Multimedia Appendix 1 for the questions used in the study).

Data Analysis

The study used inductive, deductive, and abductive qualitative content analysis [25-27]. The analysis process is described in Table 1. Initially, the entire dataset was retained and coded using an inductive approach until full saturation was achieved and no new codes were identified. In this process, individual responses or clusters of ideas relevant to the research questions were used as units of analysis. Coding was facilitated using ATLAS.ti Windows (version 22; ATLAS.ti Scientific Software Development GmbH). One author conducted the initial inductive coding, assigning initial codes aligned with the research inquiries. These codes were then subdivided into 2 categories corresponding to the respective research questions, as delineated by Partanen et al [12]. In the deductive and abductive phases, we used an analysis matrix derived from the FITT and FITTE frameworks.

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Table . Description of the analysis process.

Phase of the analysis process	Approach of the analysis	Description of analysis phase
Decontextualization	Inductive approach [25,26]	• The first author segmented the texts into meaning units, conducted an initial round of coding, and labeled the codes with descriptive names.
Recontextualization	Inductive approach [25,26]	• The first author generated inductive codes through group coding. • Inductive codes were discussed among all authors.
Creating categories	Deductive approach [25,26]	• The first author sorted the codes into categories. • All categories were compared with the dimensions and attributes of the FITT[a] and FITTE[b] frameworks. • All authors discussed the categories and subcategories, differences in interpretations were discussed, and a consensus was formed. • All the dimensions were organized into client-related or professional-related subcategories to provide a more detailed analysis. • Codes that could not be included in the analysis matrix led to the creation of additional categories and subcategories.
Abstraction and interpretation of the main categories	Deductive approach [25,26]	• Main categories were formulated around the main dimensions of the FITT and FITTE frameworks. • Dimensions of fit and environment served as the main categories, with subcategories organized for clients and professionals. • The environment dimension was divided into two separate main dimensions: interactive sociotechnical environment and organizational and sociopolitical context. • All authors reviewed and discussed the categories to ensure consistency in abstraction and interpretation.
Abductive reasoning	Abductive reasoning [27]	• A revised framework was created using abductive reasoning by linking the categories and subcategories formed during deductive analysis to the dimensions and attributes of the FITT and FITTE frameworks. • Categories that could not be mapped to previous theoretical frameworks were identified during the deductive analysis phase. • An abductive leap occurred when the results of the deductive analysis were combined with the dimensions and attributes of the FITT and FITTE frameworks. This abductive reasoning led to a more multidimensional framework, where clients' and professionals' perspectives were separated into distinct dimensions, and the concept of the environment was expanded to include two different levels. • All authors participated in discussions on abductive reasoning to ensure consistency in definitions and their appropriate application to the data.

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[a]FITT: Fit between Individuals, Tasks, and Technology.

[b]FITTE: Fit between Individuals, Tasks, Technology, and Environment.

Ethical Considerations

The present study is part of a larger research project, "The Significance of the Therapeutic Relationship to Rehabilitation" [28]. Ethical approval for the main study, in accordance with the tenets of the World Medical Association Declaration of Helsinki, was obtained from the Ethical Review Board of the Social Insurance Institute of Finland (Kela) in Helsinki (protocol code 4/1/500/2019; November 22, 2019).

Results

Overview

The results stemmed from the phased process of inductive, deductive, and abductive content analysis described in the "Data Analysis" section of this paper. We begin by presenting key findings from the deductive analysis (refer to Table 1) that describe the adoption of TR into outpatient rehabilitation practice. The findings from the deductive analysis are presented according to the main dimensions of the FITT and FITTE frameworks. The contents of the main categories are summarized in Multimedia Appendix 2. Subsequently, we present the findings from the abductive analysis, which illustrate how sociotechnical frameworks may be used to examine the implementation of TR in outpatient rehabilitation.

Individual-Task Fit

We identified 8 main categories in the individual-task fit dimension. The main categories, "Peer support" and "Support for participation," could not be mapped onto the analysis matrix. Our findings emphasized that an optimal fit between individuals and technology highlighted the importance of skills and abilities, as well as attitudes and preferences. Main categories and subcategories are presented in Multimedia Appendix 2.

Clients need technical skills as well as sufficient motor and cognitive skills. Clients' challenges in functioning also limited their opportunities to participate in TR. Professionals' responses primarily focused on the clients' skills and abilities, with fewer mentions of their skills. However, professionals felt that strong core competence in their profession facilitated the adoption of TR.

The responses pointed out that the suitability of TR is not so much dependent on a client's diagnosis as it is on personal factors and life situations. Within the category "Support for participation," which emerged from the data, the therapists expressed that in some clients' situations (for example, clients with severe impairment and pediatric clients), a supportive person makes it possible for the client to participate in TR.

> *Physiotherapy for those with severe physical impairments is very difficult to carry out remotely without a supportive person present to help the client.* [Physiotherapist]

Attitudes and preferences of professionals, clients, and their close associates played an important role in the adoption of TR. Because of negative attitudes, such as prejudice and doubts about technology, the use of TR may not have even been experimented with. The clients did not always have previous experience using remote technology, so experimentation helped them to better understand TR and, thus, assess its suitability for themselves. Professionals sought advice, support, and guidance and also participated in training related to the rapid transition to TR.

Task-Technology Fit

The dimension task-technology fit included 5 main categories. One main category, "Perceived engagement of clients and their close associates and networks," did not fit the analysis matrix. Main categories and subcategories are presented in Multimedia Appendix 2.

The optimal fit between task and technology included collaboration and the engagement of the client and close associates. These viewpoints emerged in the category, "Perceived Engagement of the Clients and Their Close Associates and Networks." The professionals reported that tasks given via remote connection require an expanded perspective on engagement. In the subcategory "Remote Connection Supports Network Collaboration and Communication in Rehabilitation Practice," the professionals expressed that communication with other professionals increased, for example, through video conferencing applications. In addition, families, close associates, and other networks were easily reachable.

> *On the other hand, these collaborators have been able to take a peek at what I actually do in speech therapy. I think it will affect the cooperation in the future.* [Speech therapist]

The professionals' perceptions of the benefits of TR varied. Some of the participants felt that TR, with different forms of connections, activated the client, but others felt that in-person rehabilitation was more useful and effective. The professionals reported changes in practice due to TR. They felt that familiarizing themselves with TR and putting it into practice was time-consuming. Using TR required learning different technologies and guiding clients. TR challenged the professionals' creativity and competence, as they had to sensibly adapt methods and exercises for remote use, necessitating a re-evaluation of the materials and equipment needed for the practice.

Individual-Task Fit

We identified three main categories in the individual-task fit dimension. Main categories and subcategories are presented in Multimedia Appendix 2.

The professionals' responses indicated that preplanning and organizing tasks are more demanding with remote connections, falling into the category "Complexity of task." Professionals found it more challenging to adapt plans on a situation-specific basis compared to in-person meetings, as the client's environment is either not fully visible or only partially seen.

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> *Teletherapy requires more precise planning beforehand, and changing the plans when the situation requires it is very challenging when you only have a limited view of the operational environment.* [Physiotherapist]

The professionals experienced an increased workload with the adoption of TR, both mentally and physically. This type of work increased their cognitive load, requiring significant effort and intense concentration to maintain client interaction via remote connection. In the subcategory of "Doing rehabilitation tasks in front of a screen," professionals reported that prolonged use of a tablet or other device could be tiring for clients. In the subcategory "In-person contact during the familiarization phase," it was considered important for getting to know the client, professionals expressed that getting to know a new person takes time and is easier through in-person contact.

Interactive Sociotechnical Environment

The interactive sociotechnical environment included 3 main categories. One main category, "Digital environment," could not be mapped onto our analysis matrix. Main categories and subcategories are presented in Multimedia Appendix 2.

Within the temporal environment, professionals reported that reduced transitions freed up their resources for other purposes. They noted that practicing therapy remotely could save both resources and time. With the shift to TR, adjustments were made to the frequency and duration of rehabilitation appointments as needed. Professionals felt they had the flexibility to schedule sessions according to the clients' individual needs.

> *It's been easier to book (eg, 2 teletherapy) sessions in the same week when you don't have to schedule commuting.* [Occupational Therapist]

> *It's been easier to book (eg, 2 teletherapy) sessions in the same week when you don't have to schedule commuting.* [Occupational Therapist]

In the category "Physical environment," professionals reported learning how to practice therapy remotely from their homes, having a new kind of opportunity to work from home, and having their studies renovated. Remote connection brings a new aspect to the environment that we named "Digital environment." Remote connection supports the flexibility, accessibility, and regional equality of therapy services. The professionals also felt that the experience of attendance changes with a remote connection. Some participants reported that clients changed appointment times and failed to report cancellations more than in in-person rehabilitation. At the same time, some participants reported that clients' absences and cancellations decreased because the therapist had a direct connection to the client's home.

Organizational and Sociopolitical Context

The organizational and sociopolitical context dimension included 4 main categories. The main category, "Sociopolitical context," did not fit the analysis matrix. Main categories and subcategories are presented in .

In the "Resources" category, the professionals reported that the transition to TR incurred both one-time and ongoing expenses. In the category "Organization's goals and processes," professionals perceived TR's value as an addition to traditional rehabilitation services. They planned to continue using remote rehabilitation in the future, at least to some extent. In particular, they preferred conducting network and other meetings remotely. Within the subcategory "Information security," therapists expressed the need for uniform guidelines and practices for the safe use and selection of software. In the category "Current legislation and guidelines," professionals reported spending a considerable amount of time trying to understand and comply with various instructions and guidelines.

The main category, "Sociopolitical context," explains how the societal situation affected therapy practice, and professionals had to adopt TR on short notice. The societal situation (ie, the COVID-19 pandemic) forced professionals to take a digital leap.

> *The digital leap was enormous, but I'm glad it was taken now that there was no choice. Now there's no threshold for using telerehabilitation alongside face-to-face rehabilitation.* [Occupational Therapist]

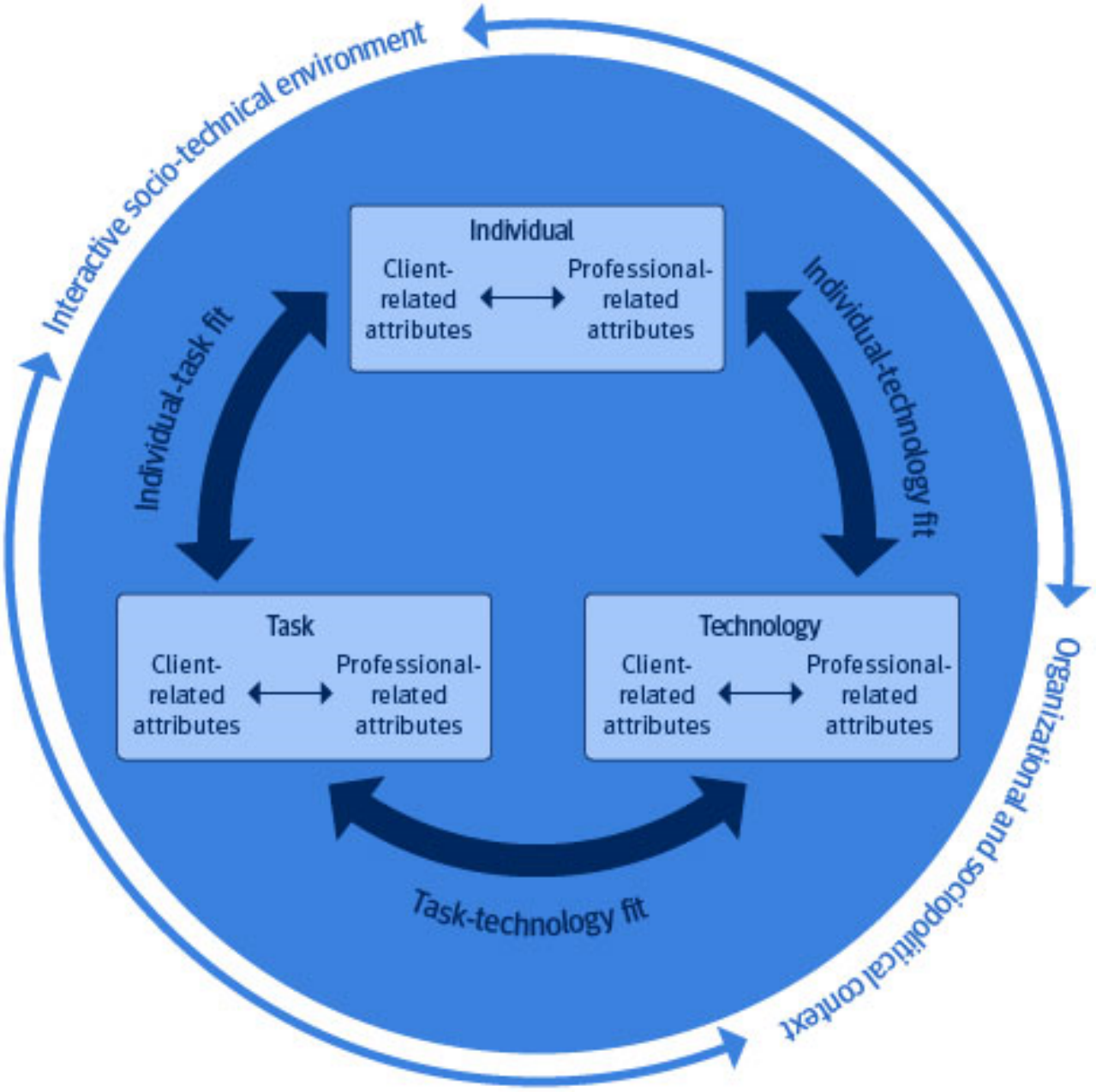
The professionals reported that this unexpected change caused stress, but on the other hand, it accelerated the adoption of TR. Under normal circumstances, TR would not have been put into practice.

Extension of the FITTE Framework to the Fit between Individual, Task, Technology, Interactive Sociotechnical Environment, and Organizational and Sociopolitical Context Framework

Abductive reasoning (refer to Table 1) was a creative, dialogic process in which we examined the results of the deductive analysis about the FITT and FITTE frameworks. As a result, the 5 main categories generating refined perspectives on the FITTE framework were identified. In addition, the perspectives of clients and professionals were separated into their dimensions, and the environment was divided into two levels: one describing the interactive, practical work environment, and the other addressing the organizational and sociopolitical context of rehabilitation practice. Based on the abductive reasoning phase, we propose extending the FITTE framework to the Fit between Individual, Task, Technology, Interactive Sociotechnical Environment, and Organizational and Sociopolitical Context (FITTIO) framework. Figure 1 is an extended version of the FITT and FITTE frameworks ([6] and [10], respectively), illustrating the proposed FITTIO dimensions and attributes.

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Figure 1. Fit between Individual, Task, Technology, Interactive Sociotechnical Environment, and Organizational and Sociopolitical Context framework.



The environmental dimensions, interactive sociotechnical environment, and organizational and sociopolitical context are essential to the FITTIO framework. These dimensions lay the foundation for analyzing and understanding TR practice. The organizational and sociopolitical context defines resources, guidelines, and organizational goals for the use of TR. In this frame, the interactive sociotechnical environment can occur. The interactive sociotechnical environment is the place where professionals meet their clients and collaborate with necessary networks. Both of these environmental dimensions affect all other dimensions.

In FITTIO, the individual-task fit is built on both the clients' and professionals' skills, attitudes, and knowledge of how to use a new technical system. From a client's perspective, the key points are support in participation and professionals' competence to adjust technological attributes suited for rehabilitation purposes. The optimal task-technology fit focuses on learning how to use the new technical system and the changes it brings to practical work. TR practice emphasizes collaboration with the clients' networks. The individual-task fit dimension focuses on the complexity of the task, mental and physical workload, and personal contact and feedback on performance. The FITTIO framework guides observation through either client-related attributes or profession-related attributes.

Discussion

Principal Findings

In TR, the professionals' practice depends on both social and technical components. Our key findings from the deductive analysis demonstrated that, from the sociotechnical point of view, the adaptation of TR in outpatient rehabilitation practice highlights the fit between individual and technology, as well as the environmental dimensions.

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In individual-task fit, adequate skills of professionals and clients, support for participation, and a positive attitude are essential. Our findings align with Kujala et al [11], indicating that most challenges were related to a nonfit between individuals and technology. The professionals in our study expressed concerns that some clients might be unable to use the technology due to disabilities, echoing the findings of Noblin et al [13]. To achieve the optimal task-technology fit, the professionals needed familiarization, changes in methods and materials, and collaboration with the clients and their close associates and networks. The individual-task fit revealed that the professionals found TR tasks to be more complex than in-person practice and that TR increased professionals' workload and clients' need for personal contact.

The FITT and FITTE reference questions are particularly well-suited for the design of technology used in clinical settings. When looking at clients in a nonclinical environment, the impact of everyday life, personal context, and environment increases [7,12]. In our study, professionals stated that the sociopolitical situation regarding remote services within the rehabilitation system varied and that there were differences in policies between organizations. Furthermore, in Estel et al [1], most physiotherapists were unaware of the current legal viewpoints related to digitalization. Jacob et al [4] pointed out the importance of organizational aspects in their review of existing theoretical frameworks used in technical adoption. Earlier studies on FITT and FITTE have identified the potential to extend the frameworks to represent these attributes. These studies have reported that policy, management, organizational, interdisciplinary collaboration, and cultural attributes are crucial factors influencing the adoption of TR [10,11,13,14,21].

In our previous study, we pointed out that TR creates a new kind of shared participation [12]. A social system in rehabilitation is traditionally based on the relationships between professionals and clients. According to our findings, social systems in TR cover professional peers, assistive persons, and clients' close associates' network engagement. Similar to our findings, Zhai et al [14] suggest extending the FITT framework to cover network engagement and collaboration across the institution. Our findings demonstrate that, to fully understand the sociotechnical adaptation and nonadoption of TR in rehabilitation practice, some of the FITTE framework's dimensions should be specified more accurately.

From FITTE to FITTIO

In our abductive reasoning process, we identified refined perspectives and new insights that complement the previous frameworks. Based on these findings, we propose contributing to the evolution of the FITTE framework by introducing the FITTIO framework. FITTIO separates the clients' and professionals' perspectives into their dimensions and divides the environmental dimension into two distinct dimensions: an interactive sociotechnical environment and an organizational sociopolitical context. This updated framework analyzes the interactions between individual, technology, task, and environmental factors that influence technology adoption in a rehabilitation setting in a more multidimensional manner than previous frameworks.

Similar to Prgomet et al [10], our findings highlight the importance of analyzing the environment as a whole and the involved attributes more precisely. In the original FITT framework, environmental factors were encapsulated as part of individual attributes [6]. Prgomet et al [10] added the environment as its dimension, which helped to analyze the factors related to the context in which individuals, tasks, and technology interplay.

In FITTIO, we apply the proposition of Kujala et al [11] to add context, including organization and management, to the environment dimension, and we divide the dimension into two. The interactive sociotechnical environment describes the interactive, practical environment for therapy. It includes temporal, spatial, and digital qualities, which direct the analysis to when, where, and in what kinds of environments nonfit occurs. The sociopolitical context describes the organizational and sociopolitical attributes that set the frame for the entire rehabilitation practice. With these specifications, FITTIO aims to capture the complexity of the environment of outpatient rehabilitation.

As Ammenwerth et al [6] noted, a detailed analysis using the FITT framework reveals whether problems in the use of technology were based on the nonfit between individual and task, individual and technology, or task and technology. When exploring the adoption of technology from a professional's perspective, the focus in the framework differs from when examining it from the client's perspective. Based on our findings, we agree with Kujala et al [11] that both health care professionals and clients should be represented in the individual dimension. Ruyobeza et al [29] suggested that a more detailed task definition may be crucial in assessing the task and skills fit. We agree that a more detailed analysis of required skills, as well as a more precise task analysis, is needed to gain a good understanding of the fit between the individual and the task. In our view, separating the client-related attributes and the professional-related attributes directs the analysis more closely to the needed skills and abilities. Therefore, the FITTIO framework helps to modify tasks, select suitable technology, and guide and help individuals in using the technology or training the skills required.

Frameworks provide shared terminology behind the core conceptual issues, which may be essential for multidisciplinary cooperation in health care and shared interpretation of the problems [4,30]. Sociotechnical systems theories have been used for several decades to explain and understand the interwoven relations of human and technical factors [5]. Since Ammenwerth et al [6] created the FITT framework, it has been used and modified [10,11,29] to gain a better understanding of the adoption of IT systems in health care. When looking at the use of TR as a contextual phenomenon, previous frameworks have not sufficiently addressed the complexities of outpatient rehabilitation. The FITTIO framework provides conceptual tools for making contextual interpretations of the adoption of TR in different clients' cases in outpatient rehabilitation. With these conceptual tools and shared terminology, the FITTIO framework can strengthen the interdisciplinary engagement in TR development.

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The FITTE framework and the sociotechnical theory complement each other in the development of TR. The FITTE framework provides concrete tools and more detailed guidance for analyzing the fit between technology, task, and individual, while sociotechnical theory broadens the perspective toward the FITTIO framework by taking into account the organization, environment, and social context. Therefore, the FITTIO framework can be interpreted as an interconnection of the FITTE framework and sociotechnical theory.

By combining all these viewpoints into the FITTIO framework, the effectiveness and acceptability of TR may be improved, especially when considering both clients' and professionals' needs and abilities, as well as the organizational structures and social context. The FITTIO approach ensures that TR services are of high quality and support rehabilitation goals and the implementation of rehabilitation by technology-mediated means.

Strengths and Limitations

This study has some strengths and limitations. First, the sample included 629 professionals across Finland who were recruited to participate in the survey during the first wave of the COVID-19 pandemic. Due to the anonymous nature of our questionnaire, it was impossible to analyze the differences between professionals who participated and those who did not. Therefore, our study is at risk of nonresponse bias.

It is also important to note that during the first wave of the COVID-19 pandemic, it was strongly recommended to practice rehabilitation only via remote connection. In our sample, many participants conducted TR against their wishes and expressed critical views on TR. The open-ended questions enabled us to identify novel factors related to the sociotechnical adaptation of TR that have not been explicitly studied previously. These insights can be used to further explore optimal design, adaptation, and implementation of TR across different clients and settings.

This study was limited to professionals' perspectives and lacked insights from clients. Until now, only a few studies using the FITT and FITTE frameworks have focused on clients' points of view in technology adoption [7,22,31,32]. Thus, future research should include diverse client groups, multidisciplinary providers, and other rehabilitation settings.

In the future, the FITTIO framework should be refined by comparing it with other technology adoption models. The framework still needs to be verified by linking its concepts and their relationships with empirically collected data from different client groups and professionals.

Conclusion

In TR, professionals' practice depends on both social and technical components. Based on our findings, which improve the understanding of the FITT and FITTE frameworks in analyzing the technological and nontechnological factors affecting the adoption of TR, we propose an extension from FITTE to FITTIO. In the FITTIO framework, we divided the original dimensions into more specific ones. These specifications allow for a more detailed analysis of TR practice and reveal where adoption and nonadoption occur. In addition, the FITTIO framework provides a shared terminology and conceptual tools for making contextual interpretations of the adoption of TR in outpatient rehabilitation. This study improves understanding of the sociotechnical nature of TR, which may be used in the design and adoption of technological solutions in different rehabilitation settings.

Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to concerns regarding participant confidentiality and data protection.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Open-ended questions used in the study.
[DOCX File, 14 KB - rehab_v12i1e74296_app1.docx]

Multimedia Appendix 2
Main category contents.
[DOCX File, 18 KB - rehab_v12i1e74296_app2.docx]

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Abbreviations

FITT: Fit between Individuals, Tasks, and Technology
FITTE: Fit between Individuals, Tasks, Technology, and Environment
FITTIO: Fit between Individual, Tasks, Technology, Interactive Sociotechnical Environment, and Organizational and Sociopolitical Context
TR: telerehabilitation

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Original Paper

Home-Based Nonimmersive Virtual Reality Training After Discharge From Inpatient or Outpatient Stroke Rehabilitation: Parallel Feasibility Randomized Controlled Trial

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Abstract

Background: Nonimmersive virtual reality training (NIVRT) can be used to continue rehabilitative exercise for stroke recovery at home after discharge from inpatient or outpatient therapy.

Objective: The objectives of this randomized controlled feasibility trial were to assess home-based NIVRT as telerehabilitation with patients living with stroke, and its potential to improve standing function and gait.

Methods: Patients approaching discharge from inpatient or outpatient stroke rehabilitation were randomly allocated to NIVRT or iPad interventions. NIVRT provided interactive games and exercises designed to improve balance, stepping, and aerobic capacity. iPad apps addressed cognition and fine motor skills. Participants were visited in their homes by a physiotherapist, taught to use the program, and asked to do 30 minutes of exercise 5 days a week for 6 weeks, asynchronously. Feasibility was assessed by measuring recruitment, adherence, ability to set up and learn NIVRT, enjoyment, intent to continue, perception of impact, and safety. Participants completed assessments of standing balance, gait, and general function, before and after the intervention, by a blinded assessor.

Results: NIVRT participants (n=11; 10 male participants; mean age 64, SD 12 years) did an average of 26 sessions (total 700 minutes), while iPad participants (n=9; 6 male participants; mean age 61, SD 20 years) did an average of 33 sessions (total 1241 minutes). Space was tight in 5 homes. All but 1 participant learned NIVRT and progressed. Most enjoyed it and felt that it improved their recovery. There were no serious adverse events. Most assessments showed improvement over time for both groups.

Conclusions: Home-based NIVRT is safe and feasible to continue rehabilitative exercise after discharge. More research on efficacy and effectiveness in this population is required.

Trial Registration: ClinicalTrials.gov NCT03261713; https://clinicaltrials.gov/study/NCT03261713

International Registered Report Identifier (IRRID): RR2-10.1186/s13063-019-3438-9

(JMIR Rehabil Assist Technol 2025;12:e64729) doi:10.2196/64729

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KEYWORDS

virtual reality; telerehabilitation; stroke; home; exercises; physical activity; physiotherapy; exergames; rehabilitation intensity; randomized controlled feasibility trial; motor; movement; patient care; patient engagement; health intervention; stroke rehabilitation; interactive games; game therapy; interactive therapy; rehabilitation

Introduction

More than 108,000 individuals experience a stroke each year in Canada [1], with roughly 40% having moderate to severe disability requiring intense therapeutic intervention [2]. Rehabilitation is essential to maximize recovery after stroke [3]. Substantial evidence suggests that greater benefit is obtained by providing a greater intensity of rehabilitation [4]. Unfortunately, many patients complete their formal rehabilitation before recovery is complete [5]. When a patient is discharged home, maintaining a regimen of therapeutic exercise until recovery has plateaued is essential. However, outpatient and community-based rehabilitation may be inaccessible for reasons such as lack of programs, transportation difficulties, inclement weather, fatigue, or financial limitations [6]. For these patients, home-based therapy may be preferred. Home-based care (eg, doing a prescribed number of isolated exercises every day, intended to improve muscle strength, coordination, balance, and gait [7]) does not lead to worse outcomes compared to institution-based care [8].

Despite its importance, home-based exercise can be dull, and patients tend to reduce their adherence over time [7]. One rehabilitation approach that has been shown to mitigate these obstacles is nonimmersive virtual reality training (NIVRT, also called exergaming), in which a camera, coupled with computer software, allows a patient to interact with a game or exercise presented on a TV. NIVRT is convenient, engaging, and motivating [9], and may encourage the user to increase their rehabilitation intensity, either by doing more repetitions per session or by doing more sessions per week [10,11]. NIVIRT can be used as a form of asynchronous telerehabilitation, in which the therapy is done without the therapist being present, either in-person or virtually [6].

Telerehabilitation using NIVRT has been shown to be as good as conventional therapy for the rehabilitation of upper extremity deficits, activities of daily living, and postural balance after stroke [12-14]. One meta-analysis found that NIVRT-based telerehabilitation improved upper extremity function more than an active control, as assessed by the Fugl-Meyer Assessment [15]. Safety, feasibility, and enjoyment have been shown for upper extremity home-based NIVRT [13,16], and there is budding evidence of feasibility for lower extremity motor recovery, gait, and balance in subacute and chronic stroke [16-18]. Lee et al [17] reported a small but significant benefit to doing balance and gait-related NIVRT via telerehabilitation, with moderate usability (the exercises were easy to learn but technical issues were common) and no reported falls. Users in several studies reported NIVRT to be motivating [16]. In addition, the use of NIVRT (not telerehabilitation) for the improvement of gait in chronic stroke is enjoyable and safe [19]. Laver et al [20] reported insufficient evidence to determine the effects of telerehabilitation on improvement in mobility after stroke, although Hao et al [15], in their updated meta-analysis, found that there was no difference between NIVRT and traditional therapy in gait speed, walking endurance, balance, and functional mobility. However, Hao et al [15] only included 5 studies in their analysis. Of the 5 studies, one was conducted in a simulated home environment at the hospital, one compared telerehabilitation using NIVRT to no home-based therapy, one compared the NIVRT telerehabilitation intervention with a similar clinic-based one or conventional hospital-based therapy, one compared the same NIVRT performed in the clinic and the home, and one recruited people living with chronic stroke living in long-term care, and used an active control group [21-25]. Compared to upper extremity therapy, there are few studies investigating the use of NIVRT as telerehabilitation for balance, gait, and function, particularly in the subacute phase after stroke, when rehabilitation is more likely to provide benefits [26].

The purpose of this study was to investigate if an NIVRT-based telerehabilitation program for balance, gait, and function, provided shortly after discharge from inpatient or outpatient rehabilitation, is acceptable and has the potential for benefit. Before creating a strong protocol for a definitive efficacy study, feasibility, safety, and acceptance need to be clarified [27]. The potential efficacy of NIVRT can be tested with a small sample, which will also assess the selected outcome measures and provide data for future sample size estimation. The results of this randomized controlled feasibility trial will inform the methods and sample size of a future randomized controlled trial.

The primary objective was to assess the feasibility of using NIVRT as telerehabilitation with patients poststroke. There were five components to this feasibility objective:

- To estimate the recruitment of participants into the study
- To assess the ability of participants and their study partners to install and use the NIVRT technology within their homes
- To assess the ability of participants to learn NIVRT given the training provided and to adhere to the exercise protocol (retention
- To determine the safety of NIVRT
- To determine the acceptability of NIVRT for stroke recovery (enjoyment, perceived efficacy)

The second objective was to assess the potential of telerehabilitation using NIVRT with patients living with stroke to maintain or improve physical outcomes of standing balance, gait, general function, and community integration after discharge from inpatient or outpatient rehabilitation, compared to those who performed a program of iPad apps designed for fine hand motor skills and cognitive training.

Methods

Study Design

This study was a prospective, single-site, assessor-blinded, parallel-group randomized controlled feasibility trial.

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Participants were randomized to NIVRT or iPad (active control intervention). The protocol for this study has been published [28]. The iPad control group was chosen to ensure that all participants had equal contact time with the research team and approximately equal time spent doing an engaging activity, but the control activity would not be expected to have any direct influence on the physical outcomes of balance, gait, and function. Using an active control group also aided in recruitment [28]. CONSORT (Consolidated Standards of Reporting Trials) guidelines for randomized pilot and feasibility trials were followed [29,30]. The CONSORT checklist is available in Multimedia Appendix 1.

Participants

In total, 20 participants were recruited from a tertiary-care urban hospital located in Ontario, Canada, between July 2017 and October 2018. Participants were recommended by staff physiotherapists. Because this was a feasibility study rather than an efficacy study, no sample size calculation was performed. Instead, the sample size was determined based on recruitment expectations, available funding, and the potential to address the feasibility outcomes.

Patients were eligible if they were approaching discharge from either inpatient or outpatient stroke rehabilitation, with the intent that they would participate post discharge. While there was no eligibility criterion regarding the chronicity of stroke, inpatient and outpatient stroke rehabilitation at this facility was generally reserved for patients in the subacute phase after stroke. Potential participants must (1) have had an ischemic or hemorrhagic stroke resulting in physical impairment, (2) be cognitively able to provide informed consent and therefore presumed able to learn NIVRT, (3) be able to stand independently for at least 2 minutes and able to perform mild to moderate exercise, (4) have a study partner (a family member or friend who would be trained to use NIVRT along with the participant and be present in the home during NIVRT), (5) be able to read, speak, and understand English, (6) have no plans to travel away from home for more than 2 days a week, and (7) have enough space in their home to do NIVRT. Patients were excluded if they had an unstable medical condition, seizures, or vertigo. Participants were recruited by a research assistant, who randomized them to NIVRT or iPad groups in a 1:1 ratio with permuted blocks, using a computer-based randomization platform (Sealed Envelope). Allocation was concealed from the assessment physiotherapist (who did the assessments) and from other participants. It was impossible to blind the participants as to their allocation.

Age, sex, BMI, hand dominance, weeks since stroke, type, and side of stroke were recorded. The Motivation for Physical Activity Question (which has high levels of reliability) [31] was administered during the preassessment and the Physical Activity Enjoyment Scale (PACES) (which has satisfactory or better validity and test-retest reliability when administered to older adults) [32,33] was administered at the postassessment to help describe participant samples.

Interventions

NIVRT was provided using the Jintronix NIVRT platform. Infrared sensors combined with Microsoft software enabled a Kinect camera (Microsoft Canada Co) to track the participant's movements, allowing them to interact with a game or exercise presented on a TV screen (Figure 1). Games and exercises addressed rehabilitative goals of improving balance (eg, slalom skiing, moving a ball around a maze), range of motion (eg, arm circles), strength (eg, sit-to-stand), reaching (eg, "planting" and "harvesting" tomatoes), stepping (eg, whack-a-mole), and aerobic capacity (eg, marching on the spot). Parameters such as range of motion, distance, speed, or accuracy were selected based on the participant's physical abilities, fall risk, tolerance, and rehabilitation goals. For example, for slalom skiing, the speed at which the gates appeared, the distance to lean, the proportion of right to left leans, the addition of banners to squat under, and the number of gates could all be customized. For more details, see Sheehy et al [28].

iPads (Apple) for participants in the iPad group were loaded with apps designed to address memory and cognition, visual tracking and scanning, and fine motor skills. There was no specific selection of apps for all iPad group participants. The iPad intervention provided the participants with an activity that was engaging and took the equivalent amount of time to the NIVRT program; however, the apps were not expected to impact balance, gait, and mobility.

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Figure 1. Participant performing nonimmersive virtual reality training in his home.



Outcome Measures

To address the first feasibility objective, the number of participants recruited over 15 months was recorded and presented relative to the number of patients admitted for stroke rehabilitation.

The ability of participants and their study partners to install and use the NIVRT technology and to learn the individual NIVRT games and exercises was assessed through comments provided by the participant and study partner in a logbook, field notes recorded weekly by the intervention physiotherapist, and during a semistructured interview (Multimedia Appendix 2), administered to the participant and study partner at the end of their participation. Questions regarding the acceptability of NIVRT were included in the interview and assessed with the PACES.

Adherence to the protocol and progression were monitored asynchronously by tracking the use of NIVRT (using data stored within the Jintronix platform) and the iPad (using a logbook). If a majority of participants performed less than 450 minutes of NIVRT (75 minutes per week) over the course of the trial, the use of NIVRT for motivation would be reconsidered. If no progression was observed, the potential factors responsible (eg, poor ability to learn) would be deliberated. Retention was tracked using a spreadsheet; a loss of greater than 25% would suggest that the protocol should be reviewed prior to launching a future definitive randomized controlled trial.

The intervention physiotherapist inquired about major adverse events (eg, death or injuries serious enough to require withdrawal from the study) and minor adverse events (eg, mild joint or muscle soreness that responded to changes in the intervention) at each contact with the participant. The occurrence of major adverse events would indicate that telerehabilitation provided via NIVRT according to the protocol is too risky to continue.

To address the second objective, the following tests were administered in-person by the assessment physiotherapist, all of which have adequate to excellent reliability, validity, and responsiveness to change (unless noted below):

1. Berg Balance Scale (BBS), which tests balance and mobility [34-36].
2. Timed Up and Go (TUG) test, which tests ambulatory function. A total of 3 variations were administered: original, manual dual-task (carrying a cup of water), and cognitive dual-task (counting backward in 7's from 100) [37-40].
3. Five Times Sit-To-Stand (FTSTS) test, which assesses lower-extremity strength [41,42]. Responsiveness to change has not been confirmed in stroke populations.

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4. Community Balance and Mobility (CB&M) Scale, which tests more difficult tasks relevant to community ambulation [43,44].
5. Stroke Impact Scale (SIS) (v3.0), which assesses 59 components of health status, each scored from 2-5 for a maximum total of 295 (higher scores equal less impact of the stroke), as well as a separate visual scale measuring recovery from 0 (no recovery) to 100 (full recovery) [45].
6. Community Integration Questionnaire (CIQ), which assesses integration in home, social, and productivity domains with a maximum total of 29 (higher score equals greater integration) [46,47].

These final two outcome measures were included for their potential to assess the impact of improved balance, gait, and mobility on quality of life and community integration.

Procedures

After consenting, participants first attended two one-hour preassessment sessions at the hospital, administered by the assessment physiotherapist who was blinded to intervention allocation. Upon completion of the preassessments, each participant was randomized to either the NIVRT or iPad group by the intervention physiotherapist, who was blinded to the preassessment results. The intervention physiotherapist created a customized program of NIVRT or iPad apps, in consultation with the participant's clinical physiotherapist and occupational therapist, and within 5 days visited the home of the participant and their study partner. For NIVRT group participants, the NIVRT equipment was installed in the home and the participant and study partner were trained on its use (including safety considerations and what to do should a fall or injury occur). The study partner was instructed to assist with technical requirements, motivation, and supervision as needed, but not to physically assist or guard the participant during exercises. For iPad group participants, the iPad was brought to the home and the participant and study partner were trained on the apps. For both groups, written material supplemented the training, and a logbook was provided to write down comments and the time spent doing each app (iPad users only). Participants were requested to perform the intervention 30 minutes a day, 5 days a week, for 6 weeks, asynchronously, without direct supervision from the intervention physiotherapist.

The intervention physiotherapist contacted each participant by phone at least weekly to review the programs, answer questions, and suggest progressions. The NIVRT programs were modified and progressed remotely if participants consistently achieved 100% on an activity, found the activity too easy, became bored, or wished to work on different therapeutic goals. Suggestions for new or modified iPad apps were made if participants became bored, found the apps too easy, or wished to focus on different tasks. Field notes were recorded after each interaction.

After 6 weeks of intervention, participants returned to the hospital for the postassessment, which was completed in one session. Participants in the iPad group gave the iPad to the intervention PT before their postassessment appointment. For NIVRT participants, the intervention PT visited the home to remove the equipment.

Data Analysis

Participant demographics (including the Motivation for Physical Activity Question and PACES) were described using means and SDs, or proportions, and compared using independent samples *t* tests, Fisher exact tests, and Mann-Whitney U tests. Quantitative outcome measures were described using means and 95% CIs and SDs. Missing data were addressed by removing cases analysis by analysis. Scales were compared using mixed-model analyses of variance (within-group factor: time; between-group factor: group; interaction: time × group). If the interaction was insignificant, the interaction was removed, and the main effects of each factor were assessed. Assumptions (eg, presence of outliers, normal distribution of data, homogeneity of variances, and homogeneity of covariances) were assessed before the analyses of variance were carried out [48]. Data analyses were performed with SPSS (version 28.0.1.1; IBM Corp).

Qualitative data were analyzed using thematic analysis following the model provided by Castleberry and Nolen [49]. Interviews were transcribed. They were compiled, along with logbook entries and intervention physiotherapist records of contact with participants, then disassembled (ie, coded) by 2 research team members and reassembled into themes, using an iterative process begun with deductive reasoning (using the objectives as premises) and including inductive reasoning as required [49,50]. The 2 research team members did this independently and then conferred to review and interpret the themes. Each team member engaged in a reflexivity exercise before beginning the analysis. Disagreements were moderated by a third team member until consensus was reached.

Ethical Considerations

Research ethics approval was obtained from the Bruyère Health Research Institute (M16-17-013) and the University of Ottawa (A01-15-03) research ethics boards. The trial was registered at ClinicalTrials.gov (NCT03261713). Participants and their study partners provided written informed consent. Data were deidentified and associated with participant study IDs only. Participants did not receive any compensation other than travel expenses (eg. parking fees or return taxi fare or bus tickets; plus a CAD $5 (US $3.50) coffee shop voucher if the visit was over the lunch hour) for the postassessment sessions.

Results

Participants

Of the 20 participants recruited, 17 participants were recruited through the outpatient service and 3 from the inpatient service; all completed the study. From July 1, 2017, to September 30, 2018, there were 403 inpatient and 290 outpatient admissions. See Figure 2 for the CONSORT flow diagram, Table 1 for a summary of participant demographics, and Multimedia Appendix 3 for details of the participants. There was one outlier, in which a participant in the iPad group was enrolled 81 weeks post stroke. Otherwise, there were no differences between groups.

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Figure 2. CONSORT (Consolidated Standards of Reporting Trials) 2010 flow diagram.

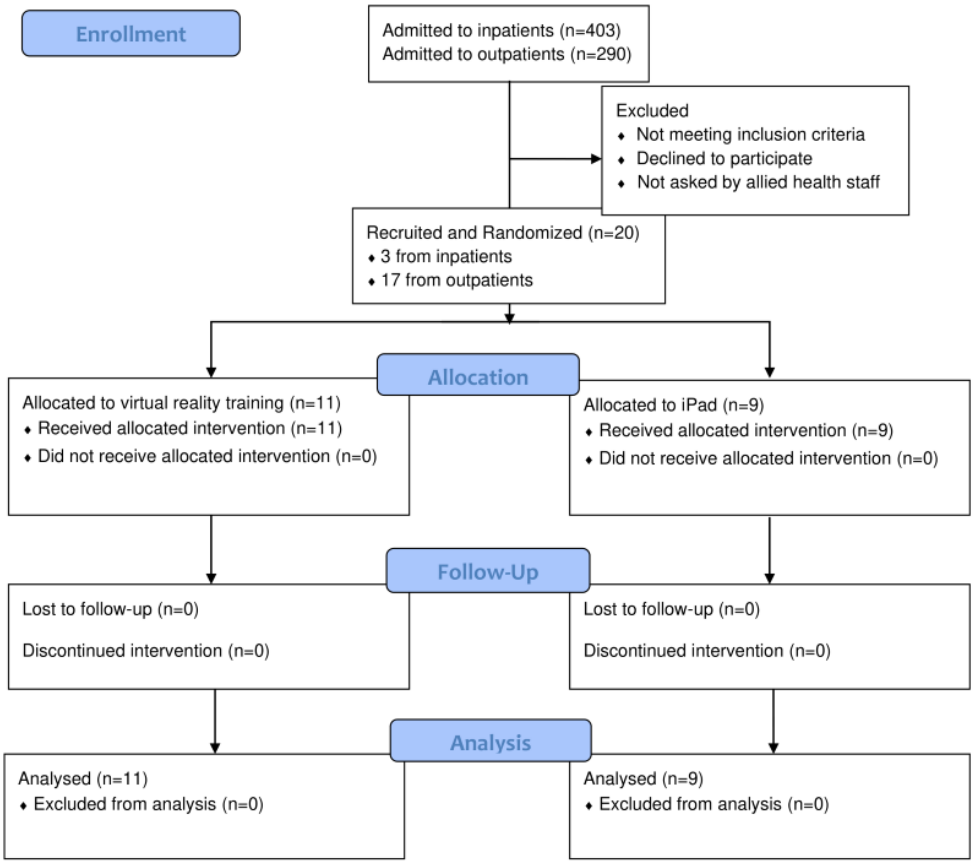


Table 1. Summary of participant demographics.

Demographics	Nonimmersive virtual reality training group (n=11)	iPad group (n=9)
Age (years), mean (SD)	63.7 (11.9)	61.0 (20.3)
Sex, n		
Male	10	6
Female	1	3
BMI (kg/m^2), mean (SD)	24.9 (3.3)	27.5[a] (3.9)
Hand dominance, n		
Right	9	8
Left	2	1
Weeks since stroke, mean (SD)	15.1 (7.9)	16.9[a] (8.1)[b]
Type of stroke, n		
Ischemic	8	9
Hemorrhagic	3	0
Side of stroke, n		
Right	6	4
Left	5	5
Motivation for physical activity question, mean (range)	5.4 (0-6)	5.8 (4-6)
Physical activity enjoyment scale, mean (SD)	92.5 (19.9)	101.0 (19.6)

[a]Based on 8 participants.

[b]There was one outlier who enrolled 81 weeks after their stroke. If their data are included, the average weeks since stroke was 24.0 (SD 22.7).

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The qualitative data were used to contextualize the quantitative data associated with each component of the primary (feasibility) objective. The themes agreed upon by the research team were installation and technology (related to primary objective 2), ability to learn and progress (primary objective 3), games and glitches (primary objective 3), perceived usefulness (primary objective 5), enjoyment (primary objective 5), and interest to use again (primary objective 5).

Primary (Feasibility) Objective 1: Estimation of Recruitment of Participants

Approximately 1% of inpatients (3/403) and 6% of outpatients (17/290) were recruited. Inpatients were hesitant to participate as they felt anxious and overwhelmed around the time of discharge. Physiotherapists and occupational therapists in the outpatient stroke program used NIVRT with some of their patients; however, no participant mentioned that they had used NIVRT before. One participant mentioned that it would have been helpful to begin using NIVRT as an inpatient to develop the routine of using it.

Primary (Feasibility) Objective 2: Ability to Install and Use Nonimmersive Virtual Reality Training Technology

The NIVRT system was successfully installed in all participant's homes; however, some issues were identified. One issue was space. Of the 11 participants using NIVRT, 4 had it installed in their living room, 3 in their basement, 2 in their den, and 2 in their bedroom. The choice was informed by the available space and the proximity of the participant's TV. One participant wanted to keep the computer equipment out of the reach of grandchildren. All participants used their own TV, which was mounted on a wall (5 participants) or a horizontal surface (6 participants). A total of 5 participants had less than 2.0 m of unobstructed space in front of the camera, which led to difficulties with the camera properly tracking the movement of the lower extremities. One TV did not have an accessible HDMI port; an HDMI-to-AV converter was used, resulting in mediocre picture quality. All participants had Wi-Fi in their homes.

Most participants managed the use of the computer well, although one participant had difficulties with turning the computer on and off and using a mouse. One participant mentioned difficulty with typing and suggested a one-piece system with one-button accessibility. The computers were set up to not require passwords; however, unexpected issues arose, such as power outages, computer sound not working, and a Windows feature update that caused incompatibility with the Jintronix software for a time. All issues but one (the need for the HDMI-to-AV converter) were resolved remotely.

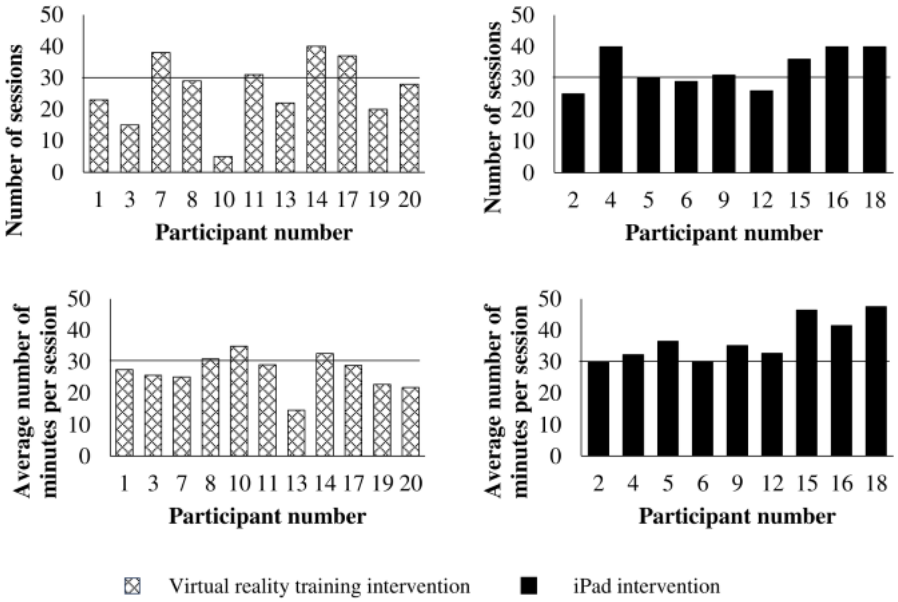
The requirement for the participant and study partner to speak English was important, as several participants and study partners had difficulty communicating the intricacies of computer set-up and NIVRT (or iPad) use.

Primary (Feasibility) Objective 3: Ability to Learn Nonimmersive Virtual Reality Training and Adhere to the Exercise Protocol

All participants but one learned to use NIVRT and progressed throughout the study. The single participant had poor motivation, despite encouragement from their study partner, and only completed 5 NIVRT sessions. Participants provided a variety of comments on their perceptions of the difficulty of the program. Some felt that it was too easy at times while others found that it was initially difficult but got easier over time.

All participants completed the study. Overall adherence to the program (30 minutes of intervention 5 days per week for 6 weeks for a total of 30 sessions and 900 minutes of therapy) was excellent. NIVRT participants did an average of 26 sessions with a total of 700 minutes while iPad participants did an average of 33 sessions with a total of 1241 minutes (Figure 3).

Figure 3. Number of sessions and average number of minutes of exercise per session for each participant. Horizontal black lines indicate the requested number of sessions or minutes per session.



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Several comments within the "games and glitch" theme related to the participants' interaction with the NIVRT. Most participants commented that the Kinect camera had difficulty tracking their movements. While participants enjoyed games with direct feedback (eg, kicking a soccer ball), some games were described as "frustrating" (eg, putting cutlery in a drawer, which required advanced visuospatial skills). Many participants found the scoring confusing (eg, scoring did not reflect improvement) and the feedback annoying (eg, even when the exercise was done incorrectly, the system said "nice job"). One participant mentioned that they did not like the playback feature (after an exercise, the system replayed a short video of their performance).

Primary (Feasibility) Objective 4: Safety of Nonimmersive Virtual Reality Training

There were no serious adverse events. There were 3 minor adverse events. One participant complained of shoulder pain for 20-30 minutes after doing NIVRT, due to "frozen shoulder." They continued the program, adjusting as necessary. One participant suffered from a flare-up of gout, which was successfully treated, after which they were able to return to the program. One participant reported fatigue if they did NIVRT on the same day as other therapies.

Primary (Feasibility) Objective 5: Acceptability of Nonimmersive Virtual Reality Training

Most participants enjoyed doing the NIVRT. Two participants said that while it was initially interesting and fun, later it became more like a chore. Others described NIVRT as "boring," "simple," and "convenient." A total of 3 participants would have liked an in-person or group component to the program.

Participants and study partners commented in detail on the specific games and exercises. There was a wide variety of opinions regarding which games were enjoyable. Many liked exercises that focused on strengthening, balance, coordination, weight shift, range of motion, and stretching, while others specifically did not like the strengthening games.

Almost all participants reported that NIVRT was useful and improved their recovery. Notably, 1 participant reported improved gait, independence, and strength, and 2 mentioned improvements in daily tasks like putting on their pants and doing bilateral upper extremity activities. Some mentioned that NIVRT was motivating and that scheduling the NIVRT encouraged self-discipline to continue exercising after discharge. On the other hand, 2 participants found that NIVRT was more difficult to do than physiotherapy since there was no accountability. Several participants commented that NIVRT was a useful tool to improve recovery, but should be combined with walking, physiotherapy, and specific hand exercises (NIVRT does not focus on the hand). A total of 2 participants found that 5 times a week was excessive. When asked, 6 participants (out of 11) or their study partners were interested in continuing NIVRT. A single participant shared that they would prefer activities that garner a sense of community.

Second Objective: Potential of Nonimmersive Virtual Reality Training to Improve Physical Outcomes and Community Integration

The results regarding the potential for NIVRT to affect physical outcomes and community integration are found in Table 2 and Figure 4. All assumptions were met except that the Levene test of homogeneity of variance for the post assessments of the CB&M scale was significant (P=.03), and there was one legitimate outlier on the BBS, which slightly affected the normal distribution and the homogeneity of variance for the preassessment. Since the deviations were small, parametric testing was performed as planned. There were no statistically significant interactions between group and time (ie, the intervention did not affect one group more than the other), and no statistically significant differences between groups. However, when the groups were combined (main effect of time), there was an improvement over the 6-week intervention period for several outcome measures.

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Table 2. Outcome measures over the 6-week intervention period, presented as means and 95% CIs, with mixed-model analysis of variance results for interaction, group, and time.

Outcome measure	Nonimmersive virtual reality training, mean (95% CI)			iPad, mean (95% CI)			Interaction *F* test (*df*)	*P* value	Group main effect *F* test (*df*)	*P* value	Time main effect *F* test (*df*)	*P* value
	Pre	Post	Participants, n	Pre	Post	Participants, n						
BBS[a]	50.1 (46.7-53.5)	49.6 (44.3-54.9)	11	53.4 (49.7-57.2)	54.0 (48.1-59.9)	9	0.273 (1)	.61	1.637 (1)	.22	0.003 (1)	.96
TUG[b] original	10.9 (7.8-14.0)	10.8 (7.8-13.8)	9	11.6 (8.5-14.7)	10.3 (7.3-13.3)	9	0.845 (1)	.37	0.003 (1)	.95	1.028 (1)	.33
TUG man[c]	13.4 (9.0 - 17.9)	12.5 (9.3-15.7)	9	14.4 (10.0 - 18.9)	12.0 (8.8-15.2)	9	1.738 (1)	.21	0.009 (1)	.92	8.194 (1)	.01 [d]
TUG cog[e]	17.4 (11.2-23.6)	15.3 (11.2-19.4)	9	16.6 (10.4-22.8)	13.2 (9.1-17.2)	9	0.625 (1)	.44	0.186 (1)	.67	11.043 (1)	.004[d]
FTSTS[f]	17.5 (11.7-23.3)	14.2 (9.0 - 19.3)	10	14.8 (8.7-21.0)	12.9 (7.4-18.3)	9	0.626 (1)	.44	0.286 (1)	.60	9.866 (1)	.006[d]
CB&M[g]	38.5 (23.4-53.7)	44.2 (25.0-63.4)	11	46.3 (29.5-63.1)	52.4 (31.2-73.6)	9	0.007 (1)	.93	0.451 (1)	.51	4.440 (1)	.05[d]
SIS[h]	228.1 (206.5-249.7)	237.6 (220.8-254.3)	9	236.1 (214.5-257.7)	249.9 (233.1-266.6)	9	0.355 (1)	.56	0.676 (1)	.42	10.202 (1)	.006[d]
% Recovery (part of the SIS)	51.9 (39.4-64.3)	65.6 (54.3-77.0)	8	65.0 (53.3-76.7)	74.4 (63.8-85.1)	9	0.732 (1)	.41	2.288 (1)	.15	21.232 (1)	<.001[d]
CIQ[i]	16.2 (12.7-19.6)	15.4 (12.1-18.7)	9	15.1 (11.4-18.8)	15.4 (11.9-18.8)	8	2.902 (1)	.11	0.060 (1)	.81	0.528 (1)	.48

[a]BBS: Berg Balance Scale.

[b]TUG: Timed Up and Go test.

[c]TUG man: Timed Up and Go manual dual-task test.

[d]Statistical significance.

[e]TUG cog: Timed Up and Go cognitive dual-task test.

[f]FTSTS: Five Times Sit-To-Stand test.

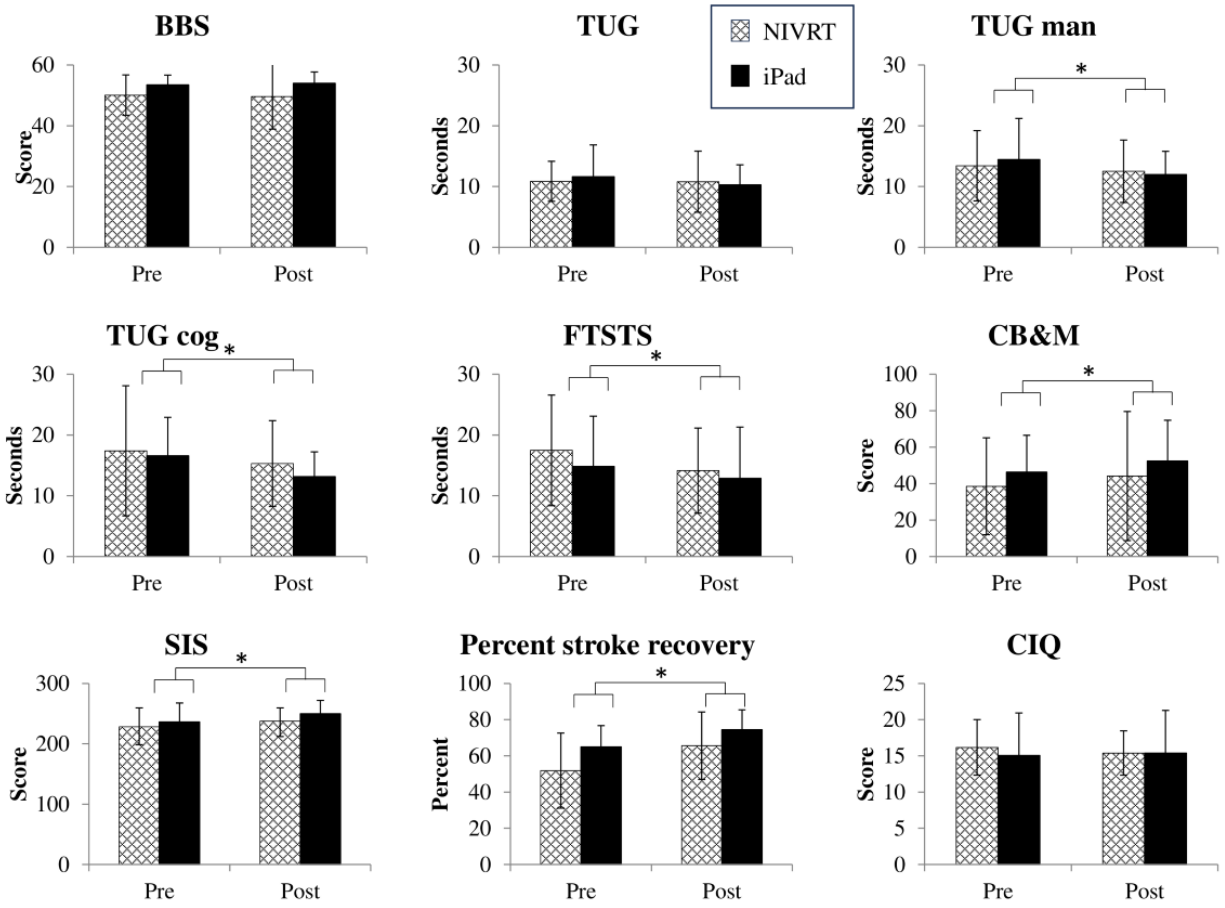
[g]CB&M: Community Balance and Mobility.

[h]SIS: Stroke Impact Scale.

[i]CIQ: Community Integration Questionnaire.

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Figure 4. Physical outcome measures over the 6-week intervention period, presented as means and SDs. Comparisons with * are statistically significant for the main effect of change over time. BBS: Berg Balance Scale; CB&M: Community Balance and Mobility Scale; CIQ: Community Integration Questionnaire; FTSTS: Five Times Sit-To-Stand test; NIVRT: nonimmersive virtual reality training; SIS: Stroke Impact Scale; TUG: Timed Up and Go test; TUG cog: Timed Up and Go cognitive dual-task test; TUG man: Timed Up and Go manual dual-task test.



Discussion

Principal Findings

This study shows that NIVRT provided via telerehabilitation is a feasible way for individuals who have recently had a stroke to continue with rehabilitative exercise focusing on lower-extremity function, balance, and gait at home. The results of this study will inform the methods and sample size of a future randomized controlled trial on the use of NIVRT in community-based stroke recovery.

A majority of the participant sample identified as male. Females and women are frequently underrepresented in stroke rehabilitation studies, which may limit the generalizability of the outcomes [51,52]. Female survivors of stroke show less functional recovery than males and experience greater barriers to regaining participation poststroke [53]. It is possible that existing negative attitudes and beliefs of women patients with stroke towards NIVRT affected their interest in the study [51]. Wiley et al [54] emphasized the importance of reinforcing positive expectations toward exercise after stroke for all genders. It is important to review eligibility criteria to avoid gender bias and provide recruitment strategies and resources for future NIVRT studies that are appealing to women and encourage their participation [51]. Maintaining a screening log that includes gender would also alert research team members if recruitment strategies need to be adjusted [51].

Only 1%-6% of patients were eligible and interested in the research program, highlighting several items to be considered while planning a definitive study and implementing NIVRT into practice. If patients had the opportunity to use NIVRT in the hospital setting, this might increase their comfort using the technology in the home [55]. The emphasis on remote care and telemedicine during and since the COVID-19 pandemic shutdowns may help future recruitment. Tracking every admission rather than relying on clinicians to suggest potential participants might lead to greater recruitment as well since gatekeeping by clinicians has been found to be a barrier to recruitment [56]. Including patient partners to help set priorities, inform the methods of the study, and review patient-facing materials for simplicity and ease of understanding may help recruitment in future studies and is suggested to improve the relevance of health research [57].

Inpatient and outpatient stroke rehabilitation is generally targeted towards subacute stroke; however, we did have one participant in the chronic stage. In a future definitive study, the stage of stroke recovery should be included as an eligibility criterion.

While all participants were able to have NIVRT installed in their homes and use the technology, certain characteristics of

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the participants and their homes were necessary for the success of using NIVRT. An unobstructed area of 2.0 m by 1.5 m was essential for NIVRT. Obstructions within that space prevented the Kinect camera from tracking both the upper and lower extremities. It was very helpful if the participant knew the basics of how to use a computer, such as how to use a mouse and log on and off, and was able to communicate with the study team. The capacity to perform these was sometimes impacted by cognitive, communicative, or physical impairments following stroke, in which case a knowledgeable study partner was essential. It was also important that a research team member with technical knowledge be available to troubleshoot; this did not need to be in-person for most issues. The selected NIVRT platform was learned by almost all participants, showing that NIVRT is suitable for this population, given a small amount of home-based, in-person training. These findings echo those of another study; their similar home-based NIVRT system was easy to learn, enjoyable, and met their rehabilitation needs [58]. In future studies, cognitive screening (eg, requiring a Montreal Cognitive Assessment score of ≥26/30) is suggested as an inclusion criterion [59].

Adherence to both the NIVRT and iPad interventions was excellent, similar to a previous study using the Jintronix platform [60]. The NIVRT intervention was set for each participant by the intervention physiotherapist, who aimed for 30 minutes a day. The participants had limited ability to modify this, and some found the games frustrating or boring. Others found the NIVRT intervention enjoyable, which emphasizes individual differences based on one's impairment, rehabilitation goals, and personal interests. On the other hand, participants in the iPad group were provided with a selection of suitable apps and directed to work on them for 30 minutes a day. Some participants frequently went beyond these recommendations, suggesting that they found the iPad apps to be particularly engaging, helpful, and easily accessible, more so than the NIVRT games. Indeed, the PACES showed that participants in the iPad group had greater enjoyment in their exercise program than those in the NIVRT group. There were fewer technical issues with the iPad group, and fewer complaints of boredom or repetition, which might have influenced the difference in this score. Hadjipanayi et al [61] have suggested that if NIVRT is used as a therapy rather than just for fun, the knowledge of this therapeutic purpose can diminish the enjoyment experienced and lead to boredom, which creates a challenge for NIVRT designers. On the other hand, if participants feel that the NIVRT serves a purpose (ie, enhancing stroke recovery), they may adhere even if boredom sets in, as seen in the current study. Emphasizing to patients the need for repetition of functional tasks to maximize stroke recovery is important.

Torriani-Pasin et al [62] assessed a non-NIVRT remote, asynchronous home-based exercise program for people with stroke and had an adherence rate (percent of sessions attended) of 41%. Their primary barrier was an inability to customize the exercise program to the participant. The ability to customize the Jintronix NIVRT program may have positively influenced our adherence rate. Simply directing individuals with stroke to keep exercising without a specific program or follow-up does not lead to ongoing participation in physical exercise [63], but engaging in NIVRT programs may lead to greater amounts of home-based rehabilitative exercise performed after stroke. Exercise duration is a very important influencer of adherence. Longer exercise sessions and exercising only once a week are associated with poorer adherence [64]. NIVRT has been shown to be more motivating than conventional rehabilitation [58], and most participants perceived that NIVRT enhanced their recovery and would be interested in continuing beyond the research study. Long-term adherence to the NIVRT program could be obtained by reducing the requirement to 3 times a week and encouraging other activities for variety (eg, walking, group-based exercise).

Our participants reported few adverse effects and no serious adverse events, which suggests that with safety considerations in place, NIVRT targeting balance and stepping can be done safely in the home. Our previous study investigating the use of NIVRT for individuals with mild cognitive impairment living in the community also showed that home-based NIVRT was safe [65]. Other studies on telerehabilitation after stroke with exercises performed in standing also found low rates of adverse events [17,62,66]. A Cochrane review reported no serious trial-related adverse effects using telerehabilitation after stroke [20]. The use of a reliable study partner is suggested to mitigate the risk of falls or injuries, as well as help with the technology [17].

There were no differences between groups for the physical and life participation outcome measures. This was expected, as this study was not powered to detect differences. Both groups improved significantly in many of the tests over time, which was expected, since all participants except one were in the subacute phase of their stroke recovery and were undergoing natural recovery as well as increasing their ability to adapt to the home environment soon after returning home. The NIVRT group demonstrated a clinically important improvement for the FTSTS test (ie, a decrease of more than 2.3 seconds) [67]. For the other outcome measures, changes recorded were not beyond the smallest real difference or minimal clinically important difference. Feasibility for this slate of outcome measures was shown, although two participants could not complete the TUG or FTSTS tests due to weakness. Participants using a gait aid could not carry the cup of water for the Timed Up and Go manual dual task. Of all the participants, 2 had difficulty understanding the questions in the SIS and the CIQ due to language barriers or cognitive issues.

While the use of NIVRT and similar technologies for telerehabilitation of standing balance and gait is less common than for upper extremity recovery, one group reported small but statistically significant improvements in functional gait (measured with the TUG test) and fear of falling for subacute stroke participants using a home-based augmented reality exercise program, compared to those using a similar written program with pictures [17]. There was no difference between groups on balance measures. While this study was adequately powered, the intensity (30 minutes per day, 5 days per week for 4 weeks) may have been too low for the best benefit. Our study, while underpowered, provided 6 weeks of intervention. Indeed, Kwakkel et al [68] have determined that 15 hours of additional training is required to produce a significant improvement in

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activities of daily living. A future, adequately powered study would establish if NIVRT is efficacious. Supporting evidence has shown that virtual reality training (immersive and nonimmersive) can have a large effect on balance (standardized mean difference 0.51, 95% CI 0.29-0.72) and a moderate effect on walking (standardized mean difference 0.31, SD 0.09-0.53) in people with chronic stroke [69]. While some have found no significant improvement in quality of life and community reintegration with NIVRT compared to conventional treatments [70], a recent review found that virtual reality (including NIVRT) outside of telerehabilitation shows a notable benefit for quality of life compared to standard rehabilitation [71]. It is important to consider these outcome measures for future studies.

This study, along with past work [17,58] supports the feasibility of using NIVRT for telerehabilitation of standing balance and gait after stroke. The next step is to develop a definitive randomized controlled trial to determine the efficacy of NIVRT in this context, using patient-oriented research considerations [57]. It will be important to have an active control group, so that interaction with the research team and rehabilitation intensity are equalized between groups, allowing for a specific assessment of the impact of NIVRT itself. The use of consistent outcome measures (including measures of impairment, function, and participation) across studies investigating stroke rehabilitation is also essential [20,72,73]. They should include a clear description of the intervention [74], follow TIDieR (Template for Intervention Description and Replication) and CONSORT recommendations to ensure validity and consistency [75,76], and incorporate cost-effectiveness assessments [20].

Limitations

Several equity issues became apparent. As discussed above, females were underrepresented. All participants had Wi-Fi, and the majority had experience with using computers or other technologies, showing a selection bias towards those of higher socioeconomic status who were more experienced with computers. Variations in access and use of health care technologies have previously been shown to be influenced by social inequalities [77]. Therefore, the results from this study cannot be transferred to individuals with lower socioeconomic status or those who do not have Wi-Fi or previous experience with technology. While there has been an important increase in the number of older adults who own and use digital technologies, there is a wide range of digital skills and aptitudes [78,79]. Supporting participants through digital literacy programs (such as Connected Canadians) may help facilitate the use of NVIRT. Another limitation is that the participants were not tracked or restricted as to what other rehabilitation or exercises they were performing throughout the study. This could have influenced change in the outcome measures.

Clinical Implications and Conclusions

The use of NIVRT to engage people who have had a stroke in continuing rehabilitative exercise after discharge from inpatient and outpatient stroke rehabilitation is feasible and safe, and shows potential for benefit. The results of this study support not only the ongoing investigation of the use of NIVRT for asynchronous telerehabilitation but also its immediate clinical use for some individuals. The Canadian Stroke Best Practice Recommendations Virtual Stroke Rehabilitation Interim Consensus Statement 2022 [38] strongly recommends that “virtual stroke rehabilitation should be available as an alternative or adjunct to in-person therapy” and that individual preferences should be considered.

Acknowledgments

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Authors' Contributions

LS, HS, and HF contributed to conceptualization. HF handled funding acquisition. LS and ATH contributed to investigation. LS, ATH, HS, MB, CY, VW, and HF assisted with methodology and writing – review and editing. LS assisted with formal analysis, data curation, project administration, and writing – original draft. LS, HS, and HF contributed to resources. HS, HF, and MB assisted with supervision and validation.

Conflicts of Interest

LS received a travel subsidy from the StrokeCog Clinical Trials Training Platform to attend the World Stroke Congress, Toronto, 2023.

Multimedia Appendix 1
CONSORT 2010 checklist.
[DOC File , 218 KB - rehab_v12i1e64729_app1.doc]

Multimedia Appendix 2

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Interview questions for participants and study partners.
[DOCX File , 17 KB - rehab_v12i1e64729_app2.docx]

Multimedia Appendix 3
Detailed demographic data for each participant.
[DOCX File , 16 KB - rehab_v12i1e64729_app3.docx]

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Abbreviations

BBS: Berg Balance Scale
CB&M: Community Balance and Mobility
CIQ: Community Integration Questionnaire
CONSORT: Consolidated Standards of Reporting Trials
FTSTS: Five Times Sit-To-Stand
NIVRT: nonimmersive virtual reality training
PACES: Physical Activity Enjoyment Scale
SIS: Stroke Impact Scale
TIDieR: Template for Intervention Description and Replication

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Review

The Effectiveness of Telerehabilitation in Managing Pain, Strength, and Balance in Adult Patients With Knee Osteoarthritis: Systematic Review

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Abstract

Background: Knee osteoarthritis (KOA) is a chronic, degenerative joint disease characterized by pain, stiffness, and functional impairment, significantly affecting mobility and quality of life. Traditional rehabilitation, mainly through in-person physiotherapy, is widely recommended for KOA management. However, access to these services is often limited due to geographic, financial, and mobility constraints. Telerehabilitation has emerged as an alternative, providing remote rehabilitation through digital platforms. Despite its increasing adoption, its effectiveness in improving key functional parameters such as pain, strength, and balance remains uncertain. While previous studies have focused primarily on pain relief and overall functional improvement, a broader assessment of its impact on mobility and fall prevention is needed.

Objective: This systematic review examines the effectiveness of telerehabilitation in improving pain, strength, and balance in adults with KOA compared with traditional rehabilitation or no intervention. In addition, it evaluates the impact of different telerehabilitation models, such as therapist-guided versus self-managed programs, and explores the feasibility of integrating telerehabilitation as an alternative in KOA management.

Methods: A systematic search of 4 databases (PubMed, PEDro, Cochrane, and Scopus) was conducted to identify randomized controlled trials (RCTs) published from May 2004 to May 2024. Inclusion criteria consisted of adults with KOA, evaluation of telerehabilitation either as a stand-alone intervention or in comparison to traditional rehabilitation or no intervention, and measurement of at least one primary outcome (pain, strength, or balance). A total of 2 independent reviewers assessed the risk of bias using validated tools. Due to variations in intervention programs and assessment methods, a narrative synthesis was performed instead of a meta-analysis. The review followed established guidelines, and data extraction was conducted using appropriate software.

Results: A total of 6 RCTs (N=581 participants) met the inclusion criteria. The results indicate that telerehabilitation effectively reduces pain and improves strength and balance, although the extent of benefits varies. Some studies reported similar pain reductions between telerehabilitation and traditional rehabilitation, while others highlighted greater functional improvements in telerehabilitation groups. Therapist-guided telerehabilitation was associated with higher adherence rates and better functional outcomes compared with self-managed programs. The risk of bias assessment showed that most studies were of moderate to good quality, though common issues included selection bias, performance bias, and participant attrition.

Conclusions: Telerehabilitation is a promising alternative for KOA management, especially for individuals facing barriers to in-person therapy. It is effective in reducing pain and improving strength and balance, though its success depends on patient engagement, intervention delivery, and rehabilitation protocols. Therapist-guided programs yield better outcomes than self-managed approaches. Further research is needed to standardize intervention protocols, integrate emerging technologies, and evaluate cost-effectiveness to guide clinical practice and health care policies.

Trial Registration: PROSPERO CRD42024564141; https://tinyurl.com/25ykvy7d

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KEYWORDS

telerehabilitation; knee osteoarthritis; pain management; remote physiotherapy; digital health; remote therapy; physiotherapy; pain management; strength; balance; functional mobility; rehabilitation technology

Introduction

Knee osteoarthritis (KOA) is a chronic, progressive condition characterized by the degeneration of joint cartilage and subchondral bone, leading to pain, stiffness, and functional impairment [1]. It is one of the most prevalent forms of arthritis, significantly affecting millions of individuals worldwide, particularly older adults, and is a leading cause of disability [2]. Epidemiological data indicate that KOA disproportionately affects women, with an estimated prevalence of 10% in men and 13% in women ages 60 years and older [3]. The burden of KOA is expected to rise due to increased life expectancy and the growing obesity epidemic, both of which are major contributors to the disease's progression [3]. Despite the availability of various treatment strategies, including pharmacological interventions, physical therapy, and surgical options, accessibility and effectiveness remain substantial challenges, prompting the exploration of alternative therapeutic approaches [4].

Among conservative treatments, physical therapy with structured exercise programs is considered a cornerstone in KOA management. Evidence consistently supports its role in improving joint function, reducing pain, and enhancing overall quality of life [5]. However, access to traditional in-person rehabilitation is often restricted by geographic, financial, and mobility-related barriers, which prevent many patients from receiving the necessary care [6]. These limitations were further exacerbated by the COVID-19 pandemic, which significantly disrupted health care services and underscored the urgent need for innovative, remote solutions to ensure continuous patient care [7]. In response to these challenges, telerehabilitation has emerged as a viable alternative, leveraging digital technologies to deliver rehabilitation programs remotely.

Telerehabilitation encompasses a broad spectrum of services, including guided exercise programs, educational resources, and real-time feedback from health care providers through telecommunication platforms [8]. This approach offers several advantages, including improved accessibility, convenience, and the ability to provide continuous, personalized care, which is particularly beneficial for chronic conditions such as KOA [4]. Furthermore, telerehabilitation allows health care providers to monitor patient progress and modify treatment plans accordingly, ensuring a more tailored therapeutic experience [9]. Despite its potential, the integration of telerehabilitation into routine clinical practice has been slow, partly due to uncertainties regarding its effectiveness compared to conventional in-person rehabilitation.

Current evidence on telerehabilitation for KOA includes several randomized controlled trials (RCTs) suggesting its benefits in improving pain, physical function, and patient-reported outcomes [1]. However, existing studies exhibit considerable heterogeneity in design, intervention protocols, and outcome measures, making it challenging to derive definitive conclusions regarding its overall efficacy. Previous systematic reviews, such as Xie et al [1], focused primarily on pain and functional improvements without incorporating other critical outcomes, such as strength and balance, which are essential for functional mobility and fall prevention in patients with KOA. Furthermore, past reviews have not comprehensively examined differences between telerehabilitation modalities, such as real-time therapist-guided interventions versus self-managed web-based programs, limiting the depth of analysis regarding intervention effectiveness.

This systematic review aims to address these gaps by synthesizing findings from RCTs that have investigated the impact of telerehabilitation on key clinical outcomes, including pain, strength, and balance, in adult patients with KOA. By expanding the scope beyond pain and function, this review provides a more comprehensive understanding of telerehabilitation's role in enhancing musculoskeletal performance and reducing fall risk—factors crucial for long-term mobility and independence. In addition, this review includes an updated literature search extending to May 2024, incorporating 6 newly identified RCTs, thereby significantly expanding the available evidence base.

Another key differentiator of this review is its methodological rigor. Unlike previous reviews, this study applies dual risk-of-bias assessments using both the Physiotherapy Evidence Database (PEDro) scale and the Downs and Black checklist, ensuring a more robust evaluation of study quality. Furthermore, while past reviews often compared telerehabilitation to a single standard-of-care intervention, this review adopts a broader comparative framework, analyzing its effectiveness against multiple rehabilitation strategies, including clinic-based physiotherapy, home-based exercise programs, and no intervention groups. This approach allows for a more nuanced understanding of telerehabilitation's place within the spectrum of KOA management strategies.

Initially, this review intended to conduct a meta-analysis; however, substantial heterogeneity across studies—stemming from differences in intervention protocols, outcome measures, and control groups—precluded a reliable quantitative synthesis. High statistical heterogeneity (I^2 values exceeding 50%) indicated that pooling results would not yield meaningful conclusions. Consequently, a narrative synthesis was chosen to provide a detailed qualitative comparison of the available evidence. This decision ensures that findings are interpreted within the appropriate clinical context rather than forcing an unreliable statistical synthesis.

The specific objectives of this review are 2-fold: first, to assess whether telerehabilitation is associated with significant improvements in pain, physical function, strength, and balance

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in patients with KOA compared with traditional therapy or usual care; and second, to determine whether different telerehabilitation modalities yield varying degrees of effectiveness in managing KOA symptoms. By addressing these questions, this review seeks to establish a clearer understanding of telerehabilitation's role in KOA management and provide evidence-based recommendations for its integration into clinical practice.

In conclusion, as the prevalence of KOA continues to rise, so does the demand for accessible and effective rehabilitation strategies. Telerehabilitation represents a promising solution, offering remote, individualized, and scalable interventions for KOA management [4]. This systematic review will contribute to the growing body of literature by providing a comprehensive evaluation of telerehabilitation's impact on pain, strength, and balance in adults with KOA, ultimately informing clinical decision-making and guiding the development of future therapeutic interventions.

Methods

Study Protocol and Registration

All analyses were based on data from previously published studies. Thus, no ethical approval or patient consent was required. The review was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (see PRISMA checklist in Multimedia Appendix 1) [10]. The a priori protocol for the review is published in the International Prospective Register of Systematic Reviews (PROSPERO; CRD42024564141).

Information Sources

A search for RCTs was conducted across the databases PubMed, PEDro, Cochrane, and Scopus. A total of 207 studies were identified: 83 papers from PubMed, 10 from PEDro, 1 from Cochrane, and 113 from Scopus. The primary keywords used were telerehabilitation, pain management, strength, balance, and physical therapy. Only articles published in English were selected.

Search and Eligibility Criteria

Overall Search Strategy

The search strategy was systematically developed by the research team following established systematic review guidelines. The search was conducted on May 1, 2024, across multiple electronic databases using a predefined combination of keywords: (osteoarthritis OR osteoarthrosis OR cartilage OR degenerative arthritis) AND (telemedicine OR e-health OR telehealth OR telerehabilitation OR internet OR web OR online) AND knee osteoarthritis. The exact search strategy, including Boolean operators, filters, and databases, has been provided as supplementary material.

In addition to the database search, manual screening of reference lists from the identified papers was conducted to ensure comprehensive literature coverage. The inclusion and exclusion criteria were determined based on the PICO (Population, Intervention, Comparison, Outcome) framework [11,12], ensuring methodological rigor and relevance.

Interventions

The studies included in this review evaluated the impact of internet-based rehabilitation programs in comparison with conventional rehabilitation approaches, such as in-clinic or hospital-based therapy, as well as no intervention (waiting list control). In the internet-based rehabilitation programs, therapy was either provided as a stand-alone treatment or in combination with traditional physiotherapy. These programs typically featured video demonstrations, graphical educational materials, real-time communication with health care providers (including physicians and therapists), and group discussions designed to support self-directed rehabilitation for individuals with KOA. The rehabilitation methods used encompassed a range of strategies, including structured exercises, patient education, and self-management techniques.

Outcome Measures

The primary outcome measures assessed in the included studies were pain, strength, and balance. These outcomes were evaluated using various validated assessment tools and aimed at determining the effectiveness of internet-based rehabilitation in improving these key functional parameters in individuals with knee OA.

Inclusion Criteria

For this systematic review, only RCTs were selected, with restrictions on the publication year (2004-2024). Participant characteristics were (1) adult patients with KOA, (2) types of interventions: the articles had to assess the effect of telerehabilitation either as a stand-alone therapy or in comparison with another intervention, and 30 outcome measures: the factors evaluated were pain and/or strength and/or balance.

Exclusion Criteria

The exclusion criteria included patients under the age of 18 years, studies without described protocols, incomplete papers, systematic reviews or meta-analyses, case studies, and papers written in languages other than English. We selected only RCTs as they provide the highest level of evidence by minimizing bias through randomization. This strengthens the validity of our findings and ensures methodological rigor. In addition, the PEDro scale and Modified Downs and Black checklist, used for quality assessment, are specifically designed for RCTs, further reinforcing the reliability of our review.

Data Extraction and Management

The papers for this systematic review were managed using the "RAYYAN" platform, where duplicate entries were initially removed. In the first stage, 2 independent reviewers, TP and MI, blindly screened the titles and abstracts of the papers and removed those deemed unsuitable. In the subsequent stage, the 2 reviewers examined the full texts of the articles based on the predefined inclusion and exclusion criteria. After identifying the appropriate RCTs, data extraction was performed.

Risk of Bias

In this systematic review, the PEDro scale and the Modified Downs and Black checklist were used to assess the risk of bias.

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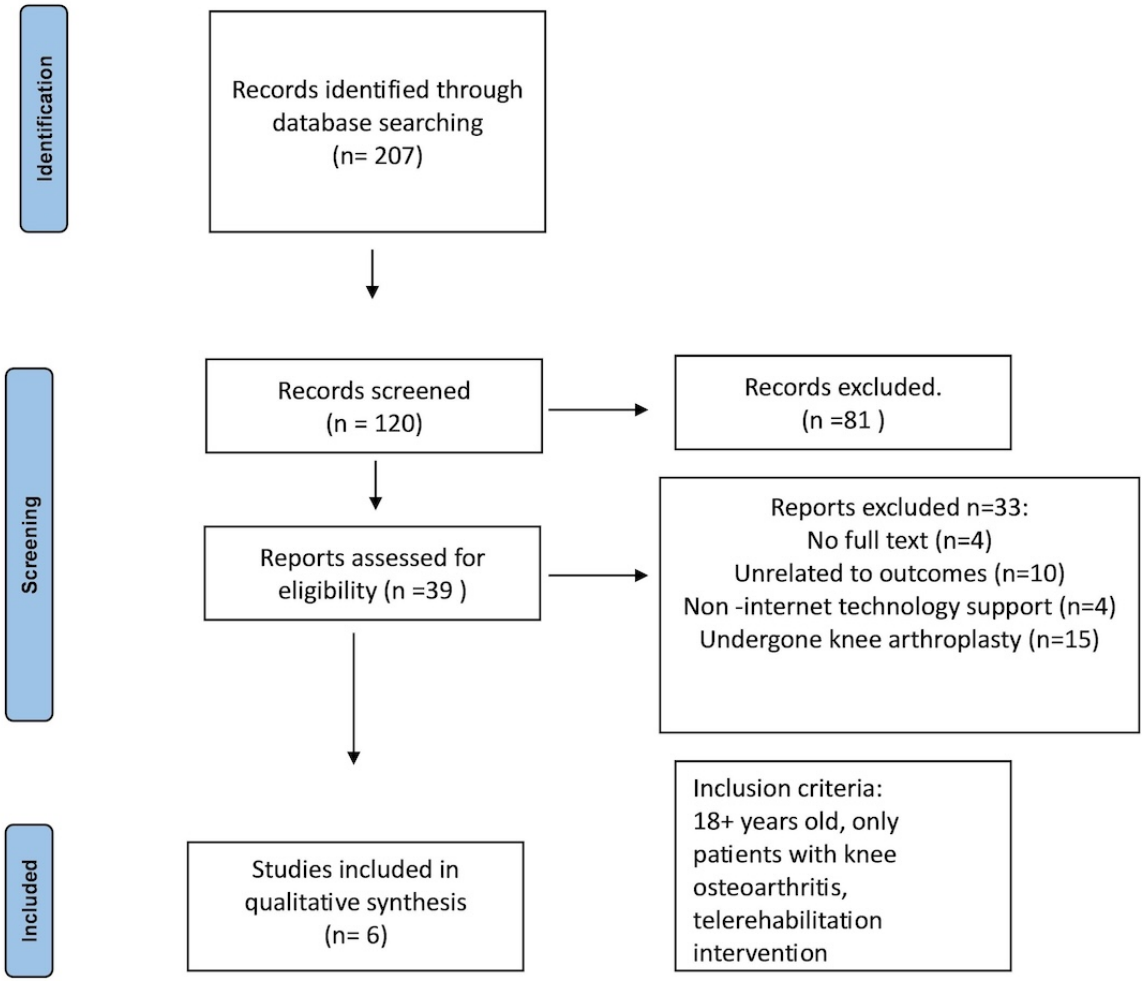
A total of 2 independent reviewers, TP and MI, applied these tools and rated the RCTs. Any disagreements between the two reviewers were resolved through discussion or with the help of a third evaluator, GG.

Results

Search and Selection

A systematic search was conducted across multiple databases, including PubMed (n=83), PEDro (n=10), Cochrane (n=1), and Scopus (n=113), identifying a total of 207 records (Figure 1). After removing duplicates, 120 records remained for screening, where 2 independent reviewers (TP and MI) assessed titles and abstracts using the "RAYYAN" platform. Following this process, 81 records were excluded, and 39 reports were assessed for eligibility. Of these, 33 reports were further excluded due to reasons such as the absence of full text (n=4), irrelevance to the outcome (n=10), noninternet technology support (n=4), or participants having undergone knee arthroplasty (n=15). Ultimately, 6 studies met the predefined inclusion criteria, involving a total of 581 patients with KOA who received telerehabilitation intervention. The inclusion criteria required participants to be at least 18 years old, diagnosed with KOA, and undergoing telerehabilitation intervention.

Figure 1. Flow chart of the search and selection process.



Intervention Programs

The interventions in the 6 included RCTs were as follows: (1) telerehabilitation compared with electrotherapy and home exercise [9], (2) telerehabilitation through Zoom (Zoom Video Communications) compared with individual home rehabilitation with the help of a booklet [13], (3) telerehabilitation combined with a web-based PCST (pain coping skills training) rehabilitation program compared with usual care [14], (4) telerehabilitation compared with clinic-based rehabilitation [6], (5) telerehabilitation compared with home rehabilitation [15], and (6) telerehabilitation with an 8-week PAINCOACH (pain management coaching) program compared with rehabilitation without PAINCOACH [16]. In most cases, both groups in all the studies followed the same rehabilitation program, with the main difference being that the intervention group was always guided by a physiotherapist through telecommunication.

Risk of Bias

For the PEDro scale, the reviewers applied the 11 criteria included in the tool and categorized the studies based on their total scores: 0-3 were considered "POOR," 4-5 "FAIR," 6-8 "GOOD," and 9-10 "EXCELLENT." The PEDro scale criteria are outlined in Table 1.

The above RCTs were evaluated using the PEDro scale [17]. The average score across the 6 studies was 6.3/10, indicating good quality. More specifically, 1 study scored 8/10 [16], 2

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studies scored 7/10 [13,15], and 2 studies scored 6/10 [6,9], all of which are considered good quality according to the scale. However, 1 study scored only 4/10, which classifies it as a fair-quality study (Table 2) [14].

Table 1. Physiotherapy Evidence Database (PEDro) scale criteria.

RCT[a]	1	2	3	4	5	6	7	8	9	10	11	Score[b]
Azma et al [9], 2017	+	+	–	+	–	–	–	+	+	+	+	6/10
Tore et al [13], 2022	+	+	–	+	–	–	+	+	+	+	+	7/10
Lawford et al [14], 2018	+	–	–	–	–	–	–	+	+	+	+	4/10
Odole and Ojo [6], 2013	+	+	–	+	–	–	–	+	+	+	+	6/10
Bennell et al [15], 2016	+	+	+	+	+	–	+	–	–	+	+	7/10
Rini et al [16], 2015	+	+	+	+	–	+	–	+	+	+	+	8/10
MO average												6.3/10

[a]RCT: randomized controlled trial.

[b]Average=6.3/10, green=excellent (9-10), blue=good (6-8), yellow=fair (4-5), and red=poor (0-3).

Table 2. Downs and Black scores.

RCT[a]	Downs and Black score[b]	Level of methodological quality
Azma et al [9], 2017	18/28	FAIR
Tore et al [13], 2022	20/28	GOOD
Lawford et al [14], 2018	16/28	FAIR
Odole and Ojo [6], 2013	19/28	FAIR
Bennell et al [15], 2016	19/28	FAIR
Rini et al [16], 2015	22/28	GOOD

[a]RCT: randomized controlled trial.

[b]RED=POOR (≤14), YELLOW=FAIR (15-19), BLUE=GOOD (20-25), GREEN=EXCELLENT (26-28).

Based on the Downs and Black checklist [18], 4 studies were classified as “FAIR” quality [6,9,14,15], and the remaining 2 studies were classified as “GOOD” quality [13,16].

Limitations

Although the initial objective of this systematic review was to conduct a meta-analysis, significant heterogeneity among the included studies prevented a reliable quantitative synthesis. Variability in intervention protocols (eg, therapist-guided video calls, self-directed web-based programs, and mobile apps), diverse outcome measures (eg, Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC], Visual Analog Scale [VAS], timed up and go test [TUG], and 30-second chair stand test [30-CST]), and differences in comparison groups (eg, traditional physiotherapy, no intervention, home-based exercises) introduced methodological inconsistencies. In addition, high statistical heterogeneity (I^2>50%) further undermined the validity of a meta-analysis. As a result, a narrative synthesis was conducted to provide a qualitative comparison of findings.

Study Characteristics

The baseline descriptive characteristics (country, sample size, age, and gender) of the 6 studies included in the systematic review are summarized in Table 3. A total of 2 studies were from Australia, 1 from the United States, 1 from Brazil and Iran, 1 from Turkey, and 1 from Nigeria. The mean age of patients with KOA ranged from 37 to 72 years, and all studies included both men and women.

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Table 3. Summary of studies on telerehabilitation in knee osteoarthritis.

Study title	Authors	Sample size and condition	Assessment tools	Method	Outcome
Efficacy of telerehabilitation compared with office-based physical therapy in patients with knee osteoarthritis: A randomized clinical trial	Azma et al [9], 2017	Knee osteoarthritis (N=54)	• VAS[a] • KOOS[b] • WOMAC[c]	• Telerehabilitation group: 3 times/week for 6 weeks. • Control group: 3 times/week in the clinic for 6 weeks.	Significant improvement in both groups on all scales, no significant differences between groups.
The quality of physiotherapy and rehabilitation programs and the effect of telerehabilitation on patients with knee osteoarthritis	Tore et al [13], 2022	Knee osteoarthritis (N=48)	• 30 CST[d] • KOOS • NRS[e] • IPAQ-SF[f] • FSS[g] • QUIPA[h] • EARS[i] • HADS[j] • TKS[k] • PAR-Q+[l]	• Telerehabilitation through Zoom for 8 weeks, 3 times per week (Group A). • Control group exercised alone at home (Group B).	Group A showed significant improvement in strength, balance, and other parameters compared with group B.
Moderators of effects of internet-delivered exercise and pain coping skills training for people with knee osteoarthritis: exploratory analysis of the IMPACT randomized controlled trial	Lawford et al [14], 2018	Knee osteoarthritis (N=148)	• NRS • WOMAC	• Intervention: Exercise and pain management training via Skype and on the web. • Control: Educational materials only.	Significant pain reduction in employed individuals of the intervention group compared with the control group.
A telephone-based physiotherapy intervention for patients with osteoarthritis of the knee	Odole and Ojo et al [6], 2013	Knee osteoarthritis (N=50)	• VAS • IKHOAM[m]	• Telerehabilitation with physiotherapist guidance 3 times/week for 6 weeks. • Control group: clinic-based physiotherapy.	Significant improvement in both groups in pain and functionality, no significant differences between groups.
Telephone coaching to enhance a home-based physical activity program for knee osteoarthritis: a randomized clinical trial	Bennell et al [15], 2016	Knee osteoarthritis (N=168)	• NRS • WOMAC • PACE[n] • AAS[o] • GROC[p]	• Both groups received 5 individual physiotherapy sessions over 6 months. Group A received an additional 6 coaching sessions by telephone.	Significant improvement in pain and function for both groups, with Group A showing greater improvement in physical activity at 6 months.
Automated Internet-based pain coping skills training to manage osteoarthritis pain: a randomized controlled trial	Rini et al [16], 2015	Knee osteoarthritis (N=113)	• AIMS 2[q] • ASES[r] • PASC[s] • PANAS[t]	• PainCOACH[u] program for 8 weeks. Control group: same program without PainCOACH access.	Significant improvement in self-efficacy and pain reduction in women from the intervention group.

[a]VAS: Visual Analog Scale.

[b]KOOS: Knee Injury and Osteoarthritis Outcome Score.

[c]WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

[d]30-CST: 30-second chair stand test.

[e]NRS: Numeric Rating Scale.

[f]IPAQ-SF: International Physical Activity Questionnaire—Short Form.

[g]FSS: Fatigue Severity Scale.

[h]QUIPA: Quality Indicators for Physiotherapy Management of Hip and Knee Osteoarthritis.

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[i]EARS: Exercise Adherence Rating Scale.
[j]HADS: Hospital Anxiety and Depression Scale.
[k]TKS: Tampa Kinesiophobia Scale (ή Tampa Scale for Kinesiophobia).
[l]PAR-Q+: Physical Activity Readiness Questionnaire Plus.
[m]IKHOAM: Ibadan Knee/Hip Osteoarthritis Outcome Measure.
[n]PACE: Patient-Centered Assessment and Counseling for Exercise.
[o]AAS: Active Australia Survey.
[p]GROC: Global Rating of Change.
[q]AIMS 2: Arthritis Impact Measurement Scales 2.
[r]ASES: American Shoulder and Elbow Surgeons.
[s]PASC: Pain-Related Anxiety and Avoidance Scale.
[t]PANAS: Positive and Negative Affect Schedule.
[u]PainCOACH: pain management coaching.

Outcomes of Interest

In this systematic review, the outcomes of interest were pain, strength, and balance in patients with KOA undergoing telerehabilitation. Pain was assessed in all studies using a variety of tools. The WOMAC was one of the most used tools for pain measurement, especially in studies like those by Bennell et al [19], where significant improvements were observed at the 6th- and 12th-month follow-ups. Other pain measurement tools included the VAS and the Numeric Pain Rating Scale (NPRS). Both tools were used in studies by Lawford et al [14] and Azma et al [9], showing that telerehabilitation interventions led to significant pain reduction compared with traditional physiotherapy. In some cases, such as in the study by Rini et al [16], it was found that women in the telerehabilitation group experienced a greater reduction in pain compared with men.

In terms of strength and balance, fewer studies evaluated these outcomes, and the tools used were less consistent. The 30-CST and the TUG tests were used to assess lower body strength and balance. In particular, the study by Tore et al [13] found significant improvements in both strength and balance in the telerehabilitation group compared with the control group. This study was one of the few that specifically measured these outcomes. The improvements in strength and balance in this study highlight the potential benefits of telerehabilitation for enhancing these physical capacities, though such outcomes were not consistently reported across other studies.

Discussion

Principal Findings

This systematic review examined 6 RCTs assessing the effectiveness of telerehabilitation for KOA. The findings indicate that telerehabilitation can serve as an effective alternative to conventional rehabilitation, demonstrating improvements in pain management, strength, and balance. However, the extent of these benefits varied across studies, with some showing significant clinical improvements while others reported comparable outcomes between telerehabilitation and in-person rehabilitation.

For instance, Azma et al [9] and Odole et al [6] reported significant pain reduction in both intervention and control groups, suggesting that while telerehabilitation is beneficial, it may not always be superior to conventional rehabilitation. On the other hand, Tore et al [13] found substantial improvements in strength and balance among telerehabilitation participants, highlighting its potential to address key functional limitations in patients with KOA. This aligns with the broader understanding that while telerehabilitation effectively delivers structured rehabilitation, its impact may depend on factors such as intervention format, patient adherence, and baseline severity of KOA.

Compared with previous systematic reviews, such as Xie et al [1], which primarily focused on pain and physical function, our study expands the scope by incorporating strength and balance—2 critical components of functional ability and fall prevention that were previously overlooked. In addition, Xie et al [1] included studies up to April 2020, covering 6 RCTs with 791 patients, whereas this review extends the search to May 2024, adding 6 more RCTs. This expanded dataset strengthens the generalizability of our findings and provides a more comprehensive evaluation of telerehabilitation's role in KOA management.

Heterogeneity in Study Design and Outcomes

The included studies exhibited substantial heterogeneity regarding intervention modalities, outcome measures, and patient populations, which limited direct comparisons with a very high homogeneity index (I^2=95%). Some trials, such as Bennell et al [15] and Rini et al [16], incorporated therapist-led coaching, whereas others, like Lawford et al [14], relied on self-guided programs with minimal professional interaction. Pain was assessed using different tools (eg, WOMAC and VAS), strength was measured through varied functional tests (eg, 30-second chair stand test), and balance assessments included diverse protocols (eg, timed up and go test). Such methodological variability complicates the pooling of results, necessitating a narrative synthesis rather than a meta-analysis.

Furthermore, differences in study populations introduced additional variability. Odole et al [6] included relatively younger participants, while Azma et al [9] focused on older adults with advanced KOA. Given that older patients often have greater physical limitations combined with cognitive impairments and reduced exercise adherence, the effectiveness of telerehabilitation may differ across age groups. Future research should conduct subgroup analyses comparing intervention

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effectiveness across different demographic and disease severity levels to clarify which patients benefit most from telerehabilitation.

Comparison With Previous Work

Unlike previous systematic reviews, which primarily examined general digital rehabilitation interventions, this review categorizes telerehabilitation strategies based on their mode of delivery, distinguishing between real-time therapist-guided interventions and self-managed programs. This distinction is crucial, as previous findings have been inconsistent due to a lack of differentiation in rehabilitation modalities.

Furthermore, while Xie et al [1] relied solely on the PEDro scale for risk-of-bias assessment, this review uses both the PEDro scale and the Downs and Black checklist, offering a more rigorous evaluation of methodological quality. In addition, a sensitivity analysis was conducted to assess the robustness of findings, an approach not included in previous reviews. These methodological enhancements provide a stronger foundation for evaluating telerehabilitation's effectiveness and guide recommendations for its integration into clinical practice.

Risk of Bias and Study Quality

Several methodological limitations were identified across the included RCTs. Selection bias was evident in studies such as Lawford et al [14], where randomization procedures were not fully detailed, raising concerns about allocation concealment. Performance bias was also a common issue, as blinding of participants and therapists is inherently difficult in telerehabilitation studies. This could have influenced subjective outcomes such as pain perception. In addition, high attrition rates were noted in studies like that of Rini et al [16], potentially affecting the validity of long-term conclusions.

Despite these limitations, most included studies were classified as fair to good quality. Future research should prioritize strategies to mitigate bias, such as using more robust randomization methods, improving participant retention, and using objective outcome measures where possible.

Integration of Telerehabilitation Into KOA Management

Telerehabilitation offers multiple advantages, particularly for patients with mobility limitations or geographic barriers to health care access. Its flexibility allows for continuity of care, reducing dependence on in-person visits. However, several challenges remain for its widespread implementation.

One major issue is adherence, as engagement tends to decline in self-managed programs. Bennell et al [15] found that interventions with therapist-guided coaching led to higher adherence rates than fully self-directed programs. This suggests that maintaining patient interaction with health care professionals—even remotely—may be key to optimizing outcomes.

In addition, regulatory and reimbursement barriers limit the accessibility of telerehabilitation in many health care systems. Standardizing reimbursement policies and integrating telerehabilitation into clinical guidelines could enhance adoption. Furthermore, technological barriers, such as digital literacy challenges among older adults, must be addressed through user-friendly platforms and comprehensive patient education programs.

Strengths and Limitations

A key strength of this review is its inclusion of a broader range of outcome measures beyond pain reduction, allowing for a more holistic assessment of telerehabilitation's benefits. The extensive literature search across multiple databases minimized selection bias and ensured a thorough synthesis of available evidence. The use of validated quality assessment tools further strengthened methodological rigor.

However, several limitations should be acknowledged. Heterogeneity in intervention protocols and outcome measures limited direct comparisons and precluded meta-analysis. Language bias may also be present, as only English-language studies were included. In addition, most studies had short follow-up periods, making it difficult to determine the long-term sustainability of telerehabilitation outcomes. Future trials should incorporate extended follow-up periods to assess whether improvements in pain, strength, and balance persist over time.

Future Directions

To refine the evidence for telerehabilitation, future research should focus on the following:

1. Long-term outcomes: conducting longitudinal studies to determine whether benefits persist beyond the immediate post-intervention period.
2. Standardized protocols: developing uniform telerehabilitation protocols to facilitate comparisons across studies.
3. Technology integration: exploring artificial intelligence-driven rehabilitation tools and wearable motion-tracking devices to enhance remote therapy effectiveness.
4. Subgroup analyses: identifying which patient populations (eg, age groups and severity levels) derive the greatest benefit from telerehabilitation.
5. Cost-effectiveness studies: evaluating the economic impact of telerehabilitation compared to traditional rehabilitation models.

Conclusion

This systematic review highlights the potential of telerehabilitation as a viable alternative to conventional rehabilitation for KOA, demonstrating benefits in pain reduction, strength, and balance. However, its effectiveness varies depending on intervention type, patient engagement, and delivery method. In comparison to previous reviews, this study broadens the scope of analysis, incorporates 6 additional RCTs, applies a dual-method risk-of-bias assessment, and differentiates telerehabilitation modalities.

By distinguishing therapist-guided interventions from self-managed programs, this review provides novel insights into how telerehabilitation can be optimized for KOA management. Addressing current methodological limitations and refining intervention strategies will be crucial in ensuring its long-term

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success. With further research and policy support, telerehabilitation has the potential to become an integral component of rehabilitation care, improving accessibility and patient outcomes in KOA treatment.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.
[PDF File (Adobe PDF File), 143 KB - rehab_v12i1e72466_app1.pdf]

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Abbreviations

30-CST: 30-second chair stand test
KOA: knee osteoarthritis
NPRS: Numeric Pain Rating Scale
PAINCOACH: pain management coaching
PCST: pain coping skills training
PEDro: Physiotherapy Evidence Database
PICO: Population, Intervention, Comparison, Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: International Prospective Register of Systematic Reviews
RCT: randomized controlled trial
TUG: timed up and go test
VAS: Visual Analog Scale
WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

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Original Paper

Design Requirements for Cardiac Telerehabilitation Technologies Supporting Athlete Values: Qualitative Interview Study

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Abstract

Background: Cardiac telerehabilitation (CTR) interventions can provide accessible and affordable remote rehabilitation services. However, as cardiac rehabilitation (CR) primarily targets inactive patients, little is known about the experiences with CR of highly active patients (ie, recreational athletes or, simply, athletes) with established coronary artery disease. Consequently, existing CTR interventions do not address the specific needs of the athletic subpopulation. Understanding the needs and values of athletes is crucial for designing meaningful CTR interventions that enhance user acceptance and engagement, thereby facilitating effective rehabilitation for this patient subgroup.

Objective: This study aimed to inform the design of technologies that facilitate CTR for athletes. We intended to identify athletes' values related to CR, including health and sports tracking, as well as high-level requirements for technologies that can facilitate the CTR of athletes according to the identified values.

Methods: We used value-sensitive design with a human-centric design approach to elicit design requirements for CTR that can serve athletes with established coronary artery disease. To identify athletes' values, we conducted 25 value-oriented semistructured interviews with 15 athletic patients and 10 health care professionals involved in CR programs. In a second phase, we conducted 6 card-sorting focus group sessions with 13 patients and 7 health care professionals to identify desired CTR features. Finally, we derived high-level CTR technology requirements connected to the athletes' needs and values.

Results: We defined 12 athlete values divided into 3 categories: *body centric*, *care centric*, and *data and technology centric*. We clustered findings from the card-sorting activity into CTR technology requirements, such as *remotely monitored sport-specific training* and *training data representations next to clinical limitations*, and paired them with corresponding values.

Conclusions: Athletes have distinct values and health goals in CR compared to general populations targeted by CTR interventions. Designing patient-centric CTR interventions that address these needs is crucial to support optimal recovery, safe return to sports, and adherence to CTR technologies in the home environment.

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KEYWORDS

athletes with established coronary artery disease; cardiac telerehabilitation; value-sensitive design; sports monitoring; card sorting; qualitative research; artificial intelligence; AI

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Introduction

Study Background: Cardiac Rehabilitation, Cardiac Telerehabilitation, and the Athletic Cardiac Subpopulation

Cardiovascular disease (CVD) remains one of Europe's leading causes of mortality [1]. Interventions focused on promoting a healthy lifestyle, such as exercise-based cardiac rehabilitation (CR), can have a significant impact on the outlook of individuals with CVDs, reducing morbidity and mortality and increasing their quality of life [2,3]. In recent years, especially after the COVID-19 pandemic, the acceptance of cardiac telerehabilitation (CTR)—or virtual CR—has been on the rise in many jurisdictions [4,5]. CTR mostly relies on digital and wearable technologies that facilitate delivering CR services to patients in their own homes, encompassing elements such as video-streamed exercise and therapy sessions and remote monitoring of health and behavior, as well as applications enabling patient–health care professional (HCP) communication and information provision [6-8]. For positive rehabilitation outcomes to be achieved, users (ie, patients) need to accept, engage with, and adopt CTR interventions—this requires the technology to be usable and offer perceptible value for the patients [9,10].

To better recognize what drives the use and perceived value of technology-centric CTR, recent human-computer interaction (HCI) literature has underlined the importance of using human-centric design in CTR development by acknowledging the collective perspectives of the *prospective users*, including their experiences and needs [4,11]. In this study, we looked into the experiences and needs of an underresearched prospective CTR user group—*athletic patients with established coronary artery disease(CAD)*, the most prevalent cardiovascular condition [12]. Although physical activity is associated with a significantly lower risk of CVDs, highly active individuals are not immune to the development of CAD, and vigorous exercise can be the trigger for life-threatening cardiac events [13,14]—approximately 10.6% of all acute myocardial infarctions may be attributed to physical exertion [15]. Middle-aged and older athletes are at the highest risk of adverse cardiovascular events during exercise as the prevalence of CAD increases with age [15]. Although the prevalence of athlete patients in CR programs is not well defined, there has been growing attention toward middle-aged and older athletic patients with cardiac conditions in the past 10 years—more and more studies show that athletes can develop CAD and its consequences [16], investigating the significant impact of adverse events on sports practice and discussing the exercise recommendations and restrictions that apply based on the type and severity of the underlying problem [2]. To foreground this type of CTR user, we adopt the term *athlete* from clinical literature as it is the most accurate description of our target group—highly active patients who engage in at least 4 hours per week of exercise and potentially participate in competitive athletics (eg, cycling, triathlon, and marathon) recreationally [17].

Research Gap and Opportunity: Designing CTR for Athletes

There is a notable scarcity of research on athletes in CR, especially on technological interventions for athletes in CR, with recent work on this subgroup focusing mainly on clinical evidence (eg, etiology and prevention strategies [16]). This lack of knowledge can be attributed to the fact that, in a largely sedentary population, the central objective of rehabilitation is *improving and increasing* physical activity [2]. Consequently, the primary focus of most existing health technology, including CTR interventions, has been providing support to predominantly inactive and frail populations in their effort to combat sedentary lifestyles and instill healthy lifestyle habits [18-22]. Therefore, we highlight the lack of adequate consideration for the perspectives of athletic patient populations who are already physically active and require guidance on safely and gradually resuming sports rather than being educated on the importance of physical activity in the design and development of technologies that support CTR.

Despite the incomplete evidence on athletes' rehabilitation needs and challenges, there is evidence suggesting that athletes with established CAD may perceive traditional CR programs as ill-fitting due to disparities in exercise pace and objectives [23]. They require personalized guidance to ensure optimal recovery, mitigate the risk of exercise-induced events, and safely resume their preferred sports practice [24]. Current CTR technologies designed using behavior change and persuasive techniques to motivate general patient populations to adopt an active lifestyle [25-27] might not serve the objectives of the athletic patient population [23]. At the intersection of HCI and clinical research, there is an increasing focus on the significance of tailoring cardiac technologies to align with precision medicine principles. This involves *considering individual patient differences*, ultimately aiming to mitigate complications associated with CVDs [28,29]. Recent efforts from the HCI community have looked into tailoring CTR content and mode of delivery to various user groups (eg, by identifying the right CTR interfaces based on older patients' technology familiarity or by customizing tracking devices based on lifestyle [4,30,31]).

Failing to acknowledge the nuanced needs of the athletic user group in the design of CTR interventions can result in poor user experience and low technology engagement and adoption. This, in turn, can affect the effectiveness of the rehabilitation treatment and induce serious psychological side effects such as depression and anxiety [4,32-34].

Study Objectives

Our overall aim was to provide insights into the design of CTR technologies aiming to support athletic patients. Our study used a human-centric design approach called value-sensitive design (VSD)—a theory-driven approach to technology design that integrates human values throughout the design process [32,35], with values reflecting what individuals consider important in life and care, driving their needs (in this work, the terms *needs* and *values* are to be regarded in the context of the VSD framework) [36].

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To achieve our aim, we had the following objectives: (1) to elicit athletes' values regarding CR, including health and behavior tracking; and (2) to define design requirements for CTR technologies that meet the athletes' values.

We conducted 25 individual, value-oriented semistructured interviews with 15 athletes with established CAD and 10 HCPs involved in CR programs to understand athletes' current challenges in CR, behavior tracking, and technology-centric care and derive values. To identify technology-focused CTR design requirements that can cater to these needs and values, we conducted 6 card-sorting focus group (FG) sessions with 13 patients and 7 HCPs.

Our work contributes in three key ways: (1) we inform the design and development of CTR technologies personalized for the underresearched athletic subgroup of patients with cardiac conditions; (2) we uncover the currently underrepresented needs, values, and desired CTR features of athletes with cardiac conditions; and (3) we use VSD as an investigation method for participatory design, something novel in the current design of CTR [37].

Related Work

The research presented in this paper spans multiple domains, encompassing clinical research on athletes with heart conditions, characteristics of recreational athletes, the design of CTR interventions, and human-centered approaches to CTR and health technology (ie, eHealth) design overall.

Recreational Athletes in Cardiac and HCI Research

Existing studies on the requirements and perceptions of CTR technologies have been conducted in heterogeneous populations and in patients with low exercise capacity [38,39] and a sedentary lifestyle [40] or specifically in older adults [41]. Nonetheless, the needs of highly active patients (ie, athletes) regarding CTR have not yet been addressed. In a wider perspective, apart from a few clinical case reports, there is a clear lack of documented information regarding athletes in CR [23,42,43]. Existing knowledge of this population points to the many benefits that CTR interventions could have for their rehabilitation. First, athletes need tailored evaluation and sport-specific guidance before resuming intense activities, preferably in their sports setting and not in traditional hospital-based CR [24]. Furthermore, there is evidence that athletes are eager to return to sports quickly [23,42-44]. CTR helps achieve this by (1) starting right after hospitalization, shortening the outpatient gap between hospitalization and the CR program; and (2) providing remote supervision to alleviate sport-related anxiety in the posthospitalization phase [23,45]. In addition, in the realm of HCI literature concerning recreational athletes, there is a notable emphasis on their heightened data literacy and the practice of monitoring health and performance via wearable and mobile technologies [46]. Athletes use fitness trackers and mobile apps to measure palpable goals such as speed, duration, and intensity and recalibrate their subjective, lived sense of performance [47]. Digital and data literacy and self-monitoring proficiency are positive indicators for adherence to CTR and more effective self-management [45,48].

Given that our research sits at the crossroads of recreational athletes and patients with cardiac conditions, we delved deeper into the established traits of these groups. Regarding recreational athletes, Tholander and Nylander [47] highlight the significance of soft, less measurable goals such as lifestyle and well-being maintenance and identity building as a foundation for sports performance and exercise. Dionigi et al [49] reinforce the intrinsic motivation and self-reliance that athletes exhibit, with less dependence on social support or external incentives. On the other hand, the values of patients with cardiac conditions regarding health care have been identified in recent work by Bente et al [50]. These values include the need for security; support; not wanting to feel anxious; tailoring of treatment; and personalized, accessible care. Nonetheless, the convergence of values and traits between these 2 groups remains unexplored. Transitioning from a highly active lifestyle to a sudden halt caused by a CAD diagnosis can alter one's relationship with sports, health, and technology. We aimed to investigate this aspect in our research.

CTR: Features and Current Designs

During CR, patients are offered hospital-based support that consists of therapies addressing healthy and sustainable behaviors (eg, group exercise training 2-3 times per week, education, psychoeducational therapy, and smoking cessation therapy) with a focus on increasing physical activity and fitness [51,52]. CTR interventions facilitate the delivery of these therapies in the home environment [34]. CTR interventions can be remote (with asynchronous communication between clinicians and patients during exercise sessions), virtual (with real-time audiovisual communication between clinicians and patients during exercise sessions), or hybrid (a combination of in-person CR and remote or virtual services) [33]. While our study emphasized technology-driven rehabilitation design, we did not exclude elements of hybrid interventions (eg, face-to-face consultations) from our card-sorting FG. Previous research indicates that certain patients prefer a blend of remote and in-person services for the social benefits [11]. Thus, we aimed to provide all options to our participants without exclusion.

According to recent reviews of CTR design features and the definition of CTR, there are four clusters of design features: (1) *education and assistance*; (2) *consultations, coaching, and guidance*; (3) *monitoring behaviors for supervision and self-management*; and (4) *peer support* [4,53,54]. Nonetheless, in recent work, Andersen et al [45] point out that existing cardiac technologies mostly focus only on individual information processing. Within our work, we aimed to address the relational aspects of rehabilitation in the home by renaming the fourth category as *coexperience (social aspect)*, focusing on features related to data in a social context and connecting with peers and family.

CTR features encompass technology and care service features. Technology features facilitate users' achievement of a certain goal (eg, data interpretation and irregularity alerts), whereas care service features involve patient actions supported by technology (eg, consultation requests) and services for CTR technology provision (eg, wearable technology support) [4].

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These 2 categories are strongly intertwined as the accuracy and engagement of the technology can influence the quality of the care service (eg, asynchronous SMS text messaging or video calling facilitating consultations [55,56], wearable sensors enabling remote supervision [30], or gamified user experiences providing exercise instructions [57]), whereas the delivered care service can dictate the perceived value and engagement with technology (eg, the type of information provided through digital technologies [58] or allowing family members to participate in remote exercise sessions [59]). HCI practitioners design or optimize interactions between care technologies and patients based on the nature of the intervention (remote, virtual, or hybrid) and its focus (eg, educational content technologies). For instance, in a recent study, Tadas et al [11] looked into patient-data interaction mechanisms that facilitate the transition from program to self-management. Similarly, Kjærup et al [60] investigated user preferences for a data collection application that turns patients into active diagnostic agents. On the other hand, by tackling ways in which care services are provided through technologies, Sankaran et al [27] designed more intelligible CTR exercise prescriptions and progress reports to stimulate patient behavior change motivation in mixed sedentary and more active patients. However, generally, the aim of current CTR interventions revolves around supporting patients in learning about and maintaining healthy behaviors by using various techniques, theories, or methods related to cognition and behavior in their design [37,54,61]. A multitude of CTR interventions are designed using behavior change techniques [55,58,62] and motivational techniques [59,63,64] to stimulate patients to implement healthier behaviors and sustain them in self-management [8,37]. For instance, Dithmer et al [65] redesigned remote training sessions into a collaborative game by using collaboration, goals, and rewards in an attempt to increase adherence to the physical activity component of CTR. On the other hand, Ding et al [66] used individualized goal-setting strategies based on exercise progress to engage patients with myocardial infarction in home-based exercise, whereas Hallberg et al [67] used motivational messages and periodic clinical feedback to support patients in hypertension self-management. Nonetheless, these interventions might not align well with existing indications of operational preferences of the athletic population regarding lifestyle choices, potentially leading to low end-user engagement, satisfaction, and self-management [23,32]. In this study, we aimed to advance the design of technology-centric, exercise-based CTR interventions by investigating the larger spectrum of CTR design features through the lens of the values of athletes with cardiac conditions.

Applying Human-Centered Design Through Human Values

Although CTR has been proven a safe and effective alternative to center-based CR for patients with CAD [39,54], engagement with and adherence to the program are highly impacted by the usability, reliability, and engagement of the designed intervention [6,68]. Ensuring ease of use and user satisfaction can be achieved through human-centered design (HCD) approaches (eg, user research or participatory design)—increasingly used in eHealth design [69]. Recent HCI research on eHealth for chronic conditions stresses the need for human-centric, in-depth investigations into target group challenges. For instance, Min et al [70] investigated epilepsy care challenges and proposed design guidelines for information management and care coordination technology. Cha et al [71] studied parental risk management for the glucose levels of children with diabetes and suggested support technology guidelines. Similarly, Sepehri et al [72] consulted parents of children with health complexity to gather needs for digital management systems. Finally, Bhat et al [73] gathered qualitative data on informal caregivers' roles in chronic disease management to inform technologically assisted care options. In the context of CTR interventions, several studies use human-centered methods to elicit needs or desired functionalities. For instance, the Teledialog CTR program was designed through qualitative user need elicitation, cultural probes, and user testing [74]. Similarly, Beleigoli et al [31] conceptualized a technology-centric CTR program through multi-stakeholder engagement in barrier elicitation and co-design. By innovatively using data-enabled design mixed with human-centric methods, Khanshan et al [75] iterated on a CTR platform. Using a more traditionally qualitative approach, Dinesen et al [76] investigated the needs of homogeneous populations regarding CR and, accordingly, designed a system of multimodal CTR technologies. Nonetheless, a recent systematic scoping review points out that less than one-fifth of CTR interventions reported including end users in the design and development of these systems [54]. HCI practitioners and technology designers are increasingly encouraged to actively involve patients in the design and development of CTR technologies [6,8].

In our pursuit to define design guidelines for CTR interventions that address the needs of the athlete subpopulation, we conducted an empirical study inspired by the VSD tripartite methodology [77,78]. Holistic approaches to eHealth design, such as the Centre for eHealth Research Roadmap, stress the importance of identifying the diverse and potentially conflicting values of various stakeholders (eg, "what do patients value in health and life that they ultimately expect technology to cater to?" [79]). There are recent HCI inquiries that demonstrate the application of VSD methods in the design and development of eHealth interventions (eg, an artificial intelligence application targeting individuals with dementia [80] or a mobile app aimed at weight loss maintenance [81]). An in-depth inquiry into the design of cardiac technologies by Cruz-Martínez et al [32] underlines the importance of addressing patient values in the design of cardiac technologies. Similarly, Ramachandran et al [54] emphasize in their review that considering the needs and preferences of patients during the initial stages of program design can help alleviate issues with poor implementation and adoption of CTR. Although the values of patients with cardiac conditions as a foundation for eHealth design have been identified in recent work by Bente et al [50], these values are generic (eg, "To have or maintain a healthy lifestyle"); do not explore specific behaviors tackled by CR, such as exercise behavior or coping mechanisms; and do not address the athlete subpopulations, whose objectives might differ from those of the general population. In the following sections, we present

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our investigation into the value-centric design of CTR technologies for athletes.

Methods

Study Rationale and Design Overview

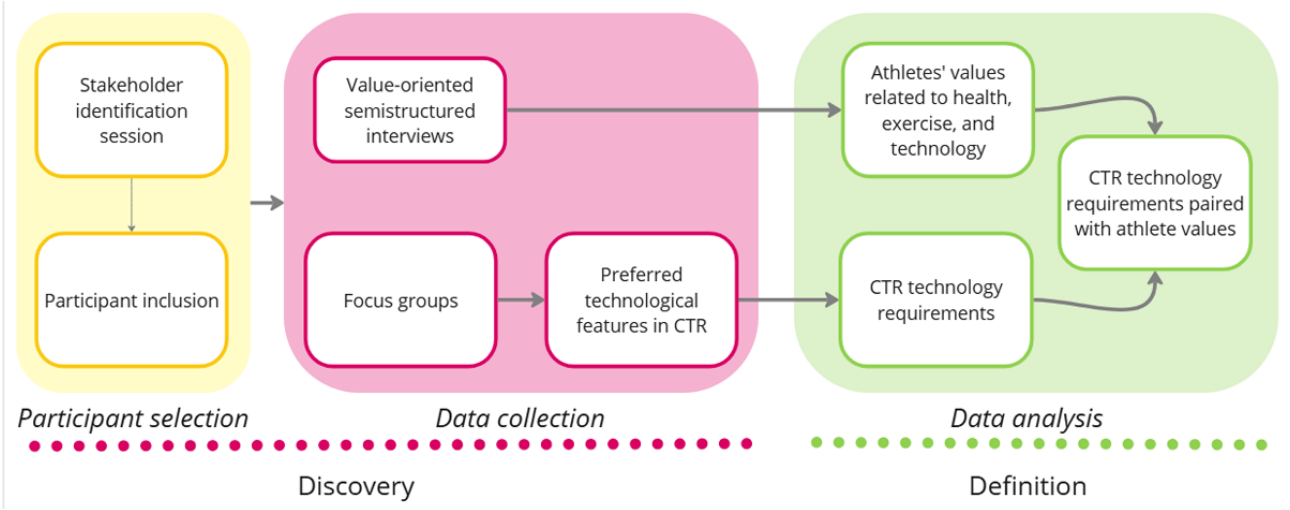
We conducted a qualitative study guided by the HCD paradigm and the participatory health research (PHR) paradigm. The HCD paradigm implies that design activity should prioritize defining the meaning that a product, system, or service offers to people, focusing on *motivation, discourse, and learning before addressing implementation* [82]. It relies on techniques that *engage, interact with, and empathize with people*, uncovering needs, desires, and experiences beyond their own awareness [82]. Similarly, but more focused on the knowledge creation process within a health care problem, the PHR paradigm is a collaborative research approach that actively engages stakeholders as cocreators of knowledge throughout the research process, ensuring greater relevance, applicability, and impact of the findings [83].

To operationalize this participatory approach, the VSD framework was used to identify and embed stakeholders' values into the design of CTR interventions. VSD recognizes the interplay between human experiences and technology, where values are both embedded in and influenced by technology [36]. CTR, deeply reliant on technologies, impacts users' daily lives, from private digital consultations to continuous heart rate (HR) monitoring during routine activities [4]. Thus, CTR designers must understand and incorporate what users value in their everyday lives to create interventions that seamlessly align with and support those values. Recent research by Cruz-Martínez et al [32] and Tadas and Coyle [48] highlights the need for incorporating patients' values into designing cardiac technologies to enhance sustainable self-management, technology adherence, and intervention effectiveness.

We used participatory qualitative methods that align with tools used in HCD and PHR (eg, card sorting and FGs) and are rooted in the VSD framework (eg, value-oriented interviews and stakeholder identification sessions). We elaborate on these methods in the following subsections.

To achieve our research goals (ie, elicit athletes' values in CR, including health and behavior tracking, and define design requirements for CTR technologies addressing athlete values), our study comprised two main phases: (1) *a discovery phase*, including key stakeholder identification and recruitment and data collection through 25 value-oriented semistructured interviews and 6 card-sorting FGs; and (2) *a definition phase* in which, through data analysis, the values (elicited in the interviews) were defined and matched with the identified CTR requirements (derived from the FG results; Figure 1).

Figure 1. The structure of our study divided into two phases: (1) discovery, including participant selection and data collection; and (2) definition, including data analysis. CTR: cardiac telerehabilitation.



Ethical Considerations

This work was conducted by 2 Dutch institutions: Eindhoven University of Technology in collaboration with Máxima Medical Center Veldhoven—a teaching hospital that offers both conventional in-hospital CR and CTR. The study protocol was reviewed by both the university's ethical committee and Máxima Medical Center's medical ethical committee and received a waiver that ethics approval was not required. The collected data were stored and processed according to the data policies and agreements of Eindhoven University of Technology. Informed consent was obtained from all participants, and each participant received a €20 (US $22.07) gift card as compensation.

Stakeholder Identification Session and Participant Selection and Recruitment

VSD posits that technologies—in this case, CTR technologies—have real and sometimes nonobvious impacts on those who are directly or indirectly affected by them [85]. VSD encourages designers to identify a robust set of direct and indirect stakeholders at the beginning of the design process and legitimate those likely most affected and who should be included in the design process [78]. To identify stakeholders in addition to athletes in the context of CR, we first conducted a stakeholder identification session using the IGOHcaps method [86]. This method seeks to identify health care actors (or stakeholders) in a dynamic environment. As CR is a complex, multifaceted

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system of health care services that changes its dynamic over a long period (ie, from hospitalization to self-management and further), the IGOHcaps method was considered suitable for identifying the right participants for our study. The stakeholder identification session lasted 60 minutes and involved an eHealth designer and 5 clinicians working in CR: 1 (20%) cardiac nurse practitioner, 2 (40%) cardiologists, 1 (20%) sports physician, and 1 (20%) resident sports physician.

The IGOHcaps method proposes identifying health care actors as *humans* or *organizations* that *provide*, *control*, *support*, or *accept* health care services (ie, rehabilitation or telerehabilitation). A set of well-defined guidelines are used in the process, such as "actors depend on a specific context and time frame" [86]. On the basis of this method, participants were first asked to identify as many actors as possible using Post-its on big posters in 10-minute sessions per category (ie, providers, controllers, supporters, and acceptors). Finally, participants put all the identified actors together, removed redundancies, and added missing actors, creating a broad overview of direct and indirect stakeholders involved in CR and CTR.

On the basis of the outcomes of the stakeholder identification session, we selected actors fitting the following criteria: (1) *human providers*—directly impacted by CTR technologies and in direct contact with athletes—related to cardiac health (eg, cardiologists), exercising (eg, physiotherapists), psychosocial therapies (eg, psychologists), and general rehabilitation (eg, nurse practitioners; Table 1 and Textbox 1) and (2) *athletes with established CAD* (human acceptors) who exercise >4 hours per week and finished CR within at most 1 year before the moment of the interview (Table 2). In the end, 15 athletes and 12 HCPs were included. The number of participants aligns with recent research suggesting that 9 to 17 [87] or 15 to 30 [88] participants can be sufficient to reach data saturation in qualitative studies that deal with homogeneous populations (in our case, athletes with cardiac conditions and HCPs working in CR), narrowly defined objectives (in our case, CTR requirements for athletes with cardiac conditions) [87], and a structured interview guide [88].

Table 1. Other stakeholders (health care professionals; HCPs) participating in our study[a].

HCP ID	Experience (y)	Expertise
HCP1	27	Sports physician
HCP2	3	Physiotherapist
HCP3	6	Sports physician in training
HCP4	16	Clinical psychologist
HCP5	14	Nurse practitioner in CR[b]
HCP6	13	Exercise instructor (department of physiotherapy) and lifestyle coach
HCP7	27	Primary care physiotherapist
HCP8	>20	Physiotherapist
HCP9	12	Cardiologist
HCP10	10	Nurse practitioner in CR
HCP11	19	Cardiologist
HCP12	8	Nurse practitioner in CR

[a]HCPs 1, 2, 3, 7, and 8 participated in both the focus groups and interviews, HCPs 11 and 12 only participated in the focus groups, and the rest of the HCPs participated only in the interviews.

[b]CR: cardiac rehabilitation.

Textbox 1. The roles of participating health care professionals in the rehabilitation trajectory.

- Sports physician: conduct of cardiopulmonary exercise testing, formulation of training recommendations (including any restrictions), consultations for discussion of test results and recommendations, and supervision of results of exercise stress tests [89]
- Physiotherapist: supervision of the individually tailored exercise training program and support for a physically active lifestyle
- Clinical psychologist: assessment of the psychiatric problems (that were already present or developed after the cardiac event), supervision of psychoeducational prevention modules (group sessions), and individual treatment of patients if necessary
- Nurse practitioner in cardiac rehabilitation (CR): case manager (ie, patient advocate that supports, guides, and coordinates patient care), intake session for discussion of lifestyle behavior and changes and individual goals, performance of assessments for risk of anxiety and depression, and end evaluation of CR program
- Exercise instructor (department of physiotherapy): supervision of the individually tailored exercise training program and support for a physically active lifestyle (similarly to a physiotherapist)
- Cardiologist: treating physician of patients with cardiac conditions, referral for CR, medication optimization, and risk assessment

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Table 2. Athletes (patients) who participated in our study; all athletes participated in both the interviews and focus groups except for P1 (absence due to injury) and P9 (lack of time availability), who only took part in the interviews.

Patient ID	Gender	Age (y)	Employment status; family and living situation	Sports practiced	Self-monitoring technology used	Time since finishing the program
P1	Male	76	Retired; living with spouse	Tennis, cycling, and fitness	Chest strap HR[a] monitor	Just finished the program
P2	Male	70	Retired; living with spouse	Table tennis and cycling	Bicycle computer, chest strap HR monitor, and blood pressure monitor	5 months
P3	Male	44	Employed; living with spouse	Mountain biking, running, boxing, and fitness	Smartwatch and ChatGPT (for training schemes)	Just finished the program
P4	Male	65	Retired; living with spouse	Cycling	Smartwatch, chest strap HR monitor, bicycle computer, Strava app, and blood pressure monitor	4 months
P5	Male	75	Retired; living with spouse	Tennis, padel, and golf	Golf watch	1 month
P6	Male	79	Retired; living alone and close to his children	Running and competitions (eg, track races)	Smartphone step counter	1 year
P7	Male	46	Employed; living alone and close to his parents	Strength training and cycling	Fitness watch and cycling mobile app	Just finished the program
P8	Male	57	Employed; living with spouse and children	Running (competitive), tennis, and mountain biking	Fitness watch, mobile app, and bicycle computer	10 months
P9	Male	54	Employed; living with spouse and children	Running and high-intensity training	Fitness watch and mobile app	7 months
P10	Male	57	Employed; living with spouse and children	Mountain biking and spinning	Fitness watch, mobile app, and chest strap HR monitor	2 months
P11	Male	58	Employed; living alone and close to his siblings	Fitness, cardiovascular fitness, and high-intensity training	Blood pressure monitor and smartwatch	2 months (did not participate in the physical training program)
P12	Male	65	Employed; living with spouse	Running, mountain biking, and padel	Fitness watch	4 months
P13	Female	73	Retired; living with spouse	Cardiovascular fitness, strength training, and spinning	Bicycle computer	Just finished the program
P14	Male	62	Employed; living with spouse	Fitness training, bodybuilding, and cycling	Smartwatch	6 months (did not participate in the physical training program)
P15	Male	68	Retired; living with spouse	Running, competitions (marathons and ultramarathons), and cycling	Fitness watch and chest strap HR monitor	9 months

[a]HR: heart rate.

Patient recruitment was conducted over several weeks via the hospital by a clinician (second researcher), whereas HCPs were recruited through the extended networks of the project's members from the same hospital.

Semistructured Interviews

To incorporate athletes' values into technologies, we first needed to identify these values. To do so, we conducted 25 individual, semistructured interviews with 15 athletes (P1-P15; Table 2) and 10 HCPs (HCP1-HCP10; Table 1). Each interview was conducted following 2 variations of an interview script (one for athletes and one for HCPs) developed by looking at recent value-oriented studies [50,81]. The interview guides explored themes such as the value of physical activity in athletes' lives, good and bad experiences with CR, information flows and relationships with HCPs, social support, and technology used for managing sports and health (Multimedia Appendix 1).

In total, 2 researchers conducted the interviews, which lasted 60 to 70 minutes and were audio recorded. Recordings were used for verbatim transcriptions and translations from Dutch into English.

Card-Sorting FGs

One significant assumption of the VSD framework is that certain technologies or tools support certain values more promptly while being less suitable to address others [77]. This suggests that more or less suitable "properties" or "features" can be

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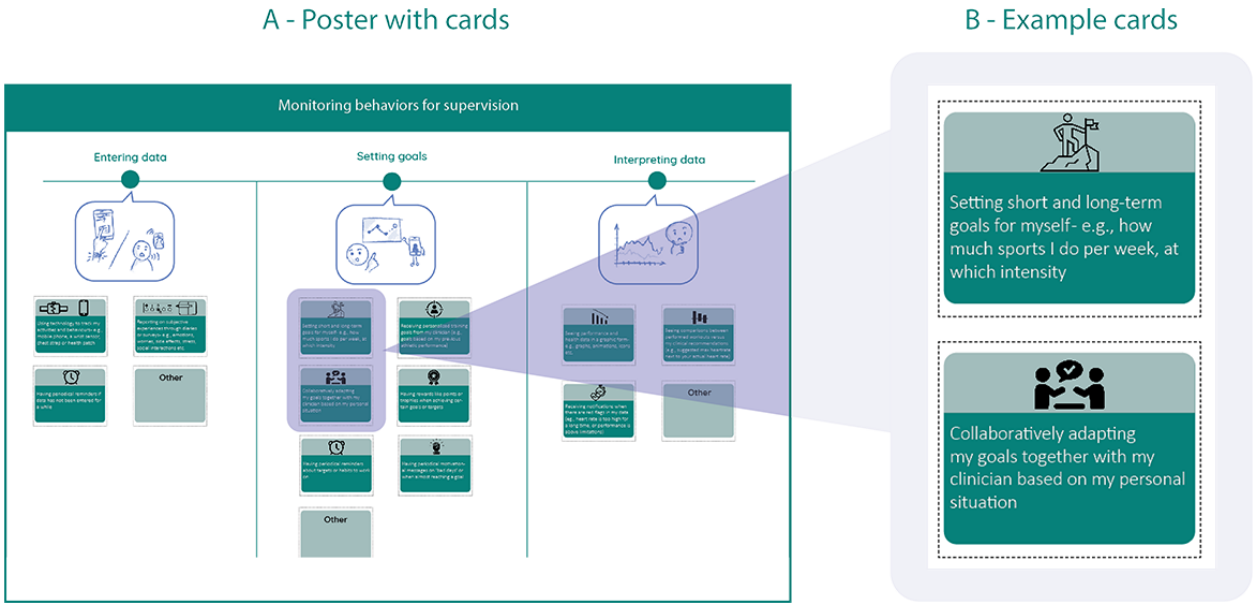
designed into technologies to address specific human values. As mentioned in the Related Work section, CTR interventions are complex systems comprising health care services (such as education, coaching, and consultations) delivered through multimodal technologies—often a combination of (commercial) wearable sensors and digital (mobile or desktop) applications [5,90]. We aimed to derive high-level design recommendations for CTR technologies; however, we included both technology features and care service features as they heavily depend on each other—care service features dictate the content and features of the technologies used (eg, designing a platform monitoring individual sports training is different from designing a platform monitoring synchronous group training). Nonetheless, we stressed the importance of technology to our participants during the card-sorting activity—while some cards pertained to care service features (eg, "to have face-to-face consultations"), participants were asked about ways in which technology could mediate or enable those features.

To further explore desired CTR features that could potentially support athletes in rehabilitation, 6 FGs were held. A total of 87% (13/15) of the athletes who participated in the interviews took part in the FGs. Athletes were divided equally into 4 FGs (FG 1 had 4 participants). HCPs 1, 2, 3, 7, 8, 11, and 12 were divided into 2 additional FGs (FG 5 with 3/7, 43% of the participants and FG 6 with 4/7, 57% of the participants). Each FG lasted 60 to 100 minutes and was facilitated by a clinician and a designer. The FGs were exploratory and creative and applied participatory methods from design thinking [91]. All 6 FGs were given the same assignment—a closed card-sorting task of features of CTR interventions. Card sorting is a method that helps understand the people we are designing for [92]. In our case, we aimed to understand what athletes would find most important and useful in CTR that suited their values. Therefore, HCPs were asked to respond from the athletes' perspective.

We extracted features from recent studies reviewing telerehabilitation technologies [4,5,8,18,61] as well as reviews of cardiac self-management eHealth and telemonitoring [32,37]. To reduce the complexity of the resulting list of extracted features, they were divided into 4 main categories based on the composition of telerehabilitation systems, as described in the Related Work section: *education and assistance*; *consultations, coaching, and guidance*; *monitoring behaviors for supervision and oneself*; and *coexperience (social aspect)*. Because the existing categories were still broad and lacked visual structure, each category was divided into subcategories based on the user journey proposal by Knoche et al [84] of patients using intelligent data-driven health technologies (Multimedia Appendix 2). In addition, we provided empty cards for each category for extra suggestions.

The 4 categories were presented on posters containing individual cards depicting technology features (Figure 2 [84]). Participants were asked to work together to sort cards one by one on a canvas divided into 3 sections (ie, *must have*, *nice to have*, and *not needed*; Figures 3 and 4). Participants were asked to explain the motivation for their choice for each card, encouraging group discussions. The entire interaction was audio and video recorded with the consent of the participants.

Figure 2. (A) Poster with cards related to monitoring behaviors; (B) 2 example cards zoomed in. Sketches depicting subcategories (eg, setting goals) were inspired by the user journey of a patient interacting with intelligent health interfaces [92].

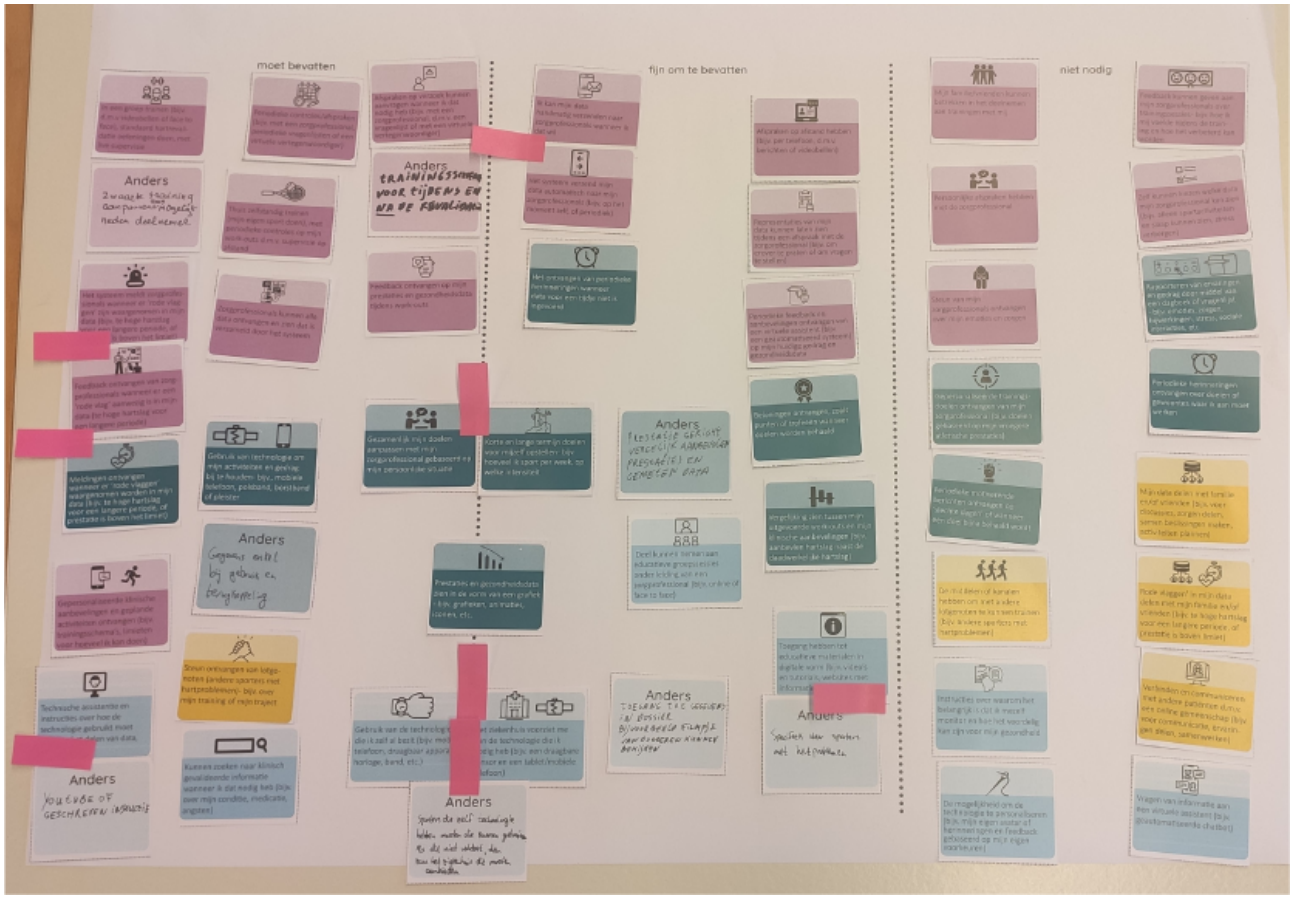


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Figure 3. An example depicting card-sorting activity outcomes from focus group 1—cards from different categories sorted as "must have," "nice to have," and "not needed" from left to right.



Figure 4. Focus group 4—patients interacting with the cards during the card-sorting session.



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Data Analysis: Defining Values and Matching Design Requirements

Overview

To ensure transparency and minimize researcher bias, the data analysis process was iterative and collaborative. Both the interview and FG recordings were initially auto-transcribed using Amberscript (Amberscript Global B.V.). The transcriptions were then reviewed alongside the recordings to correct errors from the automatic transcription process and subsequently translated. Thematic analysis was conducted following the 6-step framework by Braun and Clarke [93] to identify and analyze patterns in the data. First, the researchers familiarized themselves with the data by reading the transcripts and notes taken during the interviews and FGs multiple times.

Defining Athletes' Values

IBS analyzed the interview transcriptions (n=25) to identify quotations about what athletes with CAD find important in life and care. Inductive coding was used to identify codes related to athletes' individual needs regarding exercising, CR, and lifestyle. These codes were grouped under subthemes illustrating more generic needs of the group (eg, "exercise support for one's fitness level"). LF checked the identified needs for analysis validation. To define values, we followed their VSD definition of being *more generic ideals or drivers of athletes' needs* [50,79]. Consequently, according to the VSD methods, we developed a value-oriented coding manual by assigning a small description to each initial code related to a need (by rereading the data; Multimedia Appendix 3). Afterward, the needs were grouped based on underlying themes (ie, desires) that could drive the specific needs—the values. LF verified the links between needs and values, and the coding manual together with representative codes were discussed among the group of authors. Codes that did not directly refer to athletes' needs (eg, "miscommunication between healthcare professionals") were grouped under non–value-related themes and, because of the scope of this work, were not emphasized in this paper.

Sorting Preferred CTR Features

The results of the card-sorting activity were organized based on the preferences of each FG—each feature received a score (2—*must have*, 1—*nice to have*, and 0—*not needed*) and was ordered from highest scoring to lowest scoring. If participants could not agree on a category, the scores were averaged. By ordering them by score in Microsoft Excel, we identified preferred CTR features from the most desired (highest scoring) to the least desired (lowest scoring). Participants' observations during the FGs (either recorded or written on cards) were noted next to each corresponding feature to be used in the requirement definition phase.

Defining CTR Requirements Paired With Values

The features (cards) that were a "must have" for at least 2 FGs together with participant observations were clustered under themes representing requirements. Occasionally, participants within a group held differing opinions on specific features—some felt that they did not need a feature, whereas others felt that it must be included. We opted to incorporate disputed features as requirements if they provided substantial value to certain participants. For example, one athlete whose family resided at a distance and lacked a strong local social support system considered sharing data with family crucial. In contrast, other participants who lived with family did not consider this feature desirable. Given the importance of this feature for the peace of mind and safety of some athletes, we included data sharing with family as a requirement.

Through small iterations during the analysis process, the emerging requirements were linked to one or more identified values. This enabled an iterative reflective process of requirement adaptation according to the expressed needs and values of athletes. These phases were conducted by IB , with LF consistently checking after each iteration. The resulting list of requirements connected with values was checked and discussed among the rest of the research team. This led to defining high-level requirements and guidelines for a technology-mediated CTR intervention that could support athlete values. Preferences and requirements about improvements to colocated CR services also surfaced in our FGs. As these insights are out of the scope of our study, they will be mentioned but not discussed in this paper.

Reflexivity and Research Positionality Statement

To explore how CTR technologies can align with the values and needs of athletic patients, this study represented a collaborative effort between HCI researchers specializing in the social implications of interactive systems and human-data interaction in health and broader contexts and clinicians with expertise in sports cardiology and CR. While this work is focused on technology design, the second author (ie, clinician in training) was actively involved in all stages of the research, ensuring the clinical validity of the derived conclusions as well as the ethical integrity of the research.

Reflexivity was integral to mitigating biases and enhancing credibility throughout the research process. We recognized the potential influence of our previous knowledge and assumptions on study design and data interpretation. To address this, we conducted collaborative discussions with team members not involved in data collection or initial analysis to challenge assumptions and refine the design. The stakeholder identification meeting of clinicians outside the research team ensured diverse views in participant selection. Furthermore, data collection was conducted collaboratively with multiple researchers present, enabling diverse observations, reducing individual bias, and fostering critical reflection through team debriefs. The iterative data analysis enabled cross-checking of the themes and values by multiple researchers to validate findings and ensure coherence. Finally, the triangulation of perspectives achieved by including both athletic patients and diverse HCPs minimized bias by incorporating varied experiences. This approach ensured a balanced and rigorous examination of the data.

Results

This section contains identified athlete values derived from the interviews, card-sorting outcomes, and CTR requirements

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derived from the card-sorting activity paired with athletes' values.

Semistructured Interviews: Values of Athletes Regarding CR

Overview

The results from the interviews conducted with athletes and other stakeholders (n=25) revealed the presence of 12 key themes encapsulating athletes' values within the context of CR and the broader context of personal health management. Each of these key values (ie, high-level desire) was generally supported by multiple identified needs (ie, demands described by participants concerning CR participation and health management). In some instances, a single need could be associated with multiple values. For instance, the need to "observe progress in one's physical performance during the recovery process" could be interconnected with values such as "a goal and performance-oriented approach" and "health and performance quantification." Moreover, the identified values represented the overarching desires of athletes, whereas some needs might only pertain to some individuals. The subsequent sections will provide insights into findings related to each of the 12 identified key values clustered in 3 groups: *body centric*, *care centric*, and *data and technology centric*. An overview of the values and needs and example quotes can be found in Multimedia Appendix 4.

Body-Centric Values

A Dynamic Lifestyle

Athletes were individuals who placed a high value on physical activity and exercise. Participants viewed exercise as part of their identity, a way to cope with psychological struggles, a way to compete with oneself and push one's limit, and a way of being part of a community when it comes to social sports. However, of utmost significance, all participants valued maintaining a healthy lifestyle and linked exercise and sports with preserving vitality and good health. All participants positioned exercising highly among life values such as being with family and enjoying work and life. The lack of CR programs addressing the sports they valued hindered their enjoyment and motivation to participate:

> *That's really important—if I can do sports, that's the foundation of the day. Then I can move forward...Maybe [I like] the adrenaline, I've always been active. Working on the farm from primary school, always at work, worked at the bakery, always training. I was at the athletics club in [city name], I went there twice a week. I have always been active...[After the cardiac event] I had the fear that I could no longer exercise. That's a pretty awful though. If I can't exercise anymore, what am I supposed to do?* [P6]

Independence and Confidence in One's Body

Athletes valued their individuality, independence, and self-efficacy. They were very sure of themselves and did not like to doubt their capacity to recover and return to their athletic capabilities and previous lifestyle. They expressed confidence in their recovery journey and relied less on clinicians, valuing their opinions alongside their own ability to discern their body's needs. Athletes knew the value of physical activity and took pride in remaining fit despite older age. Consequently, they did not need external motivation. Still, they needed facilitators to understand their limits and apply the clinical knowledge in the home environment, where they wished to safely exercise similarly to before hospitalization. Although very confident in "feeling" what their body needed, the CAD diagnosis could unbalance their "internal compass":

> *I've always had a positive perspective on life...I immediately thought "This [ie, heart attack] just happens to you and we're going to make the best of it. Seriously work on it." I have tried very hard to function properly again. And I don't suffer anymore...I feel myself if I really go too far...She [ie, the cardiologist] said "You can just exercise, of course, you should never go crazy. That's never good. But no restrictions."...She gave me that confidence.* [P14]

Coming to Terms With One's Condition

Most participants described the diagnosis as unexpected due to their healthy lifestyle and absence of symptoms. The lack of control over their diagnosis, often with a family history of cardiac conditions, coupled with sudden fatigue and loss of physical fitness, had the potential to profoundly affect their and their family's outlook on life. Athletes had high ambitions of returning to their previous exercise capacity and found difficulty in accepting a "failing body." At the onset of CR, it was crucial for athletes to cultivate coping strategies to interpret their body's signals. Clear exercise limitations, such as maximum HR, helped athletes establish boundaries. They required guidance on managing extreme fatigue and knowing when to pause and rest. In addition, athletes prioritized resolving frictions with their families regarding safe exercise and activity levels. They achieved this by negotiating the specifics of where, when, and how much exercise they engaged in. Their ultimate objective was to return to the routine and normality of everyday life:

> *You actually want to pedal higher wattages, as much as possible...I look next to me, to a colleague who had been practicing for a while. It was on 106. I thought "I should be able to do that too," but that was quite disappointing...You're on a racing bike. You are very fast on such a thing, and very far away...I always have my phone and things with me, data, so they [ie, family] can find me...I have that app from my odometer—it also tells my son where I am at that moment...those are the things I take with me to be able to cycle safely.* [P4]

Care-Centric Values

A Goal- and Performance-Oriented Approach

Athletes found goals and performance important during the CR program. One crucial need was to return to previous athletic capabilities by having clear, progressive performance targets. Health and athletic goals intertwined, for instance, reaching target HRs and regaining the ability to mountain cycle. They valued pushing their limits and making steady progress

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alongside clinical validation of their advancements. As a result, some participants found the exercise program too easy and the CR intervention less effective. They suggested adjusting exercises to match their intensity. Other patients found usefulness in regaining confidence under professional supervision. To reach their goals, some athletes used resources within their network, such as personal trainers, friends, or relatives who were HCPs:

> *It [ie, the exercise program] didn't make much sense...It turned out that my condition was more than sufficient. Then the real question is "why are we doing this?"...They actually slowed you down rather than stimulating you...It didn't really help much. I honestly found it slowing me down a lot. Because I have to cycle for fifteen minutes to get here [ie, hospital] and fifteen minutes back. And then I actually cycle even more intensively [commuting] than there [ie, at the exercise program].* [P2]

Concise, Actionable Guidelines

A significant number of athletes felt like they had been "left in a void" during CR—clinicians did not pay enough attention to their needs because athletes already knew the value of exercise. Most athletes expressed the need for clear, preferably quantifiable indications of exercise limitations (eg, the maximum HR they could reach), personalized variations of sport-specific training schemes that made them feel safe but performant, and education on the influence of medication on performance. Some athletes found open-ended exercise limitations (eg, "Do whatever feels good") enough for safe sport resumption, whereas others found them confusing and insufficient:

> *I still find it difficult to understand, what is very good with the beta blockers [ie, medication used for secondary prevention].... It's still a difficult process to find out where to be in your exercise. And if they could have given some guidance in that, what can you do maybe with intervals, like boxing, which is very high interval training and where should you be. Should you be careful with some things or with your HR, or yeah, they didn't think much about it.* [P3]

Trustworthy, Readily Available Support

Athletes expressed their challenges and objectives adeptly, valuing clinicians who offered clear, concise, and actionable solutions. They sought easily accessible health care services for emergencies or alarming symptoms—some had needed rescue during mountain cycling or gym workouts. They appreciated impromptu talks with physiotherapists during training and desired swift access to clinicians for direct, sincere responses to inquiries without delays encountered in current e-consultation systems. Moreover, athletes appreciated clinicians who gave patients control over health-related decisions and involved them in the decision-making process regarding their health journey:

> *If I send it [ie, exercise recommendations] via email, it will quickly reach the person. We've had a conversation [ie, consultation] and I'll fill that in a bit afterward. It is annoying for people if they have to wait two weeks for a letter containing those recommendations. They have just received that advice, and then they actually can read it that evening, so I will send it that way.* [HCP3]

Care With a "Personal Touch"

Although athletes were very open to exercising independently in the home environment and communicating from a distance with HCPs, they still appreciated personal approaches to health care. Many athletes mentioned that they did not want to feel or be treated like a number and wanted to maintain face-to-face contact and human interrelations periodically during the rehabilitation period. Moreover, for some, there was a significant dip in morale after hospitalization, and empathy and reassurance were highly needed. Some patients described a lack of empathy from HCPs for being "fitter" than the general population and having better chances to recover:

> *When I had a conversation with the nurse practitioner I noticed she was not serious. She said "Within 3 weeks you will forget you had a heart attack." It was a pity for me, so I was sad about it. I thought to myself—what do I have to do now? Where are the people? How can I find the people? But I was afraid to call the nurse to ask where because they were so busy. Then I think it's a stupid question.* [P11]

In- and Outside-Hospital Oversight

Athletes were insecure about new exercise limitations, how much they could push themselves, and exercising safely outside the hospital environment. They mentioned being supervised as crucial for their confidence and reassurance, especially in the first few months after hospitalization. Within current CR, athletes participated in exercise programs not for lifestyle changes per se but to feel supervised by HCPs and have the feeling that they were doing the best they could for their health. Being supervised provided reassurance, security, confidence, and a feeling of being cared for:

> *I think in the beginning, it's quite scary to do heavy exercise without any supervision. The defibrillator should do its job when there are hard issues. I think after the hospitalization you need some reassurance from somebody looking after you if there any issues.* [P3]

Emotional Support and Sharing

Athletes did not need social support to maintain healthy behaviors. However, they appreciated the emotional support and opportunity to share their struggles and anxieties with their family and close ones but also with HCPs such as the clinical psychologist. While not essential, they valued the bonding opportunity of conversing with other patients with cardiac conditions. However, many participants did not encounter fellow athletes in their CR group. Participating in the FG provided a pleasant chance for them to share treatment options, experiences, and their common passion for exercise:

> *I think besides the rehabilitation program, the physical part, it was also nice to speak with people who also had an [heart] attack. Just to hear some experiences or like the medication I used—I had a lot*

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> *of side effects and they said "Well, I also had that. But after a while it went away, or I tried another one or asked for injections." This was nice.* [P10]

Data- and Technology-Centric Values

Health and Performance Quantification

Athletes had advanced data literacy, often using wearable sensors, bicycle computers, or mobile phones to track metrics such as HR, distance, speed, and time. However, a few participants preferred relying on their body awareness over sensing technology. In their rehabilitation, athletes diligently conducted routine checks such as blood pressure and HR measurements along with hospital tests. One participant even maintained a Microsoft Excel sheet in which they recorded their blood pressure daily. After diagnosis, some athletes' relationship with wearable sensors shifted—they used data to reassure themselves about their health and recovery. They also valued progress reports to gauge recovery, correlating their body's feedback with measurable improvements such as lifting more weight or running faster:

> *Interviewer: What do you like about your fitness watch?*
>
> *P9: The monitoring it does, so you know anything like HR, but also the exercises themselves and seeing progress—that improves and then you are really happy. That's something I saw, there was a tremendous drop [ie, in fitness] when I had surgery and the months before. It dropped significantly and now you see it. And now it's higher than even before the surgery. So that's really motivating, especially those things that you have to really work hard for to, you know, get one level up.*

Clinical Validation of Information and Data

Some athletes valued data for performance measurements, but trust in wearable data diminished after diagnosis. One participant's distrust stemmed from the wearable's failure to detect their myocardial infarction. Consequently, athletes placed importance on clinicians giving meaning and validating data on vital signs. Athletes considered it crucial to discuss various measurements such blood pressure, HR (eg, variability and zones), and performance metrics with their clinicians. They sought to derive meaning from these measurements in the context of their cardiac condition or medication intake. Some athletes remembered sharing data overviews from fitness apps with their clinicians during consultations but acknowledged receiving little substantive feedback due to the brevity of the consultations. Moreover, athletes found it significant that the information they received about their recovery process, cardiac intervention, or medication came from clinicians, not from other sources such as the internet or other people:

> *The most important thing for me was measuring [ie, during CR]. Things are tested—what you do, and then you end up with that bike test again. Measuring is knowing, I say, that was very important to me in that rehabilitation...I have to do it and measure it, and the healthcare provider can judge. What does that mean now, is that good or should I do something else? That is difficult by yourself...I sometimes go to the doctor and then he sometimes says "take a look at 'Thuisarts'" [ie, a website with general healthcare knowledge]. But I'm not into it. If there is something wrong with me, I want an expert who can tell me something.* [P5]

Reliable Information Systems

Even though athletes were willing to be supervised from a distance, exercise in their home environment, and communicate with clinicians through digital channels, they did require reliable information systems that facilitated the process instead of burdening it with technical issues. One important consideration was reliable sensors and data streams—some athletes did not fully trust data from commercial wearables and used additional devices (eg, chest strap and blood pressure monitor). Moreover, they underlined the importance of reliable infrastructures that can transmit data and information to and from clinicians without delay. They also stressed the importance of user-friendly workout schedules that could be easily implemented with technologies they already used:

> *[The most important thing to consider when developing a CTR system] To know that you have a good connection. The rest will take care of itself...The moment I step on that [ie, exercise bike], that data also ends up in the hospital...it could end up on a server in the hospital. You can, so to speak, watch it a few days later and then give feedback.* [P1]

Card-Sorting FGs: Preferred Features of CTR Systems

Overview

The card-sorting activity allowed participants to present an overview of desirable or undesirable CTR features for athletes. The characterization among *must have*, *nice to have*, and *not needed* differed from group to group based on their personal needs, group dynamic, composition (patients vs HCPs), perceived independence in one's health management journey, and experience with technology. We present a summary of the card-sorting results in the following sections and in full in Multimedia Appendix 5.

Consultations, Coaching, and Guidance

Participants considered periodic checks (either through electronic consultations or surveys), remote supervision of sport-specific training, and personalized content comprising sport-specific actionable guidelines as *must haves*. The detection of alarming symptoms in the collected data was deemed very important, as was receiving actionable feedback on how to react to these symptoms or prevent them, especially during intense exercise. Frictions arose among athletes regarding remotely supervised group training—most participants considered it essential at the beginning of the program, whereas 15% (2/13) of the athletes believed that independent training was best as they could "go at their own pace." In-person consultations were a *must have* except in FG 1, whose participants deemed them unnecessary as long as remote consultations were provided. A system that facilitated communication about exercise data between the athlete and HCPs and athlete-HCP feedback on

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training recommendations was considered a *must have* or *nice to have*. Athletes had varying opinions on monitoring emotions and receiving emotional support from clinicians. Some viewed it as essential, especially when struggling to accept their condition, whereas others believed that emotional support was better provided by family or friends. Finally, recommendations from virtual assistants (eg, automated recommendation systems) were generally ill-favored because of a lack of trust in their reliability.

Monitoring Behaviors for Supervision and Oneself

Participants felt confident about receiving notifications when irregularities in their data were detected. Most participants preferred wearable sensor monitoring of physical activity to subjective self-reporting mostly because of the trust in and objectivity of sensor data, as well as the familiarity with and pragmatic benefits of automatic data collection. Nonetheless, some participants recognized the added value of subjective data collection for clinical decision-making and depersonalization of data and for expressing anxieties and insecurities related to data inaccuracies and safe sports. Athletes underlined the importance of support for collaboratively adapting individually set performance goals with HCPs. Receiving personalized goals from clinicians was disagreed upon—some athletes felt confident in setting their own goals, whereas others felt that clinical guidance was essential at the beginning of rehabilitation until confidence in one's athletic abilities was regained. Graphical representations of performance and health data, as well as parallels between actual performance and clinical recommendations, were labeled as *must have* or *nice to have*. In line with case studies describing experiences of athletes with CR [2,75,91], our participants expressed little to no interest in motivational queues, rewards, and reminders because they already felt motivated enough to rehabilitate (exercising but also eating healthily and taking medication).

Education and Assistance

Technical assistance and instructions on using CTR technologies, as well as having the possibility of integrating their own wearable sensors into the monitoring system for familiarity, convenience, and trust, were deemed a *must have* by all participants—HCPs underlined that, at times, athletes used sensors that were superior to the equipment provided by the hospital. Access to digital information about being an athlete with CAD was important to most participants as similar reliable resources were not available online. Receiving information from virtual assistants (eg, chatbots) was not needed because of a lack of trust in the clinical validity of the information—some clinicians regarded it as a nice addition that could alleviate the workload of HCPs. Similarly, some participants considered information about why monitoring is beneficial for health as common knowledge and, therefore, not necessary.

Coexperience (Social Aspect)

Peer-based support was appreciated only within the context of the program and, preferably, in person. Online communication with peers was not viewed as important as athletes felt confident in themselves and their existing support systems and expressed that they would not make use of online communities. Sharing data with family also obtained a low score, with the exception of 15% (2/13) of the participants, who already shared their location with loved ones for safety, alleviating anxiety, and shared decision-making. Virtual environments that facilitate training with peers were not highly valued as athletes already had social groups to train with or preferred training individually.

High-Level CTR Technology Requirements Paired With Athlete Values

The derived requirements indicate that technology can facilitate exercise monitoring; the interaction among patients, clinicians, and the monitored data; and mechanisms of remote coaching and remote consultations. The independence that athletes exhibited in their health care journey was echoed in the resulting specifications, which underscored their inclination to personalize and monitor their physical and recovery progress independently, diverging from standardized exercise regimes. The pragmatism and data-centric approach were evident in the need for precise exercise restrictions, recommendations, and progress measurements. Athletes prioritized a straightforward and informative system over motivational strategies such as gamification or reward systems. The dynamic and disciplined lifestyle that they associated with their well-being and identity manifested in most of the technology requirements. However, glimpses of the desired personal touch emerged in open data-gathering approaches or the request for individualized sport-specific feedback. The derived CTR technology requirements can be found in Textbox 2, and an extended version containing paired athlete values can be found in Multimedia Appendix 6.

Moreover, although participants were encouraged to brainstorm ways in which technology could augment health care services, *technology was not consistently the preferred choice*. These insights are valuable for the HCI community as they first identify the preference for a hybrid CTR intervention, and second, they elucidate user scenarios in which technology should not be imposed as a solution, thereby averting user frustrations or resistance. Participants found face-to-face mediation in colocated contexts most effective for the group, emotional support, or trust-building interactions. For instance, while peer support was appreciated in person, it was not preferred in online groups. Similarly, at the beginning of the program, in-person clinical consultations, group education sessions, and standardized exercise sessions were preferred for building confidence and bonding. Finally, open communication was preferred over technology for social support in the home environment. These requirements relate to the values of *care with a "personal touch"* and *emotional support and sharing* as participants emphasized the importance of occasional human interaction in feeling supported by a health care system that prioritizes compassion and human connection. We used these insights to advance knowledge about technology-centric requirements in the context of CTR for athletes.

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Textbox 2. Derived cardiac telerehabilitation technology requirements.

Supporting remote monitoring

- Remotely monitored sport-specific training (eg, type of sport, duration, frequency, heart rate [HR; zones], and degree of effort) and biophysical measurements (eg, blood pressure)—before and during the cardiac rehabilitation program
- Exercise data collection and aggregation from athletes' own wearable sensors (eg, sports watches, chest straps, and mobile apps); the hospital provides patients with sensors in case they do not use one
- Simple, brief, open approach to subjective data collection gathering contextual information (eg, symptom uncertainty, sport-related anxiety, and questions about sensor data irregularities)
- Technical instructions and online assistance in monitoring, syncing, sharing, and correctly interpreting the data (eg, instructional videos or written information)
- Continuous and automatic transmission of remote data to clinicians; opting for manual, discrete transmission is possible

Supporting human-data interaction

- Graphs displaying training progress (eg, HR and intensity minutes) and sessions (eg, duration and HR zones) contrasting with limitations and recommendations (eg, exceeding maximum HR) for easy understanding by trainers, family, and clinicians
- Instant alerts for exceeding clinical limitations during training (eg, excessive time spent in HR zone 4)
- Alerts for prolonged anomalies in the data (eg, exceeding limitations and signs of cardiac arrhythmia) with follow-up recommendations for action—either adjusting performance or seeking clinical assistance
- Selecting and sharing monitored data snippets (eg, HR from a specific exercise session) with clinicians within the system, facilitating remote data-focused discussions
- An overview of clinical test results such as exercise stress tests and clinical scans
- Sharing health and exercise data with family, including exercise location and alarming signals, for discussion, negotiation, and easing concerns

Supporting remote coaching

- Setting, storing, and reviewing personal health- and sport-related goals; sharing them with clinicians for feasibility assessment, feedback, and personalization
- Tailored content, including clinically validated, personalized training schemes tailored to one's sport, goals, current condition, and past performances
- Annotating clinical training suggestions with feedback grounded in personal experiences
- Receiving clinical feedback on current performance (eg, through annotations on remotely monitored exercise data)
- Multimedia, digital information resources about athletic patients with heart problems and how to deal with exercising while having a cardiac condition

Supporting remote consultations

- Periodic clinical check-ins on exercise management (eg, updating knowledge on the exercise limits or exercise-related symptoms) through synchronous or asynchronous channels, such as video calls or online surveys
- e-Consultation functionality allowing users to ask specific questions to appropriate clinicians via chat functionalities

Discussion

Principal Findings

Overview

Recent developments in the design of cardiac eHealth have encouraged HCI practitioners and designers to account for the patients' latent and hidden needs, desires, and life values [32,48]. A recent scoping review on acceptance and adherence factors of CTR interventions emphasizes that early involvement of users in the design of CTR technologies is essential for designing meaningful and efficient interventions [54]. Nonetheless, there has been a lack of HCI studies on acknowledging the needs and values of patient subpopulations in CTR [33,34,54]. In this study, we outlined design requirements for technology-centric CTR interventions that cater to the values of a distinctive cardiac population—*athletes with established CAD*. We used methods from VSD and uncovered 12 key values of this specific population supported by underlying needs. These values included "independence and confidence in one's body" and "concise, actionable guidelines," alongside technology features grouped into design requirements addressing these values. In the following sections, we discuss the implications for the value-oriented design of CTR technologies in the context of the athletic population. We first situate our findings in the context of existing CTR research for general populations and then explore how alignments and conflicts among values can inform the design process. We discuss design guidelines based on the connections inferred between athlete values and the identified design requirements.

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CTR for Athletic Populations Versus General Patient Groups

On the basis of our findings and previous, related work, the core experience of being a patient with a cardiac condition is fundamentally the same for both athletes and general populations. However, the key difference is that athletes have distinct attitudes toward physical activity, and their identity and discipline around it shape their expectations of care, particularly regarding physical activity training, the main component of CR. As a result, while there are similarities, CTR technologies should be designed differently for athletes compared to general populations. For example, general populations typically track any physical activity, such as steps (eg, MI-Pace [66]) or standardized exercises (eg, recommended aerobic exercises for patients with CVD [62]), whereas athletes prefer sport-specific tracking and feedback (eg, for cycling, running, or weight lifting). This difference can influence monitoring system design as our participants preferred relying on their own high-performance wearables, which they were trained to use and were of better quality than standard hospital-issued devices, whereas CTR systems for general populations are designed to offer patients standard monitoring devices (eg, Fitbit [62,76], Mio Alpha and ActiGraph [64], smartphone apps [30], and Philips health watch [66]). This can also affect personal insight platforms and clinician decision support systems, shifting from generic goals such as 10,000 steps per day (eg, shared care platform [94] and HeartPortal [74]) or 150 activity minutes per week [62] to sport-specific milestones based on frequency, distance, HR zones, and perceived effort.

Some needs remain the same, such as clear technical instructions and technical support for CTR platforms (eg, the MedFit app [62]) and seamless, continuous data transmission (eg, SmartCare-CAD [64]). However, graphical data representations alongside exercise limitations are particularly relevant for athletes as they need to moderate activity rather than increase it. Their familiarity with data tracking can make them more critical of inaccuracies and more confident in interpreting data, influencing their preference for precise alarm systems. In contrast, general populations may feel overwhelmed by excessive or highly technical data [4].

While data-focused discussions with clinicians are valuable for all patients [60,66], athletes require highly personalized exercise recommendations based on personal metrics, sport-specific testing, and clinical cardiology expertise. In addition, information resources designed for general populations (eg, ActiveHeart [76]) need to be enriched with athlete-specific content to prevent misinformation. The need for periodic consultations and clinician validation remains constant with athletes and general populations [64,66,76,94], but athletes may have more specialized questions, which could benefit from new communication methods such as prestructured forms, data annotations, or digital messaging for tailored interactions. We discuss the specific implications for athletic CTR technologies in the following subsections.

Design Implications for CTR Technologies Supporting Athletes

Value Contradictions, Tensions, and Design Trade-Offs

Aligning with VSD theory, we observed value interrelations and tensions at various levels of human experience—among athletes, as well as between athletes and general populations of patients with cardiac conditions. The VSD framework acknowledges that human values do not exist in isolation [36]. Framing a design process to engage constructively in the interconnectedness of human values is a matter of design thinking and can be mediated through design trade-offs, value conflicts, or value tensions [78]. Such tensions, conflicts, and trade-offs have also been discussed in similar studies applying VSD methods to eHealth design [74,81]. The term *value tension* encourages the design of solutions that balance opposing values such that “the adjudication of the tension holds each value intact” [36]. In our case, most athletes valued data from wearable sensors to become better at sports or recalibrate internal feelings of exercise intensity, whereas other athletes (eg, P13 or P14) trusted the physical “feeling” enough and did not consider fitness trackers necessary. Therefore, one design outcome can be a wearable sensor system that offers insights into one’s performance and the meaning of data in the context of CAD after hospital dismissal, when athletes lack confidence in their bodies the most. Subsequently, tracking one’s training can become optional and periodical. On the other hand, a “design trade-off” conveys an approach in which designing for one value will diminish another value. For instance, designing a CTR technology that formalizes the role of a close family member and allows athletes to share personal data such as location and HR while exercising with them will come at the expense of the independence of other athletes who want to keep their experiences private. Offering this functionality for the safety and comfort of some athletes takes the form of a trade-off.

Our findings also align with previous research on the values of patients with cardiac conditions. The 11 values of patients with cardiac conditions as a foundation for eHealth development identified by Bente et al [50] overlap with the 12 identified values in our study (eg, “To have an overview of personal health data” overlaps with athletes’ value of “Health and performance quantification”). Nonetheless, there are also value conflicts. For instance, one key value of the population in the study by Bente et al [50] was “to be extrinsically motivated to accomplish goals or activities (related to health/lifestyle).” On the other hand, athletes valued a “goal and performance-oriented approach” to rehabilitation and were very independent in their health journey. The term *value conflict* proposes that, when values come into conflict, design resolutions can offer solutions responsive to both values. In the context of CTR individualization, one solution can be offering a standardized CTR platform that encompasses 2 different modules: one for patients who need behavior change (including information about the importance of exercise, motivational queues, and reminders) and one for athletes (including a more performance- and data-oriented interface comprising sport-specific goal setting, data overviews, and means to address sport-related questions).

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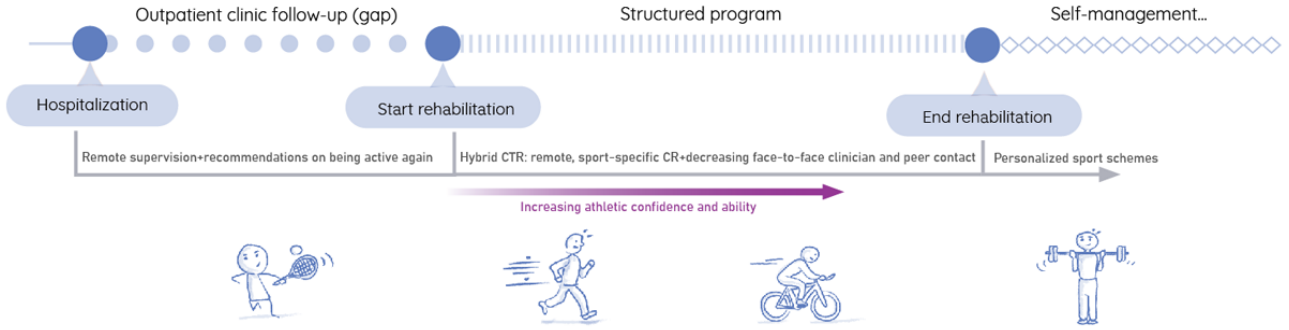
While our results mostly show generalizations of common themes and requirements, designers should be aware that values and needs are expressed through the lens of individual experiences [79]. Two patients might have completely different rehabilitation experiences, whereas clinicians might benefit from solutions that patients do not necessarily need (eg, virtual assistants that can ease clinicians' workload but are not perceived as trustworthy by athletes).

Connecting CTR Technology Requirements With Athlete Values

Preference for Hybrid CTR and Continuity of Care

Our research revealed a preference for a hybrid CTR intervention incorporating human-to-human contact for peer bonding and clinical consultations. This preference was particularly pronounced during the posthospitalization and early program stages, when there is a need for human interaction, emotional support, and sharing. Our findings also indicate a need for activity supervision and recommendations that can help regain activity after hospitalization, before the program starts. Similarly, previous research on general cardiac populations reveals that exposure to other patients can evoke feelings of safety, comfort, and camaraderie [61,95] and that support is needed in the posthospitalization gap [68]. However, athletes quickly build confidence, and their need for human contact can decrease fast after the start of the program. Peer support was seen as "nice to have" but not necessary, whereas athletes shifted their priorities toward regaining their physical condition. Although previous research on general populations suggests introducing technology later in the rehabilitation process as participants transition from program completion to self-management [11,95], our study indicates that athletes are prepared to become independent sooner. This readiness arises as soon as they regain physical strength and gain clarity regarding their new limitations, typically during the transition between the posthospitalization stage and the midpoint of the program. Our results indicate that, while the need for supervision may decrease significantly after the program ends, some participants still expressed a need for structured training plans to continue their progress (Figure 5). In the following subsections, we discuss the identified categories of CTR technology requirements that surfaced from our study and their connection to athlete values.

Figure 5. For athletes, cardiac telerehabilitation (CTR) provides chances to train in their sport at home before and during rehabilitation under remote supervision and receive guidance after the program ends. CR: cardiac rehabilitation.



Supporting Remote Monitoring

Our participants expressed attitudes similar to those found in research on recreational athletes—sports are integral to athletes' identity, well-being, and lifestyle [47]. They resisted the notion of being confined to a monotonous, standardized hospital-based program; however, their perception of safe sporting activities next to new physical limitations became distorted following the diagnosis. While athletes prioritized independence in their health journey, they still valued dependable clinical support significantly. This included receiving remote clinical monitoring of their sporting activities outside the hospital as well as biophysical measurements, ensuring ongoing clinical oversight. While current telemonitoring in CTR focuses on patient adherence to exercise targets and symptom management [62,94], for athletes, its purpose would shift toward preventing overexertion and tailoring future training programs based on their heart's capabilities and symptoms. Moreover, current telemonitoring relies on step counters, distance, or data indicating the presence of physical activity [54,61]. However, a more nuanced approach is needed for athletes, incorporating detailed sport-specific parameters such as type of sport, intensity minutes, HR zones, and HR recovery, similar to insights found in sports apps such as Strava or JOIN. Furthermore, while regular subjective data gathering, such as diaries, was not considered essential, some athletes expressed a need for documenting anxieties, particularly those related to sports, symptoms, or specific workout instances. Such documentation could provide a personalized touch and reassurance. This could be facilitated through open methods of annotating sensor data, as recently discussed by Tadas et al [11] or Akinsiku et al [96]. As already documented, athletes are accustomed to self-monitoring—they already have preferences and high expectations related to reliable monitoring systems [46,47]. Our findings show that both athletes and HCPs prefer using the athletes' wearable sensors because of familiarity, perceived device quality, and accuracy. Despite potential challenges such as data inconsistencies and integration issues, leveraging existing resources can save costs and offer valuable historical insights predating diagnosis.

Supporting Human-Data Interaction

Previous literature has underlined the trained capacity of recreational athletes to be aware of signals sent by their bodies, using data from wearable sensors (mostly HR) to recalibrate internal feelings of embodied experience [46,47]. Our research

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confirms these findings, with most participants using wearable sensors during training for self-reflection and internal recalibration. Some athletes even asserted their deep trust in their body's response to exertion, suggesting that they relied more on familiarity than data. However, this equilibrium shifted after hospitalization, when even basic activities became challenging. Accepting one's limitations and adapting to new boundaries is crucial. Athletes undergo a recalibration process by relearning how data, symptoms, and bodily sensations relate to and mutually influence one another. Graphical representations of physical and athletic progress next to clinical validation can facilitate the creation of "in-the-moment knowledge" [48] and facilitate the recalibration process. Access to clinical tests (eg, exercise stress tests), data representations incorporating clinical limitations such as maximum allowed HR, real-time notifications for exceeding limitations during exercise, and alerts for clinicians and athletes regarding data anomalies can facilitate accepting one's condition. An example of real-time training feedback based on optimal training zones is present in the work by Geurts et al [97]. These enhancements become indispensable as wearable data evolve beyond mere performance metrics [46] following a diagnosis. However, some athletes expressed skepticism regarding the accuracy and reliability of the data, recognizing that their sensors were not medical devices [98]. As a result, they sought clinical validation and aspired to engage in data-driven discussions with their clinicians even during brief online consultations. Therefore, a CTR system could streamline the process by enabling easy access to data from specific periods during these e-consultations. In addition, in contrast to findings of general cardiac populations being open to sharing collected data with peers [11], our participants found sharing wearable sensor data with peers irrelevant both before and after their diagnosis. Previous studies similarly indicate that the social value of recreational athletes' practice is not found through online communities or peer data sharing [47,49]. Finally, while the family may play a less active role in an athlete's physical recovery, they are significantly involved in mediating anxiety and emotional healing. Designers must consider the social dynamics inherent in a CTR system and its monitored data, as discussed by Andersen et al [45]. They can address family safety concerns and partner anxiety through location sharing and negotiation mechanisms akin to features in apps such as Strava or Apple Fitness+. To streamline and enhance conversations and reflections about data, designers should implement strategies that cater to low levels of data literacy and effectively communicate progress or trends, as evidenced by previous research [99,100].

Supporting Remote Coaching

A key finding of our study highlights athletes' perception of inadequate care in colocated CR as their exercise needs were overlooked due to the assumption that they were "fitter" than other patients. Unlike in general populations in which low motivation contributes to poor program adherence [101], athletes' enjoyment and willingness to attend were hindered by not being guided to exercise at the desired intensity. As patients with cardiac conditions are keen on returning to normality [95], athletes are eager to reclaim their peak physical condition. In their pursuit, they merge health and athletic objectives, such as aiming to increase their personal best timing to eventually participate in a half-marathon. While goal setting is addressed in current CTR designs, nonetheless, clinicians are the main initiators or coordinators of physical activity goals [76]. Catering to athletes' independence and autonomy, athlete-centered CTR interventions should empower athletes to establish their sport-specific performance goals, incorporating motivators and metrics (eg, desired running distance) while facilitating clinician feedback and adjustments. In line with our findings, recent research on consumer wearable systems for sports highlights the significance of incorporating sport-specific goals and recommendations as a crucial design enhancement [102].

To support values such as "To be extrinsically motivated to accomplish goals" [50], current CTR interventions focus on enhancing program engagement through persuasive strategies (eg, multimedia content [25] or collaborative gamified experiences [65]). In contrast, athletes do not require external motivators such as rewards or gamification but rather need facilitators such as personalized, sport-based training content with adapting intensity that can be static (eg, textual) but rich in clinically valid information such as intensity specificity and limitations. The CTR platform developed by Sankaran et al [27] provides a notable example of detailed visualizations depicting exercise prescriptions and progress, which could be customized for the athletic population. A crucial design feature could also involve aligning clinically suggested exercise schemes with data from the performed workout for comparison, enabling athletes to offer feedback to clinicians based on their personal experiences with the suggested exercises. Finally, to ensure a clinically validated understanding of athletes' specific situation, CTR platforms should offer personalized information resources on exercising with established CAD. Athletes currently rely on inconsistent and potentially unsafe online sources for safe exercise.

Supporting Remote Consultations

Athletes experience a high level of anxiety after hospitalization, and receiving care with a personal touch can alleviate mental struggles. These values can be addressed by facilitating person-to-person care tailored to the patients' values, beliefs, and life goals [32]. As athletes regain confidence, reacquaint themselves with their limits, and recalibrate their internal sense of "body safety," their inquiries to clinicians become more specific and briefer (eg, regarding symptoms, medication, or limitations). Unfortunately, some athletes struggled with alleviating their anxieties in the program and found relationships with clinicians cold or inaccessible. To maintain personal connectivity with the health care system and avoid depersonalization of remotely gathered data [103], CTR technologies for athletes ought to incorporate periodic "check-in points"—online consultations via synchronous or asynchronous methods. Some participants proposed periodic surveys concerning symptoms or physical recovery. In addition, athletes occasionally expressed the need to ask situational questions through chat functionalities or features akin to e-consultations. Such findings align with current HCI investigations of cardiac telehealth that emphasize the benefits of harnessing HCP-patient relationships through remote care [31,50,61,94].

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Suggestions for Future Work and Limitations

Considering the significant individual and public health challenges posed by CVDs, along with increasing medical knowledge on the risks of physical exertion in recreational athletes with cardiac conditions, CTR interventions must move beyond one-size-fits-all approaches toward highly personalized, data-driven, and athlete-centered rehabilitation experiences that empower patients to safely return to peak performance. Future research should focus on translating the identified design implications and requirements into CTR solutions tailored for athletes followed by iterative validation and implementation with key stakeholders, including athletes, caregivers, and clinicians. Operationalizing VSD in the design of complex CTR interventions will take more than making connections between values and feature requirements [32]. Future work can investigate the translation of value-sensitive requirements to CTR design and validation by using, for instance, the value hierarchies by Van de Poel [104] and validating value-sensitive CTR in actual effectiveness trials using methods such as the Multiphase Optimization Strategy [105].

Our findings provide a broad understanding of the problem at hand because of the nature of the qualitative methods. However, our study had some limitations. All participants were Dutch either being treated or working at the same hospital. We especially acknowledge the gender imbalance in our recruited patients (only 1/15, 7% were women) as the underrepresentation of women in CR research is a documented, fundamental problem [106]. One constraint was the inclusion criterion, limiting enrollment to participants who had completed the CR program within 1 year before the study's start, which restricted opportunities to include more women. Nonetheless, we recognize that this might be a systemic problem related to women's diagnosis, referral patterns, or adherence to CR programs [107,108]. These considerations may limit the generalizability to more diverse groups, such as women or athletes being treated in other cultures, countries, or jurisdictions. Future research should investigate the values and needs of such groups.

We included only patients who exercised at least 4 hours per week before diagnosis, but our findings may also apply to less athletic but active individuals. While athletes have distinct values and needs compared to general cardiac populations, some preferences overlap, warranting further research on their generalizability to a larger sample of active patients. In addition, the values of athletes with established CAD should be examined alongside those of healthy recreational athletes to better understand implications for fitness- and health-tracking technologies for athletes with cardiac conditions.

CTR is a complex combination of face-to-face and remote services, requiring consideration of technological (eg, data representations), service (eg, consultations), and functional (eg, sensors vs surveys) features. Design choices in this study were shaped by the interviewed population, making some requirements broad and exploratory. Future research should explore athletes' preferences for specific CTR functionalities (eg, alarms for red flags in the data). In addition, accessibility should be a key consideration (eg, a participant with a hearing disability emphasized the need for reliable video streaming to support lip reading, highlighting the importance of inclusive design in CTR interventions).

Finally, within HCI literature, there is criticism of ethnographic studies being evaluated on the implications they can have for design—this can give rise to the idea that design is the end point of the research [109,110]. Our study indicates opportunities for reorganizing and leveraging existing CR services for athlete rehabilitation that could be explored further in future research. While beyond this study's scope, discussions on implications for policy makers and health care institutions warrant attention in future work.

Conclusions

This study contributes to understanding how CTR technologies can address the needs and values of athletes with established CAD. Our results show that, for the independent, highly active athletic population, CTR interventions should be more focused on *remote performance tracking*, *clear data reports*, and *communication channels that enable shared decision-making between athletes and clinicians*. We propose design considerations for value-oriented CTR technologies aimed at the athletic population and encourage designers to account for the contrasting values and needs of different stakeholders in the design process. From a practical standpoint, these findings can inform the development of CTR platforms that better align with athletes' expectations by integrating performance feedback, sport-specific metrics, and adaptive supervision. Clinicians and technologists can collaborate to leverage these insights and personalize remote rehabilitation care models that gradually shift from structured guidance to independent athlete-led monitoring. In addition, health care institutions can use these results to refine hybrid rehabilitation programs, balancing digital autonomy with strategic in-person evaluations to optimize adherence and safety. Future implementations should prioritize accessibility, interoperability with wearable devices, and customizable consultation models to enhance athlete-centered care in CTR.

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Conflicts of Interest

None declared.

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Multimedia Appendix 1
Interview scripts for athletes and health care professionals.
[DOCX File , 29 KB - rehab_v12i1e62986_app1.docx]

Multimedia Appendix 2
The cards used in the card-sorting focus groups.
[PDF File (Adobe PDF File), 495 KB - rehab_v12i1e62986_app2.pdf]

Multimedia Appendix 3
The codebook developed after analyzing the interview results and example quotes.
[DOCX File , 44 KB - rehab_v12i1e62986_app3.docx]

Multimedia Appendix 4
Identified athlete values with paired needs and example quotes from the interview phase.
[DOCX File , 25 KB - rehab_v12i1e62986_app4.docx]

Multimedia Appendix 5
The card-sorting activity results—all cards sorted from most needed to least needed.
[PDF File (Adobe PDF File), 340 KB - rehab_v12i1e62986_app5.pdf]

Multimedia Appendix 6
Derived cardiac telerehabilitation technology requirements paired with athlete values, where “x” indicates a match between a feature and a value; the cards used to derive the requirements; and example notes or observations made during the card-sorting activity.
[DOCX File , 31 KB - rehab_v12i1e62986_app6.docx]

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Abbreviations

CAD: coronary artery disease
CR: cardiac rehabilitation
CTR: cardiac telerehabilitation
CVD: cardiovascular disease
FG: focus group
HCD: human-centered design
HCI: human-computer interaction
HCP: health care professional
HR: heart rate

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PHR: participatory health research
VSD: value-sensitive design

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Original Paper

Investigating the Acceptance and Implementation Conditions of Telerehabilitation in Germany Among Patients and Health Care Professionals: Qualitative Interview Study

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Abstract

Background: Telerehabilitation has become increasingly important worldwide, as the COVID-19 pandemic forced many rehabilitation centers to change their daily care routine and find new ways to provide medical rehabilitation and aftercare.

Objective: This study aims to investigate the acceptance and implementation conditions of telerehabilitation in Germany, particularly following the COVID-19 pandemic.

Methods: We conducted qualitative semistructured interviews with patients (n=9) and health care professionals (n=8) between September 2023 and January 2024. To explore individual and structural barriers to and facilitators of telerehabilitation adoption, we used the extended unified theory of acceptance and use of technology and the Consolidated Framework for Implementation Research.

Results: Patients and health care professionals perceived telerehabilitation as positive, mainly due to its flexibility and accessibility. Patients expressed high acceptance levels, anticipating health benefits, although they found it challenging to familiarize themselves with the technology and establish routines. Health care professionals highlighted the need for adequate resources (financial, time, and personnel) and management support to implement telerehabilitation successfully. Both groups saw higher acceptance and cost coverage of telerehabilitation services as essential for successful implementation and use in Germany.

Conclusions: This study identified institutional barriers, such as concerns about resource availability, team communication, and initial resistance among health care staff to the introduction of new technologies. At an individual level, we found that patients struggled with routine establishment and that digital and in-person support from institutions and peers could mitigate this challenge. Implementing a hybrid approach and improving funding and approval processes would enhance telerehabilitation integration in the German health care sector.

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KEYWORDS

acceptance; barriers; Consolidated Framework for Implementation Research; CFIR; implementation; qualitative research; telerehabilitation; extended unified theory of acceptance and use of technology; UTAUT2

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Introduction

Background

Telerehabilitation has become increasingly important worldwide, as the COVID-19 pandemic forced many rehabilitation centers to find new ways to provide medical rehabilitation and aftercare [1-3]. In this study, telerehabilitation is defined as medical rehabilitation services using information and communication technologies (ie, assessment, monitoring, prevention, intervention, supervision, education, consultations, and counseling) [4]. Telerehabilitation is used to complement or extend, but not to replace, face-to-face medical rehabilitation and aftercare. Benefits of telerehabilitation include flexibility in terms of time, location, and convenience. This is particularly advantageous for patients who are immobile or with comorbidities or those living in remote areas with poor health care infrastructure [5]. Previous research has mainly focused on demonstrating the effectiveness of standard care [6-8], with less attention given to issues such as the implementation process and acceptance [2].

Insight into the acceptance of telerehabilitation in different settings is critical as it serves as a prerequisite for using new technologies [9]. To the best of our knowledge, this is the first study that examines the acceptance and implementation conditions of telerehabilitation in the German rehabilitation context across different diagnoses since its introduction.

Aim of the Study

The aim of this study was to investigate the acceptance of telerehabilitation among patients undergoing rehabilitation and to evaluate the implementation conditions from the perspective of health care professionals.

Methods

Design

This qualitative study was part of a larger explanatory mixed methods project examining acceptance and implementation of telerehabilitation in the context of the COVID-19 pandemic. Our goal was to contextualize the results of our quantitative survey findings [10] and gain deeper insight into the acceptance of and implementation conditions required for telerehabilitation among patients and health care professionals.

Underlying Theories

This study focused on patient acceptance and the conditions for implementing telerehabilitation in Germany. To better understand the needs and experiences of the 2 stakeholder groups, this study was anchored in 2 theoretical frameworks.

For deeper insight and comparability, we anchored the interviews in the same frameworks used in the quantitative surveys with patients and health care professionals.

The extended unified theory of acceptance and use of technology (UTAUT2) [11,12] served as the theoretical basis for the patient interviews. The framework describes the different factors that may influence the acceptance and use of telerehabilitation, such as *effort expectancy, performance expectancy, social influence, facilitating conditions, hedonic motivation, habit, and price value* [12]. *Privacy concerns* were included in our study, as previous research has shown that this issue can play a role in the use of digital services, such as in the field of telemedicine [13,14]. We excluded *price value* from our interview guideline, as telerehabilitation is typically covered by Deutsche Rentenversicherung (DRV [the German Pension Insurance Association]) and is free of charge for patients (refer to Table 1 for definitions). In addition, the patient interviews also focused on general experiences and expectations of telerehabilitation use.

Table 1. Adapted extended unified theory of acceptance and use of technology (UTAUT2) dimensions included in the interview guideline.

UTAUT2 dimension [11,12]	Definition (adapted to the context of this study)
Effort expectancy	This reflects the degree of ease associated with the use of telerehabilitation.
Performance expectancy	It is the degree to which an individual believes that using telerehabilitation will help them.
Social influence	This is the degree to which a person perceives that people who are important to them believe that they should use telerehabilitation.
Facilitating conditions	This dimension reflects the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of telerehabilitation.
Hedonic motivation	This reflects the fun or pleasure derived from using telerehabilitation.
Experience and habit	Experience reflects an opportunity to use similar telerehabilitation offers and is typically operationalized as the passage of time from an individual's initial use of a technological system. Habit is the extent to which people tend to act automatically because of learning.
Privacy concerns (adapted from the studies by Zhou [13] and Smith et al [15])	These reflect fear that personal data will not be adequately protected.

The Consolidated Framework for Implementation Research (CFIR) served as the theoretical basis for the interviews with health care professionals to facilitate a better understanding of the institutional factors related to telerehabilitation implementation. The framework maps barriers and facilitators across 5 domains: *innovation*, *inner setting*, *outer setting*, *individuals*, and *implementation process*. We adapted the subconstructs to fit the study purpose and context in line with the CFIR recommendations [16] (Table 2 presents the CFIR framework with the 5 main dimensions and the subconstructs

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in this study). To identify the subconstructs relevant to our interviews, we built upon our previous quantitative survey of health care professionals. For the questionnaire, we identified the relevant subconstructs based on existing studies on the promoting and hindering factors of telerehabilitation and eHealth implementation [9,17,18]. Finally, the identified subconstructs were then discussed with the project advisory board, whose members consisted of experts from rehabilitation science and health care practice.

Table 2. Adapted and applied Consolidated Framework for Implementation Research (CFIR) dimensions included in the interview guideline.

CFIR domain	Definition (according to Damschroder et al [19])	Subconstructs of the dimension used in this study
Innovation domain	This domain discusses what is being implemented (eg, a new clinical treatment, educational program, or city service).	• Relative advantages of the innovation • Costs (eg, initial costs and monthly license fees)
Inner setting domain	This domain is defined as the setting in which the innovation is implemented (eg, hospital, school, and city). There may be multiple inner settings and multiple levels within the inner setting (eg, unit, classroom, and team).	• Available resources (eg, space, personnel, and time) • Communication (eg, information sharing practices) • Organizational culture (eg, values, beliefs, and norms) • Access to knowledge and information (eg, training programs)
Implementation process domain	This domain discusses the activities and strategies used to implement the innovation.	• Assessing needs • Engaging patients and health care professionals
Individuals domain	This includes the roles and characteristics of individuals involved in the implementation process.	• Capability (eg, necessary skills and knowledge) • Motivation • Implementation leads and teams • Support
Outer setting domain	This is defined as the environment in which the inner setting exists (eg, hospital system, school district, and state). There may be multiple outer settings and multiple levels within the outer setting (eg, community, system, and state).	• Critical incidents as driving factors (eg, COVID-19) • Policies and laws (eg, funding regulations)

Participant Recruitment and Data Collection

Two researchers (SS and MDP) conducted the semistructured interviews between September 2023 and January 2024. Patients who had the opportunity to use telerehabilitation either as part of inpatient or outpatient medical rehabilitation over the last 6 months were eligible to participate. The 6-month period was chosen to avoid recollection bias. Health care professionals were invited to participate if they were involved in the development or implementation of telerehabilitation within their institutions. Recruitment was conducted through the 13 rehabilitation centers that previously participated in the quantitative surveys. Patients and health care professionals who completed the quantitative surveys and were interested in participating in interviews were invited to contact the researchers directly by email.

As recruitment had been carried out through the rehabilitation centers, the participants and researchers did not meet or know each other beforehand. There was one exception, in which one of the researchers knew a participant in medical rehabilitation aftercare; in this case, the participant was interviewed by the second researcher in the team. While planning the exploratory study, it was assumed that 20 interviews (ie, 10 per group) would achieve thematic saturation, as the interviews were based on established theoretical frameworks and the study objectives were narrowly defined [20]. Aiming for maximum variation sampling, we contacted rehabilitation centers in an attempt to recruit patients from more underrepresented diagnostic categories (eg, orthopedics). During the interviews, it became clear that thematic saturation was achieved to the extent that participants had, in general, similar positive experiences with telerehabilitation.

We conducted all interviews online via Zoom (Zoom Communications, Inc) or Webex (Cisco Systems), with no third parties present, and we used a contextualization form to systematically document the interview conditions and interactions [21]. The audio recordings were professionally transcribed.

Data Analysis

We used qualitative content analysis based on Kuckartz and Rädiker [22] to analyze the data. The coding process was computer assisted (MAXQDA [version 2020; VERBI Software]), using a combination of deductive and inductive approaches. First, we created a codebook containing deductive categories based on the UTAUT2 and CFIR domains and anchor examples (quotations). Two researchers (SS and MDP) independently coded half of the interview material to test the categories' plausibility, clarity, and suitability. Text passages that could not be assigned to an existing code were marked, annotated with coding suggestions, and then discussed by the 2 coders. We then merged the 2 analysis documents in MAXQDA to visualize the differences and calculate the intercoder agreement. This was not done to quantify the different codes but rather to easily locate potential problematic quotes and categories. We discussed differences, similarities, and ambiguities in the coded material to further refine and adjust the categories. In addition, inductive categories were cocreated from the comments in the previous steps. The final category system consisted of 13 main categories and 35 subcategories

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for the patients and 6 main categories and 98 subcategories for the health care professionals (refer to Multimedia Appendix 1 [11,12,19,23] for detailed category systems for both groups). We then analyzed all interviews using the adapted category system, collated the data, and reached consensus on the various codes using the aforementioned principle [22]. We summarized and exported the final categories and their codes to Microsoft Excel as well as illustrative quotations corresponding to each category. For the presentation of the findings, the quotations were translated from German and carefully edited for enhanced clarity. Participants who wished to give feedback (both written and oral) on the results were invited.

Ethical Considerations

This study was approved by the Ethics Council of the University of Siegen (ER_2/2022). Prior to the interviews, all participants were informed in writing about the interview process, how their personal data would be stored, and their right to withdraw from the study and data processing at any time. All participants gave their consent to participate in the study. To ensure confidentiality and anonymity during data analysis, participants were assigned pseudonyms after the interviews were conducted, and personal data that could reveal their identity was pseudonymized. Personal data was encrypted and stored separately from the pseudonymized data for the duration of the project. In the event of revocation, only employees of the research project would have been able to reestablish a link to an individual in order to delete their data.

Results

Interviews With the Patients Undergoing Rehabilitation

Participants' Characteristics

We interviewed 9 patients, with interviews lasting between 18 and 41 minutes. They were predominantly female (n=6, 67%) and aged between 50 and 69 years (n=6, 67%). The most frequently mentioned medical diagnosis group was neurological conditions (n=5, 56%), followed by psychosomatic (n=3, 33%) and orthopedic ailments (n=3, 33%); refer to Table 3 for participant characteristics.

Table 3. Sociodemographic data of patients undergoing rehabilitation (n=9).

Sociodemographic data	Patients, n (%)
Age (y)	
30-39	1 (11)
40-49	2 (22)
50-59	3 (33)
60-69	3 (33)
Sex	
Male	3 (33)
Female	6 (67)
Diagnosis group (multiple answers possible)	
Neurology	5 (56)
Cardiology	1 (11)
Oncology	1 (11)
Orthopedics	3 (33)
Psychosomatic disorders and psychotherapy	3 (33)
Other	2 (22)
Highest educational level (German system)	
Master's degree or equivalent educational program	4 (44)
Vocational training	2 (22)
Secondary school	1 (11)
Other	2 (22)

Telerehabilitation Description and Terms of Use

Apps were mentioned as the most frequently used telerehabilitation technology, but web-based platforms were also used, mainly in aftercare. Telerehabilitation can usually be used for up to a year. The content mainly focused on balance, movement, and relaxation exercises as well as dietary tips. No prerequisites for using telerehabilitation were mentioned, apart from the basic requirement of owning an electronic device (eg, cell phone, tablet, or monitor) and a stable internet connection. In terms of cost coverage requirements, one had to have a positive employment prognosis for the German pension insurance to cover the costs (otherwise, patients had to cover the costs themselves).

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Experience and Habits

None of the patients had previously used telerehabilitation, but some reported experience with other services, such as yoga via YouTube or fitness apps. One of the main challenges that the patients described was developing a consistent routine as part of their aftercare. This competed with the demands of daily life and the lack of external monitoring and accountability mechanisms (compared to the in-hospital rehabilitation process). One interviewee explained the following:

> *And so, if I manage it twice [a week], that is a lot. It's just that, well,... I need to have the energy to do it because of my illness. The motivation would be there, but the energy is sometimes lacking. And then it's difficult for me.* [Patient 4]

Keeping a consistent routine was important not only for personal recovery but also in relation to cost coverage, as most services had built-in progress monitoring processes (eg, badges or passwords needed to proceed to the next components) to ensure patients used them regularly. Otherwise, they would lose the coverage provided by the DRV:

> *The fact that this chat also reminds you and/or the therapists that you have to do something. Because otherwise the funding would be cancelled.... If you don't do anything for a few weeks..., then the pension insurance would stop funding you. So you have to keep at it. I think... after a two-week break, then the reminder comes.* [Patient 3]

While routine proved challenging, habits were developed quickly, and some interviewees described how they did not need the guidance of the apps after a while because they had internalized the exercises. However, detailed instructions at the beginning of the exercise phase were considered helpful:

> *After doing this for months, I know the exercises I always do by heart and love most of them. But it's good to have someone show you how to do everything. A video like this shows you how to do it.* [Patient 3]

Hedonic Motivation

Despite difficulties with routine training, about half of the patients undergoing rehabilitation in this study were highly motivated to use telerehabilitation. This was mainly due to their desire to recover and return to normal activities as quickly as possible:

> *I just want to get fit again as quickly as possible and be back on the tennis court.* [Patient 9]

Effort Expectancy

The usability of telerehabilitation was generally described as straightforward and uncomplicated. However, some patients highlighted their own technological affinity and considered that older or not-so-tech-savvy patients might experience difficulties. Adaptations for older patients, for example, via larger television screens, were described as useful and necessary. They also mentioned that deviations from the standardized (Monday to Friday during regular working hours) treatment plan could lead to complicated adaptation processes for the treatment facilities. Technical challenges were occasionally mentioned, such as minor difficulties with the app, an unstable internet connection, or high data volume:

> *It's always difficult when you need Wi-Fi for technical things. I realized that on vacation. Well, we were on vacation for 14 days. We didn't have Wi-Fi. And then you need a lot of data volume if you keep playing these movies. That's why you drop it for that period of time.* [Patient 6]

In many cases, the support provided by the rehabilitation centers was described as helpful and reliable:

> *They would rather say, "As a hospital, we are on board. Take a look. It's not rocket science.... It is designed for all age groups. See how you get on.... If you can't manage, we'll see how we can help you." And that's especially for the older generation, of course, invaluable.* [Patient 1]

Performance Expectancy

Patients perceived telerehabilitation as useful for their rehabilitation process, finding its low-threshold nature beneficial for their physical and mental well-being and overall health promotion:

> *For me, it completely fulfilled the purpose I wanted it for, which was to stay on track and get my physical and mental complaints under control. So it worked really well.* [Patient 3]

The most significant benefit mentioned was the time, location, and content flexibility. Above all, reducing travel to rehabilitation centers or long waiting times for an appointment was rated as positive:

> *I actually thought it was a good solution because it allowed more flexibility in terms of time.... For me,... I would have had to travel to [the rehabilitation center], which means a half-hour or 20-minute drive each time. That's no longer necessary.* [Patient 6]

However, it was clear that telerehabilitation was only considered suitable for some patient groups. Participants mentioned fellow patients for whom its use was unthinkable due to older age, perceived effectiveness of professional exercise equipment, and the belief that face-to-face sessions promoted better discipline and correction of training techniques:

> *I also met people in rehabilitation who said, "No, if I don't have a trainer standing opposite me and pushing me, and if I don't have to go there in person, then I know I'm lying to myself and just getting lazy."* [Patient 3]

Facilitating Conditions

The flexibility afforded by telerehabilitation in the context of aftercare was seen as conducive to an easy integration into everyday life. Furthermore, content flexibility made the exercises adaptable to existing equipment, health status, or personal preferences. In addition, content that was already familiar to patients from in-hospital rehabilitation enabled treatment continuity. Another facilitating aspect of

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telerehabilitation aftercare was behavioral monitoring by the rehabilitation centers. The patients described them as supervisory bodies that would monitor regular use and progress, helping them maintain the high motivation levels required to complete the aftercare program:

> *But the point of the whole process was to stabilize me again, to stabilize me as a patient again, rather than to betray myself. It was clear that [the rehabilitation facility] where I did it [rehabilitation] was acting as a kind of controlling authority.* [Patient 2]

Participants described the timely technical support, detailed instructions provided by the rehabilitation centers, and regular interactions with the therapists as crucial for their telerehabilitation use. Depending on the setting, technical support could be requested via the app or personal contact with therapists (eg, in case of installation and use uncertainties).

Social Influence

According to our participants, there was little dialogue with other patients about telerehabilitation during this time, so peer influence was minimal. Therapists served as the main source of social influence, as they suggested the use of telerehabilitation and integrated it into their patients' care plans. In all cases, telerehabilitation was voluntary. Our participants reported that, in general, friends, acquaintances, family, and physicians reacted positively to the use of telerehabilitation and, frequently, spouses would provide support (eg, by integrating cooking and healthy eating suggestions).

Privacy Concerns

Surprisingly, in the German context, patients did not have any privacy concerns regarding telerehabilitation. The main reasons for this were limited personal or sensitive information needed to be disclosed, trust in health care professionals and app developers, simple design, existing privacy regulations, and professional experience:

> *And, let's say, fears or that I somehow also because of data protection and such/I mean, what should happen? I mean, I sit there in front of the laptop, doing my exercises. And yes, so I have no fears or concerns.* [Patient 5]

Wishes for Improvement

The patients expressed various wishes for improvement related to both the used app itself and telerehabilitation in general: a larger device was deemed necessary for performing exercises, as patients reported difficulties with the limited size of smartphone screens. This would be especially beneficial for older patients, as would a more user-friendly interface. In addition, offering shorter and simpler *beginner* exercises could provide a more accessible introduction for some patients, and integrating verbal guidance for all exercises would allow them to focus on their movements without constantly glancing at the screen. For some, a more varied and natural voice for guiding patients through exercises, along with a presentation style that feels less artificial, would enhance engagement.

Other crucial aspects concerned the app's communication tools, such as enhancing the chat function, integrating live video consultations, or adding a mailbox function for direct contact with therapists or to ensure the quick resolution of any technical issue. Introducing a reward or point system was suggested as a measure to maintain or boost user motivation. In their view, fostering better connections among patients undergoing rehabilitation by facilitating exchanges via the app or occasional in-person sessions at rehabilitation centers would significantly improve the overall experience. Finally, patients wished for improved cost transparency (concerning the coverage of digital services) and detailed information on extending the app's use beyond the set 1-year period.

Intention to Use

All participants stated that they would be willing to use telerehabilitation again as part of their rehabilitation or aftercare if offered and feasible for their condition. However, requiring additional or special training equipment may be a reason not to use telerehabilitation:

> *So that you should do muscle building or something like that, for example, I would prefer to do it in the gym, on training devices.* [Patient 6]

Interviews With Health Care Professionals

Description of the Sample

The 8 health care professionals who were interviewed were predominantly therapists (n=6, 75%) who mainly worked in neurology (n=5, 62%). All (n=8, 100%) of them were involved in the implementation of telerehabilitation. Again, the participants were mainly female, and the interview lasted between 30 and 58 minutes (refer to Table 4 for participant characteristics).

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Table 4. Health care professionals' sociodemographic data and telerehabilitation characteristics (n=8).

Sociodemographic data	Health care professionals, n (%)
Age (y)	
20-29	1 (13)
30-39	3 (38)
40-49	3 (38)
50-59	1 (13)
Sex	
Male	3 (38)
Female	5 (62)
Professional position in the organization	
Management, administration, or leadership	3 (38)
Sports therapist or physiotherapist	5 (63)
Experience in the position (y)	
<1	0 (0)
1-4	3 (38)
5-10	2 (25)
>10	3 (38)
Primary treatment specialty of the institution (multiple answers possible)	
Cardiology	2 (25)
Psychosomatics and psychotherapy	2 (25)
Neurology	5 (63)
Orthopedics	3 (38)
Context (multiple answers possible)	
Outpatient rehabilitation	8 (100)
Inpatient rehabilitation	3 (38)
Prevention	3 (38)
Aftercare	2 (25)
Type of telerehabilitation (multiple answers possible)	
App training	6 (75)
Digital training courses	3 (38)
Year of telerehabilitation implementation	
2020	3 (38)
2021	3 (38)
2022	1 (13)
Unknown	1 (13)

Characteristics of Telerehabilitation

Aftercare consists of a training program that is usually completed within a 1-year period and integrates health promotion content and physical exercises. Smartphones, tablets, or laptops are typically used as devices, though some content is also delivered via patient television during their stay at the centers. Most telerehabilitation offers have been developed either internally by the rehabilitation centers or by external developers of telerehabilitation services and were introduced during the COVID-19 pandemic between 2020 and 2022. Since then, rehabilitation centers have mainly been using apps (developed internally or by an external company), providing patients with educational resources or physical exercises that can be adapted to their particular diagnoses. Some participants also described the existence of a portal or web-based platform which can be used to obtain information and training, and, in some cases, training courses were digitized, for example, own platform or YouTube.

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Innovation Domain

Relative Advantages and Disadvantages of Telerehabilitation

The most important advantages mentioned were flexibility (in terms of time and place) for both patients and health care professionals and resource efficiency within the institution, especially in terms of time and staff:

> *Well, the flexibility, definitely.... It is much easier to reconcile work, family, and everyday life if you can do it from home rather than having to travel to another facility for half an hour or 45 minutes.* [Health care professional 3]

> *Yes, we also use it [digital education] to prepare for seminars, for example, so that patients first watch a video with basic information and then simply deepen their existing knowledge in a mutual exchange with the other rehabilitation patients and the lecturer or therapist. It just saves time, because you don't have to spend another 20 or 30 minutes giving a lecture. So the patients come to the appointment with the information already. And there is also the advantage that not everyone can absorb knowledge at the same speed.* [Health care professional 9]

Furthermore, telerehabilitation could reach more patients and meet quality standards more easily, as there was less deviation in terms of content due to the digital format:

> *What I believe is also an advantage, when you think again of the requirements for patient training, is that a digital offering naturally ensures that the content, structure, and sequence always remain the same. So, there are no differences, as we know them from traditional patient training. Therapist A presents it differently despite the manual. And therapist B finds the topic interesting in a different way and presents it differently. And so, in the end, you actually distort something that has been standardized.... Of course, this does not happen with telerehabilitation, because I have the structure once, and it stays.* [Health care professional 5]

The biggest disadvantage mentioned by some interviewees was the lack of opportunity to perform manual examinations and provide treatment (eg, by palpation) and monitor treatment progress:

> *What I miss in all this digital aftercare is what we have in therapy, the assessment that allows me to judge whether what I have done has changed anything after eight weeks. Because the patient telling me, "Yes please, change exercise 500 for me or exercise 459 is too hard," that doesn't tell me anything, right?* [Health care professional 4]

One other aspect that several health experts found disadvantageous was the technical barriers that often have to be overcome when using digital services:

> *And otherwise, there can always be technical problems. That can happen, of course. Even if it is rare for an app not to work on any patient's devices.* [Health care professional 2]

Innovation Costs

Little was known about the rehabilitation centers' implementation and maintenance costs, as many therapists had no insights into these processes. Some interviewees reported that using external developers of telerehabilitation services involved initial software and hardware costs and monthly license fees, which could serve as barriers:

> *Well, I can understand why that is a barrier, yes. Because the price of the software has to be paid in full immediately. And the providers certainly do that differently.... But in any case, as a hospital, you first have an investment in the software and then, of course, in the hardware. So, equipping a room like that is not cheap if you need several workstations,... and also the space, which must not be too small for this kind of training.* [Health care professional 2]

The need to expand the internet connection was also seen as a cost factor, as Wi-Fi accessibility for all patient rooms was now seen as essential:

> *Of course, they tried to provide the patients with good Wi-Fi, but with an app like this, you have to make sure that it works perfectly in every room. And that was a huge cost factor, especially in the old buildings, and it was a huge issue until it worked.* [Health care professional 2]

However, for the centers that developed their digital rehabilitation services in-house, these costs were not an issue:

> *So we didn't have to go to any additional expense to hire external companies, but it actually happened in the course of our day-to-day business. And that's why it wasn't such a big barrier for us.* [Health care professional 6]

Inner Setting

Available Resources

The key challenges when telerehabilitation was introduced included concerns about the availability of essential resources, such as appropriate equipment, reliable internet connection, and time to develop digital services:

> *Then, of course, good internet. That was also sometimes a problem at the beginning. But that's important too, of course. And all the equipment. Yes, and in terms of space, because of course you also need a room where you can do it all. Now that everything has settled in, it's no longer a problem. But at the beginning, I think it was quite difficult in terms of planning, where to put what and how best to do it.* [Health care professional 3]

The need to train staff in the use of new technologies and to promote their acceptance was also emphasized:

> *Well, of course you first need employees who are willing to take part. And we have workstations for app training. Of course, a certain infrastructure had*

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> *to be ensured so that training was even possible here on site. The employees had to be trained. The doctors had to be trained. That was a big step at the beginning, so a lot of extra work.* [Health care professional 3]

By contrast, the flexibility in terms of time and location afforded by telerehabilitation was emphasized as positive, particularly in light of the ongoing challenges of recruiting and retaining health care professionals:

> *And we can really compensate for therapy cancellations due to staff shortages by offering the therapies digitally.* [Health care professional 6]

Communication

Some of the health care professionals pointed out that communication processes have changed due to the use of telerehabilitation. Regular contact with patients via digital platforms facilitated ongoing support and exchange beyond in-person sessions. Furthermore, the new videoconferencing systems or employee chats facilitated the fast flow of information among staff:

> *And what we have noticed is that communication via chat and video calls—we use a videoconferencing system for this—works extremely well. We are light years ahead of email communication. We realized this after the first week... that we needed a chat [laughs] where we could exchange information quickly.* [Health care professional 2]

While most employees were satisfied with analog and digital communication, there was also some dissatisfaction with the communication processes. Some reported communication hurdles, especially when the necessary information for a good familiarization with telerehabilitation was not provided:

> *For a month I didn't really have an introduction because it was all so new. And the colleagues who were already there were supposed to support me. They had only been there for two or three months. And so I found that to be a big difficulty for me.* [Health care professional 4]

One interviewee also reported that communication about the introduction of the new offer was top down, which was interpreted as unfavorable for the implementation process:

> *Well, the conflict or the problem... at the employee and clinic management level was, of course, that it wasn't an intrinsic thing.... It wasn't the clinic thinking, hey, we've got a great idea here, but rather it was homework imposed by executive management. So, there was a project plan. There was a corresponding guideline that was formulated. No one was asked beforehand.* [Health care professional 5]

Institutional Culture

The corporate culture was considered very important, and interviewees highlighted patient-centeredness as essential, as rehabilitation and aftercare should be tailored to the patients' needs and circumstances:

> *Important, very, very important in this matter, we tell our patients along the way, no stress. The goal of our aftercare is to achieve positive results. And whether it's four months, eight months or a year later.... I don't care.* [Health care professional 1]

The health care professionals also mentioned the availability of diverse digital aftercare options, such as Zoom meetings, live events, and group sessions, so patients could choose the format that best suited their needs.

In general, regular dialogue and learning culture within teams were highly valued. Most of the interviewees felt it was important that staff members were involved in the introduction of new technologies and that the necessary training was provided, so that everyone could acquire the skills needed to use digital services:

> *And then I and other colleagues involved... discussed with them [each colleague] what we do in this introductory session with the patients. That is, to make sure that the program is clearly explained, that it is clear what will be discussed and what content will be shown.* [Health care professional 7]

Implementation Process Domain

Assessing Needs

Considering the needs of therapists and patients emerged as an essential aspect of the implementation process. Some interviewees described initial reluctance on the part of the staff to implement and use telerehabilitation, mainly when they had to create the video or audio content themselves. Taking these concerns and objections seriously and "guiding staff" on the journey to implementation was seen as fundamental. In addition to the needs and requirements of the staff, the participants felt that the circumstances of the patients (eg, advanced age or cognitive abilities) should also be considered. However, there were not many objections to using telerehabilitation, and the rehabilitation centers generally tried to facilitate it for all their patients.

Engaging Patients and Staff

Participants emphasized that therapists could only promote telerehabilitation to patients if they themselves were convinced of it and reported that implementing telerehabilitation requires particularly committed individuals. Therefore, convincing and involving the rest of the team in the implementation processes was necessary:

> *It was always openly discussed in the teams, and we just looked to see who was also enthusiastic about the topic. And not simply impose and say, now go and check it out for yourselves. And that was how it was implemented.* [Health care professional 2]

Individuals' Domain

Capability

Interviewees came from a variety of professional backgrounds (eg, physiotherapists or sports therapists and administrators) and were involved to varying degrees in the development, implementation, and delivery of telerehabilitation. Some

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respondents indicated that they now work exclusively as digital therapists. Health care professionals emphasized that a certain level of affinity for technology is required on the part of patients and health care professionals to be able to use and deliver telerehabilitation.

In individual cases, patients who were less tech-savvy were excluded from telerehabilitation. According to our interviewees, language barriers (including due to aphasia) were not necessarily an obstacle, as most exercises could often be carried out despite them. Moreover, relatives sometimes supported patients who did not have the necessary skills and knowledge, to still benefit from the service. Due to these limitations and different settings, some medical professionals suggested hybrid approaches as the most appropriate solution:

> *But in the end, I think the hybrid approach is more important. You have to say,... where does it make sense to do something digitally, and where does it make less sense?* [Health care professional 8]

Motivation

Interviewees emphasized that staff motivation plays a vital role in implementing telerehabilitation. A certain degree of independence from the employer was also seen as an essential implementation factor. As mentioned earlier, the health experts underlined that a team needs people who drive the process forward and who are willing to take responsibility and deviate from "service by the book" when necessary:

> *I am the one who has the motivation to implement these projects in the company.... I try to somehow manage to keep myself motivated to implement them. And yes, it's a difficult process. But you need one like that. Just as [laughs] you also need someone who, let's say, keeps a Friday sports group together, right?* [Health care professional 8]

The patients' motivation was also considered essential for successfully implementing telerehabilitation. As stated in the interviews with the patients undergoing rehabilitation, they were encouraged to take responsibility for their well-being and perform exercises regularly via different motivational strategies and control mechanisms, especially in the aftercare program. However, the health care professionals mainly received feedback on telerehabilitation from patients who were enthusiastic about the program; less motivated patients were more challenging to reach:

> *As you might expect, some think it's great, some think it's annoying, and some think it just belongs there, a neutral attitude. But I think it's being handled well.... We have the ability to control it. And we plan to address it regularly here at the site, and also to work together on some of the content again, just to make it more present for the patients...we are actually getting pretty good feedback.* [Health care professional 7]

Implementation Leads and Team Members

As mentioned earlier, interviewees described the involvement of the immediate team as essential to the implementation of telerehabilitation as well as the support of other departments within the organization, such as IT, human resources, or product management. Although decisions were often made at management level, they considered it essential to involve staff members and allow them to decide the extent of their involvement in implementing telerehabilitation, for example, performing on camera:

> *So the decision first has to be made at management level. And then, in our case, I think it was a sensible approach, we had project teams. One central project team that always initiated and implemented the first steps at a site.* [Health care professional 2]

According to the interviewees, most of the telerehabilitation implementation work was done by individual employees who had been given a mandate by management. On the one hand, this allowed a certain degree of freedom, but on the other hand, this meant it took more work to get colleagues onboard with the project. Overall, the process was seen as challenging, and support from senior management was crucial:

> *But it is true, as I also realized at the time, that if the chief physicians don't support it, develop it, or implement it, then, of course, you generally have problems with implementation.* [Health care professional 5]

Support

According to the health care professionals, both the rehabilitation centers and patients received support in implementing telerehabilitation or in case of technical difficulties. Therefore, the internal IT department and the external developers of telerehabilitation services were considered essential:

> *The support from the developer was comprehensive. I would say that we received very strong support [from them], with regular get-togethers and meetings on-site and online, which are still taking place.* [Health care professional 2]

When patients needed support, health care professionals were usually the first point of contact. They decided which questions they could answer themselves or in which cases IT or building services must be involved. In addition, some rehabilitation centers encouraged patients to support each other in using digital services, as highlighted by one of the interviewees:

> *Well, we're open to that and then help them with it. But I also appeal to the patients in the rehabilitation groups to help each other. Because I think that's another resource that should be used, because in my opinion patients are a team. So, they are a group that comes together again and again in different... therapies. And they get to know each other a bit over time. They should also support each other. So, if there is someone who is really good with mobile phones, they can help a patient who is a bit older and maybe doesn't have much to do with mobile phones. I think we as therapists should encourage and demand that.* [Health care professional 8]

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Outer Setting

Critical Incidents as Driving Factors for Implementation

Participants emphasized that the pandemic was one of the driving factors behind the introduction of telerehabilitation. External constraints, such as distance and hygiene regulations, had to be responded to quickly, and telerehabilitation provided an alternative. Otherwise, digitization would have progressed much more slowly without the pandemic:

> *But a driving factor was the coronavirus pandemic. [It] simply forced us to introduce digital lectures. Or rather, it was an opportunity for us to maintain the quality of the lectures and continue to offer lectures to the same extent as before and even beyond.* [Health care professional 2]

Policies and Laws

Interviewees who were able to provide information on the approval process for telerehabilitation reported that although the acceptance of telerehabilitation is growing on the part of funding bodies, the approval process still needs to be improved in some cases. Concerning funding, it was explained that DRV only funds the digital rehabilitation aftercare services but not the on-site app training at the centers, thus incurring additional costs. The health care professionals would like the payers to continue to push for digitalization and for telerehabilitation to be reimbursed at the same amount as in-person services:

> *I already mentioned briefly that acceptance on the part of cost bearers is really growing when it comes to digital [offers]. It's not happening as quickly as we would have liked.* [Health care professional 6]

It was also requested that the same quality criteria should be applied to the implementation of telerehabilitation as for analog services (eg, rehabilitation therapy standards and patient education guidelines).

Discussion

Principal Findings

This study identified several barriers, including concerns among health care professionals regarding resource availability and team communication, as well as initial staff resistance to the introduction of new technologies. Similar to other countries, health care professionals noted that, despite growing acceptance among payers, improved approval procedures and proper financing of digital services are needed for the sustainable success of telerehabilitation [24].

This study also provided insights into the challenges patients faced with the routine use of telerehabilitation in aftercare. However, they reported high acceptance of telerehabilitation and expressed a wish for improved usability, for example, in terms of voice, music, and instructions.

A direct comparison of the 2 groups' perspectives cannot be made due to the different theoretical frameworks used for each group. However, there are aspects that play a crucial role in the implementation and acceptance of telerehabilitation for both groups.

Overall, both patients and health care professionals were enthusiastic about the potential of telerehabilitation and appreciated its flexibility. For patients, this often means less travel for aftercare, while for health care professionals, the advantages relate to opportunities to work from home or to standardize certain workflows, such as training programs.

There were also similarities in terms of motivation. The patients in this study were highly motivated to use the prescribed telerehabilitation. Health care professionals confirmed this, stating that more than half of their patients were highly motivated to use telerehabilitation. In addition, rehabilitation centers valued various motivational mechanisms to maintain control over exercise performance, which patients perceived as helpful for maintaining a routine.

Another aspect that both groups found helpful was continuous, comprehensive support. Patients appreciated the prompt assistance provided by rehabilitation facilities when questions or difficulties arose, whether during in-clinic rehabilitation or aftercare. This aligned with the participating clinics' patient-centered values and therapists' emphasis on providing tailored support and exercises. Fast and continuous technical support, for example, from developers or IT departments, was also identified as essential for successful implementation.

Similar views were expressed regarding obstacles and concerns. Both groups pointed to occasional technical problems and more comprehensive structural issues, such as poor internet connections. They also mentioned that telerehabilitation is not an option for people who lack technical affinity or who are concerned that they would not be able to participate in digital programs reliably.

Both groups also mentioned that telerehabilitation is not a suitable sole therapy or aftercare option. For certain diagnoses and groups of people, it is important to provide an analog service; therefore, a hybrid service is a sensible solution. In general, health care professionals seem to be somewhat more skeptical of telerehabilitation than patients. They tended to express concerns about internal organizational processes and associated costs.

Our findings largely confirm the results of other studies and suggest that the insights gained in the international context regarding acceptance and implementation conditions can also be transferred to the German context. Overall, telerehabilitation was well accepted by patients, with all of them stating that they would use it again if the necessary conditions were met. The high level of acceptance among telerehabilitation users is consistent with other studies based on the UTAUT2 framework [9,25-27]. Previous studies have also identified support, particularly with regard to technology [28,29], patient motivation [30,31], and the advantages of telerehabilitation, such as flexibility [32,33], as factors that contribute to acceptance and facilitate implementation. However, challenges arise primarily from patients' varying levels of familiarity with technology and difficulties in establishing routines.

From the perspective of health care professionals, the most important facilitators were the perceived benefits of flexibility, resource efficiency, and improved communication with patients.

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Some authors also point out the flexibility for both sides as beneficial [34], while others fear that the use of telerehabilitation could also lead to a reduction in the effort required to communicate with patients [35]. However, challenges arise from the varying technological affinities among patients, which can hinder the adoption of telerehabilitation and require tailored support for those less familiar with digital tools [2].

However, this study also points to some divergent findings. Other studies show that *privacy concerns* can play an important role in the acceptance of digital rehabilitation services [36], which is why we expanded the UTAUT2 model. Nevertheless, all interviewees assured us that they had no *privacy concerns*.

In addition, other studies suggest that the limited knowledge of health care professionals regarding the handling and implementation processes is one of the main barriers to the introduction of telerehabilitation [2]. This cannot be fully confirmed by our interviews. Although there were requests for more in-depth training on the part of health care professionals, respondents did not generally indicate that they felt overwhelmed by the new technologies. The lack of technical skills was clearly seen as more of a problem for patients than for health care professionals.

Methodological Strengths and Limitations

Due to its qualitative approach, this study provides in-depth insights into the conditions for implementing and accepting telerehabilitation. Our methodology is based on 2 well-established theories [12,19] that have already been applied in previous studies. This facilitates the comparability of results with other research findings.

However, the predominantly positive results of this study may be due to selection bias, limited access to the field, and a preferential participation of patients and health care professionals who value digitalization. Despite intensive efforts to recruit additional interview participants, only 9 interviews with patients could be conducted instead of the planned 10. It can be assumed that patients who were motivated and satisfied with telerehabilitation were more willing to discuss their experiences. Future studies should also survey patients who discontinued or refused telerehabilitation. Our efforts to recruit such participants, for example, through patient groups and social media, were unsuccessful, so our findings do not reflect alternative perspectives.

Recruitment was also the most significant limitation regarding health care professionals. Of the 10 planned interviews with health care professionals, 8 (80%) could be conducted, mainly via rehabilitation centers that had already participated in the quantitative surveys, valued telerehabilitation, and had a narrow clinical focus (ie, mainly neurology). Despite our intensive efforts and renewed contact with the centers, we were unable to acquire additional interview partners within the time frame of this study.

Accordingly, this study mainly details the experiences and attitudes of neurology clinics and patients who were also predominantly female, more engaged, more tech-savvy, and more willing to participate in the survey than people who are reluctant to use telerehabilitation. All these aspects may limit the generalizability of the results.

Conclusions

In this study, both patients and health care professionals viewed telerehabilitation as beneficial. They particularly appreciated the flexibility and accessibility it offered. Patients demonstrated a high level of acceptance and willingness to continue telerehabilitation, citing expected health benefits and supportive environments as critical facilitators. However, challenges, such as varying technological familiarity and routine establishment, were mentioned as potential barriers to continued participation. The implementation of telerehabilitation in rehabilitation centers was influenced by available resources and the engagement and support of all health care professionals.

In light of these results, we recommend a hybrid model that combines digital solutions with traditional in-person therapy as well as increased patient-to-patient exchange and support. In addition, appropriate structural and financial conditions are needed to integrate telerehabilitation into medical rehabilitation care. This includes streamlining approval processes and ensuring equitable funding comparable to traditional rehabilitation methods to enable broader access and sustainable implementation across various health care settings.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Category systems.
[DOCX File , 63 KB - rehab_v12i1e68766_app1.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
DRV: Deutsche Rentenversicherung (German Pension Insurance Association)
UTAUT2: extended unified theory of acceptance and use of technology

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Original Paper

User Engagement and Experiences With an Online Unsupervised Tai Chi Program for People With Knee Osteoarthritis: Mixed Methods Process Evaluation Nested in a Randomized Controlled Trial

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Abstract

Background: Knee osteoarthritis is a major global health burden, and exercise is a core recommended treatment. Tai Chi is an evidence-based exercise shown to improve symptoms in people with knee osteoarthritis. However, traditional in-person delivery can limit accessibility. To address this, we developed a 12-week unsupervised online Tai Chi intervention and demonstrated its clinical effectiveness in a randomized controlled trial (RCT). This RCT compared the Tai Chi program plus educational information and an exercise adherence support app (intervention) with online education alone (control) for people with knee osteoarthritis. While the intervention improved pain and function, participants' engagement and experiences with the online delivery format remain unclear. Understanding these perspectives is critical for improving future digital exercise interventions.

Objective: This study aims to explore user engagement and experiences with an online unsupervised Tai Chi program among people with knee osteoarthritis.

Methods: Quantitative and qualitative process measures were collected via self-report questionnaires from 89 participants who were randomized into the intervention arm of the RCT. User engagement was assessed using quantitative measures, including the number of days per week Tai Chi was undertaken (with adherence defined as ≥ 2 days per week), use of the My Exercise Messages App (The University of Melbourne), and scores from the Exercise Adherence Rating Scale Section B. User experience was assessed using quantitative measures of satisfaction, likelihood of recommending the program, and perceived credibility, usability, and acceptability. Qualitative content analysis of open-text responses was conducted to explore both positive and negative aspects of the program.

Results: Sixty-four (72%) participants completed the process measures. Among those, the mean (SD) age was 62.5 (6.6) years, and 42/64 (66%) were females. The mean (SD) number of days Tai Chi was undertaken per week was 2.3 (1.1), with 54/74 (73%) classified as "adherent." Participants reported high satisfaction (median 9, IQR 7-10), a strong likelihood of recommending it to others (median 9, IQR 8-10), and perceived it as credible, usable, and acceptable. Many participants described the program as engaging and well-delivered, reporting a positive experience overall and gaining improvements in their knee condition. However, some expressed concerns with aspects of the program delivery (eg, sessions were too long and slow), encountered learning and technological challenges, and a few were dissatisfied with their outcomes.

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Conclusions: Of participants who completed the process measures, most were highly engaged with the Tai Chi program and reported a positive experience, although some had a less favorable experience. This free online Tai Chi program has the potential to enhance patient access to guideline-recommended exercise for osteoarthritis.

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(JMIR Rehabil Assist Technol 2025;12:e82115) doi:10.2196/82115

KEYWORDS

digital health; online intervention; self-managed exercise; mind-body exercise; user engagement; user experiences; exercise adherence

Introduction

Knee osteoarthritis is a leading cause of disability, affecting 654 million people globally in 2020 and placing a substantial burden on health care systems [1]. Exercise is a core component of osteoarthritis management and is recommended in many clinical guidelines [2,3]. Among various exercise options, Tai Chi is strongly recommended [2,3], with evidence demonstrating its effectiveness in improving pain, physical function, and quality of life when compared to usual care [4]. However, Tai Chi is traditionally delivered in person in a group setting and may not be accessible to everyone due to geographical, financial, and logistical barriers.

In response to these challenges, digitally delivered interventions for osteoarthritis management are rapidly expanding as a means of improving access to evidence-based health care [5,6]. In recent times, we developed and evaluated the efficacy of a 12-week online unsupervised Tai Chi program [7], designed to increase access to guideline-recommended exercise for people with knee osteoarthritis. In a randomized controlled trial (RCT), we found that this intervention led to greater improvements in pain (mean difference –1.4 units, 95% CI –2.1 to –0.7; $P<.001$) and function (mean difference –5.6 units, 95% CI –9 to –2.3; $P<.001$) compared to online education control in 178 people with knee osteoarthritis at 12 weeks [8]. We also found that more people in the intervention group achieved the minimal clinically important difference in pain and function than in the control group [8]. While the clinical effectiveness of this Tai Chi program has been established, we are unsure about participants' experiences using the program and any challenges they may have encountered. Understanding how participants engaged with and experienced the program is essential for refinement and informing the development of future online unsupervised exercise programs.

Therefore, the aim of this study was to explore user engagement (adherence) and experiences (satisfaction, recommendation likelihood, credibility, usability, acceptability, and positive and negative aspects) with an online unsupervised Tai Chi intervention among people with knee osteoarthritis.

Methods

Overview

This was a mixed methods process evaluation involving participants who were randomized into the intervention group of the RETREAT RCT (ACTRN12623000780651). The trial compared the "My Joint Tai Chi" intervention comprising an unsupervised online Tai Chi program plus educational information and an exercise adherence support app ("My Exercise Messages" app) with online education control for people with knee osteoarthritis [9]. It enrolled 178 Australian participants, with 89 randomized to the Tai Chi group. The enrollment period was from August 2023 to December 2024. The process evaluation included both quantitative and qualitative measures obtained via self-reported questionnaires.

Participants

For the overarching RCT, people were recruited from the Australia-wide community via online advertisements and social media. The main inclusion criteria were: knee osteoarthritis diagnosis using the National Institute for Health and Care Excellence clinical osteoarthritis criteria [10]; history of knee pain ≥ 3 months; knee pain on most days in the past month; knee pain in the past week during walking ≥ 4 on an 11-point numerical rating scale (NRS), and; home internet connection and a device with access to the internet. The RCT protocol [9] outlines the detailed eligibility criteria. For this study, only participants randomized to the Tai Chi intervention were eligible to be included.

Intervention: "My Joint Tai Chi"

A detailed description of the intervention ("My Joint Tai Chi") and its development has been published [7,9]. The intervention was delivered via a website [11] with the intervention design features summarized in Multimedia Appendix 1. Briefly, "My Joint Tai Chi" was co-developed by Tai Chi instructors, people with osteoarthritis, physiotherapists, and osteoarthritis researchers. The main component of the intervention was a Tai Chi program delivered as a series of 12 different prerecorded 45-mintue videos (one video per week, with each one to be performed 3 times per week for 12 weeks) of a Tai Chi lesson led by an experienced Tai Chi instructor (JH). Each video consisted of a warm-up, a cool-down, and a modified 10-form Yang-style Tai Chi sequence, specifically adapted for individuals with hip and/or knee osteoarthritis and no/minimal prior Tai Chi experience. The program began with basic movements, gradually introducing new movements each week to progressively increase the level of difficulty. The website also included educational information about Tai Chi, living with knee osteoarthritis, treatment options, and the benefits of exercise for osteoarthritis, as well as a recommendation to download and use the "My Exercise Messages" mobile app [12] to facilitate adherence to the Tai Chi program.

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Process Evaluation Measures

Participant characteristics were extracted from baseline data collected for the RCT. Data regarding the process measures were collected via self-reported questionnaires administered 12 weeks after randomization in the trial, unless otherwise stated below. All data were collected via an online data collection platform REDCap [13,14].

The process evaluation measures collected were the following:

User engagement measures:

1. Number of days per week Tai Chi program undertaken: every 2 weeks post randomization (at 2,4,6,8,10, and 12 weeks), participants were asked, "In the past 2 weeks, on how many days did you do the 'My Joint Tai Chi program'?" via email by the researcher (SZ). The average number of days per week Tai Chi was performed was calculated at each time point and across the entire 12-week period. The 12-week average was derived from data collected at each time point. If data were missing for certain weeks, those weeks were excluded from the calculation, and the average was based only on the weeks with available data. Participants were also classified as "adherent" if they reported doing Tai Chi ≥ 2 days per week, and all other participants were classified as "nonadherent." From this, we reported the percentage of participants adherent or nonadherent at each fortnightly interval. We also recalculated this by including and categorizing participants who did not provide this data as nonadherent.
2. Exercise Adherence Rating Scale (EARS) section B [15]: participants were asked to answer 6 questions regarding their Tai Chi program adherence, each rated on a 5-point Likert scale from 0="completely agree" to 4="completely disagree". Total score ranges from 0 to 24, with higher scores indicating better adherence.
3. Use of My Exercise Messages App: participants were asked, "Did you use the My Exercise Messages App at all in the past 3 months?" with response options of Yes or No.
4. Access to website: data obtained from website analytics showing the number of participants who accessed the website at least once.

User experience measures:

1. Overall satisfaction with Tai Chi program: participants were asked to score on an 11-point NRS for "Overall, how satisfied are you with the 'My Joint Tai Chi' program?" from 0="not at all satisfied" to 10="extremely satisfied."
2. Likelihood of recommending Tai Chi program to others: participants were asked to score on an 11-point NRS for "How likely would you be to recommend the 'My Joint Tai Chi' program to others with knee osteoarthritis?" from 0="not at all likely" to 10="extremely likely."
3. Credibility of Tai Chi program: participants were asked to score two items regarding how logical and trustworthy the "My Joint Tai Chi" program was, using an 11-point NRS from 0="not at all" and 10="extremely," and one item regarding how believable the program was, using an 11-point NRS from 0="not at all" and 10="fully." Higher scores indicate that the program is more logical, believable, or trustworthy.
4. Usability of Tai Chi program: participants were asked to score the usability of "My Joint Tai Chi" program using all 10 items from the System Usability Scale (SUS) [16], using a 5-point Likert scale from 1="Strongly disagree" to 5="Strongly agree." The score was converted to a range from 0 to 100, with higher scores indicating the higher usability.
5. Acceptability of Tai Chi program: participants were asked to score the acceptability of the "My Joint Tai Chi" program using all 8 items from the Theoretical Framework of Acceptability (TFA) Questionnaire [17], each with 5 Likert response options from 1 to 5. Items 2, 3, and 7 were reverse scored. To generate a single acceptability score, the total mean score of the first 7 TFA items, or the single score for item 8 regarding general acceptability, were used. A higher score indicates higher acceptability.
6. Positive and negative aspects of the Tai Chi program: participants were asked to provide up to three open-text answers each to "List the most positive aspects" and "List the most negative aspects" of the program. Providing responses to these open-text questions was optional.

Data Analysis

Quantitative measures were summarized as mean (SD) or median (IQR) for continuous variables, and counts or percentages for categorical variables.

For the open-text responses about the positive and negative aspects of the program, a qualitative inductive content analysis approach was used [18]. All open-text data were exported to Microsoft Excel and subsequently analyzed in NVIVO (QSR International Pty Ltd 2015, released 2024). Two researchers (SZ and JP) independently conducted the initial analysis, beginning by reading through all responses to familiarize themselves with the dataset. Date was deemed invalid and removed if the answer was not related to either positive or negative aspects of the program. The remaining data were then coded separately for each question by identifying "units of meaning" within participant responses that reflected either positive or negative aspects of the program. Researchers avoid using preconceived categories, instead immersing themselves in the data to allow new insights and thematic categories to emerge [19]. Each researcher independently generated preliminary themes and subthemes by organizing related codes and distinguishing them from unrelated ones. These themes and subthemes were labelled and defined, with a focus on manifest content [18,20]. Throughout the process, the researchers iteratively moved between the research question, original data, coding, and development of themes to ensure coherence and accuracy. The codes, subthemes, and themes were then discussed with the broader research team, initially with RN and subsequently with KB and RH, to consider alternative categorizations of the data (such as merging or reorganizing themes) and their descriptions.

Ethical Considerations

Informed consent was obtained from participants before their completion of baseline questionnaires via online forms using

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REDCap (Research Electronic Data Capture) [13,14]. Ethics approval was obtained (Reference number 2023-26838-47588-6) in May 2023 from the Human Research Ethics Committee of the University of Melbourne. All data collected in this study were deidentified and stored on secure university servers, accessible only to the researchers using a password.

Results

Participant Characteristics

Of the 89 participants allocated to the Tai Chi group in the RCT, 64/89 (72%) completed all process measures at 12 weeks. Table 1 presents the baseline characteristics, and Multimedia Appendix 2 presents the primary outcomes of participants who did and did not complete the process measures. No major differences were identified between these subgroups. The number of participants who self-reported their Tai Chi sessions via fortnightly questionnaires was at its lowest (56/89, 63%) during weeks eight and ten, and at its highest (67/89, 75%) during week two. A total of 74 (83%) participants completed at least one questionnaire across the 12 weeks, while 15 (17%) did not complete any questionnaire at any time point.

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Table 1. Baseline characteristics of Tai Chi group participants who provided all process measures at 12 weeks and those participants who did not.

Characteristic	Incomplete process measures (n=25)	Complete process measures (n=64)
Knee pain during walking (NRS), mean (SD)	6.3 (1.2)	6.1 (1.2)
Physical function (WOMAC), mean (SD)	29.3 (8.3)	28.2 (8.7)
Age (years), mean (SD)	60.9 (8.9)	62.5 (6.6)
Sex, n (%)		
Male	8 (32)	22 (34)
Female	17 (68)	42 (66)
Gender, n (%)		
Man	8 (32)	22 (34)
Woman	16 (64)	41 (64)
Nonbinary	1 (4)	1 (2)
Height (m), mean (SD)	1.7 (0.1)	1.7 (0.1)
Body mass (kg), mean (SD)	91.9 (22.1)	86.2 (21.5)
BMI (kg/m^2), mean (SD)	32.6 (9.0)	30.4 (7.1)
Ethnicity, n (%)		
Australian or New Zealander	17 (68)	50 (78)
Aboriginal and Torres Strait Islander	1 (4)	0 (0)
European	2 (8)	6 (9)
Asian	2 (8)	7 (11)
North African & Middle Eastern	1 (4)	0 (0)
Other	2 (8)	1 (2)
Education level, n (%)		
Did not complete primary school	1 (4)	0 (0)
Secondary/high school	6 (24)	8 (12)
Trade or trade certificate	3 (12)	4 (6)
University or tertiary institute	10 (40)	42 (66)
Higher university degree	5 (20)	10 (16)
Currently in paid employment	15 (60)	39 (61)
Geographical location, n (%)		
Major cities	18 (72)	36 (56)
Inner regional	6 (24)	21 (33)
Outer regional	1 (4)	5 (8)
Remote	0 (0)	2 (3)
Most painful knee		
Right knee, n (%)	15 (60)	30 (47)
Left knee, n (%)	10 (40)	34 (53)
Knee symptom duration (years), median (IQR)	6 (4-20)	8 (2-46)
Problems in other joints, n (%)		
Nonstudy knee	4 (16)	20 (31)
Upper body	9 (36)	21 (33)
Back and neck	9 (36)	20 (31)
Hip	6 (24)	14 (22)
Foot or ankle	10 (40)	10 (16)

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Characteristic	Incomplete process measures (n=25)	Complete process measures (n=64)
Joint replacement, n (%)		
Nonstudy knee	1 (4)	1 (2)
Hip	3 (12)	1 (2)
Comorbid conditions, n (%)		
≥1 comorbid condition	23 (92)	57 (89)
Heart disease	0 (0)	6 (9)
High blood pressure	6 (24)	24 (38)
Lung disease	1 (4)	3 (5)
Diabetes	2 (8)	2 (3)
Ulcer or stomach disease	1 (4)	1 (2)
Kidney disease	0 (0)	1 (2)
Liver disease	0 (0)	0 (0)
Anemia or other blood disease	0 (0)	0 (0)
Cancer	0 (0)	3 (5)
Depression	3 (12)	7 (11)
Back pain	8 (32)	25 (39)
Rheumatoid arthritis	0 (0)	0 (0)
Other medical problems	7 (28)	15 (23)
Current oral medication use for knee pain[a], n (%)		
≥1 medication used	18 (72)	46 (72)
Analgesia or paracetamol combinations	16 (64)	40 (62)
Anti-inflammatory tablets or capsules	9 (36)	30 (47)
Oral corticosteroids	0 (0)	1 (2)
Oral opioids	0 (0)	0 (0)
Treatments for knee in last 3 months		
≥1 treatment, n (%)	14 (56)	32 (50)
Massage or manual therapy, n (%)	11 (44)	23 (36)
Gait aid, n (%)	4 (16)	4 (6)
Electrotherapy[b], n (%)	1 (4)	4 (6)
Joint injections, n (%)	3 (12)	2 (3)
Acupuncture, n (%)	4 (17)	4 (6)
Information or education course, n (%)	3 (12)	7 (11)
Herbal therapies, n (%)	1 (4)	13 (20)
Past experience with Tai Chi, n (%)	1 (4)	5 (8)
Physical activity level (hours per week)[c], median (IQR)	20 (9-32)	20 (13-28)
Tai Chi expectations[d], n (%)		
Minimal improvement	0 (0)	6 (9)
Moderate improvement	17 (68)	34 (53)
Large improvement	8 (32)	23 (36)
Complete recovery	0 (0)	1 (2)
Health professional consultation[e], n (%)		
General practitioner	13 (52)	30 (47)

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Characteristic	Incomplete process measures (n=25)	Complete process measures (n=64)
Physiotherapist	7 (28)	11 (17)
Exercise physiologist	1 (4)	3 (5)
Dietician	2 (8)	0 (0)
Psychologist	0 (0)	0 (0)
Pharmacist	5 (20)	15 (23)
Podiatrist	2 (8)	4 (6)
Occupational therapist	2 (8)	0 (0)
Rheumatologist	0 (0)	0 (0)
Sports and exercise physician	0 (0)	0 (0)
Orthopedic surgeon	2 (8)	1 (2)
Other	2 (8)	3 (5)

[a]Defined as ≥ 1 time per week over the last 4 weeks.

[b]Electrotherapy includes transcutaneous electrical nerve stimulation, low-level laser, and ultrasound therapy.

[c]Measured using IPEQ-W (incidental and planned exercise questionnaire) with 10 questions regarding frequency and duration of incidental and planned walking, sport, and recreational activities over the past 7 days. Scores were calculated as the product of the frequency and duration scores to create a total duration for the week score, where higher scores indicate higher levels of activity.

[d]Scored from a question asking about expectation of study treatment outcomes, with scores on a 5-point Likert scale from "1=no effect at all" to "5=complete recovery."

[e]Reported yes or no if any of the listed health professionals were visited for a knee condition in the past 3 months.

User Engagement Measures

Adherence to the Tai Chi program is shown in Table 2. Among those who provided adherence data (n=74), the average number of days Tai Chi was performed per week over weeks 1-12 was 2.3 (SD 1.1), with 54 (73%) participants achieving "acceptable" adherence (doing Tai Chi ≥ 2 days per week). The proportion of participants classified as adherent in each fortnightly period was stable throughout the 12 weeks, ranging from 71% in weeks 10 to 80% in weeks 8 (Figure 1). The adherence rate was lower when including those who did not provide adherence data and were categorized as nonadherence (Multimedia Appendix 3). The EARS also demonstrated high adherence to the program, with a median score of 20 (IQR 13–23.5) out of 24 reported at 12 weeks.

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Table 2. Adherence measures in the Tai Chi group.

Adherence Measures	Tai Chi (n=89)
Average number of days Tai Chi performed per week[a]	
Weeks, mean (SD)	
1-2	2.4 (1.1)
3-4	2.6 (1.3)
5-6	2.5 (1.3)
7-8	2.7 (1.3)
9-10	2.4 (1.3)
11-12	2.4 (1.3)
Average number of days Tai Chi performed per week over weeks 1-12[b], mean (SD)	2.3 (1.1)
Classified adherent from data collected over week 1-12[b,c], n/N (%)	54/74 (73)
Exercise Adherence Rating Scale Section B[d], median (IQR)	20.0 (13.0-23.5)
Use of "My Exercise Messages" App[e], n/N (%)	48/64 (75)
Access to website[f], n/N (%)	86/89 (97)

[a]Self-reported throughout questionnaire sent at 2, 4, 6, 8, 10, and 12 weeks; 67 answered at 2 weeks, 62 answered at 4 weeks, 58 answered at 6 weeks, 56 answered at 8 weeks and 10 weeks, 64 answered at 12 weeks.

[b]74 participants in Tai Chi group answered at least one questionnaire sent at 2, 4, 6, 8, 10, and 12 weeks.15 participants did not answer any questionnaire at any time point.

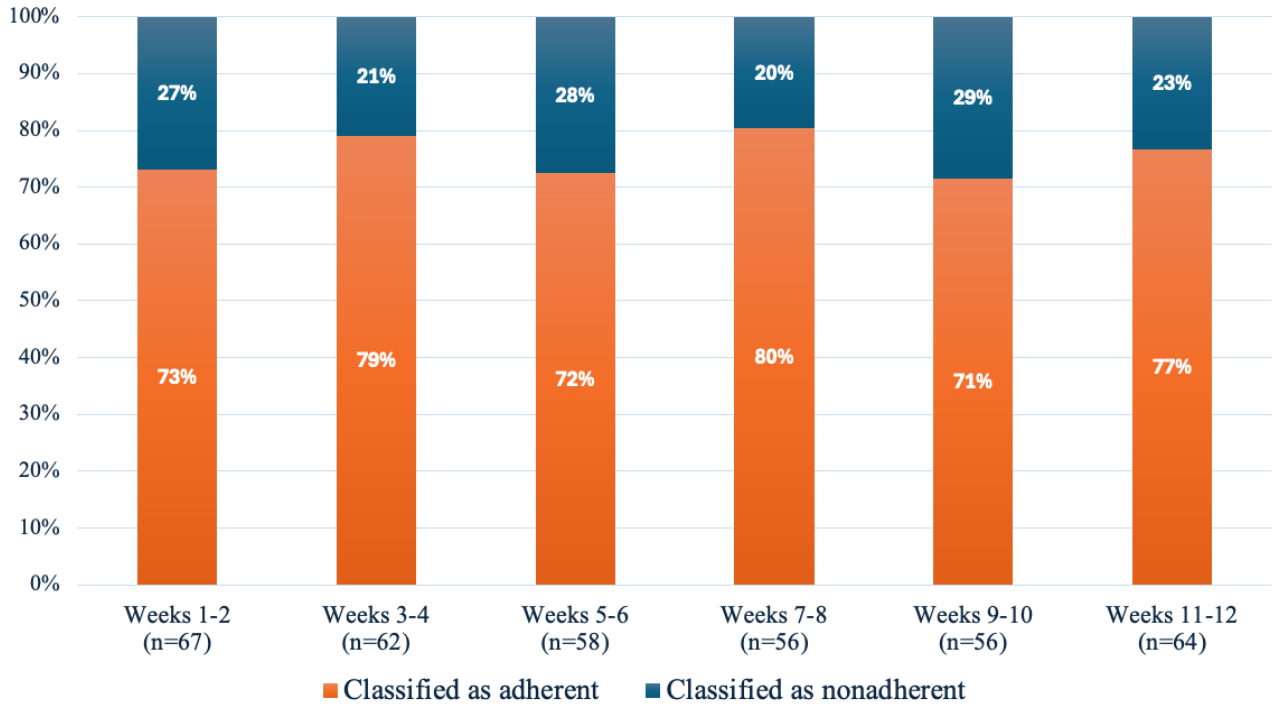
[c]Adherent defined as Tai Chi performed on average 2 or more days per week.

[d]Scores range from 0-24, higher scores indicating better adherence. Results obtained from 64 participants who answered this questionnaire.

[e]Participants were asked, "Did you use the My Exercises Message App at all in the past 3 months?" with response options of Yes/No. 64 participants answered this question.

[f]Data obtained from website analytics showing the number of participants who accessed the website at least once.

Figure 1. Fortnightly adherence rates in the Tai Chi group expressed as the percentage of participants classified as adherent (Tai Chi performed on average 2 or more days per week) and nonadherent.



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User Experience Measures

Five responses were classified as invalid. Sixty-two participants provided at least one response to these questions, while 27 participants did not provide any response. Participants reported high satisfaction and a strong likelihood of recommending the program to others. Also, they perceived the program to be highly credible, acceptable, and usable (Table 3).

Table 3. User experiences (satisfaction, recommendation, credibility, usability, and acceptability) with the Tai Chi program.

User experience	Median (IQR)
Overall satisfaction with program[a]	9 (7-10)
Likelihood of recommending program[b]	9 (8-10)
Credibility of program[c]	
1. How logical the program was	9 (7-10)
2. How believable the program was to help knee problem	6 (5-7)
3. How trustworthy the program was	9 (8-10)
Usability of program[d]	85 (72.5-95)
Acceptability of program[e]	
Average score from Questions 1-7	4 (3.6-4.3)
General acceptability score	5 (4-5)

[a]Overall satisfaction with the program was scored on an 11-point numerical rating scale (NRS) from 0="not at all satisfied" to 10="extremely satisfied." Results obtained from 66 participants who answered this question.

[b]Likelihood of recommending program was scored on an 11-point NRS from 0="not at all likely" to 10="extremely likely." Results obtained from 65 participants who answered this question.

[c]Credibility of program was scored using 2 items regarding how logical and trustworthy the "My Joint Tai Chi" program was, using an 11-point NRS from 0="not at all" and 10="extremely," and 1 item asking "Thinking back to when first starting the program, how believable the program was," using an 11-point NRS from 0="not at all" and 10="fully." Results obtained from 64 participants who answered these questions.

[d]Usability of program was scored using 10 items from System Usability Scale. Final score ranges from 0 to 100 with higher scores indicating higher usability. Results obtained from 64 participants who answered this questionnaire.

[e]Acceptability of program was scored using the Theoretical Framework of Acceptability (TFA) Questionnaire on a 5-point Likert scale with response options from 1 to 5. Items 2, 3, and 7 were reverse scored. To generate a single acceptability score, the total mean score of the first 7 TFA items, or the single score for item 8 regarding general acceptability were used. A higher score indicates higher acceptability. Results obtained from 64 participants who answered this questionnaire.

Positive and Negative Aspects

Positive and negative aspects of the Tai Chi program are presented in Table 4, alongside themes, subthemes, and exemplar quotes.

Regarding positive aspects of the program, three themes were identified. First, participants described it as an engaging and well-delivered program. They appreciated the clear instructions and demonstrations from the instructor, and felt the program was well-structured and easy to understand. They also valued the comprehensive coverage of movements and information, delivered in a flexible format that allowed them to practice, rewatch, and rewind sessions without time or location constraints. Second, participants reported improvements in their physical and mental outcomes. For example, some noticed improvements in knee pain, function, body awareness, mental focus, and alertness. Third, participating in the Tai Chi program was considered a positive experience. Most participants found it relaxing and calming, and enjoyed the opportunity to learn something new.

In terms of the negative aspects, 4 themes were identified. First, participants raised concerns about program delivery. Some found the sessions too long and unrealistic in terms of the time required, while others felt the sessions were slow, boring, and repetitive. In contrast, a few people felt the sessions went too fast and wished they could be longer. Some participants also felt there was too much talking from the instructor. The prerecorded video format meant participants were unable to communicate with an instructor and gain feedback or check whether their movements were correct, which left some participants feeling frustrated. Second, participants reported various learning challenges. These included physical difficulty in performing complex movements, particularly due to a lack of coordination, and cognitive difficulty in remembering the movements. Third, technological challenges were identified. Issues such as poor internet connection and video presentation (eg, overly close-up shots) made learning more difficult for some. Fourth, some participants expressed dissatisfaction with their personal outcomes, feeling the program neither addressed their problems nor met their expectations.

In addition, suggestions for improvements were provided. Some participants wanted more information about Tai Chi before starting the program. There was also interest in having interactive components, such as an online forum for questions or follow-up opportunities with the instructor.

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Table 4. Themes, subthemes, and exemplar quotes for positive and negative aspects of the Tai Chi program.

Themes and subthemes	Exemplar quotes
Positive aspects of the program	
Engaging and well-delivered program	
Clear instructions and demonstrations from the instructor	• "Tai Chi teacher was very impressive. Explanations and demonstrations were clear and easy to follow. It was a joy to have someone so knowledgeable and professional." • "The instructor explained and demonstrated the movements very well." • "A very knowledgeable and patient instructor who was very encouraging."
Well-structured and easy-to-understand	• "Easy to understand and follow sequences." • "The 12 week program was really well paced." • "Well-presented and each lesson leads on from the previous." • "There was appropriate repetition to allow us to learn and understand."
Good coverage of movements and information	• "Good supply of information and content." • "The actual Tai Chi movements. Feeling the Tai Chi energy within." • "Good range of exercises."
Flexible delivery mode	• "Could do in your own home and at a time that suited me." • "I found that I could rewatch and rewind if I felt I needed more practice." • "Flexible timing."
Improved outcomes	
Improved physical well-being	• "Most positive thing is that my knee does feel better." • "Found the movements helped my flexibility and strength." • "Increased my body awareness and mindful movement." • "I hope to start again and redo whole program as I have noticed huge improvement with my strength, stability and balance. But still have a long way to go."
Improved mental well-being	• "It improves my mental health like alertness." • "Meditation quality." • "Focus it provided."
A positive experience	
Relaxing and calming	• "Enjoying learning Tai Chi warming and relaxation exercises." • "Calming, gentle and relaxing." • "I felt relaxed after completing the sessions."
Good to learn something new	• "Good to learn something new, hopefully perfecting the skills." • "Learning something new for life." • "Nice introduction to Tai Chi for a first timer."
Negative aspects of the program	
Concerns with program delivery	
Sessions were too long	• "Extremely Boring. Too slow and monotonous." • "The slow pace at the beginning was difficult to adjust to." • "Too much repetition each session."
Disconfirming cases	
Too fast; Each session could go longer	• "A bit too fast for me." • "Pace could be a little slower at the beginning of course." • "I sometimes wanted the session to go longer."
Too much talking from the instructor	• "Instructor spent a lot of time explaining things whilst we were held in one position." • "I felt the instructor spoke to us like children explaining the easiest movements in too much detail and repetitively as if we are totally stupid." • "Stopping mid exercise to explain a certain move."
Lack of feedback	• "Not being able to have two way communication." • "Not sure I am doing the right movement or steps on the skills." • "Lack of feedback, would be good to do in-person class in the first session."

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Themes and subthemes	Exemplar quotes
Learning challenges	
Physical difficulty in learning complex movements, especially due to a lack of coordination	• "Tai chi isn't easy for me.. body feet arm coordination challenged me." • "Some movements to me were difficult to grasp initially" • "Unable to complete all tasks as easy as the instructor."
Cognitive difficulty in remembering movements	• "Having to remember most of the movements can be a bit daunting." • "I had great difficulty in remembering the moves, which I found frustrating and demotivating."
Technological challenges	
Video presentation	• "Felt close-up views of exercises frustrating." • "It was very distracting zooming in on her feet. It was much easier to follow when zoomed out and watching her fully • "It can be a bit confusing facing the screen and deciding which way is left or right."
Poor internet connection	• "Living remote, streaming sometimes difficult." • "Connectivity on my own system."
Dissatisfied with outcomes	
—[a]	• "My shoulder issue was exacerbated a little with some movements so I modified it." • "Did not help me with my problem." • "(The program) could have been a bit more demanding for increasing knee strength and flexibility."

[a]Not applicable.

Discussion

Principal Findings

This process evaluation of a 12-week online unsupervised Tai Chi intervention showed that among participants who completed the measures, most were adherent to the Tai Chi program, reported high satisfaction with the program, a strong likelihood of recommending it to others, and perceived it as credible, usable, and acceptable. Many participants described the program as engaging and well delivered, reporting a positive experience and gaining improvements in their knee condition. However, some participants expressed concerns about aspects of the program delivery and encountered learning and technological challenges, with a few dissatisfied with their outcomes. To our knowledge, this is the first study to evaluate user engagement and experience with an online unsupervised Tai Chi intervention in people with knee osteoarthritis.

Overall engagement with the Tai Chi program was good, with nearly three quarters of participants deemed as having "acceptable" adherence. Compared to 2 other online unsupervised exercise programs we previously developed for knee osteoarthritis, one a 12-week yoga program [21] and the other a 6-month strengthening program [22], the EARS score in our study (median score of 20 out of a maximum score of 24) was higher than those reported in the other programs (both around 15-16) [21,22], suggesting that participants were more adherent with the Tai Chi than with these other programs. Furthermore, in contrast to another 9-week online unsupervised physical activity intervention for knee osteoarthritis ("Joint2move") [23], which had an adherence rate of 46% (defined as 6 out of 9 modules completed) [24] and where module completion declined from 80% to 40% over time [23], adherence to our Tai Chi intervention remained stable (71%-80%) throughout the 12-week period, indicating sustained and consistent engagement. However, our adherence rates may be inflated as participants with missing adherence data were excluded from the calculation, which can introduce bias. Our recalculated adherence rates were lower when we included these participants and categorized them as nonadherent. One possible reason for the good engagement with our Tai Chi intervention is the incorporation of an adherence support tool, the "My Exercise Messages" app. This app was adapted from our previously developed, behavioral change theory-informed, automated SMS text messaging program, which showed improved self-reported adherence to unsupervised home exercise for people with knee osteoarthritis [25]. Given that 75% of our program completers reported using the app, it is possible that it contributed to the good adherence to our Tai Chi intervention. This is consistent with findings from systematic reviews showing that the use of behavior change techniques is associated with improved exercise adherence [26,27].

The generally positive user experiences with our Tai Chi program, as captured by the quantitative measures, align with findings from a systematic review [28] and a scoping review [29], showing that older adults reported high satisfaction, usability, and acceptability toward Tai Chi delivered remotely via synchronous videoconferencing. Specifically, satisfaction with the Tai Chi intervention (median of 9 out of 10) was slightly higher than that reported in our yoga program (mean of 8 out of 10) [21], and usability of the Tai Chi intervention (median of 85 out of 100) was higher than that of our strengthening program (mean of 5.3 out of 7) [22]. Under the credibility domain, the relatively low believability score (median of 6 out of 10) when participants first commenced the program

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likely reflects their initial uncertainty about Tai Chi, with their subsequent engagement and generally positive experiences suggesting that believability may have increased over time had this been remeasured. However, qualitative open-text responses in our study showed that while some participants described the program as well-structured with clear instructions, others found it too slow, repetitive, and boring due to excessive instructions. These contrasting experiences are consistent with our qualitative interview exploring in-depth experiences of a subgroup of 20 people who participated in this Tai Chi program [30], as well as other studies exploring home-based Tai Chi (delivered either as an addition to in-person classes or via videoconferencing) for people with chronic diseases (eg, lower back pain, dementia, and cystic fibrosis) where users also reported variable experiences [31-33]. Given that Tai Chi and yoga share similar elements of movement-based mind-body connection, we can draw further insight from 2 qualitative studies exploring yoga instructors' experience of adapting in-person yoga classes to synchronized online delivery via videoconferencing [34,35]. These studies found that the online classes were intentionally designed to be slower, simpler, and more structured than face-to-face classes, where the instructor increased instructions and emphasized interoception (a technique of focusing on internal bodily sensations to improve mind-body awareness) [34-36]. As our Tai Chi program was delivered via pre-recorded videos without any instructor interaction with participants, we deliberately designed it to be slower and more repetitive to accommodate for the absence of hands-on assistance and direct feedback from an instructor. However, this teaching format might be perceived differently for individuals with variable learning preferences and needs.

The learning and technological challenges encountered by some participants may have also negatively impacted their experience with the program. Similar difficulties have been reinforced in our qualitative study [30] and reported in other studies of online exercise programs for older adults, where participants struggled to learn movements through a two-dimensional interface and experienced various internet-related issues [34,37-39]. The nature of an online unsupervised learning format may further reduce participants' engagement, given the lack of face-to-face interaction and social support from being part of a group-based class. Collectively, our findings align with previous research showing that factors such as preferred teaching styles in mind-body exercise, movement complexity, digital literacy, and supervision are important in influencing participants' engagement and experience with online mind-body exercise programs [29,40-42].

The fact that many people with knee osteoarthritis reported positive engagement and experiences with our online unsupervised Tai Chi program, but some others had less favorable experiences, indicates that there is no one-size-fits-all approach to exercise programs. This is supported by a Cochrane review showing similar symptomatic benefits can be obtained from a range of different exercise types, dosage, and delivery modes in knee osteoarthritis [43]. Instead, offering and improving access to a variety of exercise options that align with patient preferences may be important for optimizing engagement, adherence, and outcomes. For future implementation, providing additional information about the Tai Chi exercises (such as readings or videos) prior to program commencement may help participants better prepare for online unsupervised exercise programs.

In addition, offering a suite of optional shorter, prerecorded videos may enable users to select sessions that best suit their needs, while also helping to ensure they are adequately challenged. Finally, a hybrid approach that combines in-person sessions with digital Tai Chi could provide participants with initial instruction and feedback, enhancing their confidence before transitioning to independent online practice.

To date, more than 47,747 users from over 141 countries have accessed our freely-available unsupervised online-strengthening [44] and yoga [45] programs, highlighting the global demand for unsupervised home-based resources for osteoarthritis management. Our online Tai Chi program now adds to the growing suite of online exercise resources, providing an additional accessible option to support patient uptake of osteoarthritis exercises and potentially alleviate demands on health care services.

Strengths and Limitations

Strengths of this study include a mixed methods process evaluation embedded within a robust RCT. By combining both quantitative and qualitative data, the study provided a more nuanced understanding of user engagement, program experiences, and considerations for future implementation. However, several limitations should be acknowledged. First, the process evaluation completion rate was moderate, with almost one-third of participants in the Tai Chi group not completing the evaluation. This may have introduced bias. For example, if noncompleters were those who either did not engage with the program or had less positive experience, the positive outcomes reported may have been overestimated, limiting the representativeness of the findings. Second, we were unable to capture accurate website continuous adherence metrics for the Tai Chi program, which would have provided a more objective measure of adherence. Instead, adherence data in this study were self-reported by participants, which may have introduced social desirability and recall biases that can affect the data accuracy [46,47]. However, a systematic review showed that self-reported diaries measuring the frequency of unsupervised interventions are the most commonly used method for assessing adherence [48]. While this approach has limitations, it remains a practical option when objective methods are not feasible. Future work could incorporate objective adherence metrics, such as those obtained from wearable technology or app-based logs to triangulate findings. Third, qualitative data were collected via an optional open text box allowing a maximum of 3 responses, which may mean our qualitative data may lack granularity. However, our qualitative interviews, published elsewhere [30], provide deeper information from a smaller subset of participants that complement the findings of the present study. Finally, participants were largely older adults, highly educated (university degree or higher), and located in major cities, and they were also required to own a device and access the internet. This may limit the generalizability of our findings to more culturally and linguistically diverse groups,

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socioeconomically disadvantaged populations, and people with lower digital or health literacy. Future studies could evaluate the program in broader populations to ensure its acceptability and applicability.

Conclusion

Among participants who undertook a 12-week online unsupervised Tai Chi intervention and completed process measures, the majority were adherent with the weekly Tai Chi program, reported high satisfaction with the program and were likely to recommend it to others. The program was perceived as credible, usable, and acceptable. However, some participants expressed concerns related to program delivery, encountered learning and technological challenges, and a few were dissatisfied with their outcomes. This free and scalable Tai Chi intervention has the potential to enhance patient access to guideline-recommended osteoarthritis exercise.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: SZ, KLB, RSH, RKN
Methodology: SZ, KLB, RSH, RKN
Formal analysis: SZ, PL, ADS, KLB, RSH, RKN
Funding acquisition: KLB
Project administration: SZ
Supervision: KLB, RSH, RKN
Writing - Original draft: SZ
Writing – review & editing: All authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Description of the online “My Joint Tai Chi” intervention (https://myjoint-taichi.org/).
[DOCX File , 15628 KB - rehab_v12i1e82115_app1.docx]

Multimedia Appendix 2
Summary of the primary clinical trial outcomes of Tai Chi group participants who provided all process measures at 12 weeks and those participants who did not.
[DOCX File , 16 KB - rehab_v12i1e82115_app2.docx]

Multimedia Appendix 3
Fortnightly adherence rates in the Tai Chi group expressed as the percentage of participants classified as adherent (Tai Chi performed on average two or more days per week) and non-adherent, including those who did not provide adherence data categorized as non-adherent.
[DOCX File , 77 KB - rehab_v12i1e82115_app3.docx]

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Abbreviations

EARS: Exercise Adherence Rating Scale
NRS: numeric rating scales
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
SUS: System Usability Scale
TFA: Theoretical Framework of Acceptability

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Original Paper

Effect of Intolerance of Uncertainty and Resource Consumption on Therapeutic Strategies Chosen by Physiotherapists: Virtual Patient Study

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Abstract

Background: There is a growing interest in the influence of variables that may negatively influence the reasoning of health care professionals, namely intolerance of uncertainty, defined as health care professionals' difficulty tolerating ambiguous situations that often trigger discomfort, overtesting, and suboptimal treatment choices, and resource consumption, defined as the ordering of unnecessary diagnostic tests that can waste resources and compromise decision‐making.

Objective: Our purpose was to assess the influence of intolerance of uncertainty and resource consumption on the chosen therapeutic strategy.

Methods: A total of 127 physiotherapists were challenged to play a simulation game and choose a therapeutic strategy for 3 cases of low back pain of increasing difficulty (easy, medium, and difficult). Their intolerance of uncertainty level and their resource consumption were measured (ie, requests for test results for each case).

Results: Results showed that 87.4% (111/127) of participants chose the most appropriate strategy (ie, the one in line with the strategy recommended by experts) for the easy case, 46.5% (59/127) for the medium, and 29.1% (37/127) for the difficult. For the easy case, intolerance of uncertainty and resource consumption had a negative influence on the chosen therapeutic strategy, which was less appropriate (β=–4.03, t_{121}=–3.92, P<.001). Moreover, resource consumption among highly intolerant individuals had a more adverse influence on the chosen strategy (β=–3.42, t_{121}=–5.09, P<.001). Such results were not found for the medium and difficult cases.

Conclusions: Resource consumption may have a negative influence in some cases on the treatment strategies chosen by the physiotherapists who are most intolerant of uncertainty. Future research avenues are suggested to ensure the quality of patient care concerning physiotherapists' level of intolerance of uncertainty.

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KEYWORDS

clinical reasoning; intolerance of uncertainty; physiotherapists; therapeutic strategy; simulation game

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Introduction

Deaths are extremely uncommon in specialties that offer non-nosological diagnoses (eg, nursing diagnostics and physiotherapeutic diagnoses), but mistakes frequently result in more or longer treatment. Three-quarters of these errors are cognitive and reasoning errors, and 80% of them might be prevented [1,2]. Health care professionals (HCPs) use clinical reasoning, which is defined as a "deliberate process of critical thinking about a clinical situation to reach a reasonable decision about an outcome, diagnosis, therapeutic action, or resolution of a particular patient problem" to arrive at a diagnosis and treatment proposal [3]. However, clinical reasoning is frequently performed without a thorough understanding of all the pertinent characteristics and in medical environments that are highly susceptible to uncertainty, which might result in diagnostic uncertainty [3-7]. Diagnostic uncertainty is the subjective impression that HCPs feel when they cannot offer a correct and clear explanation for the health problem described by their patients [8]. Suboptimal clinical reasoning and diagnostic uncertainty can be caused by a variety of variables and situational characteristics.

Among these, the overconfidence of HCPs has been the subject of much research [9-14]. Being confident in one's diagnosis and patient management skills is not always a bad thing, especially because it can have a positive impact on how patients view their therapeutic relationship with their practitioner, especially if they are experiencing distress [15]. Instead, the issue is the disparity, if any, between practitioners' confidence and the precision of their diagnosis, which might cause practitioners to overlook important information or particular therapy [14,16,17]. As a result, confidence in one's choices is increasingly being investigated in health care settings, such as in vaccination choices, and needs to be further studied within the framework of clinical reasoning [18]. Authors such as Zwaan and Hautz [14] consider that the future in this field of research lies in the joint study of uncertainty tolerance in combination with overconfidence and diagnostic accuracy to determine where these calibration errors occur.

Given the pervasiveness of uncertainty in medical settings, a lack of uncertainty tolerance can negatively impact both patients (particularly when HCPs fail to express their doubt to them) and HCPs (eg, health and reasoning abilities) [3,5,6,19]. Overtesting and occasionally insufficient therapy prescriptions have direct effects on patients [3]. Therefore, a high degree of intolerance of uncertainty may directly affect the diagnosis and course of treatment that patients receive. This is suggested by Simmonds et al [7] in a study showing that physiotherapists with a high level of intolerance of uncertainty will tend to suggest to their patients with low back pain a slower and less active return to their physical and professional activities than professionals with a lower level of intolerance of uncertainty.

Physiotherapists are among HCPs likely to treat patients following a referral from another HCP (usually a general practitioner [GP]). However, they are increasingly required to treat patients as the first HCP they encounter as part of direct access to care, even as they are likely to treat a wide range of conditions, both of which create uncertainty [20,21]. They establish treatment goals and an appropriate rehabilitation program after conducting an evaluation of the patient's strengths and weaknesses using the prescription [22,23]. Physiotherapists are often consulted for low back pain, a very common problem that most people will experience in their lives [24,25]. Although the symptoms are easily recognized, the cause is less so: only 15% of cases of low back pain are associated with pathology, such as a tumor, osteoporosis, or fracture, or with symptoms related to the nerve roots, whereas 85% of cases are classified as nonspecific [26]. Furthermore, a study by Fourré et al [27] showed that a low proportion of physiotherapists are aware of the guidelines for the management of low-back pain, and that this uncertainty leads to guideline-inconsistent behavior. The current literature on physiotherapists' clinical reasoning, however, appears to be focused on the identification and classification of the steps of the reasoning process without any relation to the relevant resulting variables, namely the diagnosis thought to be the most likely for a given situation and, most importantly, the therapeutic strategy offered to the patient [22,28,29]. There are also few pedagogical tools designed for physiotherapists and even fewer tools for assessing their clinical reasoning [30]. Furthermore, these studies failed to consider the influence of contextual and physiotherapist-related characteristics, such as intolerance of uncertainty and confidence in one's judgment, on clinical decision-making [7,31]. As a result, they disregarded how intolerance of uncertainty affected their investigation process and prescriptions, even though we know that HCPs who have a high threshold for intolerance of uncertainty frequently recommend further tests, which may be considered a waste of resources (ie, overtesting [3]).

This study aimed to assess whether physiotherapists propose therapeutic strategies to their patients aligned with strategies recommended by experts, which will subsequently be referred to as "most appropriate strategies" in the remainder of the paper [32]. This variable was chosen as the main dependent variable as most studies focus on measuring diagnostic accuracy of participants (ie, correctness of the final diagnosis [33]). While this measure has the advantage of being easy to measure numerically and to score objectively, authors such as Daniel et al ([34] as cited in [33]) stressed the importance of also measuring other elements that contribute to the assessment of diagnostic success, notably the use of additional diagnostic tests, or treatment decisions. By placing this study within the scope of therapeutic reasoning [35] and following the recommendations of Daniel et al [34], our goal was to assess the impact of physiotherapists' intolerance of uncertainty on the therapeutic strategy they chose and determine whether resource consumption (akin to overtesting) interacts with intolerance of uncertainty to influence the strategy chosen. Second, a subgoal was to check whether physiotherapists exhibited a confidence calibration issue between the strategy offered and its appropriateness for the case (ie, similar to the calibration issues between diagnostics and their quality).

Four hypotheses were tested: (H1) a high level of intolerance of uncertainty and greater resources consumption is associated with the selection of less appropriate therapeutic strategies, (H2) a high level of intolerance of uncertainty is associated with

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greater consumption of resources (ie, more requests for test results), (H3) level of confidence in one's therapeutic strategy will be negatively correlated with the selection of appropriate therapeutic strategies (ie, calibration issue), and (H4) intolerance of uncertainty will be positively associated with confidence in one's diagnoses.

Methods

Study Design

The methodology of this study was inspired by the approaches used by Jette et al [36] and Keller et al [37], where physiotherapists were presented with clinical cases to propose appropriate therapeutic strategies and suspected diagnoses. In our study, a simulation game was used, tailored to meet specific objectives such as incorporating measures of intolerance of uncertainty and resource consumption, modifying case formats, and introducing varying levels of difficulty. The content of the cases was adapted from Meidinger et al [32], focusing on low back pain with or without serious spinal pathologies, a condition known for its diagnostic challenges [26].

Participants

Participants were recruited via email and social media, using a convenience sampling method. An email was sent to a network of physiotherapists associated with a French university laboratory, outlining this study's purpose, estimated participation time, and access details for the game. Participants were encouraged to share the email within their networks. Concurrently, similar information was posted on platforms such as Facebook (Meta), LinkedIn (Microsoft Corp), and Instagram (Meta). Private messages were also sent to physiotherapists on LinkedIn.

Overall, 287 physiotherapists were recruited, but 160 were excluded for not meeting inclusion criteria, resulting in a final sample of 127 participants (M_{age}=33.70, SD_{age}=8.94, 36 women, 71 men, 1 other, and 18 who did not specify their gender). Of these, 105 practiced in France, 2 in Belgium, and 1 in the Ivory Coast ($M_{\text{Years experience}}$=10.30, $SD_{\text{Years experience}}$=8.95, 22 did not provide this information).

Procedure and Instruments

This study used a simulation game featuring 3 fictitious clinical cases, designed to assess clinical reasoning through interactive scenarios rather than traditional multiple-choice questions (Table 1; Multimedia Appendix 1). This choice aligns with the assertion by Halpern (1998, as cited in the scoping review of Berg et al [38]) that such questions often emphasize rote knowledge over critical thinking and reasoning. The simulation method used in this study allows for more ecological assessments, reflecting real-world clinical practice where critical thinking is essential [39]. The game began with an overview of its structure and rules, along with a reminder that advancing screens would prevent participants from returning, encouraging careful consideration before proceeding. On the next screen, participants' level of intolerance of uncertainty when caring for their patients was measured using the IUS-12-H (Intolerance of Uncertainty Scale-12 Health Care Professionals) [40]. This scale, based on the IUS-12 (Intolerance of Uncertainty Scale-12), a generalist intolerance of uncertainty scale initially validated by Carleton et al [41], has been validated in a sample of HCPs and has shown good psychometric properties [40]. The IUS-12 is scored on a Likert scale ranging from "not at all characteristic of me" (1), "a little characteristic of me" (2), "somewhat characteristic of me" (3), "very characteristic of me" (4), to "entirely characteristic of me" (5).

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Table 1. Names, visuals, and the type of game screen. It presents an overview of each screen encountered by participants in the simulation game, organized into 3 columns: name, screen, and screen type. The "name" column identifies each interface element by its purpose, such as introducing this study, presenting a clinical case, or collecting demographic information. The "screen" column specifies the format or layout used to display content—for example, whether clinical information was shown as a series of questions and answers. Finally, the "screen type" column indicates whether a screen was compulsory (displayed to all participants) or optional (available only if participants chose to access additional material, such as test results). See Multimedia Appendix 1 for a wider view of each screen.

Name	Screen	Screen type[a]
Game presentation screen		Compulsory
Intolerance of uncertainty scale screen		Compulsory
Clinical case screen with "question and answer" format		Compulsory
Therapeutic strategy selection screen		Compulsory
Additional test results selection screen		Optional
Additional test results screen		Optional
Suspected diagnosis and diagnosis confidence level screen		Compulsory
Case realism estimation screen		Compulsory
Case difficulty estimation screen		Compulsory
Sociodemographic data screen		Compulsory

[a]Compulsory means the screen was displayed to all, optional means the screen was displayed only if selected.

The screen images shown in Table 1 can be viewed in full size in Multimedia Appendix 1. Each of the 3 featured cases was introduced successively, with each 1 presented in the same format: a brief description followed by a series of questions. The cases were adapted from Meidinger et al [32] and underwent a Delphi assessment to ensure varying levels of difficulty and to address the lack of studies on the reasoning process across different situational levels [42]. The cases were categorized into "easy," "medium," and "difficult," reflecting varying degrees of diagnostic clarity and complexity: the "easy" case suggested a single, highly probable diagnosis (eg, "99% chance it's Diagnostic 1"), the "medium" case involved a couple of competing diagnoses with differing probabilities (eg, "30% for Diagnostic 1, 70% for Diagnostic 2"), and the "difficult" case required evaluating several potential diagnoses with similar likelihoods (eg, "20% for Diagnostic 1, 30% for Diagnostic 2, 40% for Diagnostic 3, and 10% for Diagnostic 4"). These levels were designed to align with the levels of difficulty identified by physiotherapists in the study by Josephson et al [26] on low back pain. Clinical cases were presented as questions to be asked (eg, "What is the patient's height and weight? 1.85 m, 80 kg"), reflecting medical practice where patient details are revealed through inquiry, encouraging multifaceted thinking [43]. The clinical cases were reviewed for consistency by a physiotherapist and a GP, with radiologists consulted on specific details. After implementation in a digital tool, they underwent a second evaluation by 4 independent physiotherapists using the same criteria. Full cases are available in the Multimedia Appendix 2.

Following the initial validation, the clinical cases were implemented in Microsoft PowerApps, a platform for developing tailored applications. They were presented in the order of "easy," "difficult," and "medium," following reviewer feedback to enhance engagement and reduce decision-making bias. Each case began with essential patient details (eg, "a 27-year-old male comes in for low back pain"), similar to what patients typically share at the start of an appointment, followed by a list of questions categorized into anamnesis, physical examination, and treatment options. Participants could view answers in real-time, simulating a clinical report-writing process (see screen "clinical case screen with 'question or answer' format" in Table 1).

After each case, subsequent screens prompted participants to select the most appropriate intervention from predefined options before moving on to the next case. The scoring grid for treatment strategies was developed based on expert consensus, distinguishing between initiating treatment and maintaining vigilance (Table 2). Participants could access additional test results (ie, x-ray, computed tomography scan, magnetic resonance imaging, scintigraphy, and blood tests) via a dedicated screen, with reminders on judicious use to avoid unrealistic overuse. A button allowed them to return to the treatment strategy screen, though accessing the results screen was recorded. On the next screen, participants selected their suspected diagnosis from a predefined list based on scientific literature and the *ICD-11* (*International Statistical Classification of Diseases, Eleventh Revision*) [32,44,45], with an "other" option allowing written input. They also rated their confidence in the diagnosis on a 0-100 scale, from "not at all confident" to "fully confident." Following the clinical cases, participants rated the realism and difficulty of each case on scales from 0 ("low realism or difficulty") to 100 ("high realism or difficulty"). These ratings were assessed after all 3 cases to provide

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participants with reference points for comparison, while minimizing the influence of any single case on the evaluation of the others.

Finally, participants were invited to share sociodemographic data by completing blank fields, including age, profession (ie, to confirm they were physiotherapists), country of practice (ie, to explore potential differences across regions), graduation year (ie, to approximate experience level), and gender (ie, via a drop-down menu with "male," "female," "do not wish to answer," and "other" and a custom field). They could also optionally share their email address.

Table 2. Scoring grid of strategies for each case[a].

	Easy case	Medium case	Difficult case
Beginning of physiotherapy treatment	2	0	0
Beginning physiotherapy treatment while maintaining a high level of vigilance	1	2	1
Referral to a physician without starting physiotherapy treatment	0	1	2
Emergency medical referral	–1	–1	–1

[a]Scoring was based on the notion of distance from a correct answer. A score of 2 was assigned to the strategy considered to be the most appropriate for the case presented. A score of 1 was assigned to the strategy considered to be good but not optimal. A score of 0 was assigned to the strategy considered to be neutral in that it has no harmful effect but no real positive effect. A score of –1 was assigned to the strategy considered to be contraindicated. This grid, based partly on the views of the Delphi experts, was devised by 3 physiotherapists by joint agreement.

Statistical Analysis

First, we performed our main statistical analyses (1) on the therapeutic strategy chosen by HCPs to assess their suitability for each case and identify factors influencing HCPs' choices (ie, with a frequency table and linear regression model). The goal was to confirm that most participants chose the correct strategy and assess the impact of their intolerance of uncertainty level and resource use on their choices. Then, (2) regression analyses were performed to see whether physiotherapists' level of intolerance of uncertainty influenced their resource consumption. Then, correlational analyses were conducted to determine whether physiotherapists' confidence was related to (3) the therapeutic strategy they chose and (4) to their level of intolerance of uncertainty.

For the secondary analyses, (5) frequency analyses were performed on participants' confidence in their choices, level of realism attributed to the cases, and level of difficulty attributed to each case. The aim was to quantify participants' level of confidence, ensure cases were rated realistically (ie, above 70 on the provided scale), and confirm increasing difficulty across cases.

Finally, we conducted exploratory analyses by performing frequency analyses on the diagnoses selected by participants for each case. These analyses aimed to confirm that most participants identified the correct diagnosis and to ascertain that the number of selected diagnoses increased with case difficulty (as suggested in the "procedure and instruments" section).

Ethical Considerations

Ethical standards were upheld throughout the recruitment process, adhering to national and institutional guidelines, including the Helsinki Declaration. The CERGA (ie, Comité d'Éthique pour la Recherche de l'Université Grenoble Alpes) reviewed and approved this study without requiring additional precautions. A confirmation letter from the CERGA stating this is available from the authors upon request. Data collected from participants were anonymized, ensuring confidentiality, and participation was voluntary, with explicit consent obtained through a simple yes or no question regarding their willingness to participate ("Do you give your consent to participate in this study?"). There was no financial compensation for participation.

Results

Assessment of the Therapeutic Strategies Chosen and the Factors Influencing This Choice

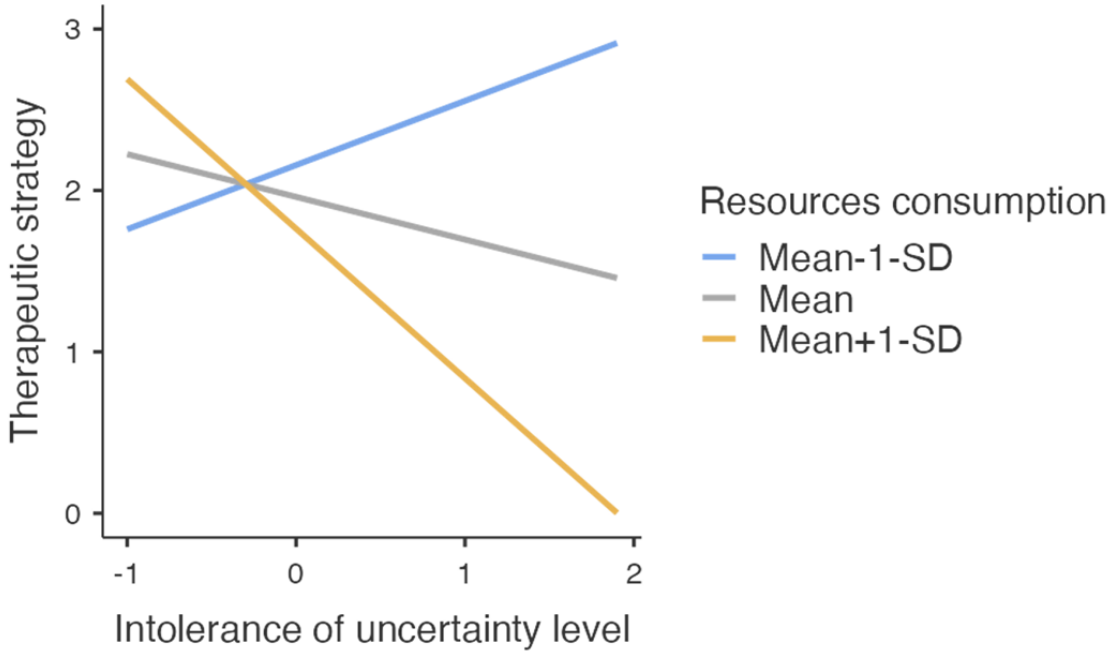
In the easy case analysis, 87.4% (111/127) of participants chose the most appropriate strategy (ie, beginning of physiotherapy treatment), 11.8% (15/127) chose the good but suboptimal strategy (ie, beginning physiotherapy treatment while maintaining a high level of vigilance), and 0.8% (1/127) chose the neutral strategy (ie, referral to a physician without starting physiotherapy treatment). No participants chose the contraindicated strategy (ie, emergency medical referral). Most participants did not use resources, with only 3.9% (5/127) requesting test results. Regression analysis revealed a significant negative effect of HCPs' intolerance of uncertainty on their selected therapeutic strategy (β=–0.26, t_{121}=–4.08, P<.001) and a significant negative effect of resource use on the selected strategy (β=–4.03, t_{121}=–3.92, P<.001). Specifically, resource consumption positively influenced the quality of therapeutic strategies for uncertainty-tolerant individuals (mean-1-SD, β=1.02, t_{121}=1.96, P=.053), but negatively impacted those with moderate (mean, β=–1.20, t_{121}=–5.91, P<.001), and low tolerance of uncertainty (mean+1-SD, β=–3.42, t_{121}=–5.09, P<.001, cf. Figure 1). Similarly, intolerance of uncertainty improved strategies when few resources were consumed (mean-1-SD), β=0.40, t_{121}=2.59, P=.011), but reduced quality with average (mean, β=–0.26, t_{121}=–4.08, P<.001), or high resource use (mean+1-SD, β=–0.93, t_{121}=–4.53, P<.001, cf. Figure 1). The model also included age, experience, and gender; however, none significantly influenced the chosen strategy (P_{age}=.90, $P_{experience}$=.73, and P_{gender}=.80).

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For the medium case, 46.5% (59/127) of participants chose the most appropriate strategy (ie, beginning physiotherapy treatment while maintaining a high level of vigilance), 28.3% (36/127) chose the neutral strategy (ie, beginning of physiotherapy treatment), and 25.2% (32/127) chose the good but not optimal strategy (ie, referral to a physician without starting physiotherapy treatment). The contraindicated strategy (ie, emergency medical referral) was not chosen by any participant. Just under half of the participants (54/127, 42.5%) requested test results. Regression analysis showed no significant effect of intolerance of uncertainty on the chosen strategy (β=–0.03, t_{121}=–0.19, P=.85), nor did age, experience, gender, or resource use significantly affect the chosen strategy (P_{age}=.74, $P_{experience}$=.70, P_{gender}=.72, and $P_{ressources\ consumption}$=.03).

In the difficult case, 41.7% (53/127) of participants chose the good but not optimal strategy for the case (ie, beginning physiotherapy treatment while maintaining a high level of vigilance), while 29.1% (37/127) chose the most appropriate strategy (ie, referral to a physician without starting physiotherapy treatment), 18.9% (24/127) chose the contraindicated strategy (ie, emergency medical referral), and 10.2% (13/127) chose the neutral strategy (ie, beginning of physiotherapy treatment). Resource use was again notable, with 44.1% (56/127) requesting test results. Regression analysis showed no significant effect of intolerance of uncertainty on the chosen strategy (β=–0.01, t_{121}=–0.71, P=.48), and other variables (ie, age, experience, gender, and resource use) did not significantly influence the chosen strategy (P_{age}=.65, $P_{experience}$=.60, P_{gender}=.51, and $P_{ressources\ consumption}$=.01).

Figure 1. Quality of therapeutic strategy chosen by level of intolerance of uncertainty and resource consumption. Uncertainty-tolerant physiotherapists (mean-1-SD, on the left of the graph) propose more appropriate therapeutic strategies (ie, in line with expert recommendations) when they consume a high level of resources (orange line) than when they consume an average amount (gray line), and even more so than when they consume a low level of resources (blue line). For physiotherapists with an average level of intolerance of uncertainty (mean, on the center of the graph), the chosen therapeutic strategy becomes increasingly appropriate as resource consumption decreases—that is, those consuming few resources select more appropriate strategies than those consuming an average amount, who in turn select more appropriate strategies than those consuming many resources. This pattern is most pronounced in uncertainty-intolerant physiotherapists (mean+1-SD, on the right of the graph), for whom low resource consumption leads to substantially more appropriate strategies than average consumption, which itself yields more appropriate strategies than high consumption.



Assessment of the Resource Consumption and the Factors Influencing This Choice

For the easy case, only 3.9% (5/127) of participants consumed resources (ie, examination results), with no significant effect of intolerance of uncertainty on their tendency to consume resources (β=–0.02, t_{122}=–0.56, P=.58), or other variables such as age, gender, and experience (P_{age}=.48, $P_{experience}$=.54, and P_{gender}=.66). For the medium case, 42.5% (54/127) of participants consumed resources, similarly unaffected by intolerance of uncertainty (β=0.14, t_{122}=1.55, P=.13) or age, gender, or experience (P_{age}=.70, $P_{experience}$=.64, and P_{gender}=.39). As for the difficult case, 44.1% (56/127) consumed resources, again with no significant effect of intolerance of uncertainty (β=0.01, t_{122}=0.06, P=.95), or other age, gender, and experience (P_{age}=.06, $P_{experience}$=.04, and P_{gender}=.57).

Assessments of the Relation Between Confidence and Therapeutic Strategy and Confidence and Intolerance of Uncertainty

Participants' confidence in their decisions was positively correlated with the quality of the therapeutic strategy chosen for the easy case (r=.41, P<.001), but negatively correlated for the medium (r=–0.31, P<.001) and difficult cases (r=–0.39, P<.001). Intolerance of uncertainty did not significantly correlate

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with confidence in decisions across all cases (easy: r=–0.08, P=.40; medium: r=–0.15, P=.09; and difficult: r=–0.09, P=.32).

Assessment of Diagnostic Confidence, Realism, and Difficulty for Each Case

Participants rated their confidence at an average of 75.7 (SD=17.16) for the easy case, 61.9 (SD=19.88) for the medium case, and 62.6 (SD=24.04) for the difficult case. The realism attributed to the cases averaged 86.5 (SD=18.64) for the easy case, 82.9 (SD=21.32) for the medium case, and 80.0 (SD=24.72) for the difficult case. Finally, difficulty levels were rated at 34.7 (SD=23.45) for the easy case, 48.8 (SD=23.81) for the medium case, and 55.0 (SD=24.22) for the difficult case.

Diagnostic Selected for Each Case

Diagnoses selected by participants for each case are shown in Table 3.

Table 3. Percentage of diagnoses selected for each case.

Diagnostic	Easy case	Medium case	Difficult case
Nonspecific low back pain (%)	120 (94.5)	8 (6.3)	23 (18.1)
Fracture of the L5[a] vertebral body (%)	0 (0)	0 (0)	4 (3.1)
Chronic or persistent lumbago (%)	4 (3.1)	21 (16.5)	12 (9.4)
Pain related to the sacroiliac joint (%)	0 (0)	27 (21.3)	11 (8.7)
Scoliosis (%)	0 (0)	9 (7.1)	0 (0)
Ankylosing spondylitis (%)	0 (0)	56 (44.1)	4 (3.1)
Muscle injury in the lower back or pelvis (%)	0 (0)	1 (0.8)	4 (3.1)
Abdominal aortic aneurysm (%)	2 (1.6)	0 (0)	1 (0.8)
Radiculopathy (%)	0 (0)	0 (0)	8 (6.3)
Metastatic bone disease in the thoracolumbar spine (%)	0 (0)	0 (0)	53 (41.7)
Other (%)	1 (0.8)	5 (3.9)	7 (5.5)

[a]L5: fifth and final vertebra in the lumbar spine.

Discussion

Summary of Results

Improving clinical reasoning requires understanding how factors such as intolerance of uncertainty influence therapeutic strategy selection. In this study, 127 physiotherapists evaluated 3 clinical cases of increasing difficulty and chose therapeutic strategies. We measured participants' intolerance of uncertainty and their consumption of resources (eg, additional test results) to assess how these variables affected their reasoning and strategy recommendations.

For the easy and medium cases, 87.4% (111/127) and 46.5% (59/127) of physiotherapists, respectively, selected the most appropriate strategy. In contrast, for the difficult case, 41.7% (53/127) chose a strategy deemed good but suboptimal, and participants considered a greater number of possible approaches. Regression analyses indicated that intolerance of uncertainty and resource consumption were significantly associated with selecting less appropriate strategies in the easy case (supporting hypothesis H1 only for that scenario), while no such associations appeared for the medium or difficult cases. Notably, high intolerance of uncertainty seemed to negatively impact strategy choice when resources were used, raising questions about the value of testing for these individuals, given its detrimental effect on treatment decisions and societal cost. Age, gender, and experience did not significantly affect strategy choice or resource consumption, consistent with the findings of Aron et al [46]. Regression models also showed no significant effect of intolerance of uncertainty on resource use across any case, failing to support hypothesis H2; this may reflect the French context, where physiotherapists cannot independently prescribe tests. Future investigations in systems granting prescribing rights (eg, Canada or Australia) or in France if regulations change [47] could clarify this relationship. For hypothesis H3, a negative correlation was found between the quality of the therapeutic strategy and the physiotherapist's confidence for medium (r=–0.31) and difficult cases (r=–0.39), indicating that physiotherapists remained confident despite not choosing the most appropriate strategies. This suggests a calibration problem, consistent with the literature on overconfidence among HCPs, although it relates here to therapeutic strategy rather than diagnosis. Conversely, for the easy case, a positive correlation between confidence and strategy quality likely reflects that most participants correctly identified the simple scenario, yielding good calibration. Hypothesis H4, which posited a positive relationship between intolerance of uncertainty and diagnostic confidence (anticipating that those less tolerant might prematurely close on a diagnosis and thus report higher confidence [13,48]), was not supported. This result may reflect sampling bias, as the study's demands likely attracted only the most motivated and confident participants, possibly skewing the findings. Future research could address this by including larger, more representative samples.

Secondary analyses revealed that participants perceived increasing difficulty across cases (34.7 for easy, 48.8 for medium, and 55.0 for difficult cases), with realism ratings above 80 for all cases (86.5, 82.9, and 80.0, respectively), suggesting reasonable validity for the cases designed in this study. Confidence levels decreased from 75.7 for the easy case to 61.9

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for the medium case and slightly rebounded to 62.6 for the difficult case, echoing Staal et al [49]. This pattern aligns with findings from Haber et al [11] regarding confidence distribution in clinical decision-making (ie, 5% of their sample was "very confident," 47% "confident," 42% "somewhat confident," 5% "not very confident," and 0% "not at all confident"). The unexpected dip in confidence for the medium case—despite its intermediate complexity—may reflect participants' lesser familiarity with its clinical presentation, a point we return to in the discussion.

Finally, exploratory analyses of diagnoses showed that most participants identified the correct diagnosis for each case, supporting the premise of the methodology that more diagnoses would be considered as case difficulty increased. Correct diagnoses fell from 94.5% (120/127) in the easy case to 44.1% (56/127) for the medium and 41.7% (53/127) for the difficult case, mirroring the confidence trend and underscoring the challenges of less familiar clinical scenarios.

Do Most Physiotherapists Recommend Good Therapeutic Strategies?

To contextualize our findings, we compare them with Jette et al [36], who reported correct therapeutic strategy rates averaging 87% for musculoskeletal conditions, 88% for noncritical medical issues, and 79% for critical medical conditions, and with Keller et al [37], who found a 71.2% rate of correct management decisions. In our sample, physiotherapists achieved 87.4% for the easy case—comparable to Jette et al [36]—but only 46.5% and 29.1% for medium and difficult cases, respectively. However, when combining the most appropriate strategies with those labeled "good but not optimal," success rates rose to 99.2% for the easy case, 71.7% for the medium case, and 70.6% for the difficult case, indicating that the sample was able to suggest strategies that were at least partially appropriate. Thus, while building on the work of Jette et al [36] and Keller et al [37], whose vignettes were concise and facilitated pattern recognition, this study contributes to the literature by offering scenarios that incorporated greater realism and complexity, including misleading information that required active information-seeking and critical evaluation. The high performance on the easy case underscores that familiar scenarios similar to those of Jette et al [36] primarily engage pattern recognition—a point explored further in the next section.

Despite these encouraging findings, additional benchmarks are needed to strengthen our conclusions. Forthcoming data from Lackenbauer et al [50] may offer further context, and future work should assess whether GPs and physiotherapists—who exhibit similar diagnostic accuracy [37]—differ in therapeutic recommendations. Although physiotherapists achieved relatively good rates when combining the most appropriate and good but not optimal strategies in our study, the selection of the most appropriate strategy decreased with increasing case difficulty. In addition, the medium and difficult cases yielded similar overall results, leading to hypotheses regarding the different treatment of medium and difficult cases compared to easy cases.

Hypotheses on the Differences Observed Between Cases

The 3 explanatory hypotheses warrant exploration in future research to clarify the observed differences between cases. The first hypothesis is based on system 1/system 2 theory by Kahneman [4,10,51-54], which posits that rapid, heuristic-based system 1 reasoning is effective when HCPs recognize familiar patterns, whereas slow, analytic system 2 reasoning is deployed for analytical thinking. The easy case likely activated system 1, enabling rapid identification of a common low back pain presentation [1]. Conversely, the medium (ie, ankylosing spondylitis) and difficult (ie, metastatic bone disease) cases were rarer in primary care [45,55], requiring analytic engagement (system 2). We hypothesize that the activated heuristics in system 1 made HCPs susceptible to external influences—namely, intolerance of uncertainty and resource use—whereas system 2's more deliberate processing in less familiar scenarios attenuated these effects [1]. Further research is needed to explore how these factors affect therapeutic strategies for less familiar clinical scenarios.

The second hypothesis relates to the concept of familiarity and the scope of practice of physiotherapists. Keller et al [37] found that specialization and exposure to similar cases increased recognition and the likelihood of suggesting appropriate therapeutic strategies. The simple case exemplifies this and may explain the high success rates observed. As such, a lack of familiarity with certain cases may exacerbate the effects of a physiotherapist's specialization. We did not collect data on participants' subspecialties (eg, pediatrics and maxillofacial), which may have influenced responses, particularly for cases outside their routine scope. Specialization should be controlled for in future studies, as it may have influenced physiotherapists' responses in difficult cases, reinforcing system 2 use.

Finally, the third hypothesis focuses on physiotherapists' perceptions of uncertainty. Although we did not directly measure perceived uncertainty, it can be hypothesized that the effects of intolerance of uncertainty and resource use were more pronounced in the easy case due to physiotherapists' engagement, while the medium and difficult cases, being less familiar, may have induced a higher perception of uncertainty, leading to disengagement. Previous research indicates that intolerance of uncertainty, more than perceived uncertainty, drives health care decisions [18]. However, perceived uncertainty might cause physiotherapists to disengage, leading to fewer optimal treatment choices and dampening the effects of intolerance of uncertainty and resource use. Future work should investigate how perceived uncertainty affects strategy quality, as it may reflect physiotherapists' engagement.

Limitations

Several limitations should guide future work. First, the generalizability of our findings is limited: different HCPs interpret and reason about clinical cases in discipline-specific ways [56], so the impact of intolerance of uncertainty on decision-making among other HCPs may differ, which questions the applicability of the results to other HCPs and warrants further studies. Second, although participants were made aware of resource usage without explicit restraint, we cannot conclusively determine how the instructions influenced their

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decision to request additional tests. Future studies could vary instructions regarding access to patient information to evaluate how these constraints affect clinical reasoning and strategy selection.

Regarding the methodology used, although we carefully implemented the clinical cases using a relevant tool, several limitations of this format must be acknowledged. First, participants could not revisit earlier choices, which likely heightened their focus on patient data compared to real practice. Future studies should vary these instructions to see how they affect consultation outcomes. Second, the on-screen presentation, which eliminated the need to memorize or record patient details, may have simplified the task. Using drop-down menus or incorporating audio and real imaging (eg, radiographs) would enhance ecological validity by mimicking real-world consultation dynamics [57]. Finally, although we included self-reported realism ratings, we did not undertake a formal validation of the clinical cases. Applying established frameworks—such as the validation grid by Downing [58] or the guidelines by Schmutz et al [59]—would strengthen the methodological rigor of case design.

Possible Improvements to the Tool

This study serves as a first step in understanding physiotherapists' clinical reasoning using digital consultation simulation tools. However, the assessment method could be enhanced by incorporating established frameworks for clinical reasoning evaluation. Daniel et al [34] identify 7 components—information gathering, hypothesis generation, problem representation, differential diagnosis, leading diagnosis, diagnostic justification, and management or treatment—that could be systematically measured and linked to therapeutic outcomes. Adapting the tool to capture these discrete elements would allow a more fine-grained analysis of participants' reasoning processes.

Incidentally, some measures could be expanded, notably as the IUS-12, which is the gold standard for intolerance of uncertainty assessment, comes with specific limitations. It does not capture how individuals represent uncertainty, react to specific uncertain situations, face different types of uncertainty, or in which cognitive domains they are particularly intolerant [60]. Moreover, self-report instruments are subject to social desirability bias and limited introspective accuracy. Although our observed range of IUS-12 scores indicates adequate variance, future research should triangulate self-reports with physiological measures (eg, skin conductance during uncertain scenarios), peer or supervisor assessments, and cognitive tasks combined with computational modeling (as in Sandhu et al [60]) to separate different forms of uncertainty and provide a more granular understanding of how uncertainty processing affects clinical reasoning. Additionally, incorporating attention-check items or repeated measures would further improve the reliability of the assessment.

Finally, revision of the tool could also involve updating the clinical cases and adding features. Cases 2 and 3 produced similar outcomes on multiple variables, suggesting that adjustments to their content or structure may be necessary to elicit distinct reasoning patterns. Enhancing immersion through expanded anamnesis (to replicate the breadth of history-taking) and replacing text-based test results with actual images could challenge participants' interpretive skills and yield more realistic cognitive demands. As interpretation depends on the specialist and the referral context [57], this change could alter HCP reasoning, increase game complexity, and affect perceived uncertainty. Furthermore, implementing a module for real-time tracking of diagnostic hypotheses—akin to the method by Pelaccia et al [61] of monitoring hypothesis evolution—would enable evaluation of how HCPs integrate new information and revise their strategies, linking hypothesis generation and diagnostic reasoning directly to therapeutic decisions and filling in this gap identified by Duong et al [35]. Implementing a similar module for therapeutic strategies could, for instance, help assess the influence of patient information or test results on the selected strategies.

Practical Implications for Resource Consumption and Management of Intolerance of Uncertainty

As noted by Infante-Guedes et al [20], research on physiotherapists' tolerance of clinical uncertainty is sparse, particularly regarding its impact on resource use and societal costs. Our findings suggest that HPCs with high intolerance of uncertainty may be prone to suboptimal resource use, especially in simple cases that rely on pattern recognition. Future studies should evaluate whether these effects extend to more analytically demanding scenarios or remain confined to familiar presentations. New studies on uncertainty tolerance and resource use should also differentiate effects by test, as HCPs with higher tolerance order fewer tests [62], and diagnosis probability adjustments vary by test [63]. Interventions that display the cost of diagnostic tests—such as a gamified approach by Ishizuka et al [64]—could heighten cost awareness and reduce test overuse.

Looking ahead, as the direct access paradigm expands in France [25,46,65,66], physiotherapists will increasingly make independent diagnostic and therapeutic decisions, directly influencing patient pathways and health care expenditures. Our results imply that intolerance of uncertainty may detrimentally affect treatment choices—particularly regarding additional testing—in trained physiotherapists. Further research should develop strategies to mitigate this effect, potentially through targeted training in uncertainty management, decision-making frameworks that emphasize cost-effectiveness, and feedback systems that highlight calibration between confidence and accuracy. Together, these strategies could improve the quality of care provided and ensure that physiotherapists are prepared to make informed decisions in an evolving health care landscape.

The Multimedia Appendix 2 includes the 3 clinical cases of increasing difficulty used in the methodology presented in this paper. The document "clinical case 1 (difficulty level: easy - suggestive of common non-specific lumbago)" presents the first case, the document "clinical case 2 (difficulty level: medium - suggestive of ankylosing spondylitis)" presents the second case and the document "clinical case 3 (difficulty level: difficult - suggestive of metastatic bone disease in the thoracolumbar spine)" presents the third case.

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Conceptualization: CB (equal), OZ (equal), AA (equal), LH (equal), PM (equal), JA (equal), NP (equal)
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Formal analysis: CB (equal), AA (equal)
Funding acquisition: AA (equal), LH (equal)
Investigation: CB (equal), AA (equal), LH (equal)
Methodology: CB (equal), OZ (equal), PM (equal), JA (equal), NP (equal)
Project administration: CB (equal), OZ (equal), AA (equal), LH (equal), PM (equal), JA (equal), RM (equal), NP (equal)
Resources: CB (equal), AA (equal), LH (equal)
Software: CB (equal), AA (equal), LH (equal), JA (equal)
Supervision: CB (equal), OZ (equal), AA (equal), LH (equal), NP (equal)
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Visualization: CB (equal), OZ (equal), AA (equal), LH (equal)
Writing—original draft preparation: CB
Writing—review and editing: CB (equal), OZ (equal), AA (equal), LH (equal), PM (equal), JA (equal), RM (equal), NP (equal)

Conflicts of Interest

None declared.

Multimedia Appendix 1
SVG images of the pictures in Table 1.
[DOC File , 7547 KB - rehab_v12i1e73818_app1.doc]

Multimedia Appendix 2
Clinical cases.
[DOCX File , 20 KB - rehab_v12i1e73818_app2.docx]

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Abbreviations

CT: computed tomography
GP: general practitioner
HCP: health care professional
ICD-11: International Statistical Classification of Diseases, Eleventh Revision
IUS-12: Intolerance of Uncertainty Scale-12
IUS-12-H: Intolerance of Uncertainty Scale-12 Health Care Professionals

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Human Guide Training to Improve Hospital Accessibility for Patients Who Are Blind: Needs Assessment and Pilot Process Evaluation

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Abstract

Background: People with disabilities are a priority population for health services research. People who are blind or have low vision (B/LV) are a segment of this priority population, who experience difficulty in accessing health care facilities due to architectural and navigational barriers. These barriers persist despite disability civil rights law in the United States.

Objective: The purpose of this study is to report on a program that was developed to train way finders in human guide technique for people who are B/LV.

Methods: This study took place at Michigan Medicine, an academic medical center in southeast Michigan. We conducted a needs assessment through cohort discovery and soliciting expert feedback. The human guide training program was developed using the PRECEDE-PROCEED health promotion program development model and targeted health care volunteers and staff. The intended components included in-person training, a web-based module, and tip sheets. Due to COVID-19, the in-person training was not implemented. We report findings from a process evaluation, measuring reach, knowledge, behavioral capability, and satisfaction pre- and postprogram.

Results: In total, 87 participants completed the training, and most of them were Michigan Medicine volunteers. There were significant improvements in behavioral capability related to the human guide technique. Participants were satisfied with the training and provided recommendations for more detailed demonstrations and scenarios in future training sessions.

Conclusions: The training improves participants' knowledge and confidence in providing wayfinding assistance to patients who are B/LV. However, further in-person training is recommended to provide hands-on experience and detailed feedback. Addressing architectural barriers and providing accessible patient education materials is crucial for improving health care accessibility for patients who are B/LV.

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KEYWORDS

low vision; wayfinding; human guide; accessibility; health services; patient education; rehabilitation; web-based training; visual impairment; orientation and mobility

Introduction

Background

Over 12.8 million adults in the United States report vision difficulty (ie, blind/low vision [B/LV]) [1]. This number is projected to increase as the population ages, in addition to an increase in chronic conditions that lead to being B/LV. For example, recent estimates indicate that the number of people who are legally B/LV over the age of 40 years in the United States is expected to double to more than 8 million by 2050, and another 16.4 million are expected to have difficulty seeing with correctable vision loss [2]. People who are B/LV are more likely than those who are not to have chronic conditions including diabetes, heart disease, hypertension, injuries, depression, and premature death [3-8]. The etiologies of B/LV are numerous and vary widely ranging from genetic, congenital, or acquired conditions, and may be stable or progressive. Patients who are B/LV require a comprehensive care coordination approach, which includes accessible health care facilities and health care providers with B/LV expertise.

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Disability civil rights law in the United States mandates accessible health care environments for people with disabilities, including people who are B/LV. The primary legislation addressing accessibility in health care settings is the Americans With Disabilities Act (ADA) of 1990 [9]. The ADA prohibits discrimination against individuals with disabilities in all areas of public life, including employment, transportation, public accommodations, and access to state and local government services. Regarding health care specifically, the ADA requires health care providers, facilities, and programs to ensure equal access for individuals with disabilities. This includes making reasonable modifications to policies, practices, and procedures to accommodate the needs of people with disabilities, providing effective communication, and removing architectural and other barriers that may prevent access. In addition to the ADA, other laws and regulations may also impact accessibility in health care settings, such as Section 504 of the Rehabilitation Act of 1973 and the Patient Protection and Affordable Care Act (ACA) of 2010. These laws further emphasize the importance of ensuring equal access to health care for individuals with disabilities. More recently, the ACA's Section 5307 mandates the U.S. Department of Health and Human Services to collaborate with external organizations to develop, evaluate, and disseminate curricula to address "cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities" [10].

Despite these mandates, patients who are B/LV experience disability-related accessibility barriers in health care settings [11-13]. Among these include inaccessible information, lack of communication support, navigational/wayfinding challenges, inaccessible medical equipment, digital accessibility issues, and attitudinal barriers. Print materials such as forms, brochures, and instructions are often not available in accessible formats, such as braille, large print, or electronic text, making it challenging for B/LV patients to access important health care information independently. Moreover, B/LV patients may encounter challenges in communicating with health care providers if there are no provisions for alternative communication methods such as screen readers for electronic health records, tactile sign language interpreters (for people who are DeafBlind), large print materials or audio descriptions of visual information and instructions [12]. In addition, patients who are B/LV may also encounter attitudinal barriers from health care providers or staff who may have misconceptions or lack awareness (due to lack of training) about the capabilities and needs of B/LV individuals, leading to stigma, discrimination, or inadequate care [12,13].

B/LV patients often encounter various architectural barriers in health care settings that can hinder their ability to navigate independently and access health care services effectively [12,14]. Architectural features such as narrow doorways, high thresholds, stairs without handrails or tactile indicators, and uneven flooring can pose significant challenges for B/LV individuals to navigate safely. Health care facilities with complex layouts, multiple corridors, and interconnected buildings can be particularly challenging for individuals who are B/LV to navigate independently without clear signage and wayfinding cues. This can make it challenging for B/LV individuals to find their way to reception areas, exam rooms, or other health care services [14]. Addressing these navigational barriers is necessary to ensure accessibility (and compliance with disability civil rights law) and requires addressing the environment through which a B/LV patient moves.

Orientation and Mobility for People Who Are B/LV

Overview of Orientation and Mobility

The process through which a person navigates indoor and outdoor environments is known as orientation and mobility. Orientation and mobility encompass a range of skills and techniques to understand one's surroundings, move around confidently, and achieve greater independence. In the case of people who are B/LV, orientation and mobility skills can be used to compensate for reduced visual information [15]. Orientation skills focus on understanding one's position within a given space, such as a room, building, or outdoor environment. Orientation skills help individuals create mental maps of their surroundings, including landmarks and spatial relationships, through training on auditory cues, feeling changes in terrain, and using other senses to gather information about the environment. Mobility skills focus on how individuals move safely and efficiently through different environments. This includes techniques for walking with a white cane or guide dog and using public transportation.

Orientation and mobility training teaches people who are B/LV how to problem-solve, facilitates independence when faced with challenges or unfamiliar situations, and is tailored to the individual's needs, goals, and vision loss. These skills are particularly important in environments that are not designed explicitly for accessibility, such as a hospital. Through using orientation and mobility skills, a person who is B/LV can find alternative routes, seek assistance from others, or use technology to gather information about the environment before arriving or in real time. Despite these benefits, not all people who are B/LV receive orientation and mobility training. To our knowledge, there are no prevalence estimates of the number of B/LV people who receive orientation and mobility training, but access to this training is impacted by the type of vision condition and other disabilities, access to social services, and geographic region [16,17].

Human Guide

A human guide (historically called a "sighted guide") is someone who assists a B/LV person in navigating their surroundings safely and independently. Human guides provide physical assistance and verbal guidance to help the B/LV individual move through various environments with confidence [18]. This assistance can be particularly helpful in unfamiliar or crowded settings where navigation may become challenging. Particularly, the use of human guides in health care may serve as a facilitator to patient wayfinding, ensuring B/LV patients can navigate architecturally complex and crowded hospital or clinic settings. Human guide technique (also known as "guide technique") is a method used by sighted individuals to assist B/LV or visually impaired people in navigating their surroundings safely and independently. It involves the guide providing physical support and verbal cues to aid the B/LV individual move through various

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environments with confidence. Tasks and responsibilities of the human guide include but are not limited to offering an arm, providing verbal directions, describing surroundings, and assisting with obstacles. It is most important for human guides to communicate effectively with the patient who is B/LV, respecting autonomy and independence while providing assistance in a supportive and respectful manner.

Overall Aim and Objectives

The overall aim of this study was to develop a program to improve navigational access for patients who are B/LV by developing and evaluating a human guide training for staff and volunteers at a large academic medical center in southeast Michigan. Specifically, our aims were to (1) develop and implement an in-person awareness and skill-building training for hospital staff and volunteers, teaching how to provide Human Guide technique; (2) adapt the in-person Human Guide training for electronic delivery via an asynchronous, web-based learning module; and (3) conduct a process evaluation of the in-person training and web-based (asynchronous video) learning module.

As described in the forthcoming sections, the in-person training was not implemented due to infection prevention precautions (related to COVID-19). Information on the design of the in-person training is provided to facilitate implementation by other health care organizations.

Methods

Setting

Michigan Medicine is an academic medical center operated by the University of Michigan Medical School. Located in southeast Michigan, Michigan Medicine operates a level 1 trauma center emergency department for adults and children, and operates an adult and children's hospital, and specialty centers in ophthalmology, oncology, and cardiovascular medicine.

Ethical Considerations

All activities involving human participants reported in this study were reviewed by the Medical Institutional Review Board at the University of Michigan and deemed quality improvement activities (HUM00208772). Therefore, the study was exempt from ethics review.

Needs Assessment

A needs assessment was conducted through two methods: (1) cohort discovery and (2) feedback from subject matter experts. These methods were chosen based on recommendations from the Centers for Medicare and Medicaid Services [19,20] to identify the number of people who are B/LV and identify barriers at points of contact throughout the health system.

Cohort Discovery

We identified the prevalence of patients who are B/LV within Michigan Medicine through DataDirect, a cohort discovery tool managed by the University of Michigan's Data Office for Clinical and Translational Research. DataDirect can be used for cohort discovery to estimate frequencies of patient groups based on specified criteria. For cohort discovery, we searched for the frequency of living patients who have an ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) or ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) diagnosis code indicating blindness or vision impairment.

Subject Matter Expert Feedback

Subject matter experts were solicited for feedback prior to the creation of the intervention. We met through the University of Michigan's Center for Disability Health and Wellness Accessibility Task Force, a group of researchers, clinicians, and staff at the University of Michigan and Michigan Medicine dedicated to improving accessibility for patients with disabilities. Experts included the (1) ASL (American Sign Language) Interpreter Services Supervisor, (2) Patient Civil Rights Coordinator, (3) ADA Compliance Officer, and (4) a community member who has low vision. We asked for feedback on the need for a patient accessibility program for people who are B/LV, and how this program might be developed and implemented.

Human Guide at Michigan Medicine Training Program

Situation and Priorities

The U.S. Centers for Medicare and Medicaid Services recommends that hospitals disseminate effective training programs to address barriers to health care accessibility for blind patients [20]. Prior to the implementation of the Human Guide at Michigan Medicine Program, there was no organization-wide training teaching skills to improve accessibility for patients who are B/LV. In addition, in mid-2021, clinic staff members reported to the Office of Patient Complaints and the Office of Patient Experience that blind patients were arriving late or missing their appointments due to wayfinding accessibility issues within Michigan Medicine facilities. This presented an immediate need for a program to be responsive to policy- and patient-level needs.

Initially, this training program was conceived as a collaboration between the Center for Disability Health and Wellness and the Office of Patient Experience, specifically the latter's HOPE Ambassador program. The HOPE Ambassadors are a group of volunteers who serve as on-site guides, assisting patients and visitors with navigating the health care facility. Before the COVID-19 pandemic, there were approximately 160 HOPE Ambassadors across 3 facilities who spoke 13 different languages. Given the HOPE Ambassadors' role in guiding patients and knowledge of routes within the hospitals, we determined that expanding their role to serve as Human Guides would serve the addressable need.

Concurrently with the conceptualization of this program, the Center for Disability Health and Wellness was leading the implementation of the Disability and Accommodations Tab: a standardized data collection instrument for patients to report disability-related accommodation needs through the electronic health record [21]. Navigation via a Human Guide is included in this questionnaire as a potential disability-related accommodation, and Human Guide–related skills are also applicable in the clinical setting; therefore, we decided to expand the scope of the training from HOPE Ambassadors to all Michigan Medicine staff and volunteers.

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Program Development

Program development was led by a Master Certified Health Education Specialist (MCHES) with 9 years of experience in health promotion program planning and evaluation, and 7 years of experience working with people who are B/LV (TGJ). An MCHES is a person who has demonstrated skills and training in health promotion program planning, implementation, and evaluation [22]. The core program planning group included stakeholders from Michigan Medicine's Center for Disability Health and Wellness (MMM, Co-Director), Michigan Medicine's Office of Patient Experience (Quinlan Davis, HOPE Program Coordinator), Michigan Medicine's Interpreter Services (Christa Moran, ASL Interpreter Services Supervisor), Ann Arbor Center for Independent Living (William Purves, Director of Planning and Program Development) who also provided a patient perspective, and a Certified O&M Specialist and Teacher of the Vision Impaired (Lori Board).

We applied methods from health promotion program planning, including aspects of the PRECEDE-PROCEED model [23,24], identifying stakeholders, developing a logic model, and aligning theory with program methods [25]. Typically, the PRECEDE-PROCEED model is applied to understand quality-of-life issues among a priority population (*social diagnosis*), and then an *epidemiological assessment* is completed before identifying modifiable predisposing, enabling, and reinforcing factors (*ecological assessment*) [24]. Through this process, program planners align administrative, policy, and educational interventions with changeable factors affecting the quality-of-life of the population. Given the established priority of developing a Human Guide intervention, which would be responsive to patient- and policy-level needs, we did not conduct the preparatory phase of identifying interventions to change behavioral antecedents. Instead, we focused on a high-need intervention with high probability of implementation—increasing the capacity of existing volunteers (eg, HOPE Ambassadors) and staff to improve accessibility for B/LV patients. A logic model of the program is provided in Figure 1, and theory alignment is provided in the next section.

Figure 1. Logic model of the Human Guide at Michigan Medicine program. Yellow indicates inputs and resources, green indicates processes, and blue indicates outcomes.

INPUTS	ACTIVITIES	OUTPUTS	SHORT-TERM OUTCOMES[a]	MEDIUM-TERM OUTCOMES[b]	LONG-TERM OUTCOMES[c]
• **Funding:** CDHW. • **Trainees:** OPE volunteers, other medical professionals. • **Staff:** evaluator, OMI and Blind trainer(s), HOPE Program Coordinator. • **Training materials:** curriculum, photographs, script for MLearning video. • **Space:** for physical training. • **Learning resources:** tip sheets, one-pagers. • **Promotional materials:** advertising the program. • **A/V equipment:** to record and prepare online training. • **CDHW website:** for learning resources and training promotion.	• **In-person training** for HOPE Ambassadors, OPE volunteers and staff, and high need staff. • **Online training** uploaded to MLearning future HOPE Ambassadors, medical assistants, and other Michigan Medicine staff. • **Online training** uploaded to YouTube for external stakeholders. • **Tip sheets and learning resources** for providing Human Guide hosted on the CDHW website.	• Number of HOPE Ambassadors and staff at in-person training. • Number of online trainings completed. • Number of website visits. • Number of tip sheet downloads.	• **Increase in knowledge** about the needs of patients who are Blind. • **Increase in the perceived confidence** in providing safe Human Guide technique to patients and visitors who are Blind. • **Increase in skills** to provide safe Human Guide technique to patients and visitors who are Blind.	• **Increase in the number** of patients and/or visitors **receiving Human Guide services** (among those who need it). • **Decrease in the number** of patients and/or visitors with Blind **reporting accessibility issues** to the Office of Patient Experience or Patient Complaints for related navigation barriers. • **Decrease in the number** of Blind patients **who arrive late** to their appointment. • **Decrease in missed appointments** among Blind patients.	• **Decrease in morbidity** among blind patients. • **Decrease in early mortality** among blind patients. • **Improve the quality of life** among blind patients and visitors.

Situation and Priorities:
- Align Michigan Medicine training opportunities with CMS recommendations.
- Clinical staff have reported immediate accessibility barriers for blind patients to OPE.
- CHDW mission: Develop and apply innovative educational strategies to address inequities.
- OPE mission: Ensure an ideal experience for every patient, every time, across the entire health system.

External factors:
- Patient transport at Michigan Medicine is unionized. Their role is different than that of Human Guides.

[a] Short-term outcomes are knowledge, attitudes, and skills.
[b] Medium-term outcomes are behavior and policy change.
[c] Long-term outcomes are changes/improvements in quality-of-life and health outcomes.
CDHW: Center for Disability Health and Wellness; OMI: Orientation and Mobility Instructor; A/V: audiovisual; OPE: Office of Patient Experience.

Program Components and Theory

The program had one overarching goal: increase the number of Michigan Medicine staff, volunteers, and contractors who have the skills to serve as Human Guides. To accomplish these goals, we intended to implement a three-component training program consisting of (1) in-person training, (2) a web-based, asynchronous learning module, and (3) a tip sheet or work guide. These three program components were designed to align with Social Cognitive Theory and theories of information processing (eg, the Consumer Information Processing Model) targeting behavior change constructs of behavioral capability, skills, and knowledge [25,26]. A description of how these constructs were applied in program development is provided in Table 1. As demonstrated in Table 1, the in-person training program targeted more theoretical constructs (compared to the web-based learning module) from Social Cognitive Theory related to behavioral capability (given the interactive nature of the in-person training).

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Table . Theoretical alignment and application in the in-person and video-based Human Guide training program.

Outcome	Theory	Theory-based method	Training component
Knowledge of Human Guide	Theories of information processing (eg, Consumer Information Processing Model and Cognitive Load Theory)	Alignment with information processing capacity	• In-person and video-based training: Teaching only the most important and useful points necessary to provide Human Guide safely and efficiently, thereby reducing information redundancy.
		Chunking	• In-person and video-based training: Providing instruction on different types of O&M tools used by Blind people, followed by providing Human Guide techniques under different scenarios.
		Using imagery	• In-person training: Training in a setting similar to clinical or real-world contexts. • Video-based training: Using images and videos that are similar to real-world Human Guide scenarios.
Behavioral capability and skills related to Human Guide	Social Cognitive Theory	Active learning	• In-person training: Alternating between didactic and interactive/hands-on simulations.
		Enactive mastery experiences	• In-person training: Increasing the challenge of simulated tasks to help indicate ability.
		Feedback	• In-person training: Providing direct feedback to trainees about their skills and opportunities to improve the Human Guide technique.
		Guided practice	• In-person training: Giving the opportunity for multiple repetitions of providing Human Guide technique, and debriefing with facilitators and peers.
		Modeling or observational learning	• In-person and video-based training: Providing examples (through demonstration) modeling Human Guide in specific scenarios.
		Verbal persuasion	• In-person and video-based training: Using messages that affirm the ability of participants to provide a Human Guide.
Awareness of Human Guide training	Diffusion of Innovations Theory	Observability	• Incentive for in-person and video-based training: Individuals who are not aware of the training program will observe their peers having a lapel pin and know they have adopted the training.

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The initial plan was to implement a training facilitated by a Certified Orientation and Mobility Specialist and B/LV cofacilitators. The training would be focused on delivering the most needed content knowledge and provide ample time for skills-based practice through roleplaying and simulations. The training curriculum covered the following core areas: (1) exposing trainees to the navigational wayfinding challenges experienced in health care settings; (2) differentiating between different conditions that cause blindness; (3) providing an overview of orientation and mobility for people who are B/LV, including the use of guide dogs; and (4) situations and techniques for providing Human Guide. The Human Guide-specific instruction included (4a) the general set-up of the Human Guide technique, (4b) providing Human Guide outdoors, (4c) navigating doorways, (4d) walking at a comfortable pace, (4e) approaching steps and taking stairs, (4f) taking elevators, and (4g) orienting in a waiting room. Throughout the training, the curriculum underscored the importance of maintaining patient or visitor autonomy by asking their preferences or wants.

The in-person training, however, was canceled after multiple scheduling attempts due to infection prevention concerns regarding the COVID-19 pandemic, and hospital restrictions on the number of volunteers permitted. The web-based learning module was designed as a very brief, asynchronous, video-based, nonexperiential training intended to serve as a "survival" training. This format and length were chosen to accommodate the busy schedules and workflows of clinical staff in Michigan Medicine. Video content was planned to be filmed at the in-person training; however, due to the aforementioned changes, we instead filmed at a Michigan Medicine clinical location. The in-person curriculum was shortened, but the abovementioned covered-areas remained the same. The training script and imagery were reviewed by subject matter experts, including a Certified Orientation and Mobility Specialist, for accuracy prior to distribution. The final training is available on the web, for free (see Data Availability section).

Program Advertisement

The program was advertised through the University of Michigan's Center for Disability Health and Wellness. The training was immediately integrated into the HOPE Ambassador program as required training prior to becoming a volunteer. Other avenues of promotion included (1) advertisement by MDisability, a family medicine clinical research program aimed at improving primary care for people with disabilities; (2) email newsletters through the Council on Disability Concerns at the University of Michigan; (3) on public-facing and internal websites; and (4) through the primary newsletter sent regularly to Michigan Medicine employees.

Process Evaluation

This study was designed as a process evaluation using methods common in health promotion program evaluation [27]. Process evaluations are a type of formative evaluation used to assess the quality and delivery of program activities and components. Although process evaluations can include a variety of measures, most process evaluations include measures of reach (ie, how many people received the program) and early indicators if the program is working as intended (ie, early impact indicators) [27].

In our process evaluation, we included four measures: (1) reach, (2) knowledge, (3) behavioral capability, and (4) satisfaction. Reach was measured based on the number of people who accessed and completed the training. Knowledge was operationalized through a 5-item program team-developed knowledge questionnaire focused on aspects included in the training (see Table 2). Participants were asked to respond to these knowledge questions as being true, false, or don't know. Incorrect and "don't know" responses were recoded as incorrect. Behavioral capability, or self-reported understanding of having the skill needed to complete a task, was asked through three items focused on (1) providing clear directions, (2) providing a human guide technique, and (3) providing a human guide technique with a service animal. Satisfaction was operationalized through three questions: (1) relevance to the organization, (2) overall satisfaction, and (3) recommending to colleagues. Behavioral capability and satisfaction questions were responded to on a 5-point Likert-type scale (ie, strongly disagree, disagree, neutral, agree, and strongly agree), with a score of 5 being "strongly agree." Individual questions are provided in the Results section.

Data were analyzed in the R statistical environment using JASP (Jeffrey's Amazing Statistics Program). We summarize the reach and knowledge questions using frequencies and percentages. We calculated means to describe behavioral capability and satisfaction. Pre- and posttest scores for behavioral capability were assessed for change using paired samples *t* tests with Cohen *d* effect sizes.

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Table . Trainee characteristics representing the reach of the human guide training program.

Characteristics	Values, n (%)
Affiliation with Michigan Medicine	
Unaffiliated	25 (29)
Nonpatient facing staff	7 (8)
Patient facing staff	10 (11)
Volunteer	45 (52)
Previously trained[a]	24 (28)
Advertising source[a]	
Center for Disability Health and Wellness	12 (14)
Office of Patient Experience	24 (28)
Recommended by a friend or colleague	24 (28)
Web search	8 (9)
ADA[b] technical assistance network	5 (6)
Other University of Michigan group	13 (15)

[a]One case missing (ie, analytic n=86).

[b]ADA: Americans With Disabilities Act.

Results

Needs Assessment

There are inadequate published definitions of diagnostic codes related to capturing patients who are B/LV. We used ICD-9-CM and ICD-10-CM diagnostic codes used by Ratakonda and colleagues [28] when studying potentially preventable hospitalizations among people with sensory disabilities. We identified that there were 55,159 B/LV patients who had an encounter in Michigan Medicine during the 2 years prior to the program (Table 3).

Subject matter experts agreed that navigating the health care system's clinics and hospitals was taxing on patients who are B/LV. The timeliness of addressing this issue was underscored by experts as the Office of Patient Experience recently reported there had been patients arriving late to appointments, despite having been on the premises before the appointment start-time, due to challenges visually navigating the environment. In these cases, not all patients were able to be worked back into the clinic's schedule leading to a delay in receiving care. In one instance, a complaint was escalated and social workers became involved to better support the patient.

Table . Patients with problem list diagnoses related to blindness.[a]

High-level diagnosis	Patients encounter between December 31, 2021, and January 1, 2023, n (%)	Total patients in electronic health record, n
Neurological vision impairment (eg, visual field defect and central scotoma)	6072 (53.2)	11,412
Retina	12,739 (50.2)	25,380
Age-related macular degeneration	25,977 (44.9)	57,912
Other vision impairments (eg, blindness and low vision, cortical blindness)	19,742 (54.3)	36,381

[a]Patients may be in more than one high-level diagnosis category.

Process Evaluation

In total, 87 people completed the web-based learning module and were included in the process evaluation dataset. These participants took the training between February 21, 2023, and December 31, 2023. The majority of these trainees were volunteers at Michigan Medicine (45/87, 52%). Over one-fourth (25/87, 29%) of trainees were unaffiliated with Michigan Medicine or the University of Michigan (eg, some trainees were from other states). Less than one-third of participants (24/87, 28%) had previously completed a human guide training. The most common advertising sources for learning about the training were from the Office of Patient Experience (24/87, 28%) and recommendations from friends or colleagues (24/87, 28%).

Completing the human guide training required scoring a 100% on the 5-item knowledge quiz; therefore, we did not calculate pre- and posttest score changes. At pretest, however, the most difficult question was "If a person identifies as blind, it is appropriate to call the person vision impaired" with almost 65% (55/85) of participants scoring incorrectly (see Table 4). This

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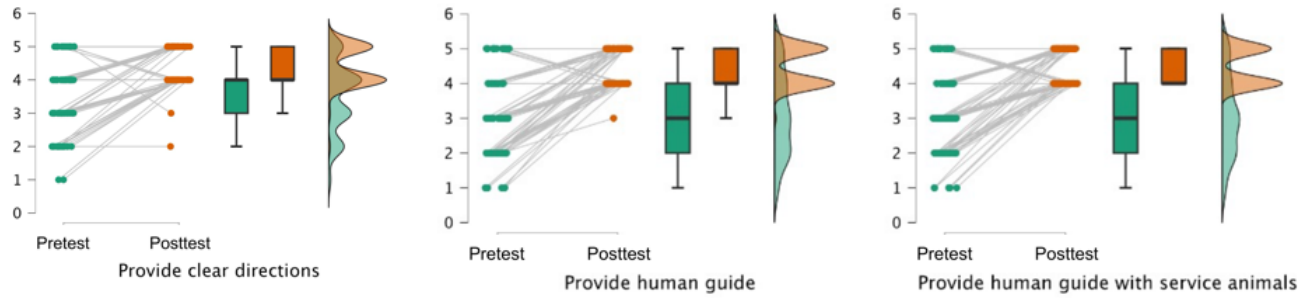
contrasted to knowledge related to not making noises to distract service dogs (correct: 79/84, 94%). There was a significant increase in self-reported behavioral capability of (1) providing clear directions, (2) providing a human guide (without a service dog), and (3) providing a human guide with a service dog. Effect sizes of the mean differences were high (*d*s>0.9) but expected given the immediate posttest nature of the survey. Rainfall plots of pre- and posttraining behavioral capability show that while there was large variability in pretest responses, the responses at posttest clustered around 4 ("agree") and 5 ("strongly agree"; see Figure 2).

Trainees reported being satisfied with the training (mean 4.5, SD 0.57) and would recommend it to their colleagues.

Table . Pre- and posttraining knowledge, behavioral capability, and satisfaction reported by human guide trainees.

Domain	Score
Knowledge (pretest), n/N (%)	
People with blindness cannot see at all. [False]	78/86 (91)
There is a legal definition of blindness and low vision. [True]	74/84 (88)
Age-related macular degeneration is a common cause of vision loss. [True]	71/85 (84)
If a person identifies as blind, it is appropriate to call the person vision impaired. [False]	30/85 (35)
When I see a service dog, I am permitted to make noises that may distract the dog as long as I do not touch the dog. [False]	79/84 (94)
Behavioral capability	
I can provide clear directions to patients/visitors who are blind/low vision.	
Pretest, mean (SD)	3.48 (1.04)
Posttest, mean (SD)	4.38 (0.60)
Cohen *d* (95% CI)	0.93 (0.64 - 1.21)
I can provide Human Guide technique to patients/visitors who are blind/low vision.	
Pretest, mean (SD)	3.12 (1.20)
Posttest, mean (SD)	4.50 (0.53)
Cohen *d* (95% CI)	1.09 (0.79 - 1.38)
I can provide Human Guide technique to patients/visitors who are blind/low vision, and who use service animals.	
Pretest, mean (SD)	3.07 (1.16)
Posttest, mean (SD)	4.50 (0.50)
Cohen *d* (95% CI)	1.23 (0.91 - 1.54)
Satisfaction (posttest), mean (SD)	
This training is relevant to providing patient care at Michigan Medicine.	4.56 (0.62)
Overall, I was satisfied with this presentation.	4.50 (0.57)
I would recommend this training to my coworkers.	4.58 (0.53)

Figure 2. Rainfall plots of pre- and posttraining behavioral capability as reported by human guide trainees. Green color indicates pretest scores and distributions, while orange color indicates posttest scores and distributions.



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Recommendations for Improvement

Participants were asked to provide feedback on how to improve the web-based learning module; 16 participants provided free-text comments. Although some of these comments were positive, most responses provided critical feedback about trainees' expectations and needs. These needs were well aligned with the goals of the in-person training, including more demonstration, enactive mastery experiences, and simulation in clinical settings.

> *I was a little confused about how to offer your hand and some other minor details about guiding, so a full video scenario would be helpful and just many videos of watching guides interact with patients over and over would help too.*

Trainees also indicated concern with navigating through doorways.

> *I would only recommend extending the camera view of walking through doorways. This is a hard skill and I was hopeful to have more of a view from both sides about how to best navigate in this area.*

Other comments indicated that the training was "informative, but also rather general." This trainee further indicated that additional practice would be needed for proficiency. Other trainees commented that they wanted to be asked additional knowledge questions related to human guide to ensure they understood the content. Lastly, three comments focused on platform or technology issues, including the training platform not allowing full screen for the videos and also a captioning error which was fixed.

Discussion

Evaluation Findings

Patients who are B/LV face obstacles in physically navigating health care environments, particularly complex and maze-like hospitals. These obstacles serve as barriers to effectively and efficiently engaging in health care and may implicate health care systems due to regulatory requirements with the ADA and ACA. Therefore, it is necessary to improve accessibility to effectively navigate health care facilities. The aim of this study was to develop a program to improve navigational access for patients who are B/LV by developing and evaluating a Human Guide training for staff and volunteers at a large academic medical center. Specifically, we aimed to (1) develop an in-person training, (2) adapt the in-person training for electronic delivery as a web-based learning module, and (3) conduct a process evaluation of both the in-person training and web-based learning module. As described earlier, we only accomplished Aim 2 and Aim 3. This web-based learning module focused on teaching human guide techniques to improve wayfinding assistance for people who are B/LV. This training was aligned with priorities set by the U.S. Centers for Medicare and Medicaid Services and needs in the local setting—particularly given the priorities to address poor patient experiences due to navigational barriers.

This early process evaluation suggests that the training is accurately targeting the intended skills and knowledge related to human guide technique. This training has also been adopted by the HOPE Ambassador program, improving the skillset of these wayfinding volunteers to meet the needs of people who are B/LV. The program could be improved, however. Results from the evaluation, and the early theory of change from the program, suggest the importance of providing in-person training allowing learners to practice human guide technique and receive just-in-time feedback. This would improve learners' experience and also aid in cementing knowledge and behavior change.

Improving wayfinding assistance through human guide does not address the root cause of navigational inaccessibility in health care settings. Addressing architectural barriers requires a proactive approach to accessibility in health care facility design and renovation, as well as ongoing efforts to improve wayfinding and navigation assistance for people who are B/LV. This may involve incorporating universal design principles, installing tactile signage and markings, ensuring clear pathways and accessible entrances, providing adequate lighting, training staff to assist patients and visitors who are B/LV, and providing web-based audio descriptions or tactile maps [29,30]. Some additional recommendations are provided in Textbox 1. By removing architectural barriers, health care facilities can create environments that are more inclusive and accessible for people with disabilities, including those who are B/LV.

Textbox 1. Recommendations to address barriers to inaccessibility in healthcare settings.

- Address architectural barriers including stairs without handrails, lack of tactile indicators and high contrast visual indicators, and narrow doorways.
- Provide educational materials in accessible and alternative formats (eg, large print and Braille).
- Expand medical education and training to include disability competencies.
- Improve accessibility and referral to orientation and mobility specialists.
- Install tactile nurse call buttons and audible entry alarms in patient rooms.
- Ensure physical and electronic signage is in large print, high contrast, and low glare.
- Design spaces with attention to lighting, windows, and flooring and the amount of glare.
- Facilitate wayfinding through use of floor guides with visual and tactile indicators (eg, follow the black line to get to radiology), audible alerts in elevators and doorways, and the use of mobile GPS.
- Enable website and portal customization options (eg, increasing font size and contrast).
- Work with patients and visitors who are blind/low vision to identify and address accessibility concerns.

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Limitations and Recommendations for Future Programs

There are several limitations to our program and program evaluation. The lack of full program implementation due to infection control policies led to potentially missed opportunities to provide just-in-time feedback to trainees on how to improve their human guide technique. This would have been responsive to trainee's needs, as indicated by the open-ended feedback. Despite this, the web-based learning module was liked by participants and had an associated increase in perceived behavioral capability. Still, we lack medium- and long-term outcome measurement. Collecting medium-term outcomes was too burdensome for this resource-limited training, particularly given the low incidence of patients and visitors needing human guide. In addition, the immediate pretest and posttest design is known to inflate effect size measures. To address these limitations, we recommend that future human guide trainings consider hosting an in-person training, in addition to web-based videos, and also consider longer posttest observations. The evaluation of this training could also be improved by reducing reliance on self-reported knowledge and behavioral capability, and instead use an observation checklist to evaluate trainees' skills. Orientation and mobility specialists may be particularly well-suited to evaluating trainee skills. This could serve a dual purpose as a data source and a feedback mechanism.

Conclusions

Patients who are B/LV experience barriers to physically navigating health care environments. Human guide is a technique that can be used to assist blind patients navigating the environment. Participants who completed our very brief, web-based video learning module reported improvements in behavioral capability with providing human guide technique to patients who are blind. We recommend the implementation of disability competency trainings in health provider preparation programs, and as required trainings for staff and volunteers working in clinical settings.

Acknowledgments

This program was funded by the University of Michigan's Center for Disability Health and Wellness which received support from the University of Michigan Medical School. We would like to thank Mark Hymes and Lori Board for their assistance with developing the program. We use both disability- and person-first language in respect for the differing perspectives of community members.

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Data Availability

Data from this study are not available for secondary analysis. The training is freely available at [31].

Authors' Contributions

Conceptualization: TGJ, CM, MMM
Formal analysis: TGJ
Funding acquisition: TGJ
Investigation: TGJ
Methodology: TGJ
Supervision: MMM
Writing – original draft: TGJ, SH
Writing – review & editing: TGJ, SH, CM, SD, MMM

Conflicts of Interest

None declared.

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Abbreviations

ACA: Patient Protection and Affordable Care Act
ADA: Americans With Disabilities Act
ASL: American Sign Language
B/LV: blind/low vision
HOPE: Helping Our Patients Everyday
ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-9-CM: International Classification of Diseases, Ninth Revision, Clinical Modification
JASP: Jeffrey's Amazing Statistics Program
MCHES: Master Certified Health Education Specialist

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Original Paper

Challenges and Opportunities of the Human-Centered Design Approach: Case Study Development of an Assistive Device for the Navigation of Persons With Visual Impairment

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Abstract

Background: Visual impairment (VI) significantly impacts quality of life, particularly in autonomous pedestrian navigation. Limitations in independent navigation lead to frustration, diminished confidence, and risks to bodily integrity for individuals with VI. In Colombia, the pilot country of this study, approximately 2 million people live with some form of visual disability. Globally, only 1 in 10 people requiring assistive devices have access to them, with factors such as deficient product design stemming from limited knowledge of user expectations, local needs, and environmental constraints, posing significant challenges, particularly in low- and middle-income countries.

Objective: We aimed to evaluate the feasibility and limitations of applying the human-centered design (HCD) principles outlined by the International Organization for Standardization (ISO) 9241-210:2019 standard in assistive technology (AT) development for individuals with VI in Colombia.

Methods: We developed a prototype navigation device using the HCD principles, emphasizing a thorough analysis of user needs and environmental contexts. The project leveraged multidisciplinary collaboration to address challenges associated with user engagement and design adaptability while managing legal and bureaucratic constraints. The navigation system integrates artificial intelligence algorithms, specifically developed by the research team as part of this work, to enhance its adaptability and responsiveness to diverse environments. The development process featured iterative prototyping cycles, incorporating user feedback at each stage, all within the boundaries of applicable regulatory frameworks.

Results: The development and evaluation of the initial prototype highlighted both the feasibility and key limitations of applying the ISO 9241-210:2019 HCD principles in AT for individuals with VI in the Colombian context. The prototype met several user-defined expectations by prioritizing affordability; extended battery life; autonomy in internet-constrained environments; and

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improved ergonomics, concealability, aesthetics, and obstacle detection. These achievements demonstrated the potential of HCD to guide context-sensitive innovation. However, the process also revealed significant barriers: limited legal and procedural clarity for engaging users in design phases, difficulties navigating ethics committees, and a lack of practical guidance within the ISO standard itself. These constraints, compounded by challenges in interdisciplinary collaboration, limited the depth and adaptability of user involvement across development stages.

Conclusions: Implementing HCD principles in AT development shows promise for creating effective and affordable solutions tailored to user needs and contexts. However, legislative and methodological barriers must be addressed to fully realize HCD's potential. Future efforts should focus on aligning research methodologies with hardware and software development practices while integrating legislative frameworks to enhance the accessibility and effectiveness of AT innovations.

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KEYWORDS

artificial intelligence; assistive technology; blindness; context; disability; electronic travel aid; human-centered design; navigation; low and middle-income countries; LMICs; user-centered design; visual impairment

Introduction

Background

Globally, over 1 billion people live with disabilities, with approximately 80% residing in low- and middle-income countries (LMICs) [1,2]. Disabilities are highly diverse, and individuals benefit from different types of technologies depending on their specific impairments. This paper focuses on pedestrian navigation technologies for individuals who are blind or have disabling low vision. Worldwide, there are 39 million persons who are blind and 246 million persons with moderate to severe visual impairment (VI) [3,4].

Persons with disabilities worldwide face a significantly higher risk of poverty compared to the general population [5]. For many, assistive technologies (ATs) are essential to performing daily activities that would otherwise be difficult or impossible. However, traditional approaches to designing such technologies often fail to reflect the lived realities of those in low-income communities. According to the World Health Organization, only 1 in 10 people in need of assistive products actually have access to them, leaving over 200 million individuals with VIs worldwide without access to assistive products [6]. This lack of access severely restricts their autonomy, social participation, and opportunities for education and employment, further reinforcing cycles of exclusion and inequality.

AT in the Context of LMICs

Technologies designed for high-income countries often fail to meet their intended impact when applied in LMICs [7,8]. This is particularly evident among individuals with disabilities, where AT devices, whether donated or purchased, face limited adoption, and even when adopted, they tend to have a short life span, that is, access to AT in LMICs can be as low as 3% [6,9]. Inadequate comprehension of the real-life experiences and daily challenges faced by individuals with disabilities in LMICs, coupled with limited awareness of infrastructure constraints and the implications of high maintenance costs, contributes to their exclusion. This hampers the development of sustainable AT solutions and limits the ability of individuals with disabilities in LMICs to lead fulfilling lives. It often begins early in the design process and can permeate the entire development chain, ultimately affecting deployment strategies and business models.

Existing Technology for Persons With VI in the Market

The simplest and most affordable electronic travel aids (ETA) for individuals with VI are ultrasonic canes and glasses. These systems use ultrasonic sensors to detect obstacles and alert the user with an audible signal. More sophisticated ETA systems provide users with detailed information about their surroundings. One of the earliest and best-known ETA models is the voice navigation system, which uses a camera to monitor the user's surroundings and uses an algorithm to process the data, converting it into a time-multiplexed auditory representation. Not all ETAs use audio signals; some use tactile interfaces, such as the AuxDeco system's front-facing display [10], or electronic signals, such as the BrainPort Vision Pro's tongue display [11]. A recent entry in the ETAs market is Biped [12], a system comprising a large harness that users must wear visibly on their shoulders, equipped with cameras and other electronic components that implement machine learning methods to assist users with VI in detecting obstacles and receiving GPS instructions. Unfortunately, more advanced systems come with significantly higher costs; the prices of most advanced ETAs range in thousands or even tens of thousands of US dollars (eg, AuxDeco: US $10,000 to US $15,000, BrainPort Vision Pro: US $8000 to US $10,000, and BIPED: US $5000).

With the widespread use of smartphones among individuals with VI, navigation such as RightHear [13] and Lazarillo [14] have become popular and affordable solutions for navigating urban environments. However, these only provide map or GPS information and lack real-time details about the surrounding area, such as collision warnings. In addition, they do not function in all environments, especially where GPS is unavailable, such as indoor spaces and rural areas.

Available Innovation

In recent years, significant research activity has focused on developing technological solutions to assist users with VI in outdoor pedestrian navigation. Despite notable advancements, current systems still fall short of providing comprehensive and robust support that fully meets the navigation needs of users with VI [15-18]. As the technology landscape evolves, addressing the unique challenges faced by these users remains a critical priority.

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A key limitation of current systems is their narrow scope in obstacle avoidance [17,18]. Despite a considerable amount of published research on obstacle avoidance, there remains a need for datasets representing the diverse obstacles encountered by users with VI. Current approaches often address only a subset of these challenges. More refined systems are needed to evaluate the level of hazard posed by obstacles and deliver appropriate instructions to the user [17-20].

In addition, most available navigation aids rely on audio feedback, typically through headsets, which may block important environmental sounds [15,18,21]. This issue can be mitigated using bone-conducting headphones, allowing users to stay aware of their surroundings [18,21].

Wearable navigation devices, although still rare, offer critical advantages [15-18,22]. The wearability of such devices is key, with options ranging from waist belts and glasses to handheld smartphones or a hybrid of both. Wearable devices are generally preferred as they free the user's hands and provide more stable image capture, making them a more practical and user-friendly choice for VI navigation.

In Multimedia Appendix 1 [23-38], we provide a comparison table summarizing the main characteristics of the analyzed related works, including the system developed in this study for reference. The table considers aspects such as indoor and outdoor use; night and day operation; short, medium, and large range operation; dynamic obstacle detection; the sensors used; the computation platform; object recognition capabilities (unevenness, low obstacles, high obstacles, and holes); and the data processing algorithm used. All of the works reviewed can deal with indoor environments, but not with outdoor environments [23-25,30,31,33]. Another environment-related property is that not all works reviewed are suitable for working in night conditions. Regarding the range of operation, most of the systems work up to medium range, but a few of them can work at large ranges [26,31]. Detecting and warning about static and dynamic obstacles is an important feature. However, it is very difficult to deal with dynamic obstacles properly, as shown in several studies [23,24,26,27,29-31].

In general, the most used sensor is the camera (RGBD [red, green, and blue, plus depth], monocular, or stereo). While cameras can be combined with other sensors, doing so imposes significant demands on the computing platform used, which, in most cases, corresponds to an embedded system. Some works [27,29,31] used smartphones, but this resulted in compromised computational power and limited access to additional features. Most of the reviewed works focus on detecting low-level objects. However, some [25,26,29,30] are able to detect both low and head-level obstacles. While navigation capabilities are increasingly gaining attention, integrating them with both low- and head-level obstacle detection is challenging, especially when user feedback is limited to audio alerts.

Context Matters in AT Design

Access to AT in LMICs can be as low as 3% [1]. The challenges in these contexts differ significantly from high-income countries, hindering AT implementation and adoption [2-4,9]. A primary barrier is cost—many AT devices are prohibitively expensive, with high import duties and maintenance costs further limiting affordability [2,5]. In addition, a lack of qualified personnel often results in misuse and premature equipment failure [2,6].

Beyond financial constraints, infrastructural and environmental factors exacerbate accessibility issues. Unreliable electricity, poor roads, limited water supply, and inaccessible architecture pose major obstacles [2,3,5]. Internet connectivity, essential for many modern ATs, remains scarce, creating a digital divide that limits access to even low-cost or free solutions [5,7]. Harsh environmental conditions, such as high temperatures, humidity, and dust, also shorten the life span of many AT products [6].

Market unpredictability in LMICs presents further challenges, with significant income disparities affecting sustainability. Successful AT deployment requires a deep understanding of local economic and cultural dynamics to ensure long-term adoption and availability [2]. Aesthetic considerations, user expectations, and safety concerns also play a critical role—people in high-crime areas often avoid using high-tech wearable ATs due to the risk of theft. Other common barriers include complexity, discomfort, and sensory overload, which contribute to low adoption rates [5,8].

This work focused on evaluating the implementation of a human-centered design (HCD) approach to enhance the development of an ETA by addressing limitations of the current literature, which include the identified barriers, contextual factors, and user expectations in Colombia (the pilot country). The resulting ETA prototype addressed the limitations of existing technologies by prioritizing cost efficiency, extended battery life, and autonomy in internet-constrained environments. Furthermore, our design enhanced comfort, aesthetics, concealability, and the accuracy of obstacle detection, specifically tailored to the local context.

Available Guidelines and Frameworks

User-centered design (UCD) approaches have become increasingly prominent in AT development in the past decade [39,40]. UCD has evolved as a design paradigm over the years, giving rise to various methodologies, such as user-centered, human-centered, and context-centered design, with the International Organization for Standardization (ISO) 9241-210:2019 standard for HCD being among the most widely recognized. The ISO 9241-210 standard [41] outlines the principles and guidelines for the HCD process throughout the design and development of interactive systems, with a focus on ensuring usability and user satisfaction. The key principles and activities of the HCD process are structured into different general phases, as described in Textbox 1.

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Textbox 1. Phases of the human-centered design process.

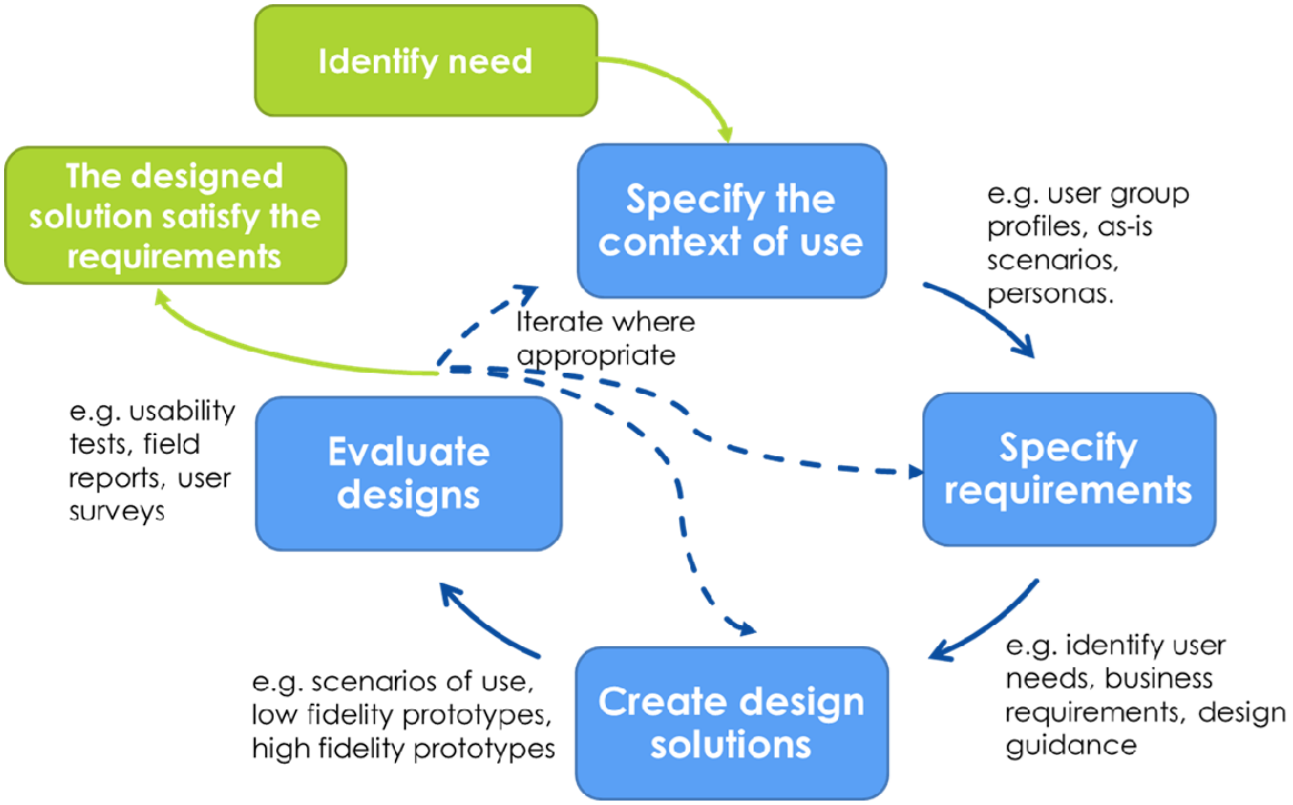
- Phase 1: "Understand and specify the context of use"—involves defining user characteristics, tasks, and goals, as well as understanding the conditions in which the product will be used.
- Phase 2: "Specify the user requirements"—focuses on comprehending user needs and expectations and establishing usability and performance criteria.
- Phase 3: "Produce design solutions"—entails the generation and refinement of design alternatives.
- Phase 4: "Evaluate designs against requirements"—involves usability testing and feedback assessment.

On the basis of evaluations, the design process iterates or progresses to the final product development stage if the requirements are successfully met. A schematic of the HCD process, as described in the ISO 9241-210:2019, is depicted in Figure 1 [41].

Despite the potential impact of implementing ISO 9241-210 in improving AT development and reducing the access gap, Ortiz-Escobar et al [42] found that it is poorly understood and rarely applied in the field of AT for persons who are blind. The review also highlights the lack of methodological rigor in participatory methodologies and the shallow inclusion of users' points when included. The study reveals that innovation tends to focus on system requirements, neglecting its users.

This paper addresses the knowledge gaps in implementing ISO 9241-210 HCD by reporting on an interdisciplinary action research project that combines applied philosophy with engineering sciences. We aimed to evaluate the feasibility and limitations of applying HCD principles in AT development

Figure 1. Schematic depicting the phases of the human-centered design process and its iterative nature, as described in the International Organization for Standardization (ISO) 9241-210:2019 standard.



Methods

Ethical Considerations

The research protocol was approved by the Swiss Federal Institute of Technology Lausanne on research involving humans (056-2021 and 068-2022), the Human Ethics Committee of Universidad del Valle (008-022), Hospital Universitario del Valle (029-2022), Universidad Autónoma de Occidente (01-2021), and Instituto para Niños Ciegos y Sordos del Valle (CEI-2022-02). All procedures were based on fully informed consent and ensured the anonymity of participants. Transportation and refreshments were provided, and each participant received COP 40,000 (approximately US $9) as compensation for their time.

Location: Pilot Country, Colombia

The vast majority of persons with disabilities live in LMICs, and they are disproportionately represented among the poor. Colombia offers the social and infrastructural diversity needed to enhance the relevance of this study.

Approximately 2 million people in Colombia live with some form of visual disability, representing over 4% of the country's

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population [43,44]. In this group, more than 80% live in poverty, and illiteracy rates are 3 times higher among individuals with VI compared to the general population [45].

Colombia is a signatory country to the Convention on the Rights of Persons with Disabilities. Although classified as a middle-income country, its socioeconomic diversity and regional infrastructure variations provide a rich context for drawing insights applicable to a range of low, middle, and high-income settings.

While Colombia has made significant progress in addressing accessibility for persons with disabilities, major challenges persist. Barriers include issues with roads (45%), sidewalks (28%), workplaces (18%), health centers (17%), and schools (15%) [46].

Testing the HCD

In this work, we implemented the HCD methodology to develop an initial prototype of a navigation AT for individuals with VI. This process followed one full iteration of the 4 design phases outlined in ISO 9241-210:2019 [41], as introduced in the previous section. The following section outlines how each phase of the HCD was operationalized in the context of our project.

Although this work constitutes one complete iteration of the HCD process leading to functional prototypes, its implementation was not linear. Due to significant challenges related to ethics clearance and national legislation (discussed in the results section), we were unable to engage end-users at the outset of the design process as envisioned by HCD principles. Ethics boards required highly detailed and finalized documentation—even for noninvasive, early-stage AT assessments. As a result, the team initiated a preparatory cycle to gather the necessary information for ethics submissions and to ensure continuity in the research and development timeline. This process is summarized in Table 1.

Table 1. Summary of the design process and methodologies implemented in this work.

Phase	Preparatory development cycle	Main UCD[a] cycle
Phase 1: specify the context of use	• Literature reviews • Internal expertise • Informal research interactions • Context study[b]	• User study (mixed methods approach): • Qualitative interviews (WG-SS[c]; 19 participants) • Semistructured interviews and focus groups (19 participants) • Focus group (5 participants) • User feedback on low-fidelity prototypes (19 users) • "Wizard of Oz" tests with users (19 users)
Phase 2: specify the user requirements	• Analyze data • Define initial requirements	• Analyze data • Refine requirements based on the user study
Phase 3: create design solutions	• Design concepts[b] • Refine design concepts using screening matrices and weighted rating techniques • Hardware low-fidelity[d] prototypes • Software test protocol[e]	• Refine the designs based on updated and validated requirements • Functional subsystems fabrication (camera casings, audio processing, etc) • Consultations: DPOs[f] and users • Subsystems integration and optimization • Functional prototype
Phase 4: evaluate the designs with users	—[g]	• Operational tests (head-level object identification, obstacle avoidance, and local navigation; 20 users) • Semistructured interviews (20 users)

[a]UCD: user-centered design.

[b]Multiple iterations.

[c]WG-SS: Washington Group Short Set of Questions [47].

[d]Evaluated by users during the user study phase.

[e]Assessed with users in the "Wizard of Oz" test.

[f]DPO: disabled persons organization.

[g]Transition to Main UCD Cycle–User Study.

During this preparatory cycle, initial design concepts were developed using literature reviews, internal technical and social science expertise, and informal research interactions. This adaptive strategy enabled the team to create contextually relevant documentation for ethics approval while simultaneously advancing hardware and software development.

Following ethics clearance, the project entered a formal user engagement stage. Hardware concepts were translated into low-fidelity prototypes, while the intended software interaction commands were structured into a test protocol. These prototypes were presented to users for direct feedback, and the interaction protocol was evaluated through "Wizard of Oz" testing to refine user requirements and system functionalities.

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In addition, during the technology development (phase 3), smaller-scale interactions with selected users and disabled persons' organizations (DPOs) were carried out. These engagements served to confirm key features and refine aspects of the developing functional technology, particularly in terms of usability, interface design, and contextual relevance.

Context Analysis

We used an action research approach [48] to accompany the technology development, addressing the fact that research into UCD implementation for persons with disabilities, including persons with VI, has largely been overlooked, despite its crucial role in improving well-being. We recruited participants through snowball sampling, facilitated by DPOs, cultural institutions, and rehabilitation centers. This method leveraged existing networks within these communities to identify and refer potential participants who met the study's criteria. We required eligible participants to be blind or have major VI, be aged ≥18 years, and be available to participate in at least three 1-hour interviews over 18 months. Recruitment continued until data saturation was achieved, ensuring comprehensive coverage of the research themes. To maintain a focused exploration of experiences specific to individuals with VI, participants with any additional disabilities were excluded. A detailed overview of participant characteristics is provided in Multimedia Appendix 2.

The study initially included 19 participants. We implemented a mixed methods approach: after collecting sociodemographic data, qualitative interviews were conducted to gain in-depth insights into individuals' lived experiences of impairment, their experiences using AT, and their freedoms and limitations. Furthermore, via semistructured interviews and focus groups, we explored how technology can help bridge the gap between the concept of well-being for individuals with visual disabilities and their current lived experiences. This information was used to inform the design phase of the AT project.

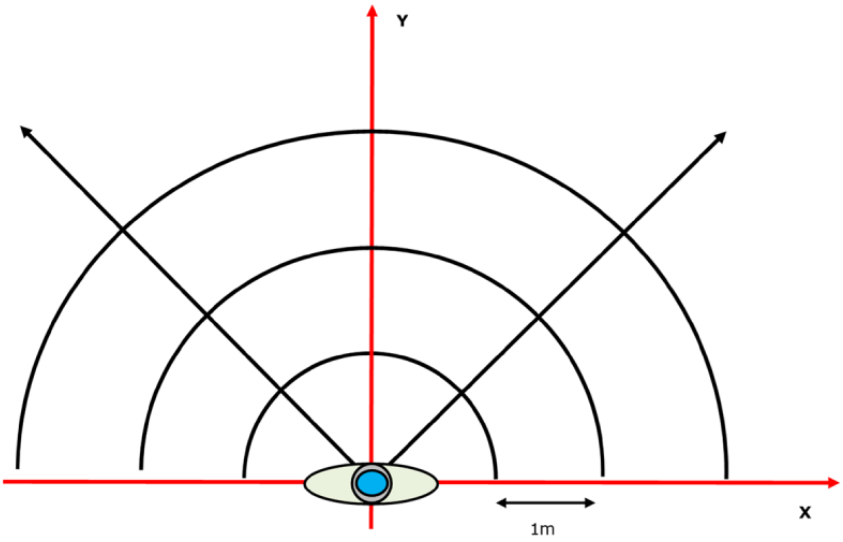
Subsequently, a focus group was conducted with 5 (26%) of the 19 participants, and the role of technology in their lives was explored in depth through questions on the following topics: (1) most frequently used ATs, (2) utility of technology, (3) the opportunities gained through it, (4) the desired opportunities, (5) the disadvantages or dangers of using technology, and (6) the characteristics that AT should have to enhance well-being.

All qualitative data were audio-recorded, transcribed, and analyzed using thematic analysis, following the approach outlined by Braun and Clarke [49]. This method supported an in-depth, flexible interpretation of the dataset, allowing for the identification of patterns of meaning across participant accounts. Two authors (LMO-E and MRV) independently coded a subset of transcripts and met regularly to discuss emerging codes and resolve discrepancies, thereby ensuring intercoder reliability. Disagreements were addressed through a consensus-based approach, with a third author (MAC) consulted, when necessary, although this was rarely required. We used strategies such as peer debriefing, triangulation with field notes, and maintaining an audit trail. Member checking was also performed with a subset of participants to verify the credibility of themes. Saturation was monitored throughout data collection and analysis and was considered reached when no new themes emerged from the last 2 interviews.

"Wizard of Oz" Test

The "Wizard of Oz" method is a well-established technique in human-computer interaction and early-stage product development. In this approach, users interacted with a prototype that appeared autonomous but was controlled by a human operator rather than the computer system [50,51]. This test was conducted with 19 volunteers with VI, using the setup illustrated in Figure 2 [52]. The procedure implemented is described in Textbox 2.

Figure 2. Ground plane view of the test pattern, with the participant with visual impairment positioned at the center of the coordinate frame.



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Textbox 2. Procedure implemented during the "Wizard of Oz" test.

1. The researchers read movement instructions to the participant with visual impairment (VI), simulating the guidance intended to be delivered by the developed navigation system. The participant with VI was exposed to four different types of instructions as follows:
   - Walking 1 m or 2 m forward.
   - Taking 2 steps in different directions (forward, left, diagonal-left, right, and diagonal-right).
   - Moving based on clock-hour directions (eg, 12-, 3-, 9-, 2-, and 10-o'clock positions).
   - Walking considering a virtual obstacle located at 1 m forward, left, diagonal-left, right, or diagonal-right.
2. The participant was instructed to perform the movements using their whole body, avoiding any independent torso movement.
3. The participant begins moving, initiating video recording.
4. Upon completing the movement, the video recording is stopped.

This procedure is performed for motions described in 1.1, 1.2, 1.3, and 1.4 and for all participants. For every motion, the participant starts from the same initial position.

The recorded video securely stored and processed using computer vision algorithms specifically developed for this study. The analysis includes measuring the distance traveled and the associated error, as well as assessing the orientation error using 2 predefined orientation methods.

Prototype Evaluation With Users

We conducted a user-perspective study with 20 participants. We initially invited those who participated in the first phase of the study, of whom 13 were available, and then recruited an additional 7 participants using the same inclusion criteria as in the first user study. We aimed to gather a comprehensive, user-centered perspective on the acceptability, appropriateness, ergonomics, and feasibility of the proposed assistive navigation system for individuals with VI.

The evaluation was conducted indoors in a controlled 6×9 m^2 test area covered by a tent (refer to Figure 3D). Each participant underwent a 2-hour session consisting of 3 operational tests—head-level object identification, obstacle avoidance, and local navigation—while wearing a selected design variant of the prototype. These tests were structured to validate the system's core functionalities (Textbox 3 [52]).

The evaluation also included a session in which each participant tried on and rated all available design variants—glasses, a cap, and a necklace—concluding with a semistructured interview.

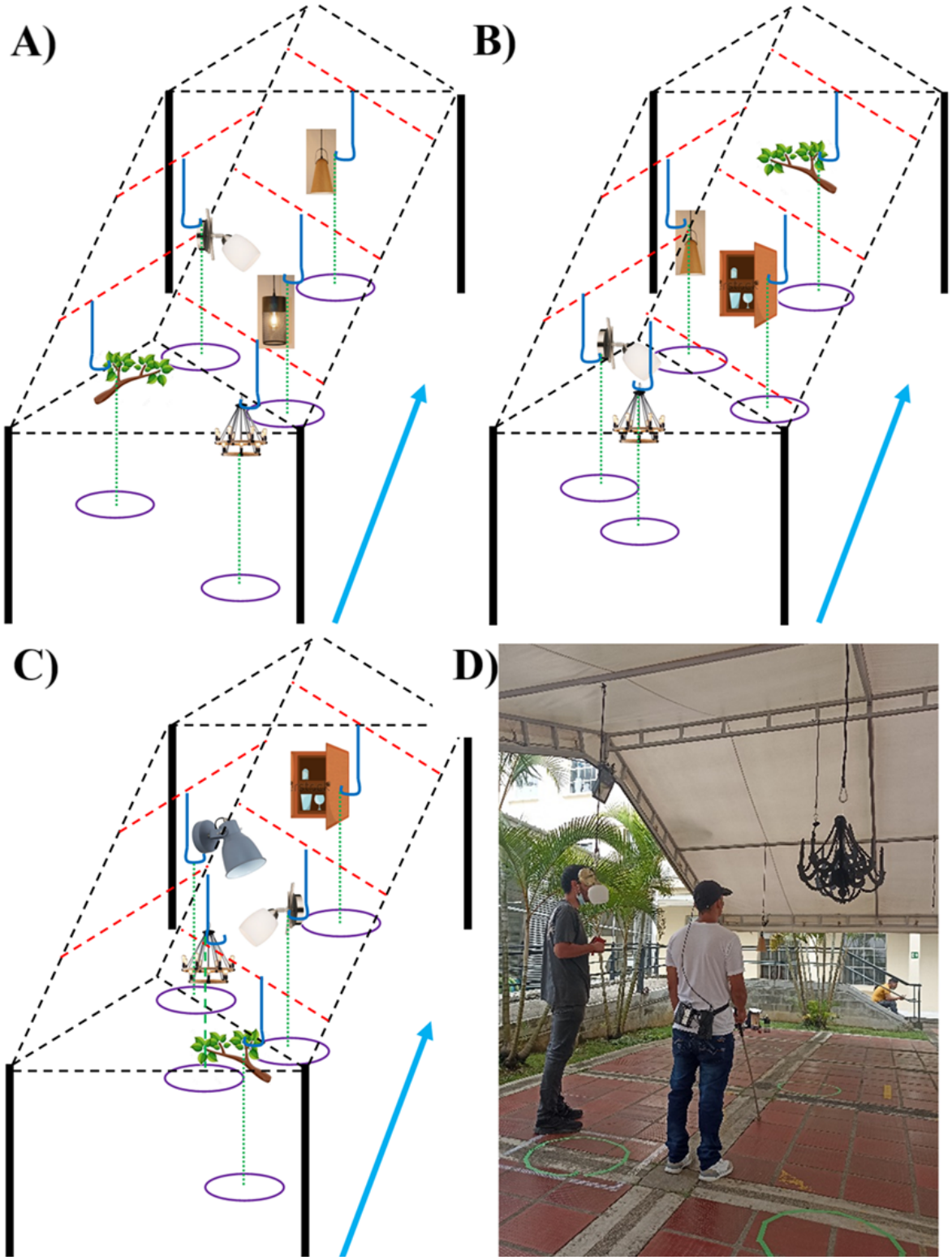
To ensure comparability, all operational tests were conducted using the same prototype variant: the cap, which had emerged as the preferred option in earlier evaluations. Although the glasses variant was appreciated for its aesthetics and integration, it was the least favored due to its weight and the resulting pressure on the nose. This feedback will inform future ergonomic refinements.

After each test, survey responses were collected, and all system data, including video streams, object recognition inferences, point clouds, and audio feedback logs, were stored in ROS bag format for subsequent analysis. Data collection followed a standardized file-naming convention, including user ID, date, time, and test name.

Each participant completed all 3 test scenarios in a randomized order to reduce learning effects. To further prevent participants from memorizing obstacle locations, the object configurations were altered between tests. The tests were conducted with the support of a companion and a test engineer, following a structured protocol to ensure safety and consistency.

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Figure 3. (A) Object configuration for the head-level obstacle identification test; (B) object configuration for the obstacle avoidance test; (C) object configuration for local navigation tests; and (D) photograph of the user perspective study test venue.



Textbox 3. Operational tests for prototype evaluation with users.

- Object identification: participants were guided to specific positions where the system described, via audio feedback, nearby head-level objects, such as tree branches or chandeliers (Figure 3A).
- Obstacle avoidance: participants walked through the space while receiving audio cues to detect and avoid obstacles (Figure 3B).
- Local navigation: participants were guided along a suggested path using real-time audio instructions to navigate around head-level obstacles (Figure 3C [52]).

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Results

Overview

This section summarizes the results of each phase of the HCD process implementation for developing a navigation system for individuals with VI, as described in the Methods section.

The project involved researchers from Colombia and Switzerland, with fieldwork conducted in Colombia. Before initiating the user and context study intended to guide the technology development, we secured support from several local DPOs. Each partner institution required clearance from its in-house ethics committee, often involving significantly different and uncoordinated processes, a common challenge, particularly in fragile research ecosystems.

A key finding concerns inadequate ethics clearance and legislation. Legislation and respective ethics committees in both countries mandated detailed, finalized research plans, even for assessing and approving noninvasive Class 1 medical devices with low-fidelity prototypes. Consequently, the research team could not formally involve end users until ethics clearance was obtained. This requirement led the team to propose a design based on literature reviews, internal expertise, and informal research interactions rather than the originally planned empirical research. Therefore, pursuing a linear application of the ISO principles proved impossible, a common observation in today's AT development literature [42]. Nonetheless, to align as much as possible with HCD principles, we conducted empirical research to identify user priorities after obtaining all ethics clearances, revealing several limitations as outlined in this section.

Phase 1: Specify the Context of Use

Findings on Perceptions and Personal Experiences

Our findings reveal a disconnect between available technology, such as ETAs, navigation apps, and ultrasound canes, and the users' needs and realities. Available products were of little or no use in the average urban environment due to damaged infrastructure, uneven terrain, or the complete absence of sidewalks in some areas. This limited utility persisted even in better-served areas due to governance and maintenance issues. For instance, traffic rules were frequently disregarded, rendering streets and available infrastructure, such as tactile paving, ineffective for persons with VI. In the social and personal sphere, interviews uncovered that few AT devices, such as the AuxDeco system and ultrasound canes, were available to persons who are blind via international donations to DPOs.

All users expressed dissatisfaction with the available technology, deeming it inadequate. Reasons cited for the nonadoption of the technology included (1) information saturation with irrelevant data, (2) difficulty and discomfort in use, and (3) drawing unwanted attention, making them feel different and excluded, akin to being labeled as "Robocop," as mentioned by many. These findings indicate that high prices are only one facet of the problem; even if the cost barrier is overcome, the devices fail to meet the users' needs. Moreover, the results unveil complex and concealed barriers faced by individuals who are blind, such as multidimensional poverty, discrimination, experiences of violence, and the association of visible technology with further stigmatization. Aside from dislike, users stated that using large, visible technology on the street exposes them to theft. They described cases of friends who have had their cell phones stolen and even shared experiences about their daily efforts to camouflage their technology use to avoid being robbed. This quote summarizes security risks linked to using technology in the streets:

> *I had a phone stolen because I was listening to the app to find out which route was coming.* [Participant 15A]

The complete results reporting on users' experiences and expectations on AT are reported in a previous study by Chavarria Varon et al [15].

Findings on Priorities, Opportunities, and Constraints

Participants prioritized technology that supported social connection and enabled greater bodily mobility. They emphasized that technologies that create social distance, by disrupting communication, obstructing physical interaction, or attracting unwanted attention and stigma, were considered unfit for purpose. Movement was a recurring theme in their narratives, with many expressing their frustration over limited freedom and the inability to fully experience their bodies in motion. Participants longed to engage in motor activities, such as running, cycling, dancing, and skating, often associating speed with a sense of vitality and freedom. Although many moved cautiously to avoid injury, there was a strong desire to reclaim and liberate their bodies through active movement, as evidenced in the following quote:

> *I would like to run...I can run, but I mean...going down some stairs fuuufff fast. That's something I can't do now. Running...or swimming. I can't swim in a river, I'm afraid of drowning.* [Participant 6A]

Most participants emphasized their desire for a device that is minimally invasive, enabling them to preserve their identity while using it. They stressed the importance of integration, minimal expression, and "street-proof" design to mitigate concerns about potential damage or theft due to its visibility.

Regarding the drawbacks and risks associated with technology, 2 main points were mentioned. First, participants expressed concerns about becoming overly reliant on technology. Second, they raised concerns about increased security risks, particularly in the local context. They noted that the more they relied on mobility-related applications, the less they exercised their orientation and mobility skills.

Regarding navigation in urban environments, some participants reported the condition of the streets as a difficulty for mobility. In some cases, the streets are unpaved, the terrain is uneven, and there are no marked areas for pedestrian traffic. Others noted that the sidewalks in the city are often occupied by cars, motorcycles, and sales stands, among others. These obstacles could be detected by properly using a cane. However, high obstacles, such as lattices, signs, fences, tree branches, umbrellas of street vendors, exterior snail-shaped stands, or the tops of fences, cannot be detected. These are just some of the objects

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with which participants reported injuring themselves while walking through the city.

To navigate more smoothly, several participants reported stepping off the sidewalk and walking along the edge of the road, despite the risk of being hit by a vehicle. While this strategy helps them avoid certain obstacles, it does not eliminate the risk of injury. For example, 2 participants reported damaging their glasses after colliding with the rear of a parked van. Such incidents typically occur on smaller streets but have occasionally been reported on main avenues as well.

Findings on Technology Implementation

The context study revealed a major gap between prototype development and market adoption of assistive and rehabilitation technologies for persons with disabilities in Colombia, an issue common in many LMICs. Most devices remain at the laboratory stage, with very few achieving local manufacturing or regulatory approval. Key barriers include weak collaboration among stakeholders, limited regulatory and commercialization expertise, and a lack of business focus in research. As a result, Colombia remains heavily reliant on imported technologies, which drives up costs and limits access. Strengthening local manufacturing could improve affordability and contextual relevance. Detailed results and analysis are presented in a previous study by González-Vargas et al [8].

Phase 2: Specify Requirements

Findings on User Requirements

Obstacle Detection and Avoidance

The AT should efficiently and promptly detect obstacles, guiding the user along a clear path to avoid them. The system should prioritize detecting high obstacles not detectable by the white cane.

User Comfort

All portable components should be compact, inconspicuous, and lightweight for prolonged wear.

Adaptation to Socioeconomic Context

To develop a solution applicable in numerous communities worldwide, the system should have the characteristics described in Textbox 4.

Textbox 4. Desired characteristics of assistive technologies (ATs).

Not depend on a continuous internet connection

- Assistive devices reliant on constant internet and GPS connection are impractical in rural areas or low-income neighborhoods with poor connectivity. Thus, the system must operate locally (not in the "cloud" or external servers) to function in locations lacking high-speed internet or GPS-denied environments.

Not put the user at risk

- All components must be easily concealable to reduce theft risk.

Be economically sustainable

- The AT's total cost should be less than 10 times that of similar market solutions. It should also use locally accessible materials and components and be easily maintainable.

Robust in tropical conditions

- The ATs should be able to withstand high temperatures and humidity.

Maintain autonomy

- The device should maintain prolonged energy autonomy.

Ease of Use

The device should feature an intuitive user interface that is easy to learn and operates independently. Audio interfaces are preferred over tactile ones for faster information acquisition without occupying the hands. In addition, the output audio interface should not impair users' hearing capacity.

Information Presentation

Data should be presented in a straightforward, concise, and easily understandable manner, aligning with findings from the "Wizard of Oz" test.

Aesthetics

Portable components should be visually appealing, with electronics easily concealable. Anything visually conspicuous, such as large electronic devices on their face, may be rejected. The design should be "aesthetically intelligent," skillfully harmonizing sensory attributes, contextual nuances, cultural significance, and functional effectiveness to craft products that evoke a greater sense of empathy from users [53].

Findings on the "Wizard of Oz" Test Outcomes

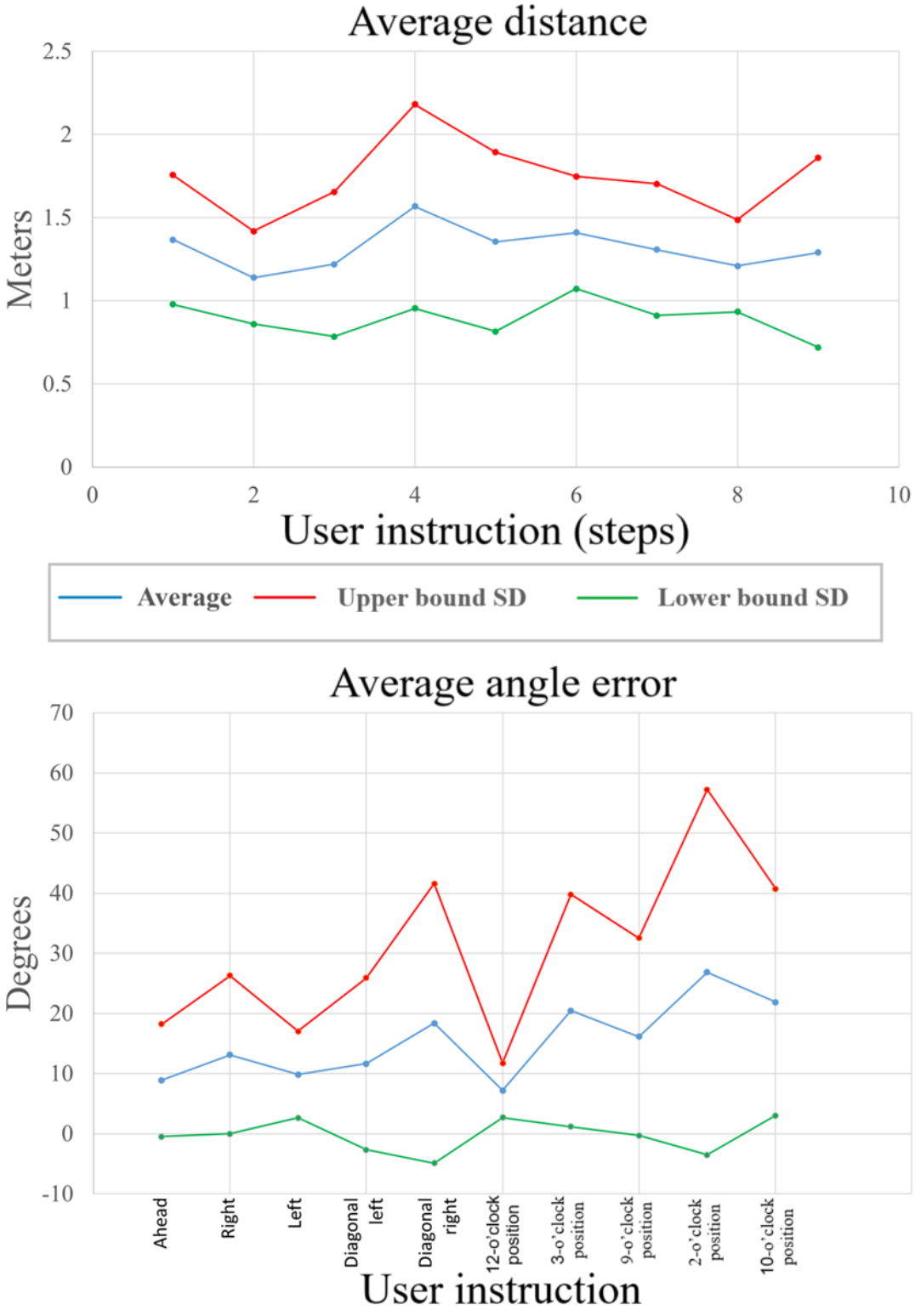
All the videos recorded in the "Wizard of Oz" tests were digitally processed to measure the distance, angle, and trajectory performed by the participants with VI (Textbox 5). Figure 4 presents the average distance traveled and the angular error for participants following the user instructions. The blue line represents the average, while the red and green lines indicate the upper and lower bounds of the SD.

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Textbox 5. Outcomes of the "Wizard of Oz" tests.

- Distance traveled: participants were instructed to move 2 steps in different directions, resulting in an average movement of 1.32 m, which aligns well with the calculation in Equation (1).
- Angular error: the angular error was measured relative to ideal orientation values (0°, 45°, 90°, 135°, and 180°). The first 5 orientation instructions ("go ahead," "to the right," "to the left," "diagonal left," and "diagonal right") demonstrated less confusion for participants compared to instructions using clock references (eg, 10-, 3-, and 12-o'clock positions).

Figure 4. Quantitative results of the "Wizard of Oz" tests. Specifically, the distance and angle average error.



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Figure 4 illustrates the average angle error for the 1.1 and 1.2 intersection subtests of the "Wizard of Oz" tests, as described in the Methods section. On the basis of the analysis of these results and the literature review, it can be concluded that the most effective way to provide distance and orientation information to users is through step counts and directional instructions (left or right, diagonal left or right, and front or back), as shown in Figure 5 [52]. Notably, clock-based directional instructions exhibit, on average, 50% more error compared to left or right, diagonal left or right, and front or back instructions. This angular error analysis supports the selection of the orientation instructions listed in Table 2, where orientation is converted from degrees to descriptive instructions.

The relationship between the range to the detected object and the number of steps required is defined by Winter [54]:



Where ρ_{obj} is the range to the detected object and $user_{Step}$ is the anthropometric measure of one step (in meters) based on the user's height.

Figure 5. Preferred orientation cues for individuals with visual impairment based on the "Wizard of Oz" test results.

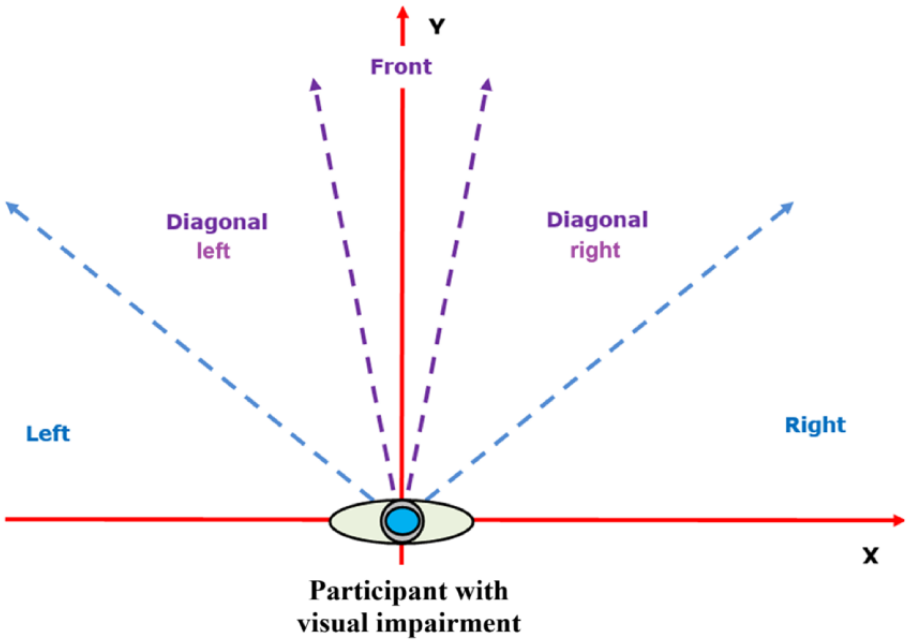


Table 2. Conversion table for orientation instructions.

Range (degrees)	Descriptive instruction
<50	Right
50-75	Diagonal right
75-105	Front
105-130	Diagonal left
>130	Left

Phase 3: Create the Design Solutions (Technology Development)

Overview

During the prototyping stage, user requirements defined in phase 2 were translated into measurable specifications, which guided the functional decomposition and benchmarking of key performance metrics. Following the design methodology proposed by Ulrich and Eppinger [55], we defined objective specifications, explored design alternatives using screening matrices, and iteratively refined the most promising concepts through early usability tests. Low-fidelity design variants were crafted and reviewed by the team and the users, leading to the selection and 3D printing of 3 wearable casing prototypes—glasses, a cap, and a necklace (Figure 6). To expedite early testing, the first functional prototype used off-the-shelf electronic components, enabling the collection of valuable user feedback in the early phases of the technology development without overcommitting time and resources to the development of customized electronics. Figure 7 illustrates the electronic components and their placement on the user's body. The ZED Mini stereo camera (Stereolabs), connected via USB and equipped with an integrated inertial measurement unit

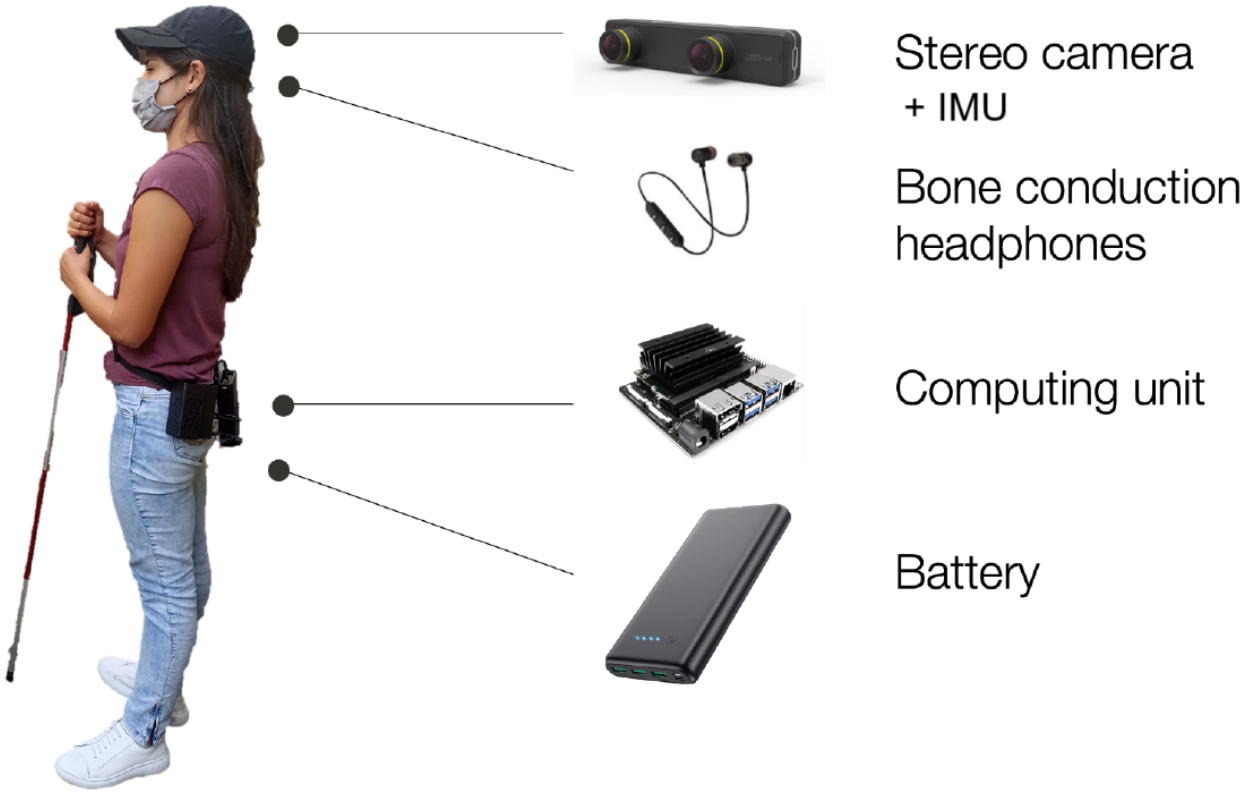
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(IMU), serves as the primary sensor. Data are processed by the Jetson Nano computing unit, which identifies head-level objects and delivers audio feedback via Bluetooth headphones (9 DIGITAL bone conduction Bluetooth headphones). The IMU helps filter frames not captured from the forward view. A battery pack powers the system, with the camera embedded in wearable accessories for aesthetic, comfort, and safety, while other components are carried on a waist belt.

Figure 6. Images of the manufactured casings for the functional prototypes.



Figure 7. Electronic hardware devices and their user-mounted positions in the proposed navigation system. IMU: inertial measurement unit.



Software Development

Addressing the user requirements in phase 2, and considering technical feasibility, and the necessity for the prototype device to be suitable for LMICs, the technical specifications were defined (Textbox 6), aligning with the rational unified process methodology [56].

Figure 8 illustrates the software architecture of the prototype, which operates in 2 stages: an offline stage for training a deep neural network, and an stage for real-time detection and classification of head-level obstacles using an optimized model deployed on a Jetson Nano.

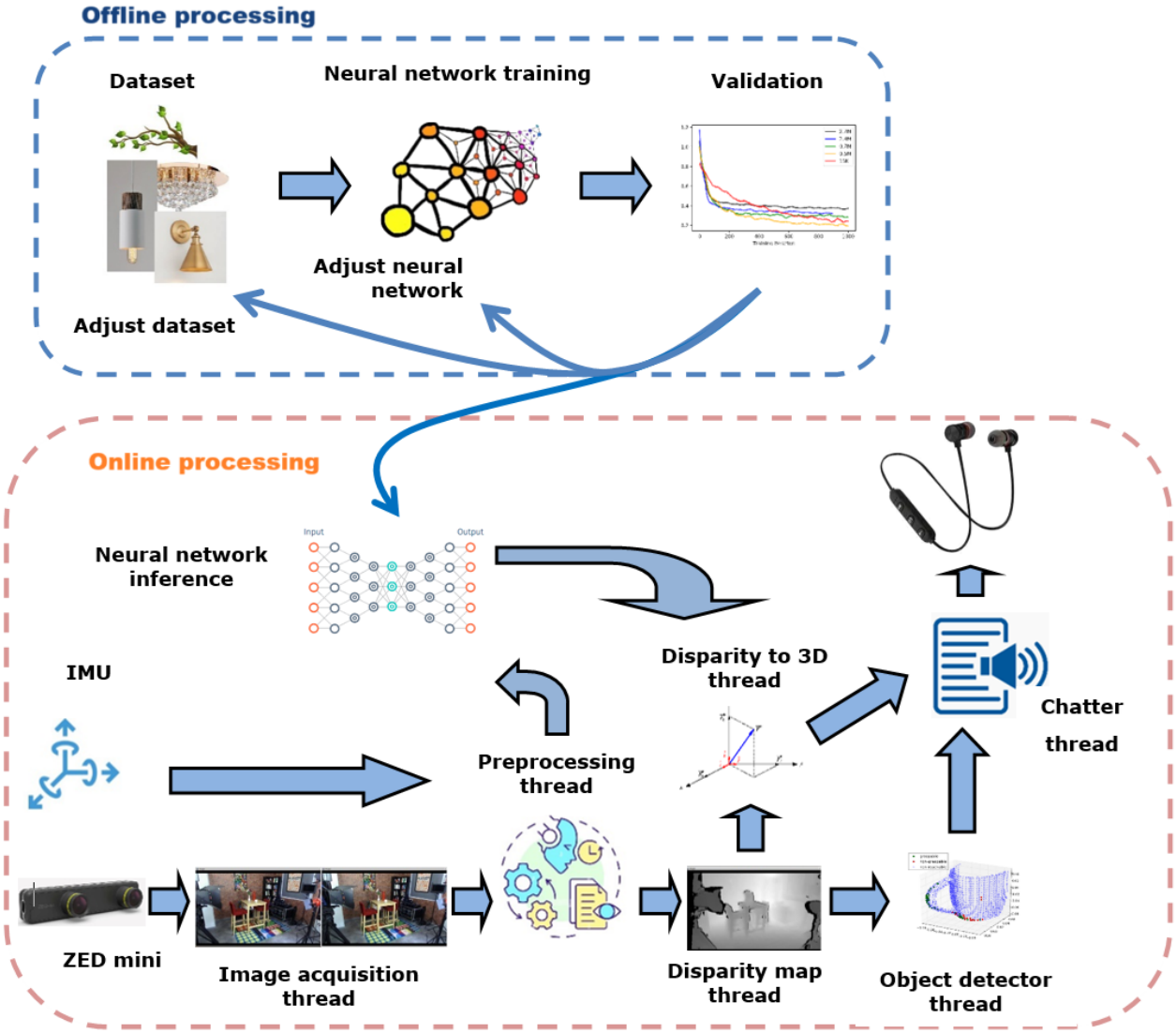
Stereo images are preprocessed to enhance quality; blurred images and those captured while the user is looking down (based on IMU data) are discarded. The cleaned images are processed by 2 components: the neural network inference node, which outputs object classifications and bounding boxes, and the disparity map node (based on Isaac ROS Image Pipeline [57]), which produces depth information.

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Textbox 6. Technical specifications of the prototype device.

- Perception data comprises stereo image and inertial measurement unit (IMU) data.
- Preprocessing improves image acquisition by excluding frames captured from nonforward perspectives using IMU data.
- The system will compute the relative distance between users and the nearest object using a disparity map obtained by processing stereo image pairs.
- The system will conduct the detection and classification of head-level objects, such as ceiling lamps, sconces, tree branches, and chandeliers.
- Other objects not classified by the neural network model will be detected as obstacles.
- The system will combine the detection results and the distance to object or obstacle estimates to generate audio alerts for users.

Figure 8. Conceptual diagram of the navigation prototype. The top section (blue border) shows the offline training phase, whereas the bottom section (red border) represents the online inference phase. IMU: inertial measurement unit.



These outputs feed into the disparity-to-3D node, which calculates the object's distance and orientation relative to the user. If the neural network fails to classify an obstacle, the object detector node uses the 3D point cloud to detect and segment unclassified but potentially dangerous objects. In both cases, distance and orientation are translated into navigation instructions. The prototype uses the disparity-to-3D node for path planning and the object detector node for obstacle detection. A comprehensive description of the software development process and system features is presented in the study by Muñoz et al [52].

Findings on Audio Interface

The audio interface integrates into the system software through the chatter node (Figure 8), which receives information from the 2 system operation modes (path planning and object detection modes) and transforms it into audio output.

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In the path planning mode, the input includes planned path directions from the system, generating corresponding audio instructions, such as "walk to the right diagonal," "walk straight ahead," and "stop." Alternatively, the system can provide the user with the number of steps required for the suggested path

In object detection mode, there are 2 inputs. The first comes from object detection by the deep neural model, you only look once (version 5), providing details about the detected object's classification, direction, and distance in steps from the user's position. An example of audio output is "Tree branch two steps to the right." The second input is obtained from local map detection, providing information about the distance (in steps) and direction of an unclassified object, for example, "Object two steps to the left diagonal." In addition, the chatter node generates extra audio warnings to enhance user-device interaction, including messages such as "low battery," "device shutting down," among others.

Navigation instructions are delivered to the user via a bone conduction headphone, which was chosen due to significant advantages, particularly for enhancing safety, improving spatial awareness, and facilitating a more intuitive navigation experience. One of the primary benefits of bone conduction headphones is their ability to transmit audio instructions while keeping the user's ears open to ambient sounds. This feature is crucial for individuals with VI who rely on auditory cues from their environment to navigate safely. Studies have shown that traditional headphones can obstruct environmental sounds, which may lead to dangerous situations, as users may not hear approaching vehicles or other hazards [58,59]. By contrast, bone conduction technology allows users to receive navigational audio cues while remaining aware of their surroundings, thereby enhancing their overall situational awareness and safety during navigation [21,60].

Phase 4: Evaluation With Users

Findings on Device Evaluation With Users

After analyzing the results of these tests, the object recognition achieved a 91% success rate on average. The risk of collision in obstacle-avoidance mode was low, with 80% categorized as low risk and 10% as medium risk. In the local navigation mode, the risk of collision was slightly higher, with 74% categorized as low risk and 13% as medium risk. Overall, users reported feeling comfortable with the system and quickly learned how to use it.

Regarding design prototypes (Figure 6), users ranked the harness or necklace first (12/20, 60% of users), the cap second (13/20, 65% of users), and the glasses last. The main reason for this choice was comfort, whereas many participants mentioned that the designs were not discreet enough.

The interview questions were designed based on the preliminary analysis of the initial data collection round, considering the capabilities approach and the functions of the assistive device prototype. Participants' answers formed the basis for developing a focus group with 6 participants.

The results of the ergonomics survey support this statement, revealing different levels of satisfaction among participants regarding different aspects of the devices. This disparity is particularly evident when examining respondents' comments for each item and observing the relationship between their answers and their needs and preferences. For instance, individuals blind from birth may prefer a device that does not obstruct their ears, while participants with residual visual abilities may find glasses obstructive.

Despite these differences, common preferences emerged, including a desire for improvements in the size, discretion, and aesthetics of the device. Participants expressed a preference for a smaller, inconspicuous, wireless device that does not interfere with their attire or activities nor reduce their body freedom, that is, occupy at most one part of their body. Also, the device should not put their life or bodily integrity at risk, or make them feel like outsiders, and it should allow them to be part of what they value. Participants expressed the importance of having choices, which is evident in their responses regarding color preferences. Those who desired the device to be available in a different color avoided asking for just one option and instead sought a variety of alternatives from which interested individuals could choose. Finally, the motivation for using this type of AT revolves around reinforcing autonomy and safety while moving around.

Discussion

Principal Findings

This paper reports on the feasibility and limitations of applying HCD principles in AT development (ISO 9241-210:2019 standard) [41]. Despite the clear benefits and good intentions of the HCD principles, we encountered substantial barriers to their implementation in the technology design due to a mismatch between available research infrastructure, methodologies, and legislative frameworks. Nevertheless, notwithstanding these shortcomings, our initial prototype demonstrates significant progress in meeting user expectations and adapting to the local context, distinguishing itself from existing ETAs in both the market and literature. We used rigorous qualitative methodologies to document users' experiences and interactions with technical features and expectations regarding AT beyond this navigation tool. In terms of improving available innovation in AT, our prototype offers key features, such as an unobtrusive interface, clear instructions, and semiconcealed electronic components, contributing to its appeal, and significantly lower cost than similar solutions (5 to 15 times lower than similar products).

One of the main challenges in applying the HCD methodology is the misfit between our research needs and available legislative infrastructure. We prioritize user involvement in our research proposal, aiming for meaningful engagement in the conception, design, and testing. However, researchers cannot engage with end users until they secure ethics clearance, which involves submitting a comprehensive and finalized research plan for evaluation and approval. Consequently, most decisions must be made before any direct interaction with users occurs, allowing little flexibility for significant design changes. This challenge is compounded by institutional bureaucracy, for example, in this project, the research team had to apply to 6 different ethics committees, each with its own procedures and legal frameworks.

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This results in limited user involvement and, therefore, a constrained application of the HCD approach.

While commendable progress has been made in ensuring that technological research respects the rule of law and the rights of its potential final users, particularly those at risk of vulnerability, such as persons with disabilities, our results indicate that more needs to be done to ensure that individuals are protected from harm and coercion, thus having the opportunity to safely contribute if they wish to innovate and research. This would allow AT developers to improve the design process and have a better chance of closing the existing AT gap. The balance between safety needs and the demands of final users and innovation research needs to be reviewed and better aligned to move forward.

In addition, while ISO 9241-210:2019 guides usability and user experience, it does not delve deeply into the technical intricacies of implementation, particularly in contexts involving mechatronic systems. In such cases, additional standards specific to hardware and software engineering become necessary to ensure comprehensive and effective development practices. In our case, we used the rational unified process methodology to obtain low-level technical requirements and foster active stakeholder participation throughout the development life cycle. Hence, while ISO 9241-210:2019 provides a solid foundation for UCD, it should be supplemented with other standards and guidelines addressing the technical complexities inherent in AT solutions incorporating both hardware and software components. This holistic approach ensures optimization of both the user experience and the technical functionality of the product for ultimate success.

This is just the first iteration of the HCD methodology, and several aspects remain to be enhanced in future redesigns. Feedback from functional tests identifies areas for improvement, including reduced system size and weight, enhancing aesthetics, and improving the concealability of components. Furthermore, integrating features such as currency detection and potholes warnings would further enhance usability and better meet user needs.

Future iterations will also involve testing the device in different Colombian cities to assess its adaptability across varied urban environments. Expanding trials to other countries and continents is envisioned in later phases, ensuring that contextual variations are considered in the development of inclusive and adaptable solutions.

Moreover, a study on legal regulations and ethical risk frameworks governing user involvement in AT development will be proposed. This will aim to establish clearer operational guidelines for navigating regulatory and ethical challenges, ultimately facilitating the safe and efficient participation of persons with disabilities in shaping the technologies they will use. Strengthening governance structures, including ethics committees, through a well-defined risk assessment approach will be key to advancing this process.

Looking ahead, sustained collaboration with end users and iterative design refinement through HCD methodology will be imperative in developing ETA solutions that fully meet the diverse needs of individuals with VI, particularly in LMICs.

Cross-fertilization of knowledge is key to addressing changes related to AT. Thus, multidisciplinary research requires significant work, commitment, and compromise, as each scientific discipline works under different scientific paradigms, which can lead to conflicts of interest. To ensure its implementation, multidisciplinarity shall be perceived as a common aim and accompanied by a work plan, as is done for other research goals. This project shows that multidisciplinary teams can lead to generating novel combinations and added-value technologies.

Finally, considering the conducted user tests, a common question was “Were you able to fully understand the audio instructions?” The percentage of users who responded positively increased over the course of the tests, with 85% (17/20), 90% (18/20), and 100% (20/20), respectively. This indicates that users gradually became more accustomed to the device. Another common question was “How confident are you to avoid more obstacles if you would repeat the test?” The percentage of participants who reported feeling confident or very confident also grew, from 60% (12/20) to 70% (14/20), and then to 90% (18/20). This demonstrates an increase in user confidence with continued use of the device.

Conclusions

This paper explores the design and development of a context-sensitive, person-centered navigation device, guided by HCD principles in accordance with ISO 9241-210:2019 standard. Despite significant challenges, the development process has yielded promising results, demonstrating notable advancements in meeting user expectations and adapting to local contexts at a notably reduced cost compared to existing alternatives, showcasing the potential of user-centered innovation in AT. However, legislative and methodological barriers, including limited flexibility for iterative design changes, significantly constrained the application of HCD principles. These limitations highlight the need for a more cohesive approach that aligns research methodologies, technology development practices, and regulatory frameworks to maximize the benefits of HCD.

Despite the decades-long promotion of HCD, its rigorous and systematic application remains elusive in the AT domain, particularly for individuals with VI [15-18,42]. A review of existing literature and practices reveals a lack of empirical evidence and methodological rigor in many user-centered-design frameworks [15-17,42,61]. Frequently, researchers mislabel informal or minimal user interactions as sufficient to qualify their developments as HCD, which is both ignorant and unethical [42]. Adherence to ISO standards remains inconsistent, with many projects failing to meaningfully engage users throughout the development life cycle. During the practical application of HCD in our work, 3 major barriers to its effective implementation were identified, as detailed in Textbox 7.

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Textbox 7. Barriers to the implementation of human-centered design (HCD) principles.

Lack of systematization

- The absence of standardized processes for integrating HCD into assistive technology (AT) development often results in superficial or late-stage user involvement. Tools and methodologies for systematic engagement are inadequate, and ethics protocols frequently impose rigid, predefined research plans that hinder iterative design changes. While standards provided by the International Organization for Standardization provide a framework, they lack specificity for complex systems, such as mechatronic devices, necessitating additional technical standards for hardware and software integration.

Regulatory constraints

- Legal and ethical frameworks, although designed to protect users, can unintentionally restrict their engagement in research. Ethics committees often require finalized research plans before allowing user interaction, leaving little room for early-stage input or midcourse corrections. These lengthy bureaucratic processes create delays, especially in multinational projects, and may isolate researchers from the users they aim to serve.

Contextual misalignment

- Assumptions that solutions designed for individuals without disabilities will work equally for individuals with disabilities often lead to suboptimal outcomes. This is particularly true in low- and middle-income countries, where additional contextual barriers must be addressed to ensure the relevance and utility of AT solutions.

To address these challenges, a more flexible, standardized, and user-driven approach to AT development is essential. Sustained collaboration with end users, iterative refinements, and multidisciplinary research are critical for driving innovation and creating effective, inclusive technologies. By fostering meaningful user engagement and adapting methodologies to real-world contexts, AT development can better align with the diverse needs of users, particularly those in underserved regions.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Comparison of the analyzed systems for the development of electronic travel aids, including the system developed in this work for reference.
[PDF File (Adobe PDF File), 179 KB - rehab_v12i1e70694_app1.pdf]

Multimedia Appendix 2
Sociodemographic data of the participants.
[PDF File (Adobe PDF File), 199 KB - rehab_v12i1e70694_app2.pdf]

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Abbreviations

AT: assistive technology
DPO: disabled persons organization
ETA: electronic travel aid
HCD: human-centered design
IMU: inertial measurement unit
ISO: International Organization for Standardization
LMIC: low- and middle-income country
RGBD: red, green, and blue, plus depth
VI: visual impairment

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Editorial

The Importance of Telerehabilitation and Future Directions for the Field

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Abstract

During the COVID-19 pandemic, telerehabilitation was critical to providing ongoing care for people with impairments or disabilities, and it remains frequently used and popular after the pandemic. Telerehabilitation has been shown to be feasible and effective in a variety of conditions, including chronic heart failure and coronary artery disease, stroke, multiple sclerosis, and spinal cord injuries, with adverse events being rare. This editorial identifies important areas and future directions for the field, including implementation considerations in the postpandemic context, issues of access and equity, and emerging innovations and personalized care. The development and implementation of this knowledge will ensure that individuals with disabilities and impairments will continue to receive effective, safe, and person-driven care remotely.

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KEYWORDS

JMIR Rehabilitation and Assistive Technologies; telerehabilitation; assistive technologies; access; equity; personalized care

Importance of Telerehabilitation, Including Demonstrated Effectiveness, Feasibility, and Safety

During the COVID-19 pandemic, telerehabilitation was critical to providing ongoing care for people with impairments or disabilities [1], and it remains frequently used and popular after the pandemic. Telerehabilitation is a subset of telemedicine that uses telecommunication technologies to deliver rehabilitation services synchronously or asynchronously to patients at a distance [2]. It allows for the provision of services to patients who would otherwise be unable to access in-person services due to distance (ie, individuals living in rural and remote locations), disabilities that limit their ability to travel to in-person appointments, and the absence of caregivers who can assist with travel. Telerehabilitation comprises diagnosing, evaluating, and managing health care for individuals with physical, cognitive, or social impairment and disability [2].

Telerehabilitation has been shown to be feasible and effective in a variety of conditions, including chronic heart failure and coronary artery disease [3], stroke [4], multiple sclerosis [5], and spinal cord injuries [6], with adverse events being rare. Indeed, the convenience of telerehabilitation may lead to decreased travel expenses for participants and higher attendance rates for individuals with other life commitments [7]. According to a systematic review of randomized controlled trials on the effectiveness of telerehabilitation exercises on pain, physical function, and quality of life in individuals with physical disabilities, when compared with other interventions, there was high-quality evidence that telerehabilitation was not different to other interventions for pain (95% CI −0.4 to 0.1), physical function (95% CI −0.2 to 0.2), and quality of life (95% CI −0.1 to 0.5) in the long term [8]. Our research team recently completed a scoping review summarizing the published literature on adverse events during telerehabilitation; we determined from the 81 included studies, adverse events related to the delivery of telerehabilitation were rare, mostly characterized as mild or nonsevere [9]. This scoping review, an ongoing systematic

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review comparing the effect of telerehabilitation versus in-person care on adverse events, and our previous research on the experiences of clinicians using a telerehabilitation toolkit [10] have helped to inform areas of future research in telerehabilitation, which are detailed below.

Implementation Considerations

In our study on clinician perspectives on the use of a telerehabilitation toolkit [10], our team identified a variety of implementation considerations related to telerehabilitation during the pandemic. These findings included the importance of adequate infrastructure, equipment, and space, as well as the key role of organizational and leadership support in adopting telerehabilitation and availing resources to implement telerehabilitation. A greater understanding of the safety and optimization of telerehabilitation could help influence government funding and guide policy makers, which is important given that a lack of leadership and organizational support was found to hinder the implementation of telerehabilitation. Future studies are also needed to understand the ongoing determinants of telerehabilitation implementation (ie, after the pandemic) and match these with evidence-based implementation strategies. Partnerships with patients with disabilities in co-designing telerehabilitation interventions are also needed.

Issues of Access and Equity in Telerehabilitation

As mentioned, one of the major advantages of telerehabilitation is its ability to address geographical and logistical barriers [2]. In-person rehabilitation often requires travel to specialized centers, which can be a burden for individuals with mobility issues, in remote locations, or facing financial limitations. Telerehabilitation can mitigate these challenges as health care professionals can deliver therapy and monitor progress remotely, promoting greater inclusivity and continuity of care. Future research should focus on understanding the long-term impact of telerehabilitation on health equity, particularly among equity-seeking groups. At the same time, it is important to note that while telerehabilitation can improve access for some groups (eg, those in rural and remote locations with access to software and hardware), it can also disadvantage groups without access to these resources and limited digital literacy; these are areas of research that need exploration. Finally, in our scoping review on adverse events, we reported a lack of studies among pediatric populations. The lack of evidence could hinder the delivery of telerehabilitation to youth and is thus recommended as a future area of research.

Emerging Innovations in Telerehabilitation and Personalized Care

In our qualitative study on clinicians' experiences of implementing a telerehabilitation toolkit during the COVID-19 pandemic, participants described innovations that resulted from implementing telerehabilitation during the pandemic. Some of these included interprofessional assessments (ie, performed in tandem by an occupational therapist and a physical therapist), which were described as especially helpful for patients with complex needs. These interprofessional collaborations in the context of telerehabilitation should continue to be studied [10]. Relatedly, the experiences, barriers, facilitators, and preferences for the delivery of telerehabilitation should continue to be studied, as should the experiences of health care professionals delivering telerehabilitation, such as the challenges of delivering remote care safely. The use of a home pulse oximetry was also described in our study [10]. Future research should continue to explore what technologies can be integrated into telerehabilitation to improve patient and caregiver outcomes. Similarly, the use of machine learning and artificial intelligence should be leveraged in order to deliver personalized or precision care for patients undergoing rehabilitation, for example, building machine learning techniques using a variety of existing data sources to optimize goal setting based on real-time data.

Conclusion

Telerehabilitation has been shown to be feasible and effective in a variety of conditions, with adverse events being rare [3-9]. However, it is still a burgeoning field, and this editorial has identified key areas of future research to advance its implementation and impact. Key areas of future research include understanding the long-term impact of telerehabilitation on health equity, particularly among equity-seeking groups, and the ongoing determinants of telerehabilitation implementation (ie, after the pandemic) and then matching these with evidence-based implementation strategies. Partnerships with patients with disabilities in co-designing telerehabilitation interventions are also needed, as is the need to expand research in telerehabilitation among pediatric populations. Finally, emerging innovations in telerehabilitation including interprofessional collaborations and the use of machine learning and artificial intelligence should be leveraged in order to deliver personalized or precision care for patients undergoing rehabilitation. The development and implementation of this knowledge will ensure that individuals with disabilities and impairments will continue to receive effective, safe, and person-driven care remotely. Consistent with these key areas of future research, *JMIR Rehabilitation and Assistive Technologies* has launched a call for papers [11] on "Advancing Telerehabilitation Research and Innovation." The call for papers invites submissions in the following areas related to telerehabilitation: effectiveness and safety, implementation considerations, health equity and accessibility, innovative technologies, and pediatric rehabilitation.

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Conflicts of Interest

None declared.

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Effects of a Home-Based Rehabilitation Exercise Program on Cardiorespiratory Performance in Community-Dwelling Adults Who Underwent Heart Surgery: Randomized Controlled Trial

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Abstract

Background: Patients undergoing heart surgery demonstrate impaired cardiorespiratory performance. Phase II cardiac rehabilitation (CR) in people undergoing open heart surgery (OHS) aims to reduce the adverse physical effects of cardiovascular diseases. Virtual reality (VR) exercise is now used in CR.

Objective: This study aimed to explore the effects of VR exercise on functional capacity, pulmonary function, and respiratory muscle strength in patients who underwent OHS and were in phase II CR.

Methods: Forty-nine patients who underwent elective OHS and were in phase II CR were randomized into a VR group (N=24) and a control group (N=25). The VR group completed 8 weeks of a home-based VR exercise program, including chest trunk mobilization and aerobic circuit training for 30 minutes, whereas the control group received an exercise brochure and information regarding the benefits of exercise. Intention-to-treat analysis was conducted, and 2-way mixed ANOVA was performed to compare between- and within-group differences in functional capacity and respiratory performance.

Results: After completing the 8-week program, the VR group showed significant improvement in functional capacity compared to the control group (66.29, SD 25.84 m; *P*=.01). Inspiratory muscle strength increased in both the VR and control groups compared to baseline (9.46, SD 2.85 and 9.64, SD 2.78 cm H_2O, respectively). In addition, after the 8-week intervention, significant improvements were found in expiratory muscle strength (15.79, SD 4.65 cm H_2O) and forced expiratory volume in 1 second as a percentage of predicted values (2.96%, SD 1.52%) in the VR group compared to the baseline session.

Conclusions: The home-based VR exercise program significantly improved functional capacity but not respiratory muscle or pulmonary function.

Trial Registration: Thai Clinical Trial Registry TCTR20230602001; https://tinyurl.com/3xn44bku

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KEYWORDS

virtual reality; cardiac surgery; cardiac rehabilitation; cardiopulmonary; aerobic exercise

Introduction

In 2020 and 2021, over three-quarters of cardiovascular diseases (CVD) and related deaths occurred in low- and middle-income countries [1]. In high-income countries, the average prevalence of total heart surgery is 123.2 per 100,000 population annually. The average coronary artery bypass graft (CABG) and valve surgery volumes are 36.7 and 30.8 per 100,000 population per year, respectively [2]. High- to middle-income countries show

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a higher rate of all cardiac surgeries than low- to middle-income countries and low-income countries [2].

Cardiac rehabilitation (CR) is recommended for patients who have heart disease and/or undergo cardiac surgery during admission at the hospital or after discharge [3-5]. CR programs aim to reduce mortality and improve mobility and the quality of life [4]. A systematic review and meta-analysis showed that CR programs in hospital-based, community-based, or home-based settings reduced mortality and hospitalization rates and improved the quality of life in patients with coronary artery disease, angina, or ischemic heart disease and undergoing CABG or percutaneous coronary intervention [6]. A study showed that patients who underwent CR exhibited a reduction in total mortality of 13%-24% within 1-3 years after a cardiac event and reduced readmission of 31% a year later [7].

The roles of physical therapy are associated with CR, mainly to improve physical activity and prescribe exercise to patients with cardiac disorders or diseases. Although exercise is essential for patients with CVD or those who have undergone cardiac surgery, CR remains extensively underused because of issues with adherence to CR programs and low participation [8]. Center-based CR participation rates among eligible patients are still low, ranging from 10% to 30% globally, possibly because of issues with accessibility, competing obligations, poor socioeconomic status, cost, and availability [9]. Adherence to CR programs is affected by several factors, for example, female sex, older age, low socioeconomic status, and lack of suggestions from a physician [4]. Further, adherence rates of 36.7% - 84.6% and dropout rates of 12% - 56% were observed in patients who engaged in CR programs. A systematic review of 43 prospective cohort studies with 63,425 patients from 10 different countries reported factors related to nonparticipation or dropout from CR, including older age, female sex, low socioeconomic status, comorbid conditions, physical inactivity, poor functional capacity, low exercise capacity, and refusal to participate. Moreover, motivational factors can affect patients' compliance with CR [10].

For several decades, virtual reality (VR) technology has been used in combination with home-based exercise CR as an alternative for outpatients with cardiac disorders or diseases to reduce barriers to CR participation (eg, long distance from CR facilities and motivation), make rehabilitation more accessible, and enable the effective and safe performance of rehabilitation exercises [9,11].

VR allows people to engage with scenarios in virtual environments. The effects of VR exercise have also been shown to be useful in CR in several studies; VR has shown efficacy in preventing the loss of pulmonary function and promoting physical ability after phase I CABG [12]. In patients with phase II CABG, a VR exercise protocol for an in-hospital CR program increased peak oxygen consumption, peak metabolic equivalents, and the anaerobic threshold, which represents a positive effect on exercise tolerance [13]. Furthermore, VR during an 8-week intervention program improved metabolic equivalents, 6-minute walk distance (6MWD), and quality of life and reduced depression in patients with ischemic heart disease [14]. Thus, using VR to exercise may be an alternative method of CR.

There are several barriers to CR referral after patients are discharged from the health care system, leading to low CR participation rates. Alternative models have been developed in response to the challenges associated with the delivery of center-based CR, such as cost and accessibility. Moreover, VR exercise has recently been implemented in Thailand, although its advantages in patients who have undergone heart surgery have not been assessed. Therefore, this study hypothesized that home-based exercise would affect cardiovascular endurance, pulmonary function, and respiratory muscle strength in patients undergoing open heart surgery (OHS) who are involved in phase II VR exercise. This study aimed to evaluate the effects of a home-based exercise program on cardiovascular endurance and respiratory performance in patients undergoing OHS.

Methods

Overview

Community-dwelling patients who underwent OHS and were in phase II CR (defined as ≥3 weeks after discharge from the hospital) were recruited in this study. G*Power (version 3.1.9.4; Heinrich-Heine-Universität Düsseldorf) was used to determine the sample size with an effect size of 0.25, a statistical power of 0.90, and an α of .05; therefore, 46 participants were enrolled. Ten percent of the total sample size was estimated to account for data dropout or technical errors. Thus, 50 participants were recruited for this randomized controlled trial. Participants who underwent heart surgery via median sternotomy and were within 3 - 6 weeks post discharge from the hospital or in phase II CR were invited to participate in the study. The exclusion criteria were unstable angina or acute myocardial infarction within the previous 3 months. Moreover, participants with an uncontrollable resting systolic blood pressure of >180 mm Hg and/or diastolic blood pressure of >120 mm Hg [15], resting respiratory rate of >30 bpm, cognitive impairment (measured by the Montreal Cognitive Assessment), or musculoskeletal conditions that affected walking were excluded. Participants who were admitted to the hospital or had active respiratory disease (eg, COVID-19) during the intervention program were required to withdraw from the study.

Eligible participants were allocated to 2 groups using simple random sampling: 25 individuals in the VR group and 25 in the control group. The same physiotherapist performed the assessment, and the participants were blinded to the group allocation. Participants who underwent VR exercise were required to attach an optical heart rate (HR) sensor to the left side above their elbow, and their resting HR was displayed on a screen (ie, a television or computer). Moderate-intensity exercise (ie, 40% - 59% HR reserve [HRR]; the maximal HR was determined by subtracting the participants' ages from 220) was decided for each individual [16]. The VR program (ie, intervention) involved moderate-intensity exercise at a prescribed 40% - 59% HRR or a rate of perceived exertion of 11 - 13 of 20, 2 - 3 times a week, over 8 weeks (Table 1). The control group received no rehabilitation program; however, an

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exercise brochure and information regarding the benefits of exercise were provided.

Table . Protocol for the home-based rehabilitation exercise in phase II cardiac rehabilitation.

Exercise	Regimen
Breathing exercise (3 min)	10 reps/set, 3 sets
Upper limbs exercise/active chest trunk mobilization (9 min)	
Shoulder flexion (anteroposterior chest wall mobilization)	10 reps/set, 3 sets
Shoulder abduction	10 reps/set, 3 sets
Shoulder flexion to the opposite side (posterolateral chest wall mobilization)	10 reps/set, 3 sets
Lateral chest wall mobilization	10 reps/set, 3 sets
Lower limb exercise (4.33 min/cycle, total 7 cycles, 30 min)	
Marching	—[a]
Hip abduction-adduction	—
Mini squat	—
Hip-knee flexion	—
Hip flexion with adduction	—
Cool down: marching	5 min
U pper extremity exercise or active chest and trunk mobilization (9 min)	
Shoulder flexion (anteroposterior chest wall mobilization)	10 reps/set, 3 sets
Shoulder abduction	10 reps/set, 3 sets
Shoulder flexion to the opposite side (posterolateral chest wall mobilization)	10 reps/set, 3 sets
Lateral chest wall mobilization	10 reps/set, 3 sets
Breathing exercise (3 min)	10 reps/set, 3 sets

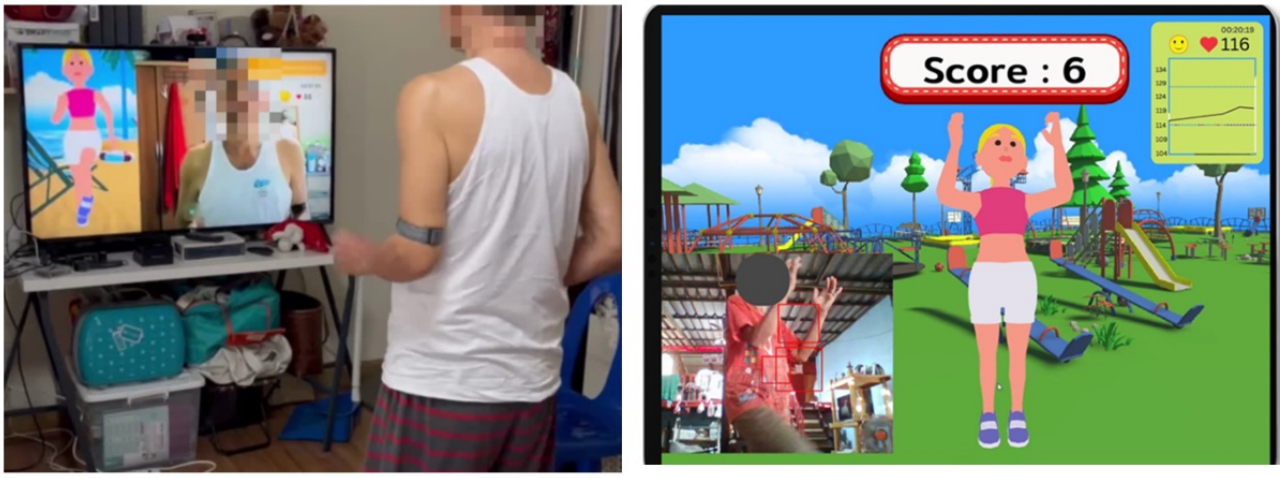
[a]Not applicable.

We developed a nonimmersive VR exercise in which the user interacts indirectly with a virtual environment through 2D flat-screen programs [17]. In addition, a Polar Verity Sense (optical HR sensor; Polar Electro) device was used to monitor the HR and display it in real time on the screen (Figure 1). The VR exercise program was set at 40% - 59% of the HRR with automatic HR adjustment for individuals. That is, if participants performed lower than 40% HRR, the VR exercise program was sped up until the participant achieved 40% - 59% HRR. In contrast, if the participant performed higher than the target HR (40% - 59% HRR), the program was slowed down until the participant achieved 40% - 59% HRR. The aerobic exercise protocol was reviewed by physical therapists and physical medicine and rehabilitation specialists.

Before and after the 8-week intervention program, all participants underwent respiratory assessment using a respiratory pressure meter (Micro RPM, Micro Medical Ltd). Maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) were defined as inspiratory and expiratory muscle strength, respectively. The protocol adhered to the American Thoracic Society's (ATS') and European Respiratory Society's (ERS') guidelines [18]. Briefly, the participant was requested to exhale until the residual volume was achieved and then to inhale deeply; then, the MIP was recorded. In contrast, the individual inhaled maximally (total lung capacity) and then exhaled quickly; then, MEP was recorded.

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Figure 1. Virtual reality exercise.



A spirometer (MicroLab Mk8 Desktop Spirometer, CareFusion Corp) was used to assess forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV1), following the ATS' and ERS' guidelines for respiratory muscle testing [19]. Functional capacity was evaluated using the 6-minute walk test (6MWT) according to the ATS' statement guidelines for the 6MWT [20]. Briefly, participants were required to walk along a 30-m-long corridor, and the 6MWD was recorded.

An intention-to-treat analysis was conducted, which included all patients randomly assigned to the study group who underwent the intervention program at least once. Two-way mixed ANOVA (2 types×2 times) was used to compare between- and within-group differences in cardiorespiratory performance. Statistical significance was set at $P<.05$. SPSS (version 24; IBM Corp) was used for statistical analyses. In addition, this trial was registered in the Thai Clinical Trial Registry (TCTR20230602001). The study was conducted in line with the CONSORT (Consolidated Standards of Reporting Trials) 2010 statement.

Ethical Considerations

The study was approved by the Human Research Ethics Committee of Thammasat University (Science; COA number 023/2565) and complied with the tenets of the Declaration of Helsinki, The Belmont Report, Council for International Organizations of Medical Sciences guidelines, and the International Conference on Harmonization's Good Clinical Practice guidelines. The participants provided informed consent to take part in the study.

Results

Out of 70 undergoing OHS, 20 were excluded because they did not meet the inclusion criteria or were unwilling to participate. Therefore, 50 patients were assessed for eligibility and randomized: 25 participants in the VR group and 25 in the control group. After hospital discharge, for ≥3 weeks, the participants were assessed for functional capacity, respiratory muscle strength, and pulmonary function. However, one participant in the VR group was assessed for respiratory muscle strength and functional capacity but not for pulmonary function because of a technical error. Therefore, data were analyzed for 24 and 25 patients in the VR and control groups, respectively. After completing the 8-week program, 8 participants in the VR and 6 participants in the control group were lost to follow-up. Nevertheless, all 49 participants were included in the intention-to-treat analysis (Figure 2).

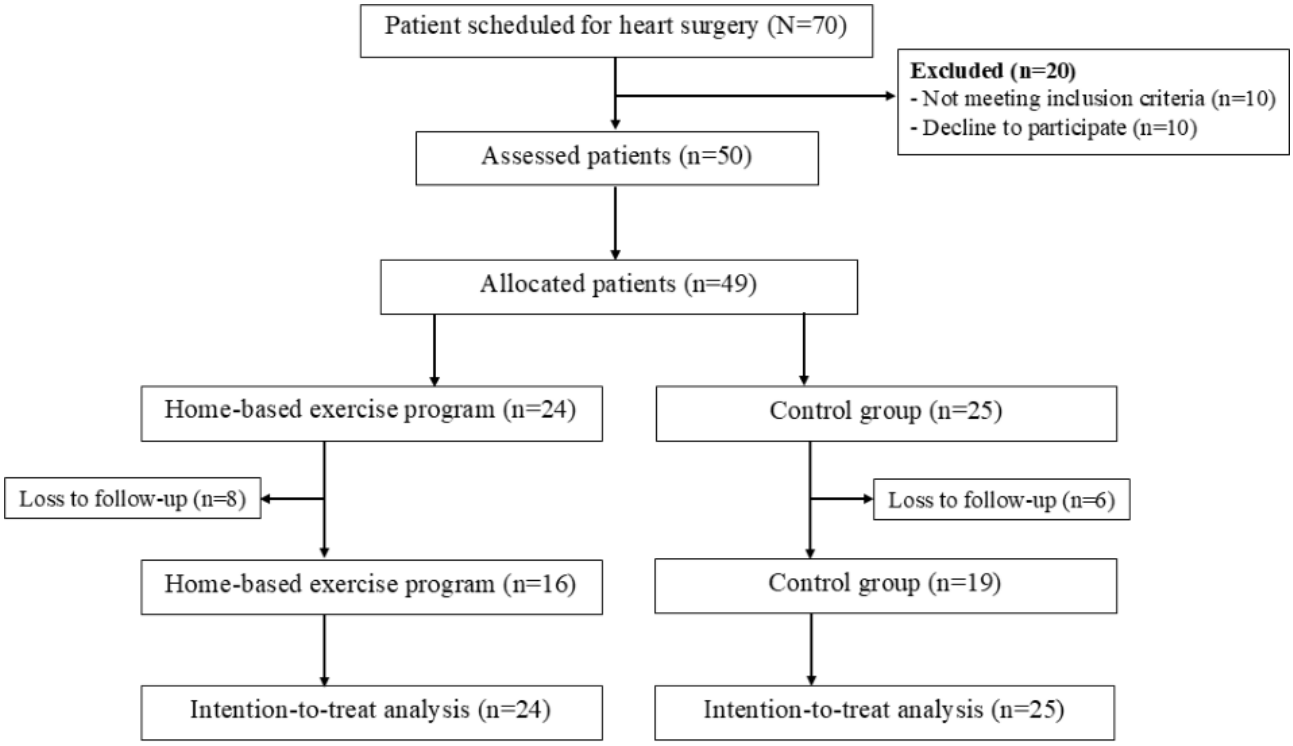
The mean age of the participants was 60.36 (SD 11.56) years, and two-thirds of the participants were male (male: n=35, 71.43%; female: n=14, 28.57%). Regarding surgery type, over half of the 49 participants underwent CABG (n=31, 63.27%), followed by valve surgery (n=14, 28.57%), and a combination of CABG and valve surgery (n=4, 8.16%). Dyslipidemia (n=25, 51.02%) was the most common comorbidity, followed by hypertension (n=23, 46.94%) and diabetes mellitus (n=13, 26.53%). There were no significant differences in patients' characteristics between the VR and control groups (Table 2).

Table 3 presents the cardiopulmonary changes before and after the 8-week intervention program. After the 8-week VR exercise program, there were significant increases in the following outcomes: 6MWD (Δ78.74, SD 15.18 m; $P<.001$), MIP (Δ9.46, SD 2.85 cm H_2O; $P=.002$), MEP (Δ15.79, SD 4.65 cm H_2O; $P=.001$), and %FEV1 (Δ4.63, SD 1.61; $P=.006$). In addition, the control group showed an improvement in MIP (Δ9.64, SD 2.78 cm H_2O; $P=.001$) and %FEV1 (Δ4.04, SD 1.58; $P=.01$) values.

Significant differences in the improvement in 6MWD (Δ78.74, SD 15.18; $P<.001$) were observed between the VR and control groups. However, respiratory muscle strength and pulmonary function were not significantly different between the VR and control groups.

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Figure 2. Flow diagram showing the study recruitment process.



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Table . Characteristics of the participants.

		Total (n=49)	Virtual reality group (n=24)	Control group (n=25)	Statistics[a]	*P* value
Age (years), mean (SD)		60.36 (11.56)	62.75 (7.97)	58.08 (13.97)	*1.429 (47)*	.16
Weight (kg), mean (SD)		63.48 (12.35)	63.55 (11.54)	63.42 (13.32)	*0.038 (47)*	.97
BMI (kg/m^2), mean (SD)		23.82 (4.42)	24.64 (4.10)	23.05 (4.66)	*1.267 (47)*	.21
Sex, n (%)					*3.953 (1)*	.047
	Male	35 (71.43)	14 (40.00)	21 (60.00)		
	Female	14 (28.57)	10 (71.43)	4 (28.57)		
Types of surgery, n (%)					4.299 (2)	.12
	CABG[b]	31 (63.27)	16 (51.61)	15 (48.39)		
	Valve surgery	14 (28.57)	8 (57.14)	6 (42.86)		
	CABG + valve surgery	4 (8.16)	0 (0.00)	4 (100.00)		
Comorbidities, n (%)						
	Diabetes mellitus				0.168 (1)	.68
	History of diabetes mellitus	13 (26.53)	7 (53.85)	6 (46.15)		
	No history of diabetes mellitus	36 (73.47)	17 (47.22)	19 (52.78)		
	Hypertension				0.525 (1)	.47
	History of hypertension	23 (46.94)	10 (473.48)	13 (56.52)		
	No history of hypertension	26 (53.06)	14 (53.85)	12 (46.15)		
	Dyslipidemia				1.647 (1)	.20
	History of dyslipidemia	25 (51.02)	10 (40.00)	15 (60.00)		
	No history of dyslipidemia	24 (48.98)	14 (58.33)	10 (41.67)		
	COPD[c] or asthma				1.063 (1)	.30
	History of COPD or asthma	1 (2.04)	1 (100.00)	0 (0.00)		
	No history of COPD or asthma	48 (97.96)	23 (47.92)	25 (52.08)		

[a]*t* test (*df*) or chi-square (*df*) values (the former are presented in italics).

[b]CABG: coronary artery bypass graft.

[c]COPD: chronic obstructive pulmonary disease.

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Table . Cardiorespiratory performance after the 8-week home-based rehabilitation exercise program.

Variable		Virtual reality group	Control group	Mean difference (virtual reality versus control group), mean (SD)	*P* value between groups
6-minute walk distance (m)					
	Before, mean (SD)	273.64 (99.10)	270.25 (89.96)	3.39 (27.02)	.90
	After, mean (SD)	352.38 (80.71)	286.08 (98.83)	66.29 (25.84)	.01
	P value within groups	<.001	.29	N/A[a]	N/A
Maximal inspiratory pressure (cm H_2O)					
	Before, mean (SD)	59.83 (21.39)	58.08 (26.94)	1.75 (6.97)	.80
	After, mean (SD)	69.29 (21.69)	67.72 (34.57)	1.57 (8.29)	.85
	P value within groups	.002	.001	N/A	N/A
Maximal expiratory pressure (cm H_2O)					
	Before, mean (SD)	57.50 (25.08)	59.04 (24.79)	–1.54 (7.73)	.83
	After, mean (SD)	73.29 (33.60)	63.12 (24.78)	10.17 (8.41)	.23
	P value within groups	.001	.38	N/A	N/A
Forced vital capacity (%)					
	Before, mean (SD)	60.54 (16.41)	63.12 (17.39)	–2.58 (4.83)	.60
	After, mean (SD)	63.50 (15.10)	63.96 (16.13)	–0.46 (4.47)	.92
	P value within groups	.058	.58	N/A	N/A
Forced expiratory volume for 1 second (%)					
	Before, mean (SD)	68.04 (18.43)	67.96 (22.08)	0.08 (5.82)	.99
	After, mean (SD)	72.67 (16.40)	72.00 (19.47)	0.67 (5.15)	.90
	P value within groups	.006	.01	N/A	N/A

[a]N/A: not applicable.

Discussion

Principal Findings

This study aimed to determine the effects of home-based VR exercise on cardiorespiratory performance in patients who underwent OHS and were in phase II CR. This study demonstrated that a home-based VR exercise program improved functional capacity, %FVC, and respiratory muscle strength (ie, MIP and MEP). In contrast, MIP increased after the 8-week program in the control group. In addition, functional capacity increased in the VR group compared to that in the control group after the 8-week program.

An improved 6MWD (78.74, SD 15.18 m) was noted in the VR group but not in the control group (mean 6MWD 15.83, SD 14.87 m). A systematic review and meta-analysis of 10 randomized controlled trials reported the benefit of VR exercise for 6MWD in participants undergoing CR with a mean 6MWD of 49.55 m (95% CI 30.59 - 68.52) [21]. However, the study reported on different phases of CR (eg, phases I, II, and III) and different cardiac diseases (eg, heart failure, ischemic heart disease, and having undergone cardiac surgery in phase I). In addition, the minimal clinically important difference for 6MWT was 36.11 m in 89 inpatients in CR phase I who had undergone elective cardiac surgery (ie, CABG) [22]. In phase II CR, the minimal clinically important difference for the 6MWD was 25 m for patients who underwent an 8-week CR program after acute coronary syndrome [23]. Therefore, the 8-week VR exercise showed benefits in improving functional capacity both clinically and statistically in patients with cardiac conditions who had undergone elective surgery.

Moderate-intensity exercise improves cardiovascular function by increasing HR, cardiac output, blood circulation, endothelial function, capillary density, and nitric oxide bioavailability, which enhance the ability to use oxygen to produce energy for activity [24]. In addition, aerobic exercise causes cardiovascular adaptation by increasing oxygen consumption, which improves cardiorespiratory fitness and endurance capacity [25]. In this study, the VR group showed significant improvements compared to the control group. The VR exercise protocol followed the American College of Sports Medicine guidelines [16] and involved moderate-intensity aerobic exercise (40% - 59% HRR), which might improve cardiorespiratory performance. Several studies have supported the positive effects of VR based on aerobic exercise, which can improve functional capacity [14,26-29]. Therefore, the results of this study are in line with those of previous studies regarding the positive effects of VR exercise on functional capacity and cardiovascular endurance.

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After 8 weeks, both the VR and control groups demonstrated significant improvements in respiratory muscle strength and pulmonary function. A previous study found that VR-based aerobic exercise helped to improve respiratory activity, effectively contributing to the evaluation of cardiorespiratory conditioning [12]. Aerobic exercise improves pulmonary ventilation (increases respiratory rate and tidal volume) and diffusion (increases pulmonary blood flow) [30]. However, this study showed no significant differences in respiratory muscle strength and pulmonary function between the 2 groups. This is probably due to improvements in respiratory muscle strength and pulmonary function in both groups, which occurred after discharge (6 - 8 weeks), following recovery from incisional pain, atelectasis, pulmonary problems, and postoperative inflammation, leading to an increased ability to perform respiratory muscle tests [31]. Moreover, respiratory muscle strength decreased on postoperative days 3 and 6 compared to that before surgery, and the healing process might have been consolidated within 2 - 4 weeks [32]. Rouhi-Boroujeni et al [33] reported that patients scheduled for CABG had a reduction in % FEV1 from 73.4 (SD 0.5) to 64.6 (SD 12.2) 1 week after surgery and then improved to 68.4 (SD 0.2) 6 months post surgery. Therefore, the recovery of respiratory performance (ie, respiratory muscle strength and pulmonary function) in the 12 months following hospital discharge was observed in both the VR and control groups. Thus, the improvement in pulmonary performance and respiratory muscle strength could be due to the postoperative recovery process [33]. In addition, VR focuses on cardiovascular endurance but is not specific to respiratory muscle strength or pulmonary function, possibly leading to the lack of significant differences in pulmonary performance between the groups. Consequently, VR exercise improved cardiovascular endurance rather than pulmonary performance.

This study had some limitations. This study was in favor of men because the rate of CABG is higher in men than women. Further, the proportion of women in the control group was extremely low, which may affect the comparisons. Besides, we did not record characteristics such as ejection fraction, functional class from the New York Heart Association, laboratory data, and physical activity level. Most of the participants in this study were classified as New York Heart Association class I and II or ambulatory patients. Therefore, the results may not be generalized to all patients in phase II CR. In addition, medication usage is not reported, which might affect the intensity of exercise; however, moderate-intensity exercise can be used with measures of HRR or subjective feeling (ie, the rate of perceived exertion).

Conclusion

A home-based exercise program improved cardiovascular endurance, pulmonary function, and respiratory muscle strength in patients who underwent OHS and were in phase II CR. However, there were no significant differences between the VR and control groups in pulmonary function and respiratory muscle strength. Therefore, the VR exercise program improves cardiovascular endurance and functional capacity in patients who undergo OHS and are in phase II CR.

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Authors' Contributions

Conceptualization: KY
Data acquisition, analysis, and interpretation: NS, KY, OS, CK, SB, KW, CB, and CT
Writing—original draft: NS, KY, CT, CB, CK, SB, KW, and OS
Writing—review and editing: KY

Conflicts of Interest

None declared.

Checklist 1
CONSORT (Consolidated Standards of Reporting Trials) checklist.
[PDF File, 79 KB - rehab_v12i1e68504_app1.pdf]

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Abbreviations

6MWD: 6-minute walk distance
6MWT: 6-minute walk test
ATS: American Thoracic Society
CABG: coronary artery bypass graft
CONSORT: Consolidated Standards of Reporting Trials
CR: cardiac rehabilitation
CVD: cardiovascular disease
ERS: European Respiratory Society
FEV1: forced expiratory volume in 1 second
FVC: forced vital capacity
HR: heart rate
HRR: heart rate reserve
MEP: maximal expiratory pressure
MIP: maximal inspiratory pressure
OHS: open heart surgery
VR: virtual reality

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Evidence-Generated Sockets for Transtibial Prosthetic Limbs Compared With Conventional Computer-Aided Designs: A Multiple-Methods Study From the Patient's Perspective

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Abstract

Background: Personalized prosthetic socket design depends upon highly skilled prosthetists. They aim to balance functional human-prosthesis coupling with safe, comfortable load transmission from the prosthesis to the skeleton, through vulnerable skin and soft tissues. Both traditional plaster and computer-aided design and manufacturing (CAD/CAM) methods are iterative, and sharing knowledge is difficult. Evidence-generated (EG) sockets derived from past computer-aided socket design (CASD) records could provide a personalized starting point for limb fitting, potentially reducing time spent on basic design and enabling prosthetists to focus on more highly-skilled customization.

Objective: This study aimed to assess the comfort of EG sockets, generated from past CASD records.

Methods: A crossover trial compared EG sockets, derived from 163 previous transtibial devices, with conventional clinician-led CAD/CAM sockets. Noninferiority was assessed for the socket comfort score (SCS) outcome measure, and semistructured interviews provided in-depth user analysis. The setting was 3 UK National Health Service clinics, with 17 participants with 19 transtibial amputations.

Results: EG sockets had no statistically significant difference in comfort compared with clinician-led control sockets (median SCS 8.6 for EG sockets and 8.8 for CAD/CAM controls; P=.43, effect size=0.05), but a lower variability in SCS across the group (95% CIs 8.0 - 9.0 for EG and 7.5 - 9.5 for CAD/CAM devices, respectively). Analysis of interviews revealed themes around fitting session experiences, similarities, and differences between the EG and CAD/CAM control sockets, and residual limb factors impacting perceptions of socket comfort. These provided insights into the participants' experience of the study and the value of expert prosthetist input in socket design.

Conclusions: EG sockets demonstrated noninferiority to conventional clinical CASD practice in terms of socket comfort. Both quantitative and qualitative results indicated how clinician input remains essential and is valued by prosthesis users. Work is underway to incorporate the EG sockets into CASD software such that they can act as a digital starting point for modification by expert clinicians at fitting, potentially reducing time spent on basic design, enabling prosthetists to focus on more highly-skilled customization and co-design with their patients.

Trial Registration: ClinicalTrials.gov NCT06597266; https://clinicaltrials.gov/study/NCT06597266

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(JMIR Rehabil Assist Technol 2025;12:e69962) doi:10.2196/69962

KEYWORDS

CAD/CAM; prosthetic socket design; transtibial; evidence-based practice; qualitative research; computer aided design and manufacturing

Introduction

The lower limb prosthetics community has worked since the 1980s toward computer-aided design and manufacturing (CAD/CAM) technologies to support prosthetic socket design and fabrication workflows [1]. Within CAD/CAM, computer-aided socket design (CASD) is defined as the strategic modification of a 3D digital representation of the residual limb shape in software by an expert human prosthetist, producing a rectified socket shape design. The "CAM" typically refers to fabricating the socket by producing a corresponding rigid foam mold carved using a computer numerical-controlled robotic carver, followed by draping or lamination. CAD/CAM have been described as offering significant potential benefits over conventional plaster of Paris approaches [2], including reduced manual work time and exposure to plaster, an occupational health risk. This could allow clinicians to spend a greater proportion of their time in direct patient interactions, which might enhance patient engagement and facilitate shared decision-making [2]. Early CAD/CAM results were comparable with traditionally produced sockets but took longer and needed more adjustments [1-4]. However, over the learning curve, today clinicians using CAD/CAM can achieve clinical results that are comparable while saving time and delivering a better quality of life outcome [5-8].

These technologies were also proposed to offer opportunities for evidence-based decision support in socket design [1]. CASD generates a perpetual, quantitative design record, whereas the plaster design is destroyed upon socket fabrication. A digital record has value for education, peer support on complex cases, and if implemented for clinical decision support, further time savings to focus on the most highly skilled and value-added parts of socket personalization [3,9]. However, despite proposals since the 1980s to augment CAD/CAM by providing the ability to refer to previous design records [10], it appears that the full potential of the benefits offered through these rich datasets to improve the prosthetic rehabilitation process has not been fully exploited.

In particular, data might be used for generating socket design recommendations, which we define as evidence-generated (EG) sockets. Since Dean and Saunders in 1985 [11], clinical innovators have considered an alternative to performing CASD in a manner analogous to manual work with plaster, whereby a user could apply averaged rectifications from previous designs as an "overlay," or select from a database of different size and shape "primitive" or "template" sockets, and scale and adjust them to fit to a newly presenting patient's residual limb shape. This has been demonstrated for transtibial [3,9,12-14] and transfemoral socket designs [15,16], and in orthotics for scoliosis braces [17,18]. Recent publications present alternative methods of informing the socket design process by data, including fuzzy logic or inference to map linguistic descriptions of socket design approaches and patient descriptors, for application to new people [19,20], simulation of load-bearing and optimization for automating transradial socket design [21,22]. However, these studies have only been demonstrated in research settings and have not yet been clinically applied. Anecdotally, today, most CASD software packages in clinical use define templates as structured design workflows or sequences to guide users in applying their own choice of rectifications and gross design features.

The application of such methods would benefit from a systematic study of rectification design practice, although this is limited in the scientific literature [23] since the "Automated Fabrication of Mobility Aids" project [12]. Recently, researchers have begun to leverage high-resolution 3D scans and CASD data to investigate rectification sizes in transtibial and transradial design [24-26], and most recently, probabilistic methods have been used to derive insights into transtibial socket design strategy through the associations between design features [27]. Building upon those insights, this study aims to evaluate an EG socket concept developed by Radii Devices Ltd and the University of Southampton, with UK service provider Opcare Ltd providing data and expert clinical design insight. The objective was to compare the EG socket design approach with clinician-led CASD, using socket comfort outcome measures and capturing the patients' experiences through qualitative interviews.

Methods

This study is reported using the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) cross-sectional reporting guidelines [28].

Patient and Public Involvement and Engagement

The study research question was informed by patient and public involvement and engagement (PPIE) group discussions [29], which highlighted how socket comfort is paramount but difficult to achieve, and that delays between assessment and device provision can impair fitting. PPIE contributors also expressed support for sharing knowledge between prosthetics centers to enable service improvement. Collaboration with the Alex Lewis Trust during the study development reinforced this and provided review and feedback of the study design, recruitment posters, participant information sheets, and consent forms. PPIE contributors are also actively involved in disseminating the study findings to patients.

Study Design

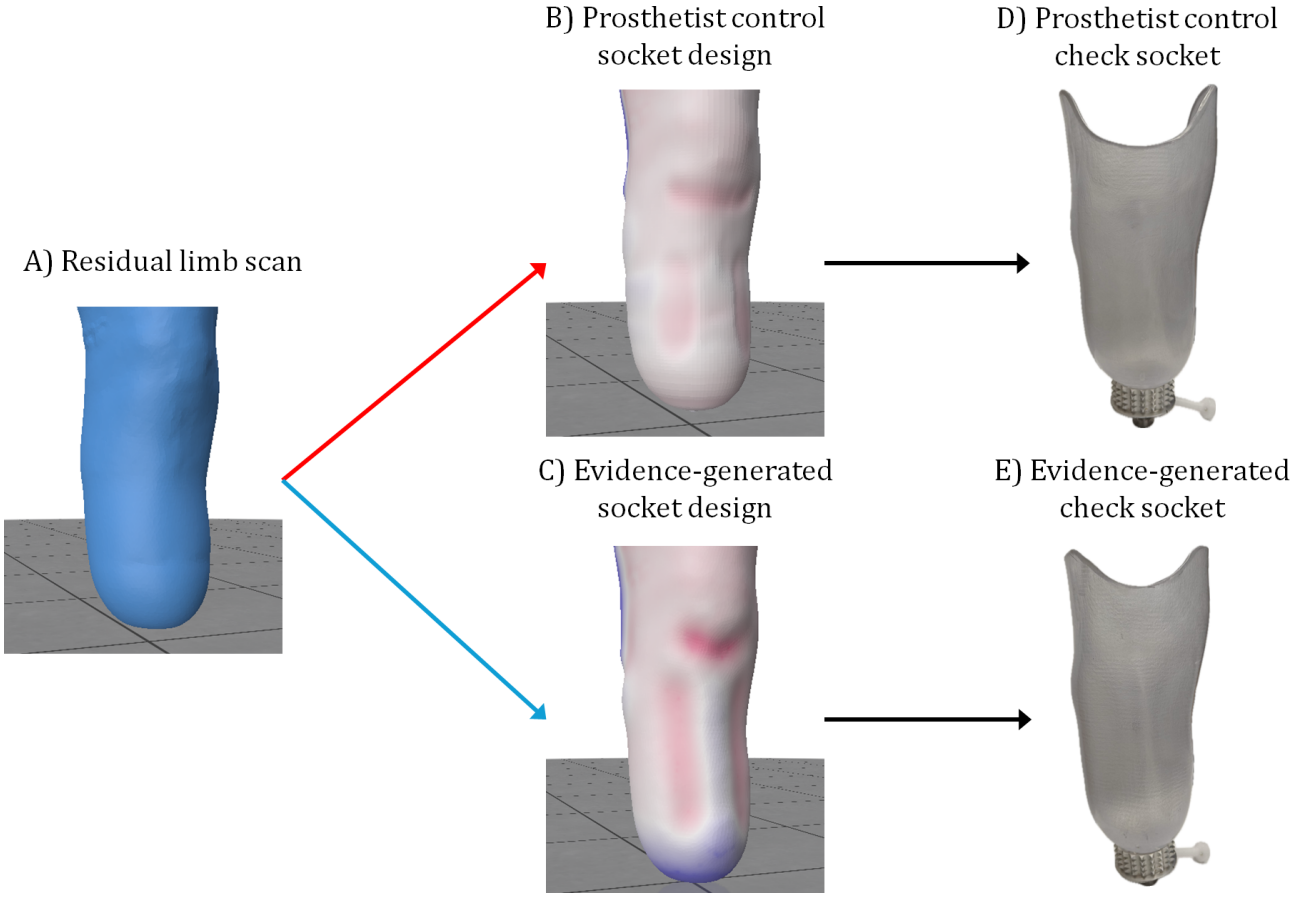
The study used a single-blind, crossover design to assess comfort at socket fitting, followed by a qualitative study of semistructured interviews. An EG transtibial draped thermoplastic check socket was compared with a control CAD/CAM socket, which was designed by a prosthetist using

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Tracer CASD software (Ohio Willowwood Co) from the same residual limb 3D scan (Figure 1). Participants used the same interface as intended in the definitive device (ie, liners or socks). Quantitative and qualitative data were collected and analyzed independently and interpreted together. This study design was selected to capture the patient's comparative experience of socket fitting from quantitative and qualitative perspectives, developed from a foundational CAD/CAM versus traditional socket comparison study [5] and with recent precedent in clinical assessment of adjustable sockets [30]. This study design was chosen because, first, new digital design and fabrication technologies are often considered in small scale or low technology readiness level trials in the scientific literature but are often not tested in power-sized, blinded, or controlled trials, with consideration of qualitative service user experience alongside quantitative outcome measures [23]; and second, it is important to understand the patient's perceived experience. This may relate to socket fit and comfort, for which detailed, open descriptions offer more nuanced insights than a simple socket comfort score (SCS) [31]. It may also relate to the user's perspective of device design and fabrication, to promote shared decision-making [32] and its potential benefits regarding patient engagement in and understanding of care.

As such, the work aligns with recently published perspectives on ethical considerations for development and clinical translation of prosthetic technologies [33].

Figure 1. For an exemplar participant: (A) the residual limb scan over a sock; (B) the prosthetist's socket rectification design; (C) the evidence-generated design before adding brimline; and (D) and (E) the corresponding fitted check sockets. In rectification design maps, the color red represents a carve or press-fit between socket and limb, white represents exact fit, and blue represents buildup or limb-socket gap.



Ethical Considerations

Ethical approval was granted by institutional (ERGO 76033.A3) and UK national review boards (IRAS 313408 and HRAREC 22/YH/0215). Inclusion criteria included people aged 18 years and older, with transtibial amputation, deemed ready for a new prosthetic socket by their prosthetist in their usual clinical pathway, and willing and able to tolerate trialing 2 sockets at a fitting session. Convenience sampling was used to identify participants at 3 UK prosthetic rehabilitation centers. All participants provided written, informed consent (Multimedia Appendix 1); and the presented data are selected to avoid identification. Participants were not compensated.

Evidence-Generated Socket Design Method

A socket generation method was applied, based upon evidence of expert practice, building upon previous work [27]. To review briefly, a dataset of 163 transtibial residual limb 3D scans and corresponding socket designs was accessed in .aop format (version AAOP1), including labeled landmarks, exported from Omega software (Ohio WillowWood Co) with cylindrical sampling at a maximum 3° spacing on a minimum of 90 slices. These were produced at a single, large UK physical enablement center by 4 prosthetists, all with a minimum BSc qualification, of whom 2 had more than 20 years of experience, one had 5 - 10 years, and the other was a first-year graduate. The corresponding patient characteristics, such as gender, age, time since amputation, and reason for amputation, were also collated. A

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Statistical Shape Model was generated to describe the residual limb shape and size with a minimal number of dimensions, corresponding to principal "modes" of variation. The training datasets were aligned with the assistance of the landmarks, registered, and a principal component analysis was conducted using the full surface shapes of the residual limb scans. Socket design features of local rectifications (patella tendon bar carve, paratibial carves, fibula head build, distal end build, distal tibia build, anterior tibia build, and supracondylar carves) and gross volume change were extracted from the dataset. Bayesian inference was applied to analyze the probabilistic association between patient characteristics and principal modes of limb shape variation (inputs), and the extracted design features for the 163 limb-socket pairs. Finally, the same inputs were obtained for the study participants, and check sockets were created by automatically applying modifications to their landmarked residual limb 3D scans, which were predicted using the statistical model. These were applied to the limb shape scan and saved as a .stl mesh file (output).

Quantitative Study

The EG socket design was generated automatically except for the brim line, which the fabrication technician was requested to apply in the same location as the control, prosthetist-designed socket. The prosthetist then worked through their standard fitting and assessment procedure for both sockets (Multimedia Appendix 2), including an SCS. At the fitting appointment, the prosthetist chose which socket was trialed first, and the patient participant was blinded to which socket was prosthetist-designed, CAD/CAM, or EG. At the end of the session, the patient participant and their clinician were allowed free choice over which check socket design was to be used for the definitive prosthesis, on the basis of their mutual agreement without any intervention from the researchers.

A power calculation indicated a sample size of 19 was required to test noninferiority in a crossover trial (power=0.9, significance level=0.05, mean difference=0, noninferiority limit=1.21 [34], and population SCS SD 1.2 [24]). A Shapiro-Wilk test indicated the control SCS data were not normally distributed (P=.01), so nonparametric descriptive statistics were calculated with CIs using the bootstrap method [35], and the paired Wilcoxon Signed-Rank test was used to assess the statistical significance of the difference between the sockets.

Qualitative Study

Following the quantitative study, 2 semistructured interviews were carried out to capture participants' views and experiences of in-clinic fitting of 2 sockets designed in different ways, and general usability of their new prosthetic socket. The first was immediately after completion of the socket fitting, and the second was 1 month afterwards (Multimedia Appendix 3). Interviews were audio-recorded, anonymized, and transcribed verbatim by a professional transcribing company. A member of the research team (FM) checked a sample of transcripts against the audio recordings for accuracy. The transcripts were analyzed using thematic analysis, which provided a flexible approach to ascertain a clear understanding of the comparability of socket comfort and views of the processes [36]. The thematic analysis approach consisted of (1) familiarization with the data, (2) coding by hand and using NVivo software (Lumivero), (3) generating initial themes, and (4) reviewing and finalizing the final themes to capture consistent patterns within the data and key meaning relevant to the research questions [36]. One team member (MD-H) led all stages of the analysis; 2 other members (FM and JB) coded different sections of the data and together agreed on the final themes, providing verification and allowing for a range of interpretations.

Results

Recruitment

In total, 17 recruited participants with 19 residual limbs completed the socket assessment study between March and November 2023 (Table 1 and Figure 2). Furthermore, 6 prosthetists designed control sockets for between 1 and 9 participants. Approval was initially granted to compare transparent check sockets, but due to slow recruitment, a study protocol amendment was approved to compare the EG check socket to a definitive CAD/CAM prosthetist-designed socket, reflecting more common practice in the participating clinics.

In addition, 2 participants exited before completing the postassessment interview, and a further 3 were not contactable for the 1-month follow-up interview.

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Table . Description of participants.

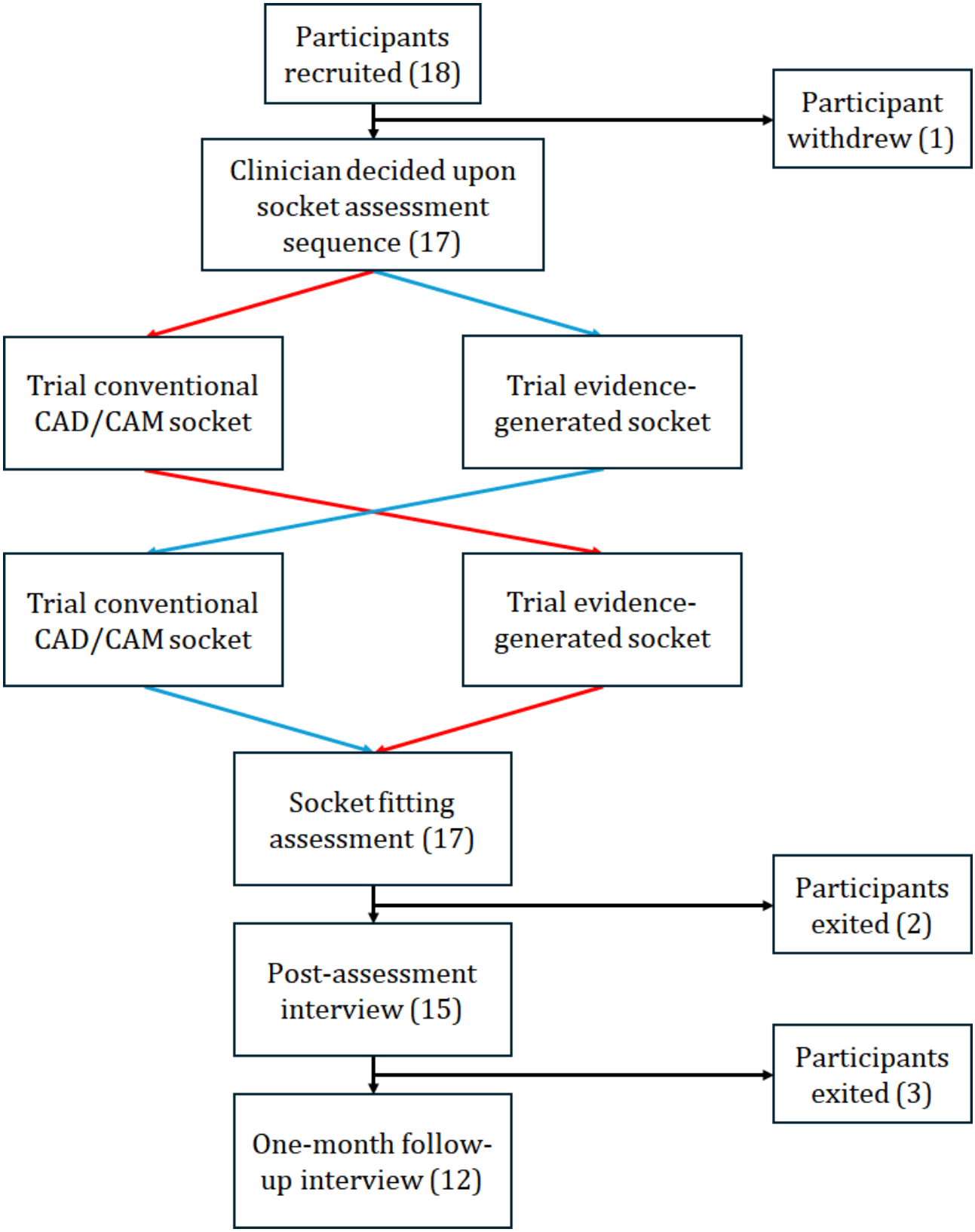
Characteristic	Statistical value
Side (n=19), n	
Left	8
Right	11
Sex (n=17), n	
Women	1
Men	16
Age (years; n=17), median (IQR)	66 (51 - 73)
Time since amputation (years; n=19), median (IQR)	4.0 (2.5 - 8.9)
Reason for amputation (n=19), n	
Infection or diabetic foot	6
Dysvascularity	4
Trauma	3
Ischemia or CLTI[a]	3
Sepsis	1
Peripheral Neuropathy	1
Chronic osteomyelitis secondary to trauma	1
Reasons for new socket (n=19), n	
Socket too large or limb shrinkage	12
Requested new suspension method	3
Socket too small or tight	2
Alignment incorrect	1
N/R[b]	3
Participant activity level (n=17)	
A1: In-house walking or transfers only	1
A2: Walking on flat ground only	6
A3: Normal everyday walking	8
A4: Additional high impact or energy activities	0
N/R	2

[a]CLTI: critical limb-threatening ischemia; activity level as assessed by the participants' normal clinical team.

[b]N/R: not reported.

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Figure 2. Study design and recruitment diagram. CAD/CAM: computer-aided design and manufacturing.



Quantitative Study Findings

The unmodified EG sockets had no statistically significant difference in SCS compared with prosthetist-designed CAD/CAM control sockets (median SCS 8.6 for EG sockets and 8.8 for CAD/CAM controls; *P*=.43 and effect size=0.05 in the paired significance test, Figure 3). Lower variability in SCS was observed across the study group for the EG sockets than the control sockets (95% CIs 8.0 - 9.0 and 7.5 - 9.5, respectively). Of the 19 EG sockets, 9 were given a comfort score within the noninferiority limit (standard error of measurement 1.21 points [34]) of the control. In total, 6 EG sockets were rated as more comfortable than the CAD/CAM control, by between 2.0 and 3.5 points; 4 EG sockets

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demonstrated lower comfort than the CAD/CAM control, by 1.5 to 2.5 points.

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Figure 3. Noninferiority crossover study results comparing socket comfort score between the prosthetist control and evidence-generated sockets, for 19 fittings across 17 participants, presented as a paired comparison chart. Color coding denotes higher (green), the same (blue), or lower (purple) socket comfort score for evidence-generated than prosthetist control devices, within the noninferiority threshold of 1.21 points.

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Qualitative Study Findings

Due to the significant impact and diverse experiences related to socket comfort, thematic analysis identified several broader themes that were beyond this paper's objective. Focus is therefore limited to specific themes that offer insights into the participants' views and experiences relating to the sockets produced by the 2 design approaches (Table 2).

Table . Themes identified in semistructured interviews relating to comparison between comfort of the fitted sockets and reflections on the socket fitting process.

Theme	Description
Theme 1	Experiences of the comparative fitting session
Theme 2	Similarity between the compared sockets
Theme 3	Differences between the compared sockets
Theme 4	Residual limb factors impacting perceptions of socket comfort

Theme 1: Experiences of the Comparative Fitting Session

Both devices were fabricated before the fitting session, and when discussing the session, participants reflected on several aspects that they felt impacted their experiences. Several participants described feeling that it went "*well*," "*fine*," or "*ok*," which illustrated that a process involving 2 different sockets was not a particular issue. For example, 1 participant discussed their experience in terms of the output of the session:

> *I got something out of it, it looks like this time if you know what I mean. At the end of this fitting there was something that looked like it was ready for me.* [Participant 10, male, 58 y, amputation following trauma, gel cushion liner]

Other participants discussed how they felt about comparing the 2 sockets and commented on how they did not know who designed either of the 2 sockets, for example:

> *I didn't know who designed and who produced each socket.* [Participant 1, male, 81 y, infection, sock]

Other participants discussed their experience in terms of their expectations of addressing their specific socket fit issues relating to their residual limb. For example:

> *The only thing I've got hope for there is that the bottom of my stump shrinks a lot more before it gets thinner and thinner because that's the only thing that's stopping me having a smaller prosthetic is that stump. It's where they added all the bits on.* [Participant 10, male, 58 y, amputation following trauma, gel cushion liner]

Theme 2: Similarity Between the Compared Sockets

Several participants described not feeling any difference in the level of comfort between the sockets, regardless of which design process was used. For some participants, this appeared to be related to feeling that both sockets were equally comfortable, with descriptions of how they found it difficult to decide if one was more comfortable than the other:

> *As far as comfort there was very little difference in it really to be honest as far as I could judge at the time.* [Participant 19, male, 71 y, amputation due to ischemia, gel liner]

Some participants compared the comfort of the two new sockets to their previous device. For example:

> *I feel a lot more comfortable really than the old one.* [Participant 1, male, 81 y, infection, sock]

This similarity in the level of comfort between the 2 new sockets was described by some participants in relation to both sockets feeling equally "*firm*," "*stable*," and "*both fitting well*," and both sockets feeling very "*natural*," as described by 1 participant:

> *Absolutely fine. They were both very, very close to being completely natural.* [Participant 4, male, 30 y, elective amputation following trauma, suction liner]

However, for other participants, the similarity between the sockets appeared to be associated with feeling similar levels of pain:

> *...walking with them as I was walking there was the same amount of pain...* [Participant 11, female, 84 y, peripheral vascular disease, cushion liner]

Theme 3: Differences Between the Compared Sockets

Other participants noticed significant differences in the comfort of the 2 sockets, from positive and negative perspectives. The reported comparative fitment assessments were associated with some of the factors the participants raised in theme 2, around similarities in fit, but also included differing, design-related factors such as the height of the socket, local shape details associated with bony prominences, and dynamic fit. Participants mentioned issues such as pressure points, discomfort at the back of the leg, and feelings of tightness. For example:

> *One felt really tight. I like it tight when I get a new socket because it lasts longer. One felt a lot more comfortable at the front where my bone is closer to the skin.* [Participant 12, male, 40 y, amputation due to chronic ulcers, seal-in liner]

Differences in the size of the sockets also affected comfort. One participant explained:

> *The taller one was a bit more uncomfortable due to how high it was. When you bend your leg down, it hits the back of your leg.* [Participant 4, male, 30 y, elective amputation post trauma, suction liner]

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Some participants felt that the height of the socket made it feel more natural. These differences impacted participants' walking, with 1 socket feeling easier to walk in than the other

> *One socket was absolutely perfect. The other one had different movement, slightly different, but it seemed like you walked quicker with it. It was a nice, easy movement.* [Participant 8, male, 76 y, ischemic amputation, pin liner]

Theme 4: Residual Limb Factors Impacting Perceptions of Socket Comfort

While comparing the 2 sockets, participants discussed sensitive areas that affected their comfort, such as spots on the crest of the shin and other specific sore areas. These issues were often ongoing and considered by the prosthetist during socket design:

> *I've always had this issue. We've had to shave out a bit of the socket to ease the pressure. But I think it's just the shape of my stump, and it's something that will always be an issue and I'm always aware of it.* [Participant 13, male, 32 y, elective amputation post trauma, no interface details recorded]

Some participants reflected on the adjustment after the fitting process, saying:

> *I don't know if the second one on the right whether it needed any more adjustment. Maybe a little bit but I would say they are fairly comfortable.* [Participant 16/17, male, 70 y, diabetic amputations, no interface details recorded]

Other factors, also not necessarily directly related to the design process, appeared to impact the participants' views of which of the 2 new sockets were more comfortable. For example, 1 participant described how their residual limb had shrunk since their last prosthetic fitting, and this led to the new socket feeling more comfortable:

> *But it does feel better and that clear one that I had in my old socket … had more movement because the stump had shrunk so much. So, it's just a case of getting used to having this because it's slightly smaller and it's hugging the stump. Perhaps where I had the freedom before where it moves about a lot more … I've got to get used to the new feelings of it.* [Participant 6, male, 51 y, dysvascular amputation, no interface devices]

Discussion

Principal Results

This study demonstrated the noninferiority of the EG socket design method in comparison with conventional clinician-led CAD/CAM socket design at initial fitting. SCS indicated similar comfort on average and reduced variability across the cohort for the EG sockets. Participant interviews confirmed this assessment and added a more detailed understanding of socket satisfaction.

Thematic analysis also revealed the patients' detailed understanding of the nuances of their prosthesis design and its fit and demonstrated the importance of ensuring a trained, experienced clinician directs the application of technology-enhanced socket design processes. The comfort results indicated noninferiority of the EG sockets' fundamental design without any personalized clinician input. However, the qualitative study provided evidence to support clinical usage of EG sockets with an expert human in the loop to make design decisions in response to patients' individual and complex needs [12,24,37]. That might include local design modifications in response to vulnerable sites on that individual's residual limb or accommodating the patient's preferences for tightness of fit. This was identified for the single participant whose EG socket was rated with SCS below 7 (participant 16/17, male, 70 y, diabetic amputation), for whom the score of 7 was attributed to an unusual tissue sensitivity at a supracondylar site, where the CAD/CAM control socket featured a local modification. The same point may explain the observed trend where all 4 EG sockets that were rated as less comfortable than the CAD/CAM control were cases where the control scored an SCS of 9 to 10, where such personalization has evidently been successful. Patient-specific local areas of sensitivity and corresponding design changes inherently cannot be generalized, so this justifies the importance of an expert in the design process, who retains clinical responsibility.

Comparison With Previous Work

The complementary evidence provided by this multiple methods approach demonstrates the value of exploring the participants' experience more deeply through interviewing, to enhance what can be learned from objective measurement [38]. However, this approach is somewhat unusual in the assessment of prosthetic technologies [30]. The study involved a large interdisciplinary team, which enabled separation of trial socket design, clinical assessment, interviewing, data analysis, and interpretation, in an attempt to minimize potential researcher biases. The combined synthesis of the SCS and interviews revealed the participants' detailed understanding of the influence of residual limb shape and corresponding socket design upon their comfort and function, illustrative of the value of excellent prosthetist-patient communication. These technologies may offer an opportunity to improve patient experience through understanding of their care [39] or even shared decision-making [40]. The use of an EG socket design process may enable greater focus on the higher value-added aspects of personalization and might be easier to perform in front of the patient [24]. Most notably, this observation justifies ongoing work with clinician stakeholders, for example, to indicate specific areas in which human input is particularly important for fitting EG sockets to newly presenting individuals, and in the development of software interfaces, building upon methods reported by Ngan et al [41].

Limitations

The study included a relatively diverse group of patients accessing prosthetic rehabilitation services, except for gender, where the recruited participants were predominantly men (16/17) [42], which may impact the study's generalizability. Women are less likely to have a major amputation and to be successfully fitted with a prosthesis [43], enter prosthetic rehabilitation later

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[44], and are underrepresented in research cohorts [45]. It is not clear why this study's convenience sampling resulted in an imbalance, but this illustrates the need to ensure that further studies include more diverse gender representation, as the experiences of men and women may be different. However, the distribution of randomly sampled people whose socket designs were used to train the socket design evidence model [27] was representative of the population of people with transtibial amputations, and external validity is supported by their diverse range of ages, reasons for limb absence, activity levels, and time since amputation. Further bias may arise from the recruited participants' age profile (median 66, IQR 51 - 73, range 30 - 84 y), which was similar on average but narrower in range than the general population of people using prosthetic limbs [42]. The participants' age profile was older on average but similar in range to the historic socket design dataset (median 60, IQR 50 - 71, range 20 - 94 y [27]). Finally, the training datasets came from clinicians at a single center, whose practice may be similar, potentially limiting the diversity of design approaches.

The study also has limitations in its single timepoint and outcome measure, where previous studies comparing CAD/CAM with plaster design and fabrication considered quality of life [7] and more extensive assessments of comfort, fit, cosmesis, weight, and function alongside clinical workload and productivity measures [9]. The study cannot indicate how socket comfort would develop long-term, and it may be preferable to use the expanded SCS for best, worst, and average comfort over a longer period [46]. However, this study replicates the clinical assessment of trial and definitive sockets in UK National Health Service settings and provides additional insight since participants could compare 2 socket options side-by-side and select their preference, with interviews proceeding a month after fitting. A different comparison, versus plaster socket design methods, might provide additional insights, but the study was designed to compare with conventional CAD/CAM as the standard of care in the participating centers, and indeed, the prevalence of CAD/CAM is rising. Finally, the study was not formally randomized, and prosthetists generally fitted their own design socket first, meaning a carryover effect cannot be excluded. Alongside this limitation, single-blinding could not apply to 3 participants for whom the EG check socket was compared with a definitive CAD/CAM control socket, instead of comparing 2 visually-similar check sockets.

Clinical Messages

First, EG transtibial prosthetic socket designs compared well with devices produced by conventional CAD/CAM clinical practice, in terms of comfort at socket fitting and patient feedback in semistructured interviews.

Second, qualitative feedback confirmed that clinician input remains essential to incorporate patient-specific socket design details in response to local sites of sensitivity or tissue vulnerability, or preference: details that cannot be generalized.

Finally, work is underway to incorporate EG socket designs into CASD software such that they can be modified at fitting, enhancing evidence-based practice as a support tool to help qualified clinicians leverage their experience and skill and enable co-design with the prosthesis user.

Conclusions

Overall, the study findings support wider clinical use of EG transtibial sockets, but also demonstrate the importance of delivering this technology in a way that facilitates prosthetist input in tailoring the design to their individual patients' needs and provides maximal opportunity for their communication. Such an implementation may enable prosthetists to take the advantages offered by technology while retaining or ideally enhancing trust through human-centered prosthetic rehabilitation.

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Data Availability

The dataset supporting the conclusions of this paper is available in the University of Southampton repository [47].

Authors' Contributions

FM contributed to data collection, data analysis, data interpretation, writing, and editing. MD-H contributed to study design, literature search, data analysis, data interpretation, writing, and editing. JB contributed to study design, data collection, data analysis, data interpretation, and editing. JS contributed to study design, technical design, data analysis, data interpretation, figures, writing, and editing. CR contributed to technical design, data analysis, underlying data verification, and editing. PW, CO, CM, and DH contributed to study design, data interpretation, and editing. CW, JK, SS, KM, SG, HH, DHS, and VK contributed to study design, data collection, data interpretation, and editing. AD contributed to study design, technical design, literature search, data interpretation, figures, writing, and editing.

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Conflicts of Interest

Authors FM, MD-H, CO, CM, SG, HH, and VK have no conflict of interest to declare. Authors JS, JB, CR, AD, and PW declare employment and shareholding in Radii Devices Ltd. Authors DH, CW, JK, SS, KM, and DHS declare employment at Opcare Ltd.

Multimedia Appendix 1
Participant consent form.
[DOCX File, 456 KB - rehab_v12i1e69962_app1.docx]

Multimedia Appendix 2
Transtibial checkout procedure.
[DOCX File, 25 KB - rehab_v12i1e69962_app2.docx]

Multimedia Appendix 3
Semistructured interview schedules.
[DOCX File, 28 KB - rehab_v12i1e69962_app3.docx]

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Abbreviations

CAD/CAM: computer-aided design and manufacturing
CASD: computer-aided socket design
EG: evidence-generated
PPIE: patient and participant involvement and engagement
SCS: socket comfort score
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Understanding Patient and Physiotherapist Requirements for a Personalized Automated Smartphone Telemonitored App for Posttotal Knee Arthroplasty Rehabilitation: Qualitative Study

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Abstract

Background: Total knee arthroplasty (TKA) is a cost-effective surgical intervention for painful knee osteoarthritis in older adults, but postsurgery rehabilitation access is limited. Telerehabilitation offers a solution, but existing models require significant therapist involvement and a costly setup. A personalized smartphone-based automated program could be a cost-effective alternative.

Objective: This study aimed to understand the requirements of both patients and physiotherapists in developing an automated telemonitored rehabilitation smartphone app for individuals undergoing TKA. To ensure uptake and long-term sustainability, this study adopted a person-based approach.

Methods: A multistakeholder qualitative study of user needs was conducted. Physiotherapists and patients who underwent TKA were recruited via purposive sampling. Individual in-depth, hour-long interviews were conducted via Zoom by an experienced, trained female interviewer with a Master of Arts in Sociology. Data were audio-recorded and transcribed by the same interviewer. Two reviewers (ESC and SSK) independently analyzed the data using thematic analysis, with data triangulation achieved through cross-checking of data sources by 3 reviewers (ESC, SSK, and AES). Interviews were conducted to data saturation.

Results: Six patients and 4 physiotherapists participated. For the patient interface, patients emphasized ease of use and specified features like a search function and multilingual options. For the physiotherapist interface, physiotherapists stated ease of accessing patient data and outcome measures for effective monitoring as important. Both patients and physiotherapists highlighted the need for timely, condition-specific information, supplemented by visual aids to support exercises, pain management, and recovery goals. They also stressed the significance of progress tracking, feedback, and the ability to access health care professionals for reassurance. Motivational features, including reminders, prompts, and exercise logs, were recommended to improve adherence. Both groups similarly identified the need for initial training to ensure confident use of the app.

Conclusion: This study provided insights into the requirements of potential end users of a smartphone app for automated telemonitored rehabilitation following TKA. This is useful for steering the development of a user-centric smartphone app.

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KEYWORDS

knee replacement; knee arthroplasty; mobile; application; interview; telemonitored; smartphone rehabilitation; mobile phone

Introduction

Total knee arthroplasty (TKA) is a cost-effective surgical intervention for managing painful knee osteoarthritis [1,2]. With an aging global population and rising obesity rates, TKA demand is projected to increase significantly [3]. In Singapore, all patients discharged post-TKA are referred to hospital-based outpatient physiotherapy, which improves physical function [4-6], but limited access, high costs, and logistical challenges often hinder adherence [7]. This highlights the urgent need for accessible, cost-effective physiotherapy alternatives [8,9].

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A systematic review conducted by Jansson et al [10] in 2020 found that telerehabilitation for lower limb joint replacements achieved outcomes comparable to in-person physiotherapy but given the high manpower and equipment requirements, it was only cost-effective mainly for those living over 30 km from care centers [9]. In contrast, a telemonitored physiotherapy program that is automated yet personalized through the ubiquitous and powerful mobile phone offers a promising, scalable solution for the majority of patients, reducing manpower demands while improving access to care.

Bahadori et al [11] emphasize that the development of TKA-related apps often fails to incorporate patient input, which can undermine the effectiveness of these interventions. Given the complexity of rehabilitation, post-TKA recovery typically requires personalized, physiotherapist-guided care [5,6,12]. To improve adherence, this study uses a person-based framework in developing the proposed solution. This framework ensures that behavior change interventions are grounded in a comprehensive understanding of users' perspectives, experiences, and psychosocial contexts [13]. By incorporating cultural relevance [14] and addressing adherence barriers, the intervention can then be designed to be effective, sustainable, and accessible to diverse populations.

Our primary objective is to identify patient needs, behaviors, and preferences to inform the development of a user-friendly and effective personalized automated smartphone telemonitored app that supports recovery post-TKA.

Methods

Study Design

We conducted a qualitative exploration using a person-based approach [13] to inform the development of a digital health behavior change intervention. To ensure methodological rigor, we adhered to the COREQ (Consolidated Criteria for Reporting Qualitative Research), which guided our assessment of the research team, study methods, findings, analysis, and interpretations [15]. Our data collection involved individual in-depth interviews with physiotherapists who work with patients with TKA, as well as patients who had undergone a unilateral TKA within the past 6 months. These participants were selected for their insight into user needs and preferences during TKA rehabilitation.

At the outset of each interview, the interviewer clearly articulated the objectives of the personalized automated smartphone app under development and provided an overview of the various phases of rehabilitation, including preoperation and inpatient and outpatient stages. Given that Singapore General Hospital performs more than half of the nation's TKA, with more than 2000 surgeries done annually [16], we have established an evidence-based rehabilitation protocol and accompanying information sheet guide [17]. These resources will serve as the foundational elements for the proposed program, ensuring that it is grounded in best practices and tailored to meet the specific needs of patients with TKA.

A semistructured interview guide was developed and piloted for the purpose of this study, organized into two main segments: (1) the contents and functions required by the patient and the physiotherapist for a personalized automated telemonitored rehabilitation app, and (2) the design elements of the user interface to address their specific needs. The questions were informed by the Technology Acceptance Model [18] and the Mobile App Rating Scale assessment [19] covering key interfaces for the recovery and rehabilitation journey, including the menu, dashboard, education materials, exercise module, and assessment tool. By aligning our questions with these domains, we aimed to gain a deeper understanding of user needs. Thus, the study aims to integrate end user insights during co-design to ensure the app's perceived usefulness, ease of use, and appeal. In line with the person-based approach [13], the interviews also used more open-ended questions and allowed for probing and clarification of responses, to capture deeper insights and provide participants the opportunity to express their perspectives freely.

Recruitment of Patients

We used purposive sampling to achieve a wide range of patient characteristics (age, gender, socioeconomic status, and education level) to obtain a rich data collection. The study team identified eligible patients through physiotherapists who attend to patients with TKA. Adult patients with previous primary TKA done in Singapore General Hospital, sufficient linguistic capacities to participate in a 1-hour interview, and the ability to navigate at least 1 smartphone app were included. The selection of patients was based on the judgment of the recruiting therapists.

Recruitment of Physiotherapists

The team contacted physiotherapists from Singapore General Hospital by email or phone. To be eligible for inclusion, physiotherapists needed to have sufficient experience in managing patients undergoing TKA, which was defined as having treated at least 5 of these patients weekly in the past three months. Again, a wide range of physiotherapist characteristics (age, experience, professional qualification, and work setting) was sought to obtain a rich data collection.

Collection and Analysis of Data

All interviews were conducted by a trained interviewer over Zoom (Zoom Video Communications Inc). The trained interviewer was not part of the study team and had been employed specifically to conduct the interviews, so there was no relationship with participants prior to the interviews. They had a Master of Arts in Sociology, worked as a research associate at the time of the study, and had prior experience conducting interviews for 20 studies. The interviewer was supportive of the idea of a personalized automated telemonitored rehabilitation smartphone app but had no previous work in this area.

The interviews lasted approximately 1 hour and were digitally audio-taped and subsequently transcribed by the same interviewer. In addition, field notes were taken by the team during the interview describing the context of the interview. Apart from relevant study team members, the interviewer, and the participants, no one else was present during the interviews. After each interview had been transcribed, the interviewer used data analysis to check which topics emerged and recruited

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additional patients and physiotherapists until data saturation was achieved.

The data from the interviews were analyzed using NVivo (version 12.0; QRS International). Thematic analysis was used to identify emerging themes. The analysis was data-driven; the 2 reviewers (ESC and SSK) independently read all transcripts to familiarize themselves with the data and recorded their initial codes. Each reviewer then organized and combined recurrent codes into broader themes. Data triangulation was achieved by cross-checking data sources and involving 3 reviewers (ESC, SSK, and AES) in the study to discuss discrepancies for a consensus. Finally, the main themes were identified based on the coded data in the NVivo. The field notes, transcripts, and themes were intentionally withheld from participants to minimize the potential for bias in their interpretation of their own responses. In the upcoming phase of rapid prototyping, the initial prototype will be presented to the same group of participants, who will then offer feedback on both its content and design.

Ethical Considerations

This study was approved by the SingHealth Centralized Institutional Review Board (2022/2177, Singapore) and all participants provided written informed consent. Ethical guidelines were strictly followed, with data deidentification ensuring participant privacy during interviews. Participants received a reimbursement of SGD $50 (US $36.98) per session for their time and inconvenience.

Results

Participant Characteristics

A total of 11 eligible patients and 4 eligible physiotherapists were invited. A total of 6 (55%) patients and 4 (100%) physiotherapists consented to take part in the study. Reasons for refusal included being busy with other commitments (n=3, 60%) and having no interest to participate in research activity (n=2, 40%). Recruitment for the interviews was done until data saturation was achieved. Among the patients, the median age was 65 (IQR 64-71) years, 50% (n=3) of the participants were male, 83% (n=5) were Chinese, and 67% (n=4) were employed at the point of recruitment. The median age for physiotherapists was 27 (IQR 24 - 36) years, and 50% (n=2) had more than 5 years of experience (Table 1).

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Table . Characteristics of patients and physiotherapists participating in the interviews.

Variables	Value
All physiotherapists (n=4)	
Age (years)	
Median (IQR)	24-36
Mean (SD)	39 (16)
Sex (female), n (%)	4 (100)
Education level, n (%)	
Undergraduate degree	2 (50)
Postgraduate degree	2 (50)
PT[a] experience (years), n (%)	
1 - 5	2 (50)
5 - 10	1 (25)
>10	1 (25)
TKA[b] experience (years), n (%)	
<5	2 (50)
5 - 10	2 (50)
All patients (n=6)	
Age (years)	
Median (IQR)	64-71
Mean (SD)	70 (7)
Sex, n (%)	
Male	3 (50)
Female	3 (50)
Ethnic group, n (%)	
Chinese	5 (83)
Malay	0 (0)
Indian	1 (17)
Marital status, n (%)	
Married	6 (100)
Number of children, n (%)	
1	2 (33)
2	1 (17)
3	3 (50)
Highest education level, n (%)	
Primary	1 (17)
Secondary	2 (33)
Tertiary	3 (50)
Employment status, n (%)	
Employed	4 (67)
Unemployed	1 (17)
Retired	1 (17)
Housing ownership, n (%)	

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Variables	Value
Purchased	6 (100)
House type, n (%)	
Public housing flats 3/4/5-rooms	3 (50)
Private apartment or condominium	2 (33)
Landed property	1 (17)
Living arrangement, n (%)	
Living with spouse	3 (50)
Living with spouse and children	3 (50)
Household income (SGD $)[c], n (%)	
<$ 2000	0 (0)
$2000-$4000	2 (33)
>$4000	3 (50)
Not shown	1 (17)
ADL[d] limitation, n (%)	
Yes	0 (0)
No	6 (100)
iADL[e] limitation, n (%)	
Yes (>2)	1 (17)
No	5 (83)
Presence of formal caregiver, n (%)	
Yes	0 (0)
No	6 (100)
Comorbidity, n (%)	
Hypertension	4 (67)
Dyslipidemia	2 (33)
Ischemia heart disease	1 (17)
Asthma	1 (17)
Use of mobile app, n (%)	
WhatsApp	5 (83)
HealthBuddy	1 (17)

[a]PT: Physiotherapist

[b]TKA: total knee arthroplasty.

[c]All income is reported in Singapore dollars (SGD $1=US $0.74).

[d]ADL: activities of daily living.

[e]iADL: instrumental activities of daily living.

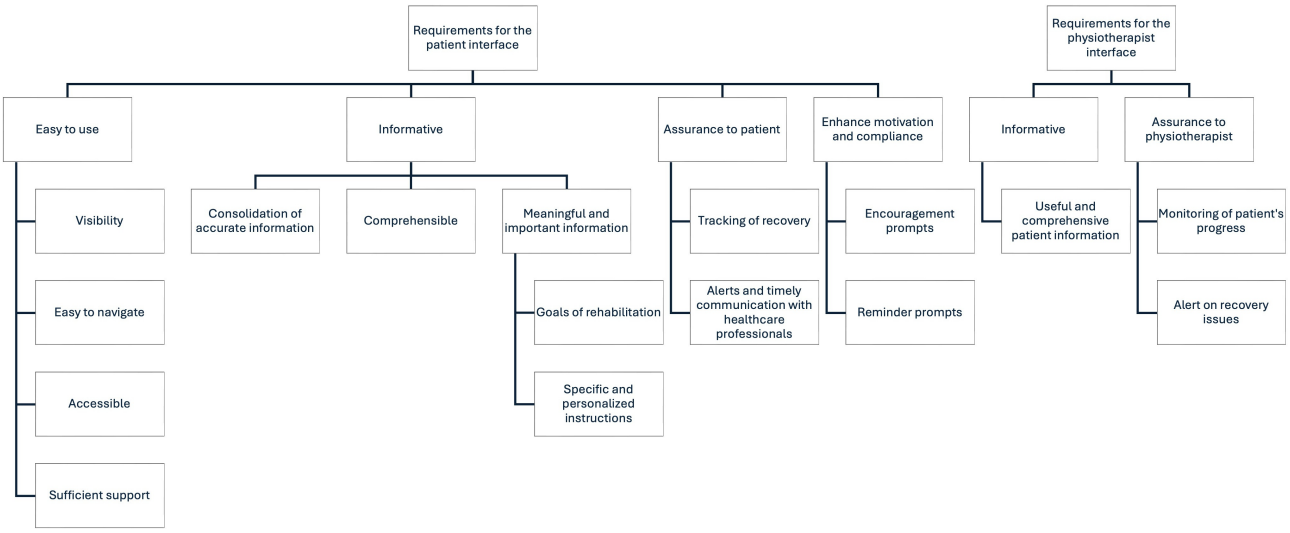
We conducted 10 individual interviews, which yielded important themes on user requirements for the interface, content, and function of the smartphone app. The coding tree is presented in Figure 1. All participants liked the idea of a telemonitored rehabilitation smartphone app and appreciated the value it would bring:

Better to do this, don't need to come down. I come down and do, taxi fare another thing. Then I have to wait ... Might as well I do at home. [Patient #5]

Is good for us. More convenient ... I stay in Tampines, so far. I take 1 hour to and fro ... help us when we are sick, we cannot come down. [Patient #6]

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Figure 1. Coding tree.



Patient App

Easy to Use

As the patients were older than 60 years of age and may not be technologically proficient, there was a unanimous consensus among participants that the app should be easy to navigate and user-friendly. This involves implementing large, visible buttons adorned with comprehensible, prominent headings and fonts. The collective emphasis was on the necessity of organizing information in a systematic manner, with intuitive categorization of information facilitating seamless navigation for enhanced accessibility:

> *Honestly, I think the interface needs to be as simple as possible. It shouldn't be too cluttered, not too many words or images.* [Patient #4]

Prior to undergoing surgery, patients are inundated with a plethora of information and training materials. Several individuals proposed the integration of a search function to streamline the identification of materials aligning with their specific interests. Additionally, they underscored the significance of information offering customization options to cater to diverse language preferences and auditory needs. Some participants also suggested adding a voice recording feature for those who may have difficulty typing. Participants expressed a consensus on avoiding additional equipment or wearables due to the associated hassles in setup, maintenance, and frequent connectivity issues:

> *Search function would definitely help so that not everybody need to start from beginning.* [Patient #2]

> *Machine ... wear and tear ... connection also loosen ... if you can put all these in the app, it would be much better.* [Patient #1]

Participants recommended that education, whether before surgery or during hospitalization, should involve a personal touch, with an instructor guiding them through the app to ensure comprehension and compliance. Following this initial human interaction, the app can seamlessly take over. Additionally, participants stressed the crucial need for readily available tech support, citing past experiences with apps that malfunctioned and lacked prompt assistance:

> *For those not so well-versed, they need at least 1 or 2 sessions hands on so they can be more confident to do it on their own.* [Patient #1]

Informative

Patients highlighted challenges with the untimely delivery of information, leading to either overwhelming or insufficient details. The current mode of patient education, conveyed through booklets, often proves impractical as it is prone to misplacement, lacks bite-sized segments, and lacks a searchable format for specific queries. Participants expressed a desire for accurate, condition-specific information available in a timely manner, encompassing both pre- and postsurgery aspects. Additionally, they emphasized the importance of having clear goals and expectations. By delivering the right information at the right time, the mobile app can empower patients to make informed decisions, better anticipate and understand the recovery process, and actively participate in their recovery journey. Participants also sought insights and guidance on when and how to access professional support:

> *I tried to search on Google ... so the information may not be correct ... it may be something else ... It is good to give information of what will be faced after surgery.* [Patient #3]

The information should be comprehensive, easily understandable, free from technical jargon, and presented succinctly. Recognizing the need for repeated reference, participants see the advantage of housing these materials in an app for convenient access:

> *You want to give the patient information that he needs, you want to avoid giving him information that he doesn't need and devalue the app.* [Patient #2]

> *Some after surgery they call in to a physio, not every time the physios are available. But if you see from the app, you can always play it again and again until they understand.* [Patient #2]

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Among the requested content, there was a distinct emphasis on the imperative need for comprehensive information concerning pain management and swelling strategies, deemed vital for ensuring a successful recovery.

Guidance for pre and postsurgery exercises can be effectively conveyed through a combination of images and videos, tailored to individual needs and abilities. The instructions should encompass precise targets and goals, providing clarity on the criteria for discharge from physiotherapy:

> *Pictures and videos people can follow ... cannot have a lot of words.* [Patient #5]
>
> *How would the patient know when they can actually stop (physiotherapy) or come to a point where there is a full recovery.* [Patient #4]

Assurance to Patient

Just as in a physical outpatient physiotherapy session, patients emphasized the importance of reporting their progress for tracking and monitoring, seeking assurance in the process:

> *To see that you are improving is important.* [Patient #3]

They expressed a desire to gain insights into whether they were on the correct path to recovery and to understand their performance relative to others. Additionally, they emphasized the crucial need for feedback on the accuracy of their rehabilitation efforts and prompt notifications if their recovery deviated from the expected trajectory. While patients acknowledged the positive impact of comparing themselves to the same age group and gender for recovery metrics—providing a sense of accomplishment and motivation—they also recognized the potential downside. They noted that for those not progressing well, such comparisons might lead to demoralization.

Understandably, patients expressed the importance of having access to health care professionals for addressing any concerns:

> *Some patients who are already very worried and verbalized that they want to have a session with a physiotherapist or a doctor to check on them, we can arrange that.* [Patient #2]

They emphasized that while the app is a valuable tool, it cannot entirely replace the role of physiotherapists. The consensus was that the app should complement physiotherapy sessions. Patients speculated that this perspective might evolve as society becomes more open, particularly with the younger generation aging.

In a majority of responses, patients individually conveyed a preference for at least 1 to 2 physiotherapy sessions, citing that the app does not provide them with 100% assurance. Many older adults expressed discomfort with the lack of human interaction, highlighting the enduring significance of personal engagement in health care:

> *Sometimes we are not very sure are we doing it correctly or not, but if we go for physio, we can understand better.* [Patient #6]

Enhance Motivation and Compliance

Participants recommended incorporating functions to boost motivation and adherence to rehabilitation. They highlighted the utility of features such as tracking sessions with an exercise log. Setting alarms and receiving prompts to complete exercises, coupled with the ability to monitor personal progress, were identified as key elements that would significantly enhance motivation and compliance. In addition, the app should incorporate features for positive reinforcement and encouragement upon completion, further enhancing the user experience and motivation for rehabilitation:

> *At the end over every exercise, every set that I do, the app actually congratulates me, so it's motivating. It will say well done you've completed this function or this set. That helps. Although you know it's just automatic, but it give you a bit of a boost, like oh I finished something!* [Patient #4]
>
> *The reward part is quite individual. For me, I'm quite concerned for my own health and I don't need any monetary rewards. But if the application can tell me well done, you have achieved your target, to me it is good enough.* [Patient #1]

Physiotherapist App

Informative

Physiotherapists expressed the need to have easily accessible patient information within the program to facilitate seamless follow-up coordination. They emphasized the efficiency of receiving prompts when patients are not progressing well, as it would save valuable time for the clinicians. Streamlining this information and notification process was considered essential to enhance the effectiveness of patient care and monitoring:

> *It will be good to keep a lookout on their range, like how much they can extend the knee … how much they are walking on a daily basis, what is their pain score when doing the exercises…so that we can see that they are improving.* [Physiotherapist #3]

Assurance to Physiotherapist

Several reporting parameters, encompassing both subjective and objective outcomes such as pain levels, range of motion, walking ability, and patient-reported outcome measures, were identified as crucial. These parameters serve as essential indicators to reassure physiotherapists about the well-being and progress of their patients. The inclusion of these comprehensive metrics allows for a more thorough and accurate assessment of patient outcomes, contributing to the overall effectiveness of the rehabilitation program:

> *For physios we look quite holistically… so we will see how they are as well, walking at home and all. So I'd prefer to have other outcome measures and patients subjectively how they feel, so that we can see the treatment is really working.* [Physiotherapist #3]

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Discussion

Principal Results

Patients outlined requirements for ease of use, the provision of information and reassurance, and the enhancement of motivation and compliance. Physiotherapists raised themes for the provision of information and reassurance. Beyond requirements, participants anticipated several benefits of the app. These included improved access to patients, heightened motivation for rehabilitation, enhanced convenience, and potential cost savings. Participants shared the collective vision for the app to not only meet specific needs but also to create a positive impact on patient engagement, overall motivation, and the efficiency of health care delivery.

Strengths and Limitations

To our knowledge, this is the first study to use a person-based framework to systematically investigate the requirements for an automated, smartphone-based solution tailored to the rehabilitation needs of patients post-TKA. By addressing a significant gap in current rehabilitation practices, our findings emphasize the potential of integrating digital health technologies into personalized care. A key feature identified by both patients and physiotherapists is the need for outcome tracking, real-time monitoring, and a feedback loop to facilitate the personalization and automation of care delivery. These features not only enhance patient motivation but also provide reassurance to both patients and clinicians, promoting improved adherence and engagement throughout the rehabilitation process.

The inclusion of users during the design phase yielded crucial revelations, pinpointing significant content and features essential for an automated telemonitored smartphone app. This approach is pivotal not only for ensuring widespread adoption but also for enhancing patient adherence and ultimately elevating overall patient outcomes. Further studies and app developers should, however, continue to involve patients in an iterative prototyping and development phase including the use of think-aloud interviews [13] to receive specific feedback for the actual app.

As the participants in this study may not fully represent the entirety of patients undergoing TKA, there may be limitations in generalizability. However, the characteristics of our participants, as evident in their diverse age range, gender distribution, socioeconomic status, and educational levels, contribute to a broad spectrum of perspectives in our data collection.

Despite the relatively small sample size, data saturation was achieved during discussions. Notably, studies, such as those referenced by Nielsen and Laudauer [20], propose that a sample size as modest as 5 users can uncover a significant percentage (75% - 80%) of usability issues in the design of user-centered systems. Furthermore, empirical data studies suggest that saturation can be reached within a narrow range of interviews, especially in studies with relatively homogenous populations and narrowly defined objectives [21], aligning with the characteristics of this study.

Comparison With Prior Work

The existing literature on telerehabilitation, including in post-TKA cases [22,23], closely aligns with the findings related to both patient and physiotherapist apps.

Easy to Use

Our findings highlight the importance of user-friendliness and accessibility for older adults, a need that is strongly supported by various studies advocating for intuitive telerehabilitation designs [24]. User-friendly interfaces that cater to the technological abilities of older users are essential, with features like large, clear buttons, and well-organized information can significantly enhance usability [25,26]. This echoes participants' feedback which stressed the need for simplicity and clarity in navigation.

Presurgery, patients often face information overload. The ability to quickly locate relevant materials can enhance their experience [27]. Hughes et al [28] emphasize the crucial role of accessible patient information in improving the effectiveness of rehabilitation programs, aligning with the feedback from our participants.

Informative

Participants expressed a strong preference for comprehensive, easily understandable information devoid of technical jargon which is consistent with research emphasizing clear communication in health care apps [24]. The participants' request for visual aids, such as images and videos for exercise guidance, is supported by studies showing that these formats can enhance understanding and information retention [29].

Additionally, the need for specific content on pain management and recovery strategies was frequently highlighted by participants and is well-documented in studies that stress the importance of addressing these areas for successful rehabilitation outcomes [30-33]. Aligned with existing literature [29,32], participants consistently expressed the desire for timely, accurate, condition-specific information, empowering them to make informed decisions about their recovery.

Assurance to Patient

The use of a feedback loop, where patients receive notifications about their performance and recovery progress, is crucial for maintaining engagement and ensuring that patients feel supported throughout their rehabilitation journey. This is particularly important for older adults, who often require extra reassurance and motivation to stay compliant with their rehabilitation exercises [33,34].

Additionally, both the findings and literature emphasize the importance of a personal touch in education and support. Participants expressed the importance of initial guidance from health care professionals to build confidence in using the app. This sentiment is echoed in the literature, which highlights clinician-patient communication as a critical factor in fostering a supportive environment [33,35]. While telerehabilitation apps provide valuable resources, they should be viewed as complementary to direct interactions with health care professionals rather than as a replacement [36].

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Enhance Motivation and Compliance

Our findings align with the recommendations of Mrklas et al [32] and Bahadori et al [11], who advocate for the inclusion of self-tracking features in mobile apps to enhance patient engagement and ensure that the information provided is both robust and contextualized. Research further shows that including motivational elements, such as exercise logs, reminders, and congratulatory messages, can significantly improve patient adherence to rehabilitation programs [29,33,37]. However, it is noteworthy that participants did not specifically mention gamification elements, which have been shown to aid compliance in telerehabilitation [33]. This suggests that gamification may not be a priority for this particular group of patients.

Implication for Future Research

The insights generated from this study have identified essential design elements, focusing on patient preferences and adherence barriers, which are guiding the development of a personalized, automated smartphone app for post-TKA rehabilitation. This app is currently being evaluated in a randomized controlled trial (ClinicalTrials.gov: NCT06248034). Findings from this trial will provide valuable evidence on the effectiveness of digital health interventions in improving post-TKA outcomes. Additionally, this research defines the foundational requirements for creating scalable, patient-centered digital solutions that reduce manpower demands and can be adapted to diverse rehabilitation contexts, contributing significantly to the advancement of digital health and personalized care.

In summary, the findings from the patient and physiotherapist apps align closely with existing literature on telerehabilitation. The emphasis on user-friendly design, timely information delivery, motivational features, and the importance of clinician support are all well-supported by current research and correspond with models of learning such as the Illeris model [38], which incorporates all 3 dimensions of learning: content, incentive, and interaction. A key feature identified by both patients and physiotherapists is the need for outcome tracking, real-time monitoring, and a feedback loop to facilitate the personalization and automation of care delivery. These features not only enhance patient motivation but also provide reassurance to both patients and clinicians, promoting improved adherence and engagement throughout the rehabilitation process.

Conclusions

This study provides a comprehensive exploration of the perspective of both patients and physiotherapists regarding the requirements for a personalized automated smartphone app designed for telemonitored rehabilitation following TKA relevant to an Asian context. To ensure the program is both automated and tailored to each individual, the findings reveal a strong consensus from both groups on the need for automating rehabilitation progression and outcome monitoring.

Such an app could serve as a powerful catalyst for boosting patient motivation, satisfaction, and active engagement throughout the rehabilitation process. By providing real-time feedback and progress tracking, it would empower patients to take ownership of their recovery, fostering a sense of agency and commitment to their rehabilitation goals. Furthermore, the app would equip health care providers with tools to identify patients who may be deviating from their expected recovery trajectory, enabling timely, targeted interventions for those in need of professional guidance. This would ultimately optimize patient outcomes and enhance the overall effectiveness of rehabilitation programs.

The insights from this study provide clear guidelines for developing a user-centric smartphone app that meets the needs of both patients and health care providers in this region.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
TKA: total knee arthroplasty

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Assessing Physical Therapists' Expectations and Experiences With an Automated Rehabilitation System Using Technology Acceptance Model: Multiple Methods Pilot Study

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Abstract

Background: Wearable sensor systems maximize visual and clinical feedback for physical therapists to enhance patient outcomes in rehabilitation medicine. However, physical therapists must adopt and accept new technologies for full integration into routine care to advance the use of technology in clinical care. Their role in technology design is critical in adopting and implementing technology. Interprofessional collaboration should be supported in the design of rehabilitation-assisted technologies.

Objective: We used the established tenets of the Technology Acceptance Model to describe physical therapists' expectations and experiences before and after using a novel wearable system in outpatient physical therapy.

Methods: This multiple methods pilot study used a comparative pre-post survey and a qualitative semistructured focus group study design. Using purposive sampling, we recruited outpatient physical therapists to pilot the novel wearable technology, describe their expectations and experiences, and participate in a semistructured focus group discussion conducted to gather training and user experience information.

Results: The study sample consisted of 5 physical therapists with an average age of 38.8 (SD 6.9) years and a work experience average of 12 (SD 7.7) years. Presurvey data show favorable expectations for usefulness and ease of use; however, favorability in both factors decreased after use. For perceived usefulness, all responses moved in the less favorable direction; mean difference −4.4 (SD 3.21); *P*=.04. All but 2 responses moved in the less favorable direction for overall perceived ease of use; mean difference −4.8 (SD 1.79); *P*=.04. Themed responses to open-ended questions in the postsurvey were feedback, setup time, accuracy, performance, and enhanced functional activities. Inductive content analysis of the focus group responses resulted in the following themes: system training, system benefits, system challenges, physical therapist perception of patients, and suggestions for improvement. The expectation for frequency of use decreased pre- to postexperience by 53% (mean −22, SD 14.40; *P*=.04).

Conclusions: The Technology Acceptance Model–based survey responses and focus group themes outcomes demonstrated that physical therapists' expectations for using new technology were not met. Engaging physical therapists in piloting novel wearable technology highlights the importance of physical therapist engagement in developing, refining, and implementing wearable devices for rehabilitation.

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KEYWORDS

wearable technology; rehabilitation; physical therapy; technology acceptance model; inertia movement units; wearables; mhealth; rehabilitation medicine; technology use; survey; mobile health

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Introduction

Advances in wearable sensor technology have accelerated the use and reliance on digital biomarkers in clinical settings to enhance patient care outcomes. In rehabilitation medicine, wearable sensor systems provide new opportunities for collecting, storing, analyzing, and visualizing movement-related data [1,2]. In addition, wearable technology enhances opportunities for real-time information to support clinical decision-making and promote treatment progress. However, the speed of innovative development and other factors, such as usability, need, trust in technology, and cost often outpace or otherwise interact with adoption [3].

In rehabilitation medicine, engaging the end users (ie, physical therapists) in piloting novel technology can enhance usability and adoption so that design and output requirements meet expectations [4]. Such partnerships can assist technology developers and engineers in the product development and refinement stage [5]. A wide range of criteria have been suggested for consideration in adopting new rehabilitative technology, including observed criteria, such as patient and provider use, positive clinical outcomes, and fiscal viability [6,7]. However, to optimize behavioral investigation, a widely accepted framework should be used in pilot testing to garner user feedback. This is critical for gaining an understanding of the acceptance and adoption of new technology before full implementation [8].

Based on the theory of reasoned action [9] and the theory of planned behavior [10], the Technology Acceptance Model (TAM) offers a parsimonious explanation of individuals' behavior toward technology acceptance [6,11]. Although physical therapists' satisfaction is a well-accepted factor in technology acceptance, behavioral intention to use technology is one of the most fundamental antecedents to technology usage [1]. The behavioral intention to use was shown to be impacted by 2 primary beliefs: perceived usefulness and perceived ease of use [3,6,11]. Perceived usefulness is the extent to which physical therapists believe that using a specific system will improve their job performance (eg, time and case management, clinical decision-making, and patient outcomes), while perceived ease of use is the extent to which they believe using the system will be effortless [6,12]. When technology is easy to use, it fosters a positive attitude, leading to greater use [3]. Thus, perceived ease of use is directly associated with perceived usefulness, and both concepts impact physical therapists' intentions to adopt technology, considering external factors, namely, the implementation process, user participation, training, and system characteristics [6,11,12].

Several reviews have shown that the TAM is validated in health care settings. In studies focused on clinicians' adoption of health-related technology, this model repeatedly explains substantial variance in the intention to use or actual use of health technologies [1,13-15]. Furthermore, this model is accepted as a method of investigating novel technology in outpatient physical therapy [16,17]. Given its accepted use in outpatient physical therapy and its predictive ability, this study used the established theoretical framework to describe physical therapists' expectations and experiences before and after using a novel wearable system in outpatient physical therapy.

The knee joint represents a significant area of interest, given the prevalence of knee injuries across populations that require conservative and postsurgical management [18]. While wearable technologies are often used in orthopedics for their diagnostic capabilities, there is less research on knee rehabilitative technologies for everyday clinical practice [18]. Thus, this study will add to the literature on the practical use of wearable technology in clinical settings as an adjunct to medically necessary knee rehabilitation.

The study builds on previous research indicating that a clinical application for the automated rehabilitation system is needed [11] and explores the question "What are physical therapists' perceptions regarding the design and functional requirements of innovative wearable technology for knee rehabilitation?" The goal is to examine physical therapists' views on knee wearable technology within a clinical setting, using their expertise to guide the system's adoption and implementation. This study establishes a framework for incorporating physical therapists' feedback into the technology design process, aiming to enhance factors that promote technology acceptance in everyday clinical practice.

Methods

Study Design and Participants

This pilot study used a multiple-methods design, a comparative pre-post survey, and a qualitative semistructured focus group. We used purposive sampling to recruit full-time physical therapists providing direct care services in outpatient clinics from 1 outpatient rehabilitation organization with several clinics throughout Northeast Florida. A research team member recruited physical therapists after administrative approval from participating outpatient physical therapy clinics.

Automated Rehabilitation System

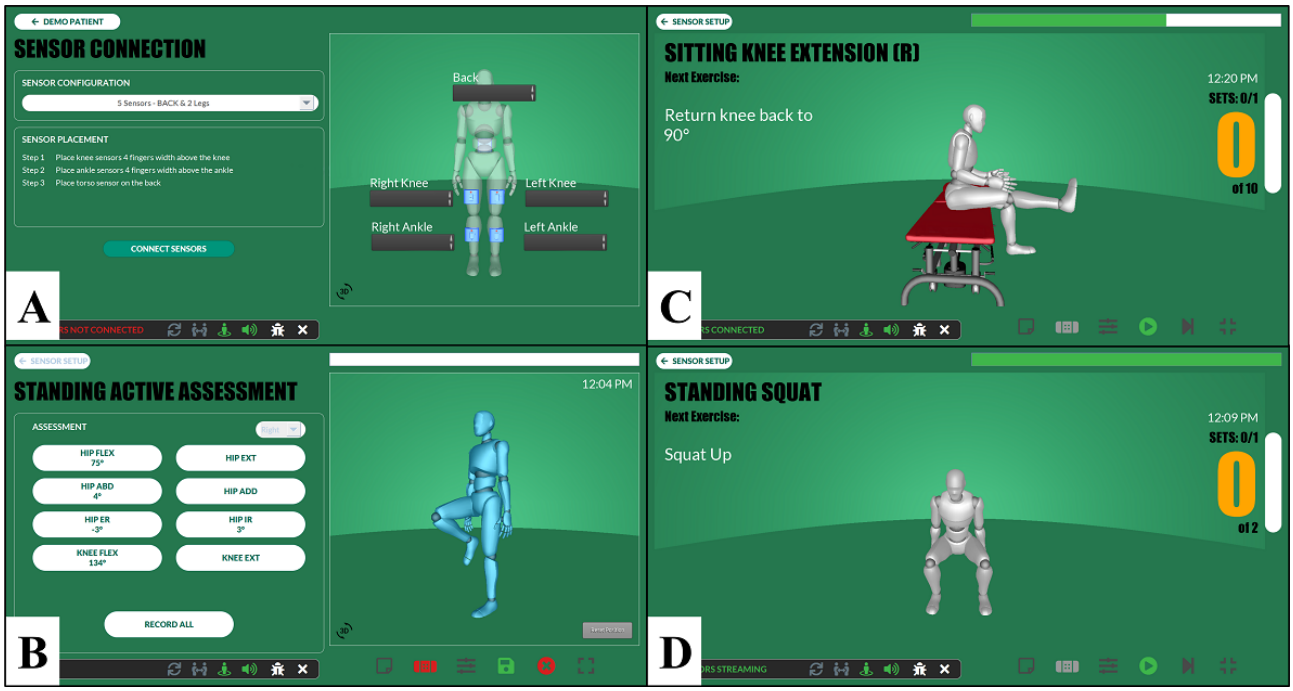
The automated rehabilitation system (ARS) is a prototype wearable sensor system that uses inertial measurement unit (IMU) sensors and ARS software on a tablet to collect, store, and visualize knee motion in real-time. The IMU sensors are enclosed in small, lightweight plastic casings (3.8 cm×3.8 cm×1.9cm) and affixed to the patient's skin using kinesiology tape at specific anatomical landmarks (anterior leg, 4 inches above and below the patella on each leg). Once affixed to the skin and synchronized to the software, the sensors transmit accelerometer and gyroscope time series data to the ARS software. This software applies pose estimation and time-series segmentation algorithms to estimate knee angles and velocity, facilitating data collection, storage, and visualization. The technical details about this system are published elsewhere [19,20].

The ARS software provides 2 graphical user interfaces (GUIs), one for physical therapists and one for patients, on the associated tablet (Figure 1). The clinician's GUI allows the creation of patient user accounts, includes step-by-step instructions for completing and storing range of motion (ROM) assessments, and provides an area for creating exercise programs and

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progressions for each patient by selecting exercises from an exercise library. The clinician's GUI also includes summary reports of completed exercises, the number of complete repetitions, knee ROM, and velocities for each exercise and repetition. The patient's GUI displays an avatar showing the patient's movement in real-time. The avatar guides the patient through the full ROM for each exercise and counts each complete repetition. The ARS is designed to improve exercise adherence, effectiveness, and care continuity while creating a more engaging experience for physical therapists and patients [19,20].

Figure 1. Graphical user interface for the automated rehabilitation system.



Protocol

After completing the electronic informed consent via Qualtrics (Silver Lake Technology Management, LLC) [21] and before exposure to the ARS, physical therapists completed a questionnaire (presurvey) of demographics and 17 items related to general expectations for the use of wearable sensor technology in clinical practice. The TAM was used as a framework for the survey, with 10 items addressing usefulness, 6 items addressing ease of use, and 1 item addressing frequency of use. The specific items representing usefulness and ease of use were developed through collaboration between research team members with clinical expertise and the system engineers. Items were designed to assess aspects of usefulness and ease of use that would inform the development and clinical adoption of wearable sensor technology. In addition to these items, physical therapists were also asked to rate the overall perception of usefulness and ease of use. Perceived usefulness and perceived ease of use were conceptualized as bipolar constructs. Items related to these constructs were scored on 21-point, bipolar slider scales with a neutral-centered starting point, such that physical therapists had to decide on which side of neutral their response would fall (directionality) and the level (magnitude) of their response [22,23]. Physical therapists indicated the magnitude of their positive or negative expectations using the anchors −10=not at all useful, 0=neutral, 10=extremely useful for perceived usefulness, and −10=extremely difficult, 0=neutral, 10=extremely easy for perceived ease of use.

The frequency of use item represents a modification of the intention to use construct from the TAM [1]. While the intention to use assesses a physical therapist's expectation to use or not use a technology, the frequency of use item was intended to assess how often a physical therapist expects to use the technology. This distinction was deemed relevant and important by the research team and system engineers to help determine the degree to which physical therapists expect to use wearable sensor technology in clinical practice with a wide variety of patients, selectively with a few patients, or not at all. For consistency, frequency of use was also measured on a 21-point scale using the anchors (−10=none of my patients, 0=about half of my patients, and 10=all of my patients). The physical therapists were also given 6 potential use cases for wearable sensor technology (eg, at home during a home exercise program) and asked to rank the use cases in order from most to least beneficial uses for wearable sensor systems.

After completing the presurvey, each physical therapist was required to attend a 2-hour in-person ARS training session provided by the research team and a member of the technology development team responsible for the GUI design. The training session included practice affixing the IMU devices around the knee, initial patient profile creation with the ARS software, using the software to complete ROM assessments, and designing exercise programs. The training concluded with a mock patient trial with 2 case studies. The physical therapists were asked to demonstrate appropriate setup and use procedures before leaving the training session. After the session, physical therapists were provided with an ARS and were asked to practice with the

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technology for a 1-month trial period. During the trial period, physical therapists were encouraged to contact a research team member for technical support and assistance. Any technical issues that a research team member could not resolve were communicated to the system engineers either by the research team member or the physical therapist for problem-solving. After the trial period, the physical therapists began applying the ARS in their physical therapy practice with qualified patients.

Physical therapists were instructed to use the system during outpatient in-clinic visits with patients who meet the inclusion criteria: patients who meet the inclusion criteria of being at least 18 years of age, seeking physical therapist services for a diagnosis related to an orthopedic knee condition (new patient or existing patient with new knee-related diagnosis) and having no cognition-related diagnoses. Physical therapists used the ARS during routine clinical assessments and treatments (on average 4 - 6 wk, 8 - 12 sessions, in-clinic only) with patients who consented to participate in the study. Physical therapists were not required to follow a specific protocol but were instructed to administer medically necessary care and use the device where appropriate during the entire episode of care. The research team and system engineers provided ongoing technical and procedural support throughout the study.

After using the device with 5 patients who completed their episode of care, the physical therapists were asked to complete a postsurvey with items related to their experience using the ARS. The survey included 17 items similar to the presurvey, with wording slightly modified to ask about experience instead of expectation. The postsurvey included 6 additional open-ended items that asked physical therapists to describe their experience using the ARS, such as situations where the ARS was most useful, weaknesses of the ARS, and recommendations for further development or modifications.

After completing the survey, the physical therapists participated in a focus group discussion via Zoom video conference (Zoom Communications) [24]. The one-and-a-half-hour focus group was held with all physical therapists and moderated by 2 research team members (CW and RO). A semistructured interview guided the discussion and included questions addressing training, experience, and perceived patient experience. The questions (Table 1) are intended to provide a richer understanding of the physical therapists' survey responses and perspectives. They were designed to promote free-flowing conversation and elicit frank discussions about their experiences with technology. Follow-up questions were asked to clarify or explain comments.

At the conclusion of the study, members of the research and technology development teams met to discuss the identified results of the surveys and interviews. This discussion provided additional context to the findings and potential modifications to the system and clinical training procedures that may inform future research and practice.

Table . Focus group questions.

Training and experience	Initial questions	Follow-up questions
Training	Tell us about your experience learning how to use wearable sensors.	• What went well, and what could have gone better?
Experience	Tell us about your initial experience using wearable sensors with patients.	• How did this change over time? • Please elaborate on the technical challenges. • Discuss the exercises you would like to see in the system. • The group mentioned visual feedback. How do you think this influenced the therapy session?

Statistical Analysis

The survey data analyses were performed using IBM SPSS Statistics (version 29.0). The pre- and postmean rank and SD were also calculated for the use case rankings. Due to low sample size and non-normal data distributions, the Wilcoxon Signed Rank test was used to assess statistically significant differences between pre- and postscores and rankings.

Qualitative Analysis

The focus group session was audio recorded and transcribed verbatim using the Zoom recording function [24]. The focus group included researchers and physical therapists; no nonparticipants were included. The transcribed responses were validated with the audio recorder for accuracy and deidentified for analysis. An inductive content analysis approach was used to examine and interpret the qualitative data. The analysis used an inductive bottom-up approach and semantic coding to identify explicitly stated ideas, concepts, and experiences. The process began with a thorough reading and rereading of the paper to increase familiarity with the content and understand the concepts in each response. Then, initial codes were generated through line-by-line coding of the transcripts. After this, subthemes were developed by clustering overlapping codes and reanalyzing them to ensure alignment with the responses. After reviewing and clustering the codes, the authors searched for subthemes that could be combined to reduce redundancy and highlight salient patterns in the data. Following this phase, 2 authors (CW and RO) discussed the subthemes, and discrepancies were resolved by a third researcher (LT). This refinement led to the identification of overarching themes. The process was continuously revised, refined, and discussed among the research team. We used the consolidated criteria for reporting qualitative research checklist to ensure explicit reporting on the study's execution [25].

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Ethical Considerations

Physical therapists who verbally agreed to participate in the study received and signed the electronic informed consent before beginning the study protocol. This study followed the research protocol approved by the University of North Florida's Institutional Review Board (approval number 21‐041 1710770).

Results

Participants

A total of 5 physical therapists aged 31-50 years with 4-25 years of practice experience consented to participate in the study. The study sample reflected an average age of 38.8 (SD 6.9) years and a work experience average of 12 (SD 7.7) years. All reported being at least somewhat comfortable with technology (Table 2).

Table . Description of participating physical therapists.

Characteristics	Clinician 1	Clinician 2	Clinician 3	Clinician 4	Clinician 5
Age (y)	31	50	41	40	32
Sex	Female	Male	Male	Female	Female
Years of physical therapy experience (y)	4	25	10	16	5
Highest degree in physical therapy	DPT	BS	DPT	DPT	DPT
Comfort level with technology	Somewhat Comfortable	Comfortable	Comfortable	Somewhat Comfortable	Comfortable

Survey Results

Pre- and postsurvey results highlight the perceptions of the therapist before and after using the technology in patient care. Table 3 highlights the pre- and postresults and mean differences according to the TAM. The physical therapists' expected frequency of using the device with patients significantly decreased from pre- to postuse of the wearable system, with a mean difference of −22 (SD 14.40; $P<.05$).

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Table . Clinicians' perceived usefulness and ease of use pre and post use of the wearable sensor system.

Constructs	Pre, mean (SD)	Post, mean (SD)	Difference, mean (SD)	*P* value
Usefulness				
Improving patient outcomes	4.4 (3.29)	−0.6 (4.98)	−5.0 (5.92)	.14
Increasing the speed of recovery	0.8 (3.03)	−1.4 (3.58)	−2.2 (4.38)	.29
Improving the quality of care I am able to provide to patients	4.0 (3.24)	0.2 (4.82)	−3.8 (5.45)	.22
Improving the cost-effectiveness of rehabilitation services	0.4 (3.21)	−0.6 (4.34)	−1.0 (5.87)	.85
Increase my patients' satisfaction with their care	5.2 (3.63)	0.8 (3.96)	−4.4 (4.04)	.07
Increase my level of efficiency in the clinic	0.0 (3.74)	−4.4 (2.19)	−4.4 (4.77)	.10
Providing me with valid and reliable information about patients	3.8 (2.05)	−1.2 (3.96)	−5.0 (2.83)	.04[a]
Improving my clinical decision-making	1.2 (1.30)	−2.0 (2.12)	−3.2 (2.39)	.07
Improve my ability to monitor patient progress	4.0 (1.41)	−1.2 (3.11)	−5.2 (3.11)	.04[a]
Overall perceived usefulness	3.8 (1.79)	−0.6 (2.97)	−4.4 (3.21)	.04[a]
Ease of use				
Learn how to use wearable sensor technology	6.2 (2.28)	4.4 (4.04)	−1.8 (4.09)	.41
Incorporate wearable sensors into my usual practice patterns	0.4 (1.82)	0.6 (2.97)	0.2 (3.96)	>.99
Explain wearable sensor technology to patients (purpose and benefits)	5.6 (2.97)	6.4 (5.32)	0.8 (3.56)	.72
Teach patient how to use wearable sensor technology	4.8 (3.11)	4.4 (3.78)	−0.4 (2.97)	.79
Maintain the equipment associated with wearable sensor technology	6.2 (3.90)	6.0 (5.66)	−0.2 (5.76)	>.99
Overall perceived ease of use	1.4 (1.95)	−3.4 (1.52)	−4.8 (1.79)	.04[a]
Frequency of use				
I would use wearable sensors with	47 (15.65)	25 (12.75)	−22(14.40)	.04[a]

[a] P≤.05; usefulness scale (−10=not at all useful, 0=neutral, 10=extremely useful); ease-of-use scale (−10=extremely difficult, 0=neutral, 10=extremely easy); frequency of use scale (0=none of my patients, 50=about half of my patients, 100=all of my patients); change reflects the post score minus the prescore such that negative values represent a decrease in perceived usefulness, ease-of-use, or frequency of use.

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Perceived Usefulness

Presurvey results indicated that physical therapists had neutral to moderate positive expectations for the usefulness of wearable sensors in clinical practice, with the lowest expectations for "increasing my level of efficiency in the clinic" (mean 0, SD 3.4), "increasing the cost-effectiveness of rehabilitation services" (mean 0.04, SD 3.21) and " increasing the speed of recovery" (mean 0.08, SD 3.03). The highest expectation was for "increasing patient satisfaction with their care" (mean 5.2, SD 3.63), "improving patient outcomes" (mean 4.4, SD 3.29), "improving the quality of care I am able to provide patients" (mean 4.0, SD 3.24), and "improving my ability to monitor patient progress" (mean 4.0, SD 1.41). The overall pre-exposure perceived usefulness mean was 3.8 (SD 1.79). Following exposure to the ARS, physical therapists' overall perceived usefulness score was −0.6 (SD 2.97), representing a statistically significant decrease in the perceived overall usefulness of wearable sensors; $P<.05$; mean difference −4.4 (SD 3.21). Although pre- and postexposure mean difference decreased for all usefulness items, the only statistically significant ($P<.05$) observed decreases were in the items related to the ability to monitor patient progress (mean difference −5.2, SD 3.11) and the quality of the information from the system (mean difference −5.0, SD 2.83).

Perceived Ease of Use

Physical therapists expressed pre-exposure perceptions that it would be relatively easy to "learn how to use wearable sensor technology" (mean 6.2, SD 2.28) and "maintain the equipment associated with wearable sensor technology" (mean 6.2, SD 3.90). Following exposure to the ARS, physical therapists' overall perceived ease of use score was −3.4 (SD 1.52), representing a statistically significant decrease in the perceived overall ease of use of wearable sensors *(*$P<.05$; mean difference −4.4, SD 3.21). No statistical changes were seen in individual questions with ease-of-use perceptions.

Use Cases

Physical therapists' ranking of the use cases remained largely unchanged between the pre- and postsurvey, with "At home during a home exercise program" consistently ranked as the most beneficial and "other" consistently ranked as receiving the lowest rank. Although in sport/recreation settings, the ranking moved from fifth-ranked in the presurvey to fourth-ranked in the postsurvey, there were no statistically significant differences observed in the rankings (Table 4).

Table . Clinicians' ranking of most beneficial uses for the wearable sensor system.

Potential Settings for ARS Use	Pre, mean (SD)	Post, mean (SD)	Difference, mean (SD)	*P* value[a]
At home during a home exercise program	2.0 (1.73)	1.0 (0.00)	1.0 (1.73)	.18
In the clinical setting as part of rehabilitation services	2.4 (1.14)	2.6 (1.34)	−0.2 (0.84)	.56
At home during usual daily activities	2.8 (1.10)	3.4 (0.55)	−0.6 (1.14)	.26
At work/school	4.4 (0.55)	3.6 (1.14)	0.8 (1.48)	.26
In sports/recreational settings	3.4 (1.52)	4.4 (0.89)	−1.0 (2.12)	.27
Other	6.0 (0.00)	6.0 (0.00)	0.0 (0.00)	>.99

[a]$P\leq.05$; Clinicians ranked use cases for the wearable sensor system in order from most beneficial (1) to least beneficial (6). Change reflectst pre score minus post score so that negative values represent a decrease in ranking.

Clinical Comments

Physical therapists were asked 5 open-ended questions at the end of the postsurvey. These responses highlighted favorable perceptions and areas where improvements could be made. For example, the physical therapists highlighted where wearable technology could be beneficial by providing visual feedback; the visual feedback would support the correct performance of exercises. They also expressed that they like the ability to assess multiple joints simultaneously. They commented that the device would be suitable for home exercise programs and would enhance their in-clinic ability to evaluate range of motion (ROM). However, the setup time and calibration requirements were barriers to use. In addition, they recommended that designers improve the ability to don and doff the sensors, improve the accuracy of the sensor's feedback, and provide more functional activities to expand the system's capabilities. Table 5 shows a summary of the comments by question.

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Table . Summary of post-survey open-ended questions.

Questions	Themes
What are one or two examples of a situation where you found using the wearable sensor system to be most useful?	• Visual feedback • Consistency in supporting correct performance • Measure multiple joints at the same time
What are one or two of the features/aspects of the wearable sensor system that you especially liked?	• Good for home exercise program • Assess ROM[a] • Visual feedback
What are one or two of the biggest weaknesses in the wearable sensor system?	• Set up time and calibration • Inaccuracy of feedback
What are one or two things you would recommend for further development of the wearable sensor system?	• Easier to don and doff • Improve accuracy
Can you think of any other ways you might want to use a wearable sensor system?	More functional activities
What would have been useful to know during the training that you were not told?	N/A[b]

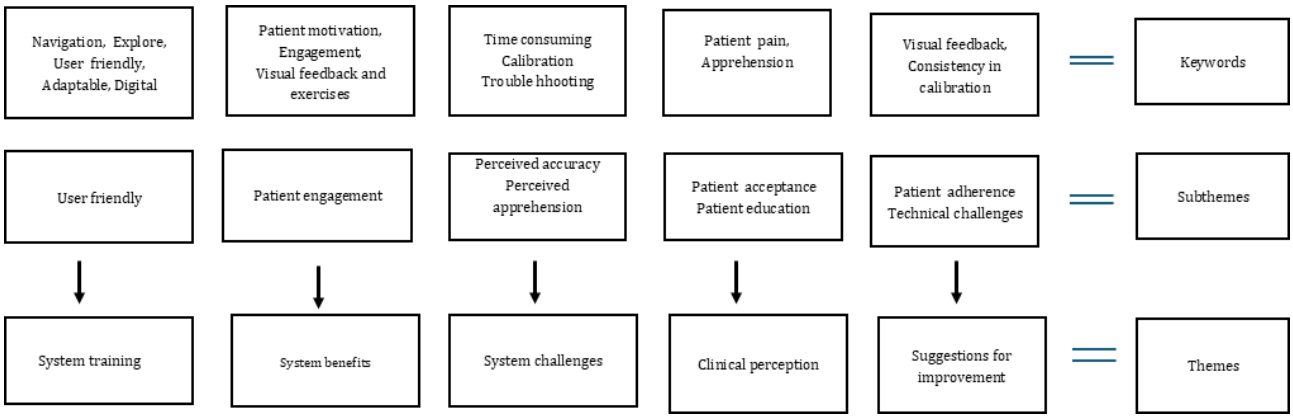
[a] ROM: range of motion.

[b]N/A: Not applicable.

Focus Group

The qualitative results from the focus group were organized by question: training and experience using the device. Within each question, the comments were organized by keywords, subthemes, and themes. Following the inductive content analysis, the focus group revealed 4 themes: system training, benefits, challenges, physical therapists' perception of patient experience, and suggestions for improvement. The themes were then evaluated against perceived ease of use and perceived usefulness. Please refer to Figure 2 for the keywords, subthemes, and theme development.

Figure 2. Summary of keywords to themes in qualitative analysis.



System Training

In the theme of system training, physical therapists expressed positive feedback about the required training session on using the device.

> *So I think the training was perfectly fine. I think the system as a whole is pretty user friendly, and as long as you kinda take the time to like, explore and kind of play around with adding new exercises, or deleting or changing [repetitions], or anything like that it's pretty easy to use.* [PT-4]

Another physical therapist agreed that the training was good; however, they commented that being familiar with technology was helpful.

> *I mean, I think it's going. I think the training that we did was good. I mean it was I didn't have any issues with it. I don't know. Technological, savvy? It helped it.* [PT-5]

System Benefits

In the theme of system benefits, physical therapists commented that the system's visual feedback motivated the patients during rehabilitation.

> *So it's almost kind of made them push themselves a little bit more. I think a lot of the patients like the fact that it's counting their reps for them.* [PT-4]
>
> *Yes, I'd agreed with that. and I'm a big fan of like bio feedback. I think when the thing is working and counting. I think that's a huge plus for the patients*

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to go through, and, you know, have something to compare their movement to that. [PT-3]

System Challenges

In the theme of system challenges, the subthemes of perceived accuracy and perceived patient apprehension were also noted. Physical therapists expressed technical challenges due to calibration issues that led to reservations about the accuracy of the data.

I think probably half the time, I would say I'd have to spend troubleshooting not half of the session time, but half of the occasions that I was using to sensors. I would have to spend some extra time troubleshooting. So I think I kind of had a few random occurrences of that where we would maybe transition from like supine mat exercises to just sitting or standing. [PT-4]

That's definitely a challenge. So the time that you're having to fight with recalibrating. It's just when it starts having a difficulty tracking. are you confident in the data that it provides you? [PT-1]

Yeah, I'd agree. The biggest barrier for me using it is just trusting that the data that it's giving me is accurate. [PT-2]

However, they were confident in the accuracy when it was working well.

As far as the watching them doing their exercise is seeing the range that is going through all that stuff. I'm pretty confident. With that I went through, and I'd kind of measured range of motion and I measured range of motion to see how close it was. So. Yeah. I was pretty comfortable with that. It's just when it starts having a difficulty tracking. [PT-2]

The physical therapists also perceived that those technical challenges impacted the patients' perceptions of the technology. When the system had difficulty, they were aware of patient time and apprehension. One physical therapist noted:

And all of a sudden, you know he's not kind of displaying the correct position. and so from there I would pretty much just kind of like, say, okay, if we can't recalibrate this and get it to appear correctly within the next slide. 2 min or so. We'll just go ahead and continue with the exercise, and you know, not worry about it. [PT-3]

Clinician Perception of the Device

The physical therapists' perception of the device also reflected their perception of the patients' experience. Thus, the physical therapists' perception of the device had several subthemes: patient acceptance and patient education. On the subtheme of patient acceptance, physical therapists perceived that patients' interest may be related to their level of pain.

I mean for a lot of people, especially like when you get the patients to come in with like a the [knee] replacement or something like that, or they're coming in a lot of pain. They're probably coming in a week, or, you know, within the first week after surgery, and it's kind of like they what they don't want anything else. They've got enough going on. They don't want anything else on top of it. [PT-3]

Another physical therapist suggested that more patient education was needed to gain patient acceptance of the technology.

So maybe, having the clinicians like talk to the patient and explain it's not going to change anything we're doing with them, and all that kind of stuff would help but just to kind of give their mind that it's not going to be a big hindrance to them. But I've definitely had an issue with a lot of people not want[ing] to do it. [PT-4]

Suggestions for Improvement

Physical therapists commented on the challenges of the system. They also made recommendations in the subthemes of patient adherence and technical challenges to improve patient adherence throughout their treatment program.

The things that we're doing are good for patients early on or for really low-level patients. But eventually, for a lot of patients, they're going to get beyond what we're doing at this time. [PT-5]

While being able to track functional movements visually was important for patient care, the therapist suggested that improving the challenges with calibration was also critical to improving the use of the system.

Being able to tracking and functional activities. It's probably the biggest improvement, and then just the consistency of the calibration that that would be the biggest issue that I run into. [PT-1]

Discussion

Principal Findings

Implementing wearable technology into clinical practice is a significant step forward in rehabilitation science. The ubiquitous nature of wearable technology to monitor health behaviors and improve physical performance, and the lack of in-clinic rehabilitation use, suggests that rehabilitation medicine should consider technology that could effectively promote practice. This study exposed a sample of orthopedic outpatient physical therapists to a new, premarket wearable system to garner their perceptions about the device for possible implementation into clinical practice. The survey and focus group results indicate that additional work is necessary before the studied prototype can fully integrate into clinical practice. These findings underscore the participating physical therapists' expectations, perceptions, and recommendations. In addition, the study emphasizes the significance of interprofessional collaboration in developing technology for clinical care. Our analysis indicates that while physical therapists were enthusiastic about the system, its perceived usefulness and ease of use did not fully meet their expectations. These perceptions were influenced by physical therapists' observations of patients' responses during rehabilitation sessions and their own experiences with the device. As a result, technical challenges reduced the overall

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perceived usefulness, ease of use, and frequency of use. The focus group offered suggestions to enhance the device's acceptability in clinical practice, as highlighted by the theme of suggestions for improvement, which aligns with the theme of system challenge.

Perceived Usefulness

Perceived usefulness, as the TAM suggests, is critical for technology adoption. In this study, survey results indicate a significant decline in the perceived usefulness of the wearable system from pre- to postsurvey. Negative perceptions were primarily influenced by doubts about the system's ability to provide valid and reliable information and monitor patient progress, as highlighted by specific survey questions. These findings were corroborated by qualitative data from focus group themes of system challenges and suggestions for improvement. From the focus group-generated theme of system challenges, subtheme of perceived accuracy, the physical therapists expressed technical issues, such as lagged visual feedback and calibration problems, which led them to question the accuracy of the data and hindered the system's usability. Consequently, troubleshooting these issues interrupted patient care. This is an important issue, as Argent et al [26] indicated that data reliability and accuracy are major challenges in accepting new wearable technology in clinical practice. Under the theme of system challenges, the subtheme perceived apprehension, technical issues causing delayed visual feedback can undermine the system's effectiveness and erode the trust of both clinicians and patients. This, in turn, heightens the physical therapist's reluctance to use the device. Health practitioners felt legally responsible for any adverse consequences resulting from potential inaccuracies or delays [27,28].

In the theme of suggestions for improvement, the subtheme of patient adherence contributed to the perceived usefulness of the wearable device. The physical therapists noted that the limited availability of exercises restricted the use of the ARS as patients advanced in their rehabilitation. The wearable system included basic knee rehabilitation exercises, but the therapists recommended that more advanced exercises were needed to optimize the system's use. As patients progress in knee rehabilitation, they outgrow the exercises available in the system. This may contribute to survey results from physical therapists that the system might be more suitable for home exercise programs rather than clinical settings.

Conversely, in the theme of system benefits from the focus group discussion, physical therapists found the avatar valuable for patient engagement, noting that real-time visual cues could encourage patients to move through their full ROM. This supports the idea that real-time feedback is important for the effectiveness of wearable technology [28,29]. Visual feedback enhances motor learning outcomes beyond traditional physical therapy , allowing patients to see the correct movements and full ROM while responding to visual stimuli and the clinician's vocal cues [30]. In addition, physical therapists favored visual feedback because it improved patients' understanding of prescribed exercises and the accuracy of gross motor activities [31].

Perceived Ease of Use

Perceived ease of use, alongside perceived usefulness, is an important factor in technology adoption. Integrating new technology into clinical practice should support rehabilitation; however, additional time and effort can hinder care delivery, making the system more challenging to use. Survey results indicate a significant decrease in ease of use during the study. This finding is corroborated by focus group results, which highlight the themes of system challenges, clinical perceptions, and suggestions for improvement. Furthermore, under the theme of system challenges (subtheme perceived apprehension) and suggestions for improvement (subtheme technical challenges), it was noted that patients felt uncomfortable with the time required for calibration and troubleshooting. Physical therapists were concerned that it was too time-consuming and distracted from the rehabilitation session. Patients required reassurance that their treatment would not change based on ARS [32,33]. In addition, within the theme of clinical perception, the subtheme of patient acceptance, pain, adversely affected the device's ease of use. This suggests that the complexity of the diagnosis and the patients' pain levels significantly influence their perception of wearable technology [34]. Patients with higher care needs might view monitoring with novel technology as unnecessary for their care. Some physical therapists also avoided using the technology, citing concerns that it would reduce patient contact time and the number of visits, negatively affecting care [35,36]. This study underscores a significant gap in the literature on technology adoption, emphasizing the importance of therapists' perceptions of patients using wearables. Few studies illustrate therapists' empathy for patients during rehabilitation with wearables [37,38].

Implications for Practice

This study highlights the importance of interdisciplinary collaboration among engineers, physical therapists, and researchers to enhance wearable sensors' design, output, and ultimate acceptability in rehabilitation. The physical therapists were initially open to the use of the ARS in clinical practice, but the challenges with the system were notable. The feedback from the physical therapists humbled the enthusiasm of technology engineers, but it provided them with valuable information to improve the prototype for potential physical therapists who may use the device in the future. System developers should be mindful of the concepts of TAM and physical therapists' expectations for use in rehabilitation. Wearable technology developers are well-positioned, in a digitally aggressive health care climate, to be "digital disruptors" in traditional physical therapy settings; however, it cannot undermine well-established processes of care and the physical therapists-patients relationship [36]. Wearable technologies are being actively promoted to physical therapists by technology developers and corporations. However, technology must meet physical therapists' demands for data validity and reliability [36,39]. Without meeting this minimum requirement, wearable technology could be seen as disruptive to patient care [40].

In the clinic, wearable monitors provide an opportunity for objectively measuring ROM and biomechanical assessment. Replacing goniometers with wearable sensor systems offers the

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benefit of digital ROM testing, where measurements could be compared with the patient's previous results or population-based norms for assessing rehabilitation progress and benchmarks for returning to work or sports participation [18]. These systems also allow for portable, less expensive, and more intuitive biomechanical tracking of activities compared with current video and marker-based systems [41]. Integrating this technology may provide quicker detection of biomechanical errors and allow for earlier physical therapy intervention to mitigate issues.

Future Research

Future collaboration should consider garnering physical therapists' expectations before developing wearable technology. Due to the fiscal impact of technology adoption, studies should consider the financial factors of wearable systems. While studies suggest promising outcomes such as decreased costs associated with visits, reducing unnecessary clinic visits, reducing patients' travel burden, and streamlining patient-clinician visits, more research is needed to quantify such results [42]. Other research postulates that a wearable rehabilitation sensor system would reduce time spent with physical therapists while instructing and tracking rehabilitation exercises [19]. This may increase clinician productivity while also promoting quality care. In addition, future research should overcome the sample size limitations and replicate the study during a period that is less likely to experience a public health crisis to promote more in-person visits.

Limitations

The study should be considered in light of the limitations. The small sample size of physical therapists increases the risk of not detecting important postexposure differences and limits the generalizability to other settings and diagnoses. While the study presents a widely accepted framework, we cannot speculate on results in other rehabilitation clinics. In addition, the study period occurred during the COVID-19 pandemic and may not be reproducible as in-person patient care was limited. The COVID-19 pandemic negatively impacted the sample size. Future studies should consider a larger sample size across various settings with data that measure the intensity of use and consider other appropriate diagnoses for wearable devices in rehabilitation. While the study uses the basic tenets of the TAM, future studies may consider more complex versions of the TAM.

Conclusions

This multiple-method study used the TAM to create a survey examining physical therapists' expectations and experiences with a new wearable system in outpatient physical therapy before and after its use. The findings indicated a decline in perceived usefulness and overall ease of use among physical therapists. While the technology has the potential to enhance the efficiency of physical therapy care and monitor rehabilitation progress, careful attention must be given to the system's design and accuracy during development. The feedback provided valuable insights for engineers and system developers to refine the system based on physical therapists' perceptions. This study underscores the importance of involving physical therapists in the prototype development phase.

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Authors' Contributions

CW, LT, and RO contributed to the conception and design of the study, data analysis, interpretation of results, and drafting/revising of the work. CEB and AJ contributed to the manuscript's writing and editing.

Conflicts of Interest

None declared.

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Abbreviations

ARS: automated rehabilitation system
GUI: graphical user interface
IMU: inertial measurement unit
ROM: range of motion
TAM: Technology Acceptance Model

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Recommendations for Combining Brain-Computer Interface, Motor Imagery, and Virtual Reality in Upper Limb Stroke Rehabilitation: Qualitative Participatory Design Study

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Abstract

Background: The high incidence and prevalence of upper limb impairment post stroke highlights the need for advancements in rehabilitation. Brain-computer interfaces (BCIs) represent a promising technology by directly training the central nervous system. The integration of motor imagery (MI) and motor observation through virtual reality (VR) using BCIs provides valuable opportunities for rehabilitation. However, the diversity in intervention designs demonstrates the lack of guiding recommendations integrating neurorehabilitation principles for BCIs.

Objective: This study aims to develop recommendations for BCI interventions using task specificity and ecological validity through simulated VR tasks for upper limb stroke survivors by gathering tacit knowledge from neurorehabilitation experts, patients' experiences, and engineers' expertise to ensure a comprehensive approach.

Methods: A multiperspective qualitative study was conducted through collaborative design workshops involving stroke survivors (n=17), neurorehabilitation experts (n=13), and biomedical engineers (n=3), totaling 33 participants. This innovative approach aimed to actively engage stakeholders in developing multifaceted solutions for complex health interventions.

Results: Six themes emerged from the thematic analysis: (1) importance of patient-centered approach, (2) clinical evaluation and patient selection, (3) recommendations for task design, (4) guidelines for structuring BCI intervention, (5) key factors influencing motivation, and (6) technology features. From these themes, the following recommendations (R) are established: (R1) MI-based VR-BCI interventions must be conducted through a patient-centered approach, based on individualized preferences, needs, and goals of the user, by an interdisciplinary team; (R2) selection criteria must include upper limb impairment, cognitive and communication assessment, and clinical traits, such as MI capacity, neglect, and depression must be assessed since they might influence intervention outcomes; (R3) tasks to perform should preferably be based on daily living activities, including unilateral and bilateral tasks, and a variety of tasks must be available for selection to ensure meaningfulness for the user and suitability to clinical traits; (R4) intervention must be structured by different progressing levels starting with simple, gross movements and adding complexity through additional movement features, cognitive demand, or MI difficulty; (R5) optimal levels of motivation must be sustained through task variability, gamification elements, and task demand adequacy; and (R6) multisensorial potential of MI-based VR-BCI must be effectively harnessed through the adequate adjustment of visual, haptic, and proprioceptive feedback modalities to the patient.

Conclusions: Current results contribute to establishing clear guidelines on patient selection, task design, intervention structuring, motivation factors, and tailoring of sensory feedback. This framework presents a foundation for optimal implementation of VR-BCI–based interventions that associate MI and motor observation, optimizing cortical activity during the intervention, patients' engagement, and clinical outcomes. Future research should explore the application of these guidelines for validation and investigate BCIs' efficacy according to different combinations of patients' profiles, task characteristics, and technology features.

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KEYWORDS

neurological rehabilitation; cerebrovascular disorders; upper extremity; brain-computer interfaces; virtual reality; qualitative research; user-centered design

Introduction

Background

Stroke is among the most common causes of disability worldwide and is the chronic neurological disease with the greatest impact at this level [1,2]. Among the multiple consequences of stroke, upper limb (UL) impairments are one of the most prevalent, with around 70% of stroke survivors showing altered arm function, 40% maintaining persistent functional disability [3], and only 5%-20% showing complete dexterity 6 months after stroke [4]. Motor control impairments result in altered movement dynamics, characterized by muscle synergies that reduce optimal motor performance and induce movement compensations [5,6].

Upper limb rehabilitation (ULR) after stroke is recognized as a complex challenge due to different factors, namely the multifactorial nature of the condition (eg, spasticity, decreased muscle strength, changes in somatosensation and perception) [7-9] and the nonlinear progression of disability over time. In addition, the complexity underlying ULR is also compounded by the need to define multiple parameters, including the type of intervention, dosage (such as duration, difficulty, and intensity), application format, and the underlying factorial paradigm, which involves different degrees of parameter interaction [10].

Multiple types of motor rehabilitation interventions have been studied throughout the years with the goal of reducing motor impairments and improving functional activities, making use of learning- and use-dependent mechanisms [11] to promote motor learning. Considering UL interventions, traditional or modified constraint-induced movement therapy, mental practice, robot-assisted movement therapy, and neuromuscular electrical stimulation are currently among the most recommended strategies [11-13]. Neuroplasticity is the structural or functional changes (or both) within neurons affecting their connectivity with each other that occur during learning after injury, being a key element of motor rehabilitation and motor acquisition [14]. Motor rehabilitation allows patients to learn,optimize and adapt their motor, sensory, and cognitive functioning through dosed, repetitive, goal-oriented, progressive, task- and context-specific training [11]. The combination of traditional therapy methods with technologies that enable the use of enriched environments, sensory stimulation, and task-specific training is a neuroplasticity promoter, enhancing functional recovery for stroke survivors [15].

Brain-computer interfaces (BCIs) have been increasingly studied over the last 20 years as a way of enhancing ULR by being a facilitator of intensive and repetitive practice [16]. BCI is a technology that allows the acquisition, analysis, and decoding of brain activity, translating it into communication and control commands for an interface [17].

Measuring and analyzing brain activity data is often done using electroencephalography (EEG) due to its noninvasive, portable, low-cost nature and high temporal resolution [16]. EEG enables the detection of various brain activity patterns, such as event-related potentials (eg, P300), steady-state visual evoked potentials, and event-related desynchronization (ERD) and event-related synchronization (ERS) that are associated with motor-related tasks [18]. Common paradigms for intervention using BCI are motor imagery (MI) and motor attempt, also associated with motor observation [7]. Studies using MI tasks frequently rely on ERD and ERS as a reliable method for detecting motor-related brain activity [19]. MI-based BCI operation is then associated with the ERD phenomena and the modulation of sensorimotor rhythms, linked to imagined limb movements. By providing feedback based on the patient's brain activity—that is, neurofeedback—BCIs close the motor-sensory feedback loop during MI training, allowing users to actively perceive and modulate their brain activity [20]. Repeated practice combined with real-time feedback promotes neuroplasticity and facilitates functional recovery [21]. Kruse et al [22] conducted a systematic review and meta-analysis showing evidence that the addition of MI-based BCI to conventional therapy may enhance the improvement of UL function and brain function recovery. Although meta-analysis on different design characteristics of BCI interventions favors motor intention over mental practice [17,23], MI offers a unique opportunity for stroke survivors who are unable to move their extremities by attempting to stimulate the brain regions responsible for movement [22,24].

MI, also referred to as mental practice and recently action imagery [25], is described as training movements or tasks in an imagined way and without producing movement, with the specific aim of improving performance [26]. Recently, Bach et al [27] proposed a conceptualization of MI, not as purely motoric and based on the execution of the movement, but in its anticipated perceptual effects, suggesting motor imagination (or "effect imagery" as proposed by the authors) is driven by the desired perceptual outcomes of actions rather than the movements themselves.

MI application is extensively recommended as an adjunct to conventional therapy [28-32]. Neuroimaging findings provided evidence that MI and physical practice are functionally equivalent, that is, they recruit overlapping brain regions within the brain motor networks underlying motor preparation and execution, including premotor, parietal, primary somatosensory, and motor cortices [33,34]. Both MI and planning and execution of movement involve the activation of the cerebellum, putamen, inferior frontal gyrus, and supplementary motor area [35]. Thus, the relevance of MI practice lies in reinforcing the motor schemas involved in actual movement through the mental visualization of motor actions [26]. MI can involve explicit or implicit tasks, where the first involves active and conscious imagination of a particular movement, and the second

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subconsciously induced processes for task-imagery problem solving, such as mental rotation of an image [31].

The use of neurofeedback associated with BCI seems to promote changes not only at the neurophysiological level but also at the clinical level [36]. This can be provided through different modalities, such as visual, auditory, and tactile feedback [37]. Virtual reality (VR) is one of the feedback possibilities to combine with BCI [7,36], which allows users to experience being represented by an avatar body rendered through a 3D environment and interact with it in a realistic way [38]. Multiple meta-analyses have described the positive effects of using VR in ULR, enhancing not only motor function but also activities of daily living (ADLs) [39,40], and practice guidelines recommend its usage to improve stroke rehabilitation outcomes [30]. Immersive VR, when used as a complement to conventional therapy, can provide a suitable environment for practicing the repetitive and specific tasks needed to improve motor skills after stroke [41].

Synergistic Mechanisms of Brain-Computer Interfaces, Virtual Reality, and Motor Imagery

Starting from the premise that one of the main goals of neurorehabilitation is to promote neuroplasticity and restore function, MI, VR, and BCI form an interconnected triad that mutually reinforce one another, representing a powerful approach to achieve this objective. The effectiveness of this approach relies on several interdependent dimensions that are dynamically interconnected and mutually influential, such as: (1) the user's ability to elicit and modulate neural oscillations associated with sensorimotor processes during MI [42]; (2) the system's capacity to accurately detect, process, and classify these signals [19]; and (3) the user's motivation, engagement, and adherence throughout the training process [43]. Each component of the intervention triad influences one or more of these dimensions, creating a reinforcing cycle that amplifies the overall effectiveness of MI-VR-BCI interventions.

MI-based BCIs typically have lower transfer rates compared to other BCI paradigms [44], and achieving effective control requires prolonged training protocols involving simultaneous learning by both the user and the system. While the user must draw on and further develop existing MI skills, the system simultaneously enhances classification accuracy through optimized algorithms and machine learning techniques [19]. However, a considerable proportion of users (approximately 15%-30%) [45] might face difficulties in effectively controlling BCI systems using MI alone, a phenomenon known as BCI inefficiency. Despite this, some authors argue that BCI inefficiency may not solely stem from biological limitations but may also be influenced by inadequate training protocols, likely due to MI being cognitively demanding, unfamiliar to many users, and often associated with fatigue or boredom during prolonged training sessions [46]. VR can counteract these challenges by increasing engagement and facilitating more vivid and effective MI. For example, immersive VR environments have been shown to elicit stronger ERD, facilitate sensorimotor rhythm modulation, and improve BCI performance [47,48]. A key mechanism underlying these effects may be embodiment—the sense of owning and controlling the avatar—which arises from the interplay between body ownership, agency, and self-location [49], with Forster et al [50] also considering the close intertwining with presence. In addition, VR supports action observation, potentially activating the mirror neuron system, both of which are known contributors to neuroplasticity [51]. Closing the loop by providing feedback during MI observation enhances neuroplasticity by engaging pre- and postsynaptic summation mechanisms, thereby promoting motor learning [21]. Furthermore, VR can enhance motor learning, improve body awareness, and elicit kinesthetic sensations even in the absence of physical movement [49,52]. Clinically, this is highly relevant for stroke survivors, who often struggle with body perception and a reduced sense of control over their affected limbs.

VR is also able to leverage certain principles of motor learning, like the specificity of the task, intensity, repetition, and relevance, necessary factors for the development and strengthening of synapses and, consequently, for motor recovery [53,54]. Another aspect that favors the association of MI, BCI, and VR is the multisensory stimulation potential associated with the latter. This combination has the potential to enhance hand function by delivering targeted sensory feedback across different systems, such as somatosensory, visual, and auditory pathways, thereby promoting neuroplasticity [55]. This feedback may help reduce the discrepancy between motor intention and MI commonly observed in BCI applications, potentially increasing the overall effectiveness of the MI-VR-BCI approach. Although it presents multiple theoretical benefits, this paradigm remains recent and innovative, raising important questions regarding its design and implementation.

BCI-based technologies have a broad range of applications and are increasingly being researched, but there remains a gap between the technology and the end user [56]. The development of BCI systems for rehabilitation must consider patients' needs while encompassing clinical applicability and technical feasibility [57]. Research states that practitioners and researchers need to involve users in creating solutions that consider factors such as convenience, ease of use, privacy, security, safety and quality standards, prioritizing users, and ergonomics [58]. Given these considerations, it is necessary to establish recommendations for the use of MI-VR-BCI and adjust the technology to meet the real needs of users and clinical practice [59]. To address the gaps in existing evidence, this study aimed to explore the insights of (1) neurorehabilitation experts regarding the most effective factors and principles of neurorehabilitation and neurophysiology relevant to adapting for BCI intervention; (2) stroke survivors to inform recommendations based on their needs, preferences, and motivation; and (3) biomedical engineers on the technical knowledge of the technology.

Using a collaborative methodology, the study sought to develop realistic recommendations for designing more effective interventions for the ULR in stroke survivors using BCI-based interventions combined with VR and MI.

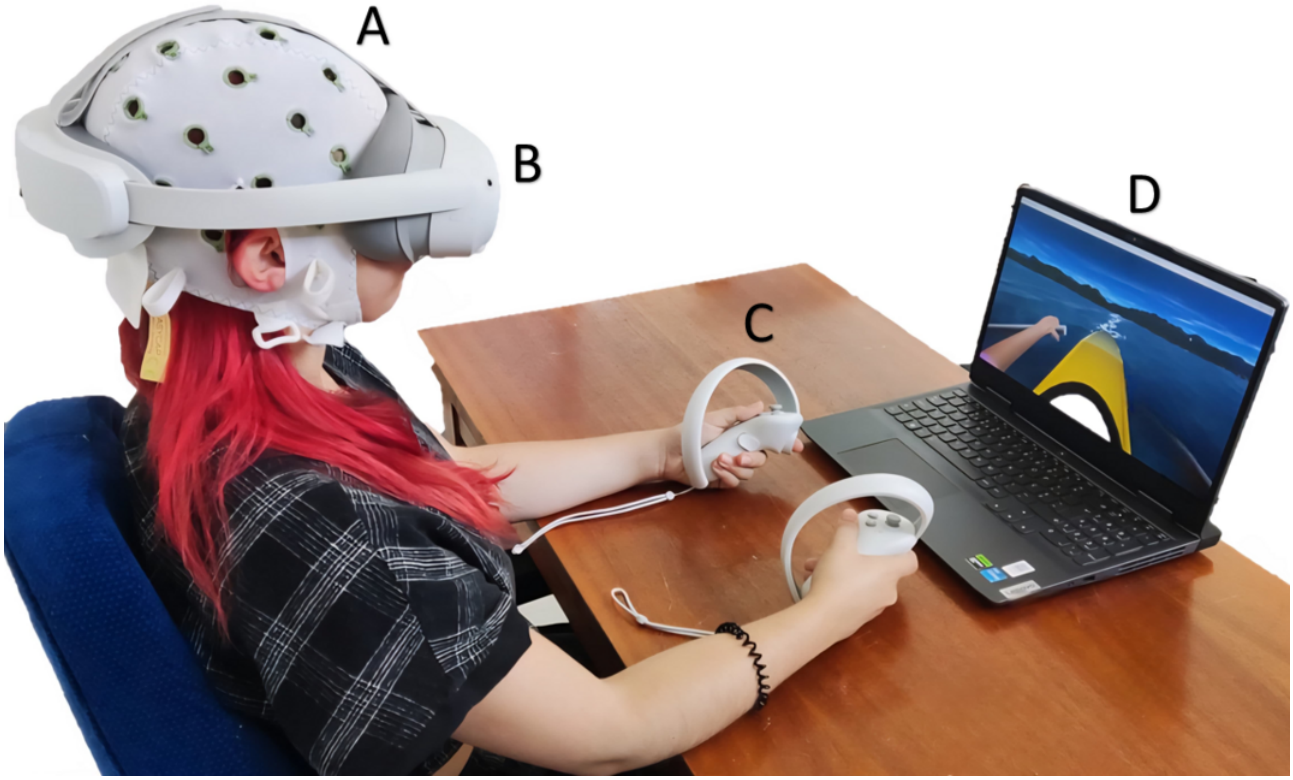
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Methods

Study Design

A qualitative design grounded in reflexive thematic analysis [60,61] was used within a constructionist epistemology and interpretivist theoretical perspective to draw from the tacit knowledge of experts and experience from stroke survivors through a reflexive thematic analysis. Thus, a multiperspective collaborative design process was used through workshops, including clinical neurorehabilitation experts, stroke survivors, and biomedical engineers [62]. For this study, both web-based and in-person workshops were planned. The first allowed the participation of geographically dispersed participants [63], and the second helped fully leverage interpersonal dynamics for enhanced collaboration and permitted experiencing the MI-VR paradigm. Technology experimentation was made through NeuRow developed by Vourvopoulos et al [64], a first-person perspective upper-limb MI training paradigm involving a bimanual boat-rowing task, with feedback delivered through a head-mounted-display VR and haptic feedback (Figure 1). Logistical and time constraints, particularly the extensive preparation and calibration required for the EEG, limited opportunities for technology experimentation including direct BCI control, only involving MI and VR. The COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist was followed for this study (Multimedia Appendix 1) [65].

Figure 1. Set up for technology experimentation. (A) Electroencephalography cap. (B) Virtual reality headset (PICO 4). (C) Haptic feedback. (D) Scenario visualized through the virtual reality.



Workshop planning was based on the literature review conducted to familiarize with the topic and identify the evidence gaps. This search focused on meta-analyses in the population with stroke, including the MeSH (Medical Subject Headings) terms “stroke” AND “rehabilitation OR intervention OR therapy” and “upper extremity,” published in the last 5 years, and guidelines for rehabilitation and in meta-analysis on “Brain Computer Interface,” “Virtual Reality,” and “Motor Imagery.”

Sample and Recruitment

The recruitment took place between January 2023 and July 2024, using a purposive sample. Participants were selected based on the researcher’s judgment [66], through the national stroke patient association’s email list, and the researchers’ professional networks. Considering the study goals, the priority in participant selection was the richness of contributions and good communication skills.

Neurorehabilitation experts were included if they had at least 10 years of experience with stroke rehabilitation. Stroke survivors were included if they (1) had a stroke-caused UL impairment, (2) were more than 18 years old at the time of the stroke and (3) had participated in at least 20 poststroke rehabilitation sessions with preferential previous technological experience either in therapy or daily life. Potential participants with stroke were excluded if they had a diagnosis of cognitive impairment or impaired communication (eg, aphasia) that limited their ability to understand complex instructions and to report their experience with stroke rehabilitation. The inclusion criteria for engineers were based on experience with BCI-based interventions and knowledge of the technical details.

Following an initial informal contact to gauge the willingness to participate, potential participants were sent an invitation letter, a consent form, a demographic characterization questionnaire, and scheduling options.

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Of the 25 neurorehabilitation experts who were contacted, 21 expressed interest in participating; however, 8 were not able to participate due to scheduling difficulties. Among the 23 eligible stroke survivors interested in taking part, 6 could not attend due to scheduling issues. Of the 4 engineers who accepted, 1 was unable to attend due to illness. A total of 33 participants were recruited, including 13 neurorehabilitation experts, 17 stroke survivors, and 3 biomedical engineers, and sociodemographic information was collected (Tables 1-3; questionnaires for stroke survivor characterization in the Multimedia Appendix 1).

Table . Description of participants (neurorehabilitation experts, n=13).

Characteristics	Value
Sex, n	
Male	8
Field of rehabilitation, n	
Occupational therapist	3
Physicians	1
Physiotherapist	7
Speech and language therapist	1
Psychologist	1
Clinical Experience with stroke (years), mean (SD)	16.1 (6.55)
Previous experience with virtual reality, n	
None	1
Slight contact	8
Some experience	3
Frequent use	1
Familiarity with technology for rehabilitation (n)	
None	1
Slight contact	7
Some experience	2
Frequent use	3

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Table . Description of participants (stroke survivors, n=17)

Characteristics	Value, n	Mean (SD)
Sex (female)	10	—[a]
Age (years)	—[a]	54.8 (8.32)
Time post stroke (years)	—[a]	5.2 (4.58)
Early chronic (6-12 months)	5	12 (1.64)
Mid chronic (>12-60 months)	5	34 (13.88)
Late chronic (>60 months)	7	132.0 (25.64)
Perceived dependency		
Completely independent	2	—[a]
Slightly dependent	5	—[a]
Moderately dependent	6	—[a]
Highly dependent	4	—[a]
Perceived movement capacity		
Movement moderately useful for ADLs[b]	3	—[a]
Some movement although not useful for ADLs	11	—[a]
Unable to move	3	—[a]
Previous virtual reality experience		
Yes, before the stroke	5	—[a]
Yes, after the stroke	3	—[a]
No	9	—[a]

[a]Not applicable.

[b]ADL: activity of daily living.

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Table . Description of participants (biomedical engineers, n=3).

Characteristics	Value, n
Sex	
Female	2
Academic degree	
Doctorate	2
Bachelor	1
Experience with BCI[a] systems development	
Some experience	1
Moderate	1
Moderate to high	1
Experience with technology for rehabilitation development	
Some experience	2
Moderate to high	1
Experience with VR[b] in stroke rehabilitation	
None	1
Moderate	1
Moderate to high	1

[a]BCI: brain-computer interface.

[b]VR: virtual reality.

Data Collection

A total of 6 workshops were conducted. Of them, 3 with neurorehabilitation experts (NEs), 2 with stroke survivors (SSs), and 1 with the participation of neurorehabilitation experts, stroke survivors, and biomedical engineers (BEs). 4 workshops were held remotely, and 2 workshops were conducted in person (workshops 5 and 6). Workshop durations ranged from 90 to 145 minutes. Each session followed a format with four key phases: (1) introduction outlining the workshop's objectives, structure, and rules, relevant theoretical background, and summary of prior findings; (2) participant introductions and icebreaker activity; (3) core activities tailored to each workshop's objectives; and (4) completion of a workshop standardized feedback questionnaire.

For each workshop, specific goals were established, and corresponding methodologies were selected based on the recommendation of Ozkaynak et al [62] and Benson et al [67]. Accordingly, multisensory elicitation activities and complementary methods were used to enhance participant engagement, leverage diverse strengths, and maximize workshop productivity and efficacy. The methodologies used included scenarios, task prototyping, World Café, and technology experimentation, implemented either in plenary formats (workshops 1-4) or, where appropriate, also in small groups (workshops 5 and 6)—involving all different stakeholders in the case of the final workshop. The workshops were planned iteratively, with the outcomes of each session informing the next to address any gaps, clarify inconclusive points, or resolve disagreements. Figure 2 presents an overview of the workshops conducted, and a more detailed description is available at Table S1 (Multimedia Appendix 1).

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Figure 2. Workshop development and implementation process. The images represent methods and materials used during each workshop. BCI: brain–computer interface; EEG: electroencephalography; MI: motor imagery; UL: upper limb; VR: virtual reality.



To ensure consistency and comparability across sessions, the research team carefully predefined and pretested the structure and focus of each workshop while also ensuring researcher training. While tailored to each workshop's specific goals and participant profiles, visual prompts and guiding questions were carefully designed and refined in advance by the research team. Summaries of each workshop were presented in the subsequent session to promote continuity. For workshops 5 and 6, a written summary was also shared with participants for validation. After each workshop, participants had the opportunity to provide feedback on their experience through a form with both closed- and open-ended questions and share their thoughts on the most important topics discussed, suggest any missing topics, and leave any other comments (Workshop Assessment Questionnaire in Multimedia Appendix 1). The analysis of the feedback questionnaires was used to plan the subsequent workshop.

Data Analysis

An inductive thematic analysis was conducted using data from the verbatim transcripts [68]. The 6-phase process of thematic analysis was followed: data familiarization, systematic data

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coding, generating initial themes, developing themes, refining and naming themes, and producing the report [60].

The workshops were initially transcribed using the Microsoft Office Word transcribe feature, followed by manual review. Each transcript was scanned for relevant quotes, which were lifted into a codebook to group them into preliminary themes according to the study's goals.

The preliminary themes were combined and reassembled into different themes and subthemes until the final thematic map was achieved. The analysis was validated by a second author and discussed with a third research member, followed by frequent debriefing sessions within the research team.

Researcher Characteristics and Reflexivity

The research team was comprised of 4 physiotherapists and 1 biomedical engineer, with clinical experience and research experience in the field of stroke rehabilitation. They believe in stroke survivors' potential to improve, the importance of their active role in their rehabilitation, and the importance of neurorehabilitation principles knowledge to support intervention. Although the research team considers the combination of MI-VR-BCI, a promising tool for upper limb stroke rehabilitation, they view it as a complement rather than a replacement for conventional rehabilitation, as supported by high-quality scientific literature. While this is the researchers' perspective, a reflexive approach was used throughout the study's conduct and data analysis, with continuous attention to positionality and potential bias. Data interpretation was conducted with transparency and critical awareness, and findings were presented in an open, reflective, and analytically rigorous manner.

Throughout the study, there was an introspective concern to maintain focus on the research question and relevant framework while promoting an environment of free participation by the participants. For the first 4 workshops, there was little to no prior contact and personal relationship with the participants. In the fifth and sixth workshops, a professional association existed between the researcher conducting the sessions and 6 patients, as well as 3 health care professionals, due to their shared involvement at the rehabilitation center. These pre-existing professional relationships did not influence the design, methodology, or conduct of the workshops.

To ensure the quality of the study, meetings were held for discussion of the methodology and analysis processes. This step reduced possible bias from the researchers and increased scientific rigor.

Ethical Considerations

The study was approved by the Ethics Committee of the Polytechnic Institute of Setúbal (CE-IPS 35/2023) and Alcoitão Rehabilitation Medicine Center (CMRA2023/006 and CMRA 2023_012). All participants were informed of the aims of the study, procedure, risks, and confidentiality through an invitation letter. Prior to taking part in this study, the participants signed the informed consent form. Participants did not receive any form of financial or material compensation. Participants were also informed that workshops would be recorded, their identity would be kept confidential, and that they had the right to withdraw from this project at any time without any prejudice.

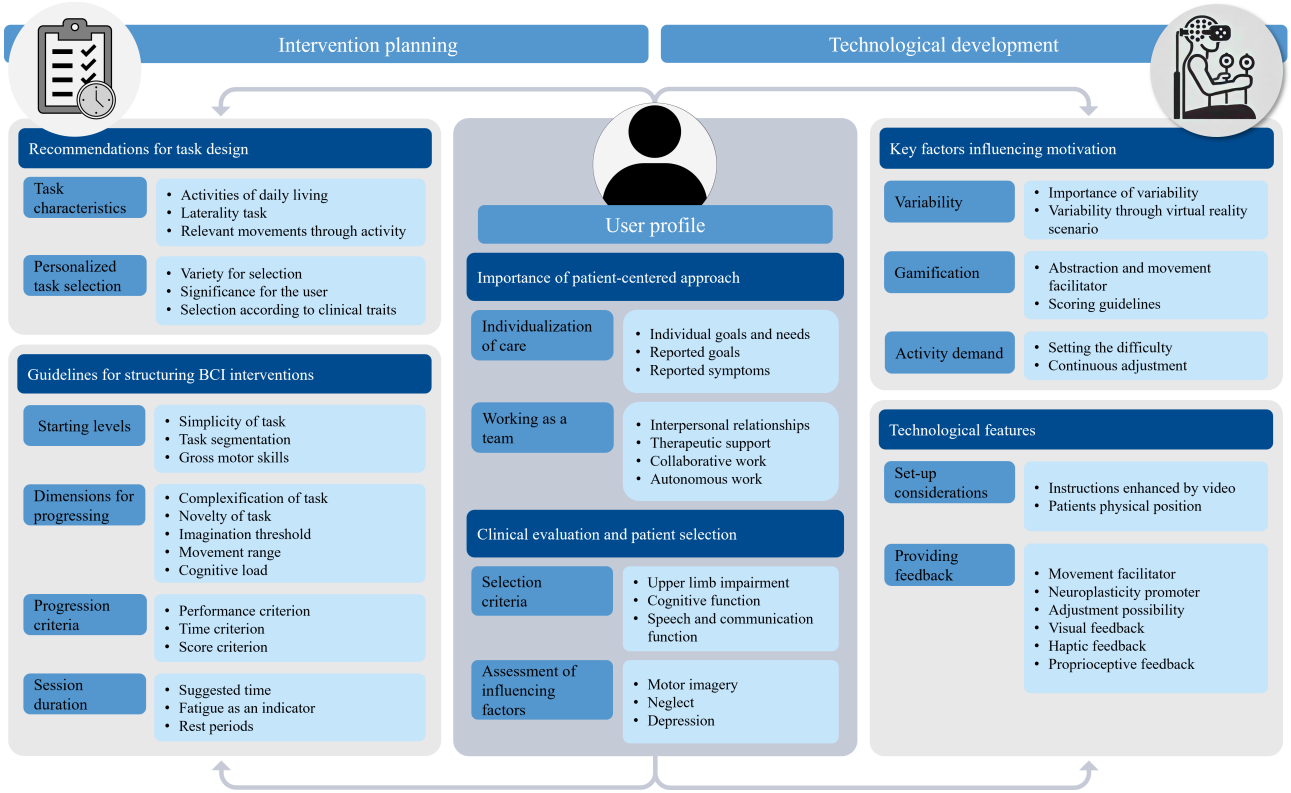
Results

Overview

The thematic analysis revealed 6 themes (Table S2 in Multimedia Appendix 1) regarding recommendations for planning and implementing MI-VR-BCI interventions and were arranged according to 3 dimensions: user profile (themes 1 and 2), intervention planning (themes 3 and 4), and technological development (themes 5 and 6), with all dimensions closely intertwined. The user profile dimension integrates the importance of a patient-centered approach and considerations on clinical evaluation and patient selection. The intervention planning dimension contemplates the recommendations for task design and guidelines for structuring BCI intervention. The technological development dimension considers the key factors influencing motivation and specific recommendations on technological features. A map was created to provide a comprehensive summary of the findings (Figure 3). Identification of the participant's group (NE, SS, and BE) and number is used in quotations, followed by the identification of the workshop.

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Figure 3. Illustration map of the themes, subthemes, codes, and how they interrelate. BCI: brain–computer interface.



Importance of Patient-Centered Approach

Individualization of Care

Participants emphasized that each stroke survivor presents unique, distinct needs and preferences, making it essential to center rehabilitation around the individual's characteristics and goals. Key goals identified by stroke survivors included enhancing functionality ("the ability to perform daily tasks") and achieving independence, or reducing dependency on others. Functionality was closely linked to autonomy, with the desire to perform daily tasks and social gestures, such as hugging, handshaking, or clapping being a significant motivator and critical target for their rehabilitation efforts.

Participants also emphasized the need to address structural impairments, such as manual dexterity, tactile sensory deficits, pain management, neglect, and perception. The diversity of symptoms and goals indicates that rehabilitation must be tailored to each stroke survivor's priorities and challenges. This individualized approach should guide the design of tasks and technological features of MI-VR-BCI solutions, ensuring that different dimensions, including dexterity, perception, or motor planning, are addressed through targeted activities. By systematically assessing stroke survivors' specific symptoms and goals, the rehabilitation process can be optimized for better outcomes and relevance.

> *We have to put the patient here at the center. Not here near me... but in the center.* [NE 13, workshop 6]

When asked to write down what is more important for arm recovery, stroke survivors wrote:

> *Participate with agility in our grandchildren's games.*
>
> *Hugging and shaking hands.*
>
> *Functional hand (for daily tasks like eating, dressing, and hygiene).*
>
> *Regaining functional autonomy.* [Group written conclusion, workshop 5]

Working as a Team

During the workshops, participants emphasized the importance of involving an interdisciplinary team in the intervention process. This collaboration enables specialists from different fields to support stroke survivors and guide decision-making, particularly during the assessment phase, to identify all possible influential factors and ensure optimal benefits. Stroke survivors should be active team members, participating equally in decisions. This collaborative approach enhances participant selection, clinical profile establishment, intervention outcomes, and the avoidance of adverse effects. Given the cutting-edge nature of BCI with extensive research exploration, participants also highlighted the importance of collaboration between clinical and research teams.

Regarding interpersonal relationships, stroke survivors valued being understood by health care professionals, which, along with positive feedback, enhanced their satisfaction and sense of contentment. Participants also stressed the importance of health care professionals being prepared to address the stroke survivor's feelings of frustration and discomfort. Stroke survivors also highlighted the importance of therapeutic guidance and specialized attention, while also being empowered to work autonomously. Correspondingly, the end of sessions and associated time constraints were seen as demotivating, as they had to wait until the next session to continue their progress.

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> *It's also important to have, realistically speaking, multidisciplinary teams so that we can all understand the patient.* [NE 13, workshop 6]

When asked to write down what builds the sensation of a "Good Session," stroke survivors wrote:

> *Involvement between therapists and patients (ability for therapists to understand us).* [Group written conclusion, workshop 5]
>
> *I learn an exercise with the therapist [...] Then I want to train, I want to exercise.* [SS 9, workshop 5]

Clinical Evaluation and Patient Selection

Selection Criteria

When considering the inclusion in a clinical program or research setting, participants emphasized the importance of stroke survivors' motivation to engage in MI-VR-BCI interventions and the need to establish the technology's true potential benefits. Clarifying the meaningful therapeutic value and assessing various clinical aspects were noted as crucial.

For UL impairment assessment, the Fugl-Meyer Assessment of motor recovery after stroke was recommended. It was observed that stroke survivors with higher UL functioning levels might struggle with interventions involving only MI, which should be considered when determining the impairment level threshold for inclusion. The intrinsic connection between motor and cognitive function was also addressed, recommending a comprehensive cognitive assessment using the Montreal Cognitive Assessment (MoCA) to evaluate spatial, temporal, and personal orientation, as well as the ability to follow instructions. Stroke survivors lacking this ability should be excluded.

Language assessment, particularly comprehension, was emphasized due to its impact on stroke survivors' ability to use the technology and understand tasks. Global aphasia was established as an exclusion criterion, with the ability to understand simple commands deemed essential. Given the nature of the intervention, which relies on mental practice rather than physical movement, participants stated that this approach offers inclusiveness, providing therapeutic options for stroke survivors often excluded from studies.

> *If a person is disorientated in all three dimensions, they're hardly going to be able to do anything. [RE 3: Exactly, exactly.] And we're wasting our time in rehabilitation work […] we must understand what the person's initial cognitive part is and then work on this motor part intensively.* [NE 13, workshop 6]
>
> *There's so little [in studies] of this ability to include certain subgroups, that perhaps developing something for this fringe of users [... would be] quite relevant.* [NE 1, workshop 1]

Assessment of Influencing Factors

Participants emphasized the importance of assessing imagery capacity, as it can directly influence intervention outcomes. While not considered an exclusion criterion, evaluating imagery capacity helps tailor the amount of imagery training required before starting the intervention. The assessment tools recommended by the participants include the Vividness of Visual Imagery Questionnaire, the Movement Imagery Questionnaire, and the Left-Right Judgment Task.

Affective changes and emotional stability may play a crucial role, as they impact motivation and intervention success. Participants recommended assessing depression and anxiety with tools like the Beck Depression Inventory or the Hospital Anxiety and Depression Scale. Emotional challenges, such as encountering activities that participants can no longer perform, may cause discomfort and need to be managed carefully.

Neglect was frequently highlighted as a clinical trait to consider in participant selection and intervention planning. Neglect can alter spatial and body perception, affecting interaction with the interface and performance of imagery tasks. While neglect may affect outcomes, participants emphasized that it should be assessed to adapt tasks rather than exclude participants. Concomitantly, many participants emphasized the potential of virtual reality as a neglect training tool, suggesting that appropriate adaptations should support participation.

> *[...] The question of motivation: if the person is depressed, we can do all the work in the world, but if we don't address the affective issue... the result may not be so positive. So we have to act on different fronts. It might be useful, or it should probably be compulsory to have a psychological assessment beforehand.* [BE 1, workshop 6]
>
> *[...] spatial organization, the ability to scan the image, the perception of space and body awareness... There are several things here that seem to be more cognitive than necessarily motor, because we're considering just imagery.* [NE 2, workshop 3]

Recommendations for Task Design and Selection

Task Characteristics

Most stroke survivors and health care professionals preferred tasks related to ADLs due to their relevance and strong connection to "muscle memory," which aids MI. These tasks were seen as familiar, mundane, or realistic, representing activities encountered in the real world and enhancing motivation in ULR sessions. A list of relevant activities may be found in Table S3 in Multimedia Appendix 1. Although for the majority, daily activity-based tasks were favored, some participants suggested that less common activities could also boost motivation and provide abstraction from the condition and UL movement difficulties.

Participants debated the relevance, advantages, and nuances of unilateral versus bilateral tasks, their influence on MI, motor planning, and neuroplasticity stimulation, with no clear consensus. Unilateral tasks were recommended for their potential to elicit specific brain activation and reduce interhemispheric inhibition—a phenomenon in which the healthy hemisphere exerts inhibitory influence on the hemisphere targeted for rehabilitation, possibly leading to counterproductive effects. Accordingly, bilateral activities would only start after mastery of unilateral ones (with the suggestion of starting with

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the less affected side). Conversely, some advocated for early integration of bilateral activities to support the learning in the lesioned side. Initiating tasks with the more affected side having a "supportive role" in the movement of the less affected one, according to an asymmetrical execution, is stated as being more similar to daily life tasks. Moreover, 1 participant stated that, in cases of severe dysfunction, symmetric tasks might be more adequate.

A combined approach of both unilateral and bilateral tasks within the same session was also suggested to leverage the benefits of each. It was emphasized that movements of the more affected side should occur more frequently, with randomized task order to prevent habituation. Respecting the natural execution of tasks (unilateral or bilateral) was deemed important to facilitate motor memory.

Specific activities to practice relevant movements were viewed as beneficial for movement planning and increased engagement. The movements and functions found relevant for stroke rehabilitation are listed on Table S4 in Multimedia Appendix 1. Tasks engaging the UL in a global and integrated manner were preferred, as they activate a wider range of brain circuits and align with everyday activities. Breaking down tasks into smaller segments was recommended to facilitate MI, especially at early stages.

> *I always prefer training things that make sense to me in my day-to-day life, […] things that are useful.* [SS 6, workshop 4]

> *To reduce the competition in terms of the cerebral hemispheres I would say that it could be unilateral. However, we know that bilateral tasks sometimes favour active movement and rehabilitation. […] I would invite unilateral activity and quite possibly try to inhibit the contralesional side.* [NE 2, workshop 1]

Personalized Task Selection

Participants defended a personalized approach to task selection, considering both user preferences and relevant clinical traits. They emphasized the importance of offering a variety of tasks to match the stroke survivor's needs, goals, and preferences, resulting from a collaborative decision-making process between the health professional and the user.

Clinical traits to consider include motor impairments and related symptoms that may influence motor planning and mental imagery, preinjury motor memory, and hemispheric dominance. Tailoring activities to align with familiar movement patterns can optimize results. Imaging findings can also guide task selection by identifying preserved brain regions and targeting specific lesions, helping to decide whether to promote contralesional or ipsilesional brain activity.

For inattentional problems like neglect, tasks involving continuous stimuli that shift toward the neglected hemispace or provide alerts can enhance awareness and engagement. For attention and concentration difficulties, discrete tasks with clear beginnings and endings are more beneficial. Continuous rhythmic activities may reduce focus and engagement, making structured tasks favorable for maintaining attention.

> *We all have mental maps, [...] several meaningful tasks, and individuals select one of them. Each also implement this possibility of variability.* [NE 4, workshop 1]

> *The activities vary greatly, they're very personal.* [SS 10, workshop 5]

> *There's another thing that it should be done which is to analyze not only from a clinical viewpoint, but also with neuroimaging findings. [...] What area was spared or was it initially recovered after stroke? From that point it's very specific to the person. Was the stroke more localized to the primary motor area only? Or somatosensory and motor? Or there's pre-motor and other regions?* [BE 1, workshop 6]

Guidelines for Structuring BCI Interventions

Starting Levels

The key concepts for the initial levels focus on simplicity, facilitated by task segmentation, and align with motor development theories that prioritize gross motor skills before fine motor activities. This approach ensures that foundational skills are established before progressing to more complex movements.

Simple tasks benefit both mental imagery and the capabilities of EEG for capturing brain activity, as EEG's limited spatial resolution makes straightforward tasks more effective for analysis. Considering motor imagination, movement simplicity helps maintain focus on the goal.

Participants noted that segmentation can facilitate MI, especially in the early stages, as visualizing complex tasks with multiple movement components is challenging. However, participants emphasized the importance of balancing segmentation with maintaining focus on the overall task, thereby preserving the connection to real-world movements. One suggestion was to complement segmented tasks with a video demonstrating the complete task to help reinforce this balance.

> *Regardless of whether the patient is more or less able, the task should be as simple as possible in terms of imagery. [...] we want a sensorimotor pattern captured that is representative of that task. If the task varies too much, or if it's fundamentally complex, I can't create an activation pattern that represents that task.* [NE 10, workshop 3]

> *It's important to start by segmenting, with very simple things, because every part of the movement is difficult to imagine. For example, holding a fork it's very difficult to imagine because you must go over there, pick it up - each person picks it up in a different way - and keep holding it. So, starting off in stages and then gradually trying to add movements.* [BE 3, workshop 6]

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Dimensions for Progressing

Progression involves gradually increasing the difficulty of a movement task by adjusting task components, modifying parameters, or modulating technological features. Due to the challenge of visualizing movements with multiple components and their correct timing, adding components to a task should only occur after mastering previous movements, which may require time and be achievable over the long term, rather than in a single session. While increasing task difficulty through imagery is a form of progression, capturing distinct cerebral activation patterns with EEG can be challenging.

Imagining familiar movements was perceived as easier due to motor memory, so introducing less familiar tasks can effectively increase difficulty. Another method is modulating the threshold of imagination, where the intensity of brain signals required to elicit movement in the virtual reality environment is adjusted without changing the task itself.

Relating activities to real-world contexts can enhance perceived difficulty. Visual alterations and cognitive cues provided by technology can facilitate this sensation. Participants also suggested that increasing the movement's range of motion could contribute to progression. Introducing dual cognitive tasks or increasing feedback stimuli during MI could raise task difficulty by adding cognitive load and making the task more challenging.

> *That's not to say that you can't do something more sophisticated. Some people have done decoding, but it's not easy [NE 3: But it's not easy]. It's true that if you think about various movements, different segments of the upper limb are located in slightly different regions, but the imagery patterns are typically a little blurred.* [BE 1, workshop 6]

> *I think that initially we should start with more familiar tasks and as activation improves, possibly as a matter of motivation, novelty and stimulating more cortical representation, we'll move on to new tasks.* [NE 5, workshop 2]

Progression Criteria

Progression criteria are an indicator that a user is ready to advance to a more challenging task level. Discussed criteria included human assessment and technology-assisted feedback. The decision to progress can be made collaboratively by the stroke survivor and the health care professional, according to the stroke survivor's performance and insights. This approach aligns with the core principles of individualization and collaboration, fostering a shared decision-making process within the therapeutic alliance. Progression can also be time-based, occurring after a period of accurately performing the proposed task.

Gamification and scoring systems can guide progression, where accurate repetitions of movement imagery are tracked, and upon reaching a predefined number, the next level is unlocked. In addition, EEG can provide an objective measure for determining the ideal moment for progression. Participants suggested that, by monitoring the connectivity of different electrodes, its increase may indicate that the imagery activity is becoming more robust, representing a readiness to advance to the next level.

> *Here you could also make a system of trying and counting successes of repetitions like in gaming, for example, with the user's decision. [NE 3: But including the user's decision].* [BE 2, workshop 6]

> [One possibility is to look at the connectivity of the EEG BE 1: Yes because, in principle, if the connectivity is too great between several zones, there will be greater recruitment because there is a lot of effort being made. As connectivity becomes more concentrated NE 3: Exactly, it means that the person is optimizing the task they are training for. Connectivity with the EEG can help. With this type of set, it will be electrode-based connectivity, you can't do the other part, which is regional. BE 2, workshop 6]

Session Duration

One key aspect discussed regarding the design of BCI-based MI interventions was the optimal session duration. The ideal length should balance achieving meaningful neural changes with maintaining motivation for effectiveness and sustained engagement. Participants suggested that sessions should not exceed 20 minutes, citing the difficulty of maintaining attention levels due to the repetitive and cognitively demanding nature of the tasks.

Neurorehabilitation experts reported a higher recurrence of fatigue during ULR compared to other interventions, indicating that UL recovery is more demanding. Fatigue emerged as a reliable, person-specific indicator to determine the appropriate end point for each session or the need for breaks. Rest is beneficial for promoting recovery processes that help the brain assimilate new skills and consolidate gains, optimizing the learning process. The importance of integrating BCI therapy with conventional therapy was emphasized, with participants stating that, respecting patients' fatigue and tolerance levels, performing BCI intervention before conventional therapy could yield better benefits, acting as a preparation for motor execution.

> *Usually, it's always the activities with UL that cause more fatigue [...] Or, they can disperse more attention.* [NE 2, workshop 1]

> *We have to assess each person and understand how long the patient can hold out. Some can take 15 minutes, others 10.* [NE 12, workshop 6]

> *Because in practice we'll be teaching the brain to think about motor skills again. Therefore, for learning, we need breaks, we need repetition. So, it's more advantageous to do repetitions and perhaps shorter cycles than doing a one-hour session.* [BE 1, workshop 6]

Key Factors Influencing Motivation

Variability

Variability was defined as the variation of a task without altering its inherent nature or difficulty. Stroke survivors expressed that

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continuous repetition negatively impacts their motivation, causing feelings of monotony and making it difficult to maintain attention and focus on the task. Variability was proposed as a means of "repeating without repetitiveness," breaking monotony and aligning tasks more closely with real-world contexts where pure repetition is rare. However, participants cautioned that variability should be introduced progressively to avoid disrupting focus.

Participants suggested that alternating the type of feedback could help break the cycle of demotivation and inattention. The effectiveness of offering varied, tactile, visual, and auditory stimuli was explored as a means to provide novel information and maintain user engagement. Incorporating variability in visual content (eg, object color) was frequently mentioned as a key strategy. In addition, introducing fictional elements, characters, or well-known celebrities could enhance task variability and further engage participants.

> *For some people can be demotivating doing the same task over and over again.* [SS 17, workshop 5]
>
> *Here, although it's the same manual clamp for the car, it has different abduction and external rotation components. But to put several doors: house or shop doors with the same movement, that's repeating without repeating. It varies according to the context, but the task is the same.* [NE 2, workshop 1]

Gamification

Creating gamified VR scenarios by introducing game-like elements, namely, scoring, helps reduce the focus on the movement itself, facilitating execution. This shift in focus alleviates negative emotions typically associated with challenges in arm movement. Promoting VR gamification supports repetitiveness, which in turn promotes the learning process.

Participants noted that assigning scores to task performances could leverage this playful atmosphere. Since individuals may respond differently to gaining or losing points, participants suggested that the scoring system could be adjusted by the professional, representing an additional method for personalizing the intervention.

> *[when playing] I would relax and practise the movements in a pleasant and emotionally unburdened way.* [SS 13, workshop 5]
>
> *If people lose, they can become demotivated. You can always do gamification to win badges, medals, points, anything and never lose.* [SS 10, workshop 5]

Activity Demand

Participants proposed that the intervention program should include a graded system for task selection with an ongoing process of monitoring and adjustment of activity demand. Adjustments may involve either increasing or decreasing task difficulty and have the goal of maintaining an optimal level of difficulty, based on each stroke survivor's capabilities. This approach aims to prevent discouragement from tasks perceived as too difficult and demotivation from tasks considered too easy. Using a rationale based on small incremental steps would allow for the inclusion of intermediate levels, preventing tasks from being excessively easy or overly challenging.

> *I think that [...] the activity can be graded, and the therapist himself can define what kind of activity can be done and the difficulty, considering the patient.* [NE 3, workshop 1]
>
> *It's roughly this game theory—you want to be in the sweet spot between the difficulty of the task and your competence […] The difficulty must be such that I can overcome it. If I can't, you adjust the difficulty. That's how you progress. And that's what best keeps the participant's attention and engagement.* [BE 1, workshop 6]

Technology Features

Set-Up Considerations

Regarding the physical position of the patient, 2 key variables should be considered, namely comfort and the promotion of postural stability. Appropriate back support and, if possible, support for the UL on a table or equivalent surface should be provided. This setup promotes an external contextual organization that could facilitate greater focus on brain activation.

When providing instructions for the task, previous action observation through video was considered a helpful strategy, particularly for stroke survivors with language impairments. In addition, this approach enhances the precision of MI-related brain activity.

> *To me it makes sense that the person is comfortable in a comfortable position and that there won't be confounding variables around while he is doing this, right? [For example] The person being unbalanced and trying to manage what is the real body with the virtual body [would be confusing or distracting].* [NE 10, workshop 3]
>
> *[...] to ensure that the task is recognized, not only in its context, but also in its objective, having an example of a person reproducing the movement would be important because it has cortical representation [...] which would give a better feedforward.* [NE 2, workshop 1]

Providing Feedback

The immersive VR environment was viewed as beneficial for creating enriched contexts that facilitate neuroplasticity through meaningful, multisensory, and enjoyable stimuli. However, for individuals with attention deficits, perceptual disturbances, or sensory impairments, overstimulation could have negative effects. This highlights the need for personalized feedback to adjust the quantity and intensity of stimuli to meet individual needs.

Regarding visual feedback, participants noted that human-like features are more interesting and meaningful to users, with recommendations to match skin tone and clothing. The use of "extraordinary" characteristics may also serve as a motivational

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factor. Visualizing movement through an avatar can aid in perceiving that movement, improving bodily awareness. In addition, related to body schema, the presence of both ULs within the field of vision could be beneficial. For those who may not tolerate virtual reality glasses, using a large screen was proposed as an alternative to induce a sense of immersion.

Considering haptic feedback, stroke survivors highlighted the importance of tactile stimulation, in addition to visual engagement, particularly vibration, which can vary depending on the task and scenario. The use of transcutaneous electrical nerve stimulation was highlighted for promoting cortical reorganization.

In addition to observing movement in VR and receiving haptic feedback, stroke survivors expressed that experiencing the movement, including proprioceptive feedback, would be more meaningful. It was suggested that a device (eg, a robotic glove) either simultaneously or after should facilitate actual hand movement to avoid muscle tone increasing by trying to move.

> *I think the strategy here is adding stimuli or cues that the brain can pick up to support the final intention. This question of the shark is excellent, because in practice I'm going to have extra motivation. By activating the amygdala I'm going to look for other resources to carry out the task.* [BE 1, workshop 6]

> *The only thing to do is open and close the glove, when we think about opening and closing. And that would solve the haptic feedback [SS 9: Exactly! It's the moment our brain recognizes...] Because our hand doesn't close, but if I'm thinking about closing and the hand closes, it might be interesting.* [SS 10, workshop 5]

Discussion

Main Findings

By undertaking a multiperspective qualitative study, this study aimed to explore the insights from neurorehabilitation experts, stroke survivors, and biomedical engineers. From the analysis of the results, 6 themes emerged with key recommendations for the design and implementation of a MI-based VR-BCI tool for UL poststroke rehabilitation, which can significantly enhance its effectiveness. By integrating the perspectives of diverse stakeholders, the study informs the development of MI-VR-BCI tools that are not only technically sound but also user-friendly and tailored to the needs of stroke survivors. The individualization of treatment throughout the intervention process, associated with multidisciplinary teamwork and shared decision-making, emerged from the study as important, representing also essential pillars of the patient-centered approach [69]. It is a recommendation in line with international guidelines for UL stroke rehabilitation and provision of health care [11,29,30,70].

This interdisciplinary collaboration has the role of providing comprehensive health care and establishing treatment goals and planning in a shared manner, having in mind the patient's functionality [11,70]. Goal establishment must consider that individual needs vary, influenced by stroke type, symptoms, and the individual's cultural and psychosocial circumstances, and must be well-documented, specific, and challenging [70]. While specialized counseling and orientation by a professional when using VR is seen as important [71], the autonomy support (providing individuals the ability to control their own behavior) also enhances UL performance and promotes the use of the more affected UL after stroke [72].

According to recommendations for stroke recovery trials, a holistic, biopsychological assessment must be performed [73,74], encompassing the 3 dimensions of the International Classification System (ICF) [75], namely body functions and structure (impairment), activities (limitations), and participation (restriction). According to international stroke assessment guidelines, the Fugl-Meyer Assessment, which evaluates impairment, should be complemented by the Action Research Arm Test to assess the activity dimension [74]. Integrating instrumental evaluations, such as inertial motion sensors, can further enhance the accuracy of UL impairment assessment [76] and provide complementary insights into patient-reported outcomes related to activity and participation [11]. The assessment of the quality of movement performed (another important aspect in the context of investigation of UL-oriented interventions) might be achieved through performance assays (such as 2D reaching, finger individuation, and grip and pinch strength) and a 3D functional drinking task [77]. These recommendations shall be taken into consideration since, despite them, most research primarily addresses structural factors, with only a portion, including activity [73], a pattern also found in BCI research.

Following the recommendations from our participants, it is essential to establish clear criteria for effectively assessing MI capability [28,29], and neuropsychological aspects like attention and concentration [22]. Considering cognitive functions, Kruger et al [78] emphasize the importance of working memory capacity for MI, as it depends on the ability to retrieve stored sensory information about a specific movement from long-term memory, transform it, and maintain it within working memory. There was a divergence of opinion among participants concerning the inclusion of patients with cognitive impairments, specifically those affecting attention, perception, and mental imagery capacity. In an observational study on influencing factors on MI after stroke, visual-spatial skills were correlated with MI visualization quality, indicating that altered visual-motor skills may impact both MI and movement [26]. Rienzo et al [34] found similar evidence but stated that, according to the evidence found, visuo-spatial and perception impairments seem to have more influence on MI tasks of an implicit and not explicit nature, since implicit MI involves manipulation of mental representations of affected body parts. In agreement, attention and spatial abilities were found to be performance predictors for MI-based BCI, together with the users' relationship with the technology (such as computer anxiety and sense of agency) [79].

Considering neglect, potentially leading to perceptual impairments and visuomotor deficits [80], there is evidence showing that not only contralesional UL visuomotor MI tasks reduced some neglect symptoms (manifested through copying and drawing tasks) but also enhanced UL sensation [81]. These

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clinical traits are more commonly associated with right hemisphere lesions, including parietal lobe and fronto-parietal pathways [80], and parietal stroke survivors are often excluded from MI studies [82]. Even so, this lesion location alone, or the presence of neglect, does not necessarily predict MI capacity, as neuroplasticity may allow other brain regions to compensate for the damaged areas [34,83]. These findings should be carefully considered, as factors such as neglect may not justify excluding stroke survivors from studies or clinically implementing MI-VR-BCI that involves explicit MI, and patients can possibly benefit from the intervention. However, these factors may influence the intervention outcomes and design, including the MI training required and the selection of task difficulty.

UL functionality should also be considered in decision-making regarding training protocol, as it directly impacts motor execution that correlates with MI capacity [26]. Initial severe UL impairment (Fugl-Meyer Assessment-Upper Limb ≤30), significant hand spasticity (Modified Ashworth Scale-Hand ≥level I+), and presence of aphasia have been associated with less favorable distal UL recovery after MI-based BCI intervention [84]. Stroke location may also play a role regarding intervention potential, as supratentorial strokes and lesions in the pontine region are associated with poorer UL recovery (with the latter linked to severe disturbances in both sensory and motor functions) [85]. Basal ganglia lesions are found to particularly disrupt frontal lobe connectivity and motor planning [85], possibly negatively influencing rehabilitation outcomes. As corticospinal tract integrity is a strong biomarker of sensorimotor function and motor recovery [86], it may be considered for establishing patient profiles and intervention conditions, with higher corticospinal tract integrity and some degree of residual muscle control possibly particularly benefiting from combined EEG and electromyography systems, enhancing BCI performance [87]. Interestingly, although sensorimotor function may be a predictor for success in intervention, in cases of severe compromise of the corticospinal tract, MI may be particularly beneficial by optimizing effector-independent learning mechanisms, relying on additional projection systems (ie, the corticoreticular tract) [88], and enhancing connectivity between the sensorimotor network and other brain networks [89]. To tailor clinical decisions regarding rehabilitation options and enhance prediction of therapy response, it will be important to assess white matter disconnection patterns (disconnectome), besides clinical presentation and stroke location [88]. In addition, stroke stage must also be considered for decision-making on optimal training protocol. While effective in both subacute and chronic phases, BCI shows greater effect sizes in the subacute stage, and efficacy may change according to BCI feature combination (for a meta-analysis [90]). Chronic phases with smaller effects might require adjustment of intervention dosage, with Salvalaggio et al [91] suggesting that effective UL interventions in the chronic phase must be delivered in a minimum of 10 hours if augmentative therapies are used, while priming interventions require higher doses (between 10 and 30 hours).

When considering task selection and execution, rehabilitation principles to augment motor control and restore sensorimotor function recommend the training to be task- and context-specific, goal-oriented, repetitive, meaningful, and function-based [29,30]. Accordingly, participants in our study mentioned the importance of the activities being based on ADLs as they represent more meaningful and useful activities when transferred to real needs. These results are in line with those collected by Isbel et al [71] in a study of a similar nature, with participants stating that the use of daily encountered activities is not only more relatable but also more motivating. The recommendation of context-specific training is also a perspective that VR can leverage by allowing the representation of different scenarios and an adequate selection according to stroke survivors' needs. Although the MI-VR-BCI paradigm does not involve motor practice, as it shares principles with scientifically supported task-practice interventions [29,30,92], its principles may be useful for task design [93].

This recommendation is significant because, although current VR development guidelines consider the importance of task relevance [94], a meta-analysis conducted [7] on the design characteristics of BCI paradigms revealed a gap regarding the tasks performed. Most common BCI tasks involved motor attempts or imagination of grasping and extending the fingers, multijoint movements, or individual finger movements, with only a few including ADLs. Aprigio et al [35] provide an overview of tasks used in conventional MI, noting that the most commonly performed activities are rooted in daily life functions. Interestingly, these align closely with the activities our participants identified as significant. Thus, it is crucial to steer BCI task development toward activities that mirror daily life functions.

When considering the practice of bilateral or unilateral activities, the effects of each activity modality remain unclear [8,30,32,95], and evidence shows that bilateral activities appear to have more impact on function-related outcome measures and unilateral activities have more impact on activity dimension [95-97]. In line with the participants' recommendations, clinical guidelines [29] recommend that both bilateral and unilateral arm training must be considered, taking into account the task and level of impairment.

Regarding intervention structuring, and in line with the recommendation to grade activity difficulty to match the stroke survivor's abilities, Proulx et al [55] emphasize the importance of tailoring tasks to individual progress. The authors advocate for adaptable difficulty levels and appropriate task demands, noting that intense active practice requires continuous attention and focus from the stroke survivor. Keeping task demands appropriately challenging requires continuous adaptation and progression [30], which in turn supports both motivation and motor learning [54] and may facilitate the experience of flow state during MI-based BCI tasks [98]. Accordingly, Di Rienzo et al [99] found that low-demand tasks can induce fatigue and boredom, reinforcing the need to optimize task difficulty. Poveda-García et al [26] suggest aligning task difficulty with motor function, as motor function correlates with MI capacity. To support this individualized balance, BCI systems may incorporate performance accommodation mechanisms (PAMs), which dynamically adjust task difficulty based on the user's performance, helping to maintain engagement and motivation.

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Jochumsen et al [100] compared various PAMs, including augmented success, mitigated failure, and input override. The authors identified that users with low BCI control experienced greater perceived control when assisted by PAMs, while those with high BCI control reported decreased perceived control and reduced performance when assisted. Accordingly, selection and implementation of PAMs should consider user performance in real time but account for individual differences in BCI control.

While task complexification was identified by the participants as a key method for progression, using EEG to capture brain activity poses challenges due to its high temporal resolution but poor spatial resolution [101]. Although BCI systems can record activity from cortical and subcortical networks, the detail and extent of the captured information largely depend on the signal acquisition method. MI activity is most effectively detected in the premotor cortex, primary motor cortex, and supplementary motor area, which are also activated alongside the basal ganglia and thalamus [102]. However, because EEG is a noninvasive method, it can only reliably capture signals from cortical areas, whereas intracortical electrodes are required to access activity from the basal ganglia and thalamus [16]. The increasing complexity of tasks, combined with the varying accuracy of MI, may not be fully captured by the recorded signals. This raises concerns that imagining an activity inaccurately could strengthen neural circuits that hinder effective motor learning. These considerations highlight the critical importance of accurately measuring brain activity and ensuring that mental imagery of tasks is closely aligned with the intended motor objectives.

As briefly mentioned by our participants, using high-density mapping could increase spatial resolution but result in a difficult signal-to-noise ratio across channels [103]. The challenges associated with data acquisition, processing, and pattern recognition in MI-based BCI interventions are increasingly being studied in order to overcome the challenges associated with using EEG and improving accuracy [104]. Saha et al [16] theoretically explore the addition of other source-capturing signals like functional near-infrared spectroscopy or magnetoencephalography in a complementary way to EEG to boost classification performance. The recommendation to create more complex scenarios by increasing cognitive demands (eg, by introducing additional visual or auditory stimuli) aligns with previous recommendations [55] and offers an alternative means of raising task difficulty. This method emphasizes cognitive mechanisms rather than relying solely on motor challenges, also recruiting dual-task mechanisms, as stated by participants.

Using connectivity as a coadjuvant progression criterion to assess MI efficacy aligns with findings from the study by Bagarinao et al [105], which indicate that MI expertise leads to more targeted recruitment of motor networks and higher brain activation intensity. Regarding the integration of MI-VR-BCI into clinical practice, participants stated it should complement conventional therapy, which is in line with the findings of Kruse et al [22] with MI acting as a priming tool with positive influence on impairment and activity outcomes in patients with stroke [106].

Motivation levels directly influence the process of ULR, posing as a fundamental aspect of intervention planning [107]. While repetition is essential for neuroplasticity and learning, requiring substantial practice volume and intensity, it can present challenges for sustaining patient engagement and motivation. In line with our recommendations, participants from Isbel et al [71] also stated that motivation can be enhanced through realism, gamification, scoring, and feedback. The usage of variability, besides having a positive impact on motivation, is a principle associated with optimized motor learning [108]. Moreover, gamification is a strategy with proven results in rehabilitation, associated with higher levels of motivation [109]. Its addition to VR shows improvements in the overall effect in comparison with only VR [36]. Gamification has been increasingly explored as a strategy to optimize MI-based BCI training protocols and outcomes. By enhancing motivation and engagement and reducing the monotony often associated, gamification may improve BCI performance (average classification accuracy of 74.35%) and support adherence and sustained participation in the intervention [110]. A recent systematic review [111] explored gamification in MI-based BCI training, highlighting the positive impact of elements, such as feedback, avatars, assistance, and social interaction, on both performance and user experience. However, most studies lacked rigorous designs, often missing control groups or relying on small samples, making it difficult to draw robust conclusions about the impact of individual game elements on effectiveness.

Regarding feedback customization recommendations, Proulx et al [55] state that treatment design for individuals with stroke must consider feedback delivery parameters, task complexity, and sensory deficits. They argue for combining various modalities of augmented feedback tailored to each individual condition, rather than a one-size-fits-all approach. Accordingly, the addition of multiple types of feedback may enhance performance and motivation and minimize frustration in healthy participants [112]. However, in patients with stroke, symptoms such as sensory hypersensitivity, including hyperesthesia, or potential cybersickness must be carefully considered, and optimal conditions should be established, ensuring adequate levels of immersion and presence to optimize the benefits of VR. When considering multimodal stimulation, feedback adjustment, and instruction modality, it is important to recognize that the relevance of different feedback types may vary depending on the nature of the task, its significance to the intended action, and the distinct brain areas and cortical networks they activate [78].

In the absence of proprioceptive feedback, visual feedback becomes particularly salient, making it a critical factor for MI-VR-BCI designs. Consistent with the statements of participants in our study, who expressed a preference for avatars with humanoid characteristics, several studies have explored the benefits of anthropomorphic design [44,47]. Through an experimental paradigm involving healthy participants, Alimardani et al [47] identified that using humanlike features raises the sense of agency, ownership, and embodiment. These findings are complemented by Bashford and Mehring [113], who showed that observing movements congruent with the imagined task can enhance the sense of control over the rendered

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body—even in the absence of accurate, real-time BCI performance. Although MI-based BCI performance may not differ between humanoid and abstract avatars, humanoid design can significantly increase users' sense of ownership and agency [44]. By reproducing a more faithful representation of the imagined movement and aligning with the users' real-world sensorimotor expectations, higher excitation of motor processes might be induced, which, in turn, may promote more efficient connectivity and aid the learning process [47]. Considering MI as not only motoric but also motivated by multisensorial movement conception and predictions [114,115], BCI researchers and designers might leverage multisensorial nature and VR environments to elicit a MI response.

Feedback in BCI systems is a multidimensional construct that encompasses more than just modality (eg, visual, haptic, or proprioceptive cues). One critical dimension is feedback granularity, which refers to the level of detail and continuity of feedback over time, encompassing aspects of spatial and temporal congruency, which are closely interrelated [116]. In discrete feedback, the system responds only when MI activity surpasses a set threshold, providing a brief, event-based signal. In contrast, continuous feedback offers real-time information about user performance, with the participants of Kjeldsen et al [117] showing a preference over discrete feedback due to a better sense of agency and movement notion. Despite this, in the same study, it was only possible to establish a correlation between higher agency and performance in the discrete feedback condition. Another key dimension is feedback bias, typically described as positive, negative, or neutral. Positively biased feedback, which rewards users regardless of classification accuracy, can temporarily enhance embodiment and MI performance [118]. Conversely, negative feedback within embodied VR, presenting movement with the contralateral side of the intended imagery during unsuccessful attempts, may impair the sense of agency and hinder MI learning [47]. When comparing contingent feedback with independent feedback through BCI-functional electrical stimulation (FES) in patients with chronic stroke, MI-contingent feedback led to significantly greater improvements in wrist extensor strength, range of motion, and functional connectivity in the affected hemisphere [20]. In addition, Maier et al [108] state that rhythmic cues, explicit feedback (knowledge of results), and implicit feedback (knowledge of performance) are neurorehabilitation principles to consider when developing interventions to elicit motor learning in neurorehabilitation. Importantly, the effectiveness of feedback strategies appears to be performance-dependent, underscoring the need for personalized feedback planning that considers both clinical characteristics and individual BCI proficiency.

A key difference between motor execution and MI is that the latter lacks sensory feedback due to the absence of movement [34]. Motor execution–based BCI interventions have demonstrated higher efficacy in UL function rehabilitation [17,23]. Adding proprioceptive feedback through externally facilitated movement can enhance neural engagement and promote more effective motor learning and recovery. When considering the addition of proprioceptive feedback, meta-analyses comparing BCI intervention designs favor the use of FES for improving UL function [17,23]. Usage of neuromuscular electrostimulation is also recommended by stroke rehabilitation guidelines [11], particularly FES to reduce motor disability and improve function in both acute and chronic phases of ULR [30].

Considering technology implementation, several key steps are essential. To support smoother adoption and informed engagement, both health care professionals and patients must receive adequate education about the MI-VR-BCI system [119]. It will also be important to establish what the neural mechanisms underlying BCI effectiveness for stroke rehabilitation are [120]. In addition, standardizing protocols and assessment timings and using validated clinical scales are recommended to ensure consistency in tracking progress, enhance decision-making, and improve comparability across patients and studies [11]. Based on participants' input, establishing normative data from healthy individuals may further support clinical interpretation by providing benchmarks for MI quality, engagement, and neurofeedback responsiveness. In addition, when considering BCIs in clinical practice, clear ethical guidelines must be established and followed to ensure proper data management, privacy, and security [121].

This study addresses important gaps in the MI-VR-BCI field by shifting the focus from technical performance in controlled research settings with healthy participants to user-centered, clinically meaningful design. Grounded in the lived experiences and expertise of stroke survivors, rehabilitation professionals, and engineers, our aim is to bridge the gap between empirical findings—often based predominantly on healthy participants—and their clinical applicability. Our approach inverts the traditional trajectory for BCI development, from system- to patient-centered, prioritizing design and outcomes that align with clinical effectiveness and established international rehabilitation guidelines. In doing so, this study raises awareness of stroke-specific symptoms often overlooked in BCI development—such as sensory deficits, altered body perception, attentional challenges, and fatigue—and how these symptoms critically influence both user engagement and system performance. While we contribute to identifying profiles of eligible patients with stroke, we also propose multidimensional guidelines for the development of MI-VR-BCI interventions and adaptation strategies for those with more complex clinical presentations. Our recommendations may help accelerate the iterative design of MI-VR-BCI interventions, paving the way for inclusive, individualized, and effective systems that address a wider spectrum of clinical needs and are truly applicable to stroke rehabilitation settings.

Ultimately, this work may lay the foundation for a more unified framework that integrates clinical profiles, BCI performance, and user experience to optimize training protocols and enhance both learning and meaningful rehabilitation outcomes.

Recommendations

A list of recommendations was created for the development and implementation of MI-VR-BCI systems (Textbox 1), grounded on the results of the workshops and informed by international guidelines for poststroke rehabilitation.

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Textbox 1. Recommendations for the development and implementation of motor imagery (MI), virtual reality (VR), and brain-computer interface (BCI) technologies.

R1: Importance of patient-centered approach

MI-VR-BCI interventions must be conducted through a patient-centered approach, based on individualized preferences, needs, and goals of the user, by an interdisciplinary team.

- Patients must be part of the decision-making processes throughout the intervention course.
- A balance between autonomous and supported work must be promoted.
- Interpersonal relationships with the professional care team positively influence upper limb rehabilitation by helping to deal with feelings of frustration and discomfort.

R2: Clinical evaluation and patient selection

Selection criteria must include upper limb impairment, cognitive, and communication assessment. Clinical traits, such as MI capacity, neglect, and depression must be assessed since they might influence intervention outcomes.

- All 3 International Classification System dimensions must be considered for a comprehensive evaluation.
- Upper limb impairment severity might influence patient adherence to MI-based approaches and should be considered in patient inclusion and task selection.
- Attentional and perception impairments might influence MI capacity and feedback processing, possibly requiring specific MI-VR-BCI adaptations.
- MI-VR-BCI interventions should prioritize inclusivity by incorporating appropriate adjustments to enhance applicability, thereby extending usability to a broader range of patients with stroke.

R3: Recommendations for task design

A variety of tasks must be available for selection to ensure meaningfulness for the user and suitability to clinical traits. In addition, tasks should preferably be based on ADLs, including unilateral and bilateral tasks.

- Unilateral and bilateral tasks engage different neurological activation patterns in the brain, and both should be used to maximize clinical outcomes.
- Task's typical performance must be considered when designing the task (eg, unilateral or bilateral, symmetry and asymmetry, laterality).
- Movements involving the upper limb in a global and integrated manner may evoke more comprehensive brain activity that closely resembles patterns associated with daily life tasks.
- The preferred type of movement and its suitability may be influenced by the level of upper limb impairment.
- Neglect-related visuospatial impairments might benefit from continuous tasks toward the neglected hemispace.
- Body schema and visuomotor field impairments must be considered and might require specific adaptations to guarantee that both hands are seen and perceived.

R4: Guidelines for structuring BCI intervention

Interventions must be structured by different progressive levels, starting with simple, gross movements and adding complexity through additional movement features, cognitive demand, or MI difficulty.

- Movement simplicity and segmentation aid both MI and signal acquisition.
- Although segmentation might be beneficial, it is important not to lose sight of the overall task. This could be addressed effectively using video.
- Signal acquisition during movement complexity progression can be challenging; however, verifying the accuracy of mental practice is important, as it may influence the reinforcement of appropriate motor schemas.
- Session duration must consider patients' tolerance and fatigue; the inclusion of breaks or rest periods might improve attention and engagement.

R5: Key factors influencing motivation

Task variability, gamification elements, and task demand adequacy should be used to sustain optimal levels of motivation.

- To introduce variability, the preferred option appears to be the visual characteristics of objects and the scenario.
- Variability should not disrupt the attention in the task.
- Gamification features should consider patient profile and optimal response, particularly leveraging scores, badges, feedback, avatars, assistance, and social interaction.
- Upper limb impairment severity might influence MI capacity and therefore, possible task demand. Performance accommodation mechanisms may help address this issue and should be adjusted to the user's MI skill level and BCI performance.

R6: Technology features

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Multisensorial potential of MI-VR-BCI must be effectively harnessed through the adequate adjustment of visual, haptic, and proprioceptive feedback modalities to the patient.

- Ensure the patient's comfort and stability.
- Consider introducing feedback gradually, based on the patient's attentional capacity.
- Allow the intensity of feedback and its parameters to be adjusted according to the patient's tolerance.
- Proprioceptive feedback might improve intervention perceived relevance and bring MI-based BCI outcomes closer to those achieved through motor attempt.
- Visual and haptic feedback variability may help reduce monotony in training protocols.
- The use of a first-person perspective, human-like characteristics, and immersive VR may increase embodiment and facilitate the learning process.
- Consider leveraging the scenario to induce the MI process seamlessly and naturally, reducing cognitive effort.
- Granularity and feedback must be considered and tailored to the patient's BCI performance and individual responsiveness.
- Consider timing and spatial congruence in relation to real-world conditions and using MI-contingent feedback.
- Consider including FES to improve outcomes in upper limb impairment.

Limitations

Although the sample's multiperspective nature is a strength, participants' limited experience with the technology, due to its innovative nature and lack of clinical implementation, represents a limitation. Despite efforts to address this through rich and elucidative activities, our study design and methodologies did not allow for full experimentation of the MI-VR-BCI paradigm, due to the logistical constraints and design methods used. Findings may be context-specific and influenced by individual participant experiences and knowledge. This reality suggests the need to validate the recommendations, using, for example, a nominal group technique. In that case, we suggest a balanced inclusion of diverse clinical neurorehabilitation experts and stakeholder representatives to capture a comprehensive and balanced range of perspectives.

Many of the recommendations suggested were based on a theoretical foundation and construct validity. Thus, it will be important to develop efficacy studies that can adequately isolate influencing variables and mechanisms of action, also helping to establish the validity of the recommendations through empirical paradigms.

Future Research

Despite promising advances, current MI-VR-BCI technologies face several limitations that hinder their clinical translation. These include low signal-to-noise ratios and variability in EEG signal quality [122], challenges in accurately classifying brain signals and supporting multiple classes [123], lengthy and demanding calibration protocols [110,124], limited real-time adaptability [125], and reliance on fixed protocols that do not allow for progression [79].

To overcome these limitations, future research should focus on developing adaptive, patient-centered MI-VR-BCI systems that are aligned with international clinical guidelines and real-world clinical needs. This includes optimizing training protocols in terms of duration, progression, and cognitive load management to sustain engagement and motivation. Equally important is raising awareness among, and involving, health care professionals and patients early and continuously in the design and implementation process [119], to ensure that technologies meet real-world clinical needs, encourage adoption, and promote meaningful rehabilitation outcomes [126].

Future studies should analyze the interaction between different types and intensities of feedback (eg, immersive and nonimmersive VR and their effects on embodiment) and their relationship with task characteristics (eg, unilateral and bilateral activities), user profiles, and BCI performance. Considering stroke survivors' characteristics, it will be important to stratify data according to stage of evolution, lesion location and network disconnection, level of impairment of somatosensory function, and perceptual and neuropsychological alterations. It is also important to establish the efficacy of gamifying training protocols and understand its relationship with motivation, engagement, and BCI performance. Studies should also establish the intervention's effectiveness across ICF dimensions, both short- and long-term, and assess the cost-benefit ratio for different intervention features.

Technological solutions should evolve to better mimic real-life conditions and address stroke survivors' clinical needs, balancing personalization with broader applicability.

Conclusions

The MI-VR-BCI paradigm was very well received by participants in our study. The recommendations presented in this study for the development and implementation of MI-VR-BCI technologies aim to enhance their impact on ULR. Grounded in comprehensive consultation with all stakeholders, these recommendations will improve the technology's relevance and potential efficacy. These recommendations should be taken into account in future studies in order to allow the analysis of the relationship between different characteristics of the stroke survivors, the MI task, and the technological features.

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Authors' Contributions

CMP, AIA, and AV contributed to the conceptualization of the study. MR and IO handled the methodology and investigation (MR workshop 1 to 4, IO workshop 5 and 6) and formal analysis. CMP performed validation. MR, IO, and AV provided resources. AV developed the software. IO and CMP were involved in writing—original draft. IO, CMP, AV, AIA, and MR managed writing—review and editing. IO carried out visualization. CMP, AIA, and AV provided supervision. AV and CMP were involved in project administration and funding acquisition.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material, including participants' characterization questionnaires, workshop feedback questionnaires, workshop detailed structure, thematic analysis synthesis and summary with the relevant activities, movements and functions identified.
[DOCX File, 149 KB - rehab_v12i1e71789_app1.docx]

Checklist 1
COREQ checklist.
[DOCX File, 314 KB - rehab_v12i1e71789_app2.docx]

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Abbreviations

ADL: activity of daily living
BCI: brain-computer interface
COREQ : Consolidated Criteria for Reporting Qualitative Research
EEG: electroencephalography
ERD: event-related desynchronization
ERS: event-related synchronization
FES: functional electrical stimulation
ICF: International Classification System
MeSH: Medical Subject Headings
MI: motor imagery
MoCA: Montreal Cognitive Assessment
PAM: Performance Accommodation Mechanism
UL: upper limb
ULR: upper limb rehabilitation

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VR: virtual reality

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Original Paper

Augmented Reality Exergames for Upcoming Cognitive-Motor Rehabilitation: User-Centered Design Approach and User Experience of Healthy Children

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Abstract

Background: Traditional rehabilitation programs for children with cerebral palsy and acquired brain injuries aim to enhance motor and cognitive abilities through repetitive exercises, which are often perceived as tedious and demotivating. Extended reality technologies, including augmented reality (AR) and virtual reality, offer more engaging methods through exergames. However, to date, no AR exergames simultaneously integrate cognitive and motor aspects within navigational tasks. Developing these exergames necessitates rigorous methodological steps, especially when using emerging technologies such as AR. The MIDE (Multidisciplinary Iterative Design of Exergames) framework advocates a participatory design approach, involving users from the outset, the objective being to optimize the interface and validate game mechanics through user experience (UX) assessment. Some researchers initially test these mechanisms on healthy children before applying them to clinical populations.

Objective: This study aims to evaluate the UX of our AR exergames, consisting of two games (AR Corsi and AR Zoo), in typically developing children.

Methods: Typically developing children participated in two 1.5-hour sessions. During each session, they played one of two AR games using the Microsoft HoloLens 2 headset: AR Corsi and AR Zoo, both of which are designed to engage executive functions and motor skills through navigational capabilities. UX was assessed after each session using the following measures: System Usability Scale scores for usability, AttrakDiff for attractiveness and game quality, MeCue for emotional experience, and Rating scale of Perceived Exertion for Children for pre- and postsession mental and physical fatigue.

Results: A total of 27 participants (mean age 11.9, SD 1.2 years) were included in the study. Mean System Usability Scale scores were 79.9 (SD 11.4) for AR Corsi and 76.3 (SD 12.1) for AR Zoo, indicating good usability. The AttrakDiff questionnaire yielded favorable results, with scores between 1 and 3 for overall attractiveness, pragmatic quality, and stimulation for both AR games. However, the hedonic quality “identity” received neutral scores (mean 0.6, SD 0.5 for AR Corsi and mean 0.7, SD 0.8 for AR Zoo). The MeCue emotions module yielded average scores of 5.2 (SD 0.7) for AR Corsi and 5.3 (SD 0.8) for AR Zoo, significantly exceeding the theoretical mean of 4 (P<.001). We observed a significant effect of physical fatigue (P=.02) and mental fatigue (P=.002) after exposure to both games. A comparative analysis of UX between the two games showed no significant differences.

Conclusions: This study demonstrates that our exergame, comprising two AR games, is user-friendly and well-received by typically developing children, eliciting positive emotions and overall appeal. Although some children reported fatigue, favorable UX evaluation confirms the validity of the game’s content and mechanisms, suggesting its suitability for use among children with cerebral palsy and acquired brain injuries.

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KEYWORDS

augmented reality; exergames; user experience; healthy children; cognitive-motor intervention

Introduction

Traditional rehabilitation programs for children with cerebral palsy (CP) and acquired brain injury (ABI) primarily aim to enhance motor abilities, such as cognition and visuospatial exploration, through repetitive exercises [1,2]. However, these exercises are often perceived as boring, tedious, and demotivating, reducing their effectiveness and leading to low adherence [3,4]. It is essential to explore more engaging and appealing approaches designed to sustain motivation throughout the rehabilitation process. That said, these programs also present additional challenges, particularly in simultaneously addressing motor aspects, such as walking, and cognitive aspects, such as executive functions, while incorporating spatial navigation tasks, which are frequently impaired in children with CP and ABI [5,6].

In this context, "extended reality" (XR) systems, which include both virtual reality (VR) and augmented reality (AR) technologies [7,8], have demonstrated effectiveness and positively impacted therapy adherence and motivation in young patients with CP and ABI [9-11]. More specifically, XR devices that combine games and exercises, commonly referred to as "exergames," provide a more playful and immersive alternative to traditional rehabilitation programs [12]. These technologies enable children to perform complex movements in a safe and immersive virtual environment [13], thereby enhancing their engagement, learning, and self-confidence while making the rehabilitation process more enjoyable [14].

Although systematic reviews and meta-analyses have confirmed the effectiveness of VR in motor rehabilitation for young patients with CP and ABI [9,10], studies specifically examining the use of immersive AR in these children remain limited. To date, research in AR has primarily focused on gait training [15,16], without integrating cognitive components or spatial navigation, which are critical for these populations. However, AR offers several significant advantages, including a reduction in side effects such as cybersickness [17], which is commonly associated with VR, while maintaining a high level of immersion and interaction [8,18]. Moreover, AR provides greater flexibility in designing spatial navigation exercises by leveraging the integration of virtual elements into the child's actual environment. Developing AR-based cognitive-motor exergames could offer an innovative and engaging approach for young patients, addressing both their physical and cognitive stimulation needs.

The development of an XR rehabilitation device is complex and involves multiple methodological steps [12,19,20] to ensure usability, acceptability, and effectiveness. Among current methodologies, the MIDE ("Multidisciplinary Iterative Design of Exergames") framework applies a multidisciplinary approach and an iterative methodology to ensure that each exergame meets necessary health objectives while providing an appealing and accessible design for its target demographic [21]. This framework comprises a three-phase approach: (1) contextual research is conducted to understand the needs of users and therapists through direct interactions and literature review; (2) the design and development phase entails collaboration between therapists and users to cocreate and customize game content; and (3) the device's effectiveness, usability, and user acceptance are evaluated. Even with guidelines, only 10% of studies incorporate user experience (UX) evaluation in the design of rehabilitation video games for children [22].

A comprehensive understanding of UX is crucial when developing a novel rehabilitation device. User-centered models facilitate deeper comprehension of the needs and expectations of the users for whom these systems are created. For instance, Hassenzahl [23] proposes a theoretical model of UX that distinguishes between the perspectives of the designer and the user, where the designer implements elements such as content and functionality to foster positive pragmatic and hedonic qualities in the user, thereby significantly influencing the user's overall perception of the device's attractiveness. Similarly, Mahlke [24] includes emotions as an important component in his model, acknowledging their vital role in the UX. Emotions directly affect perceptions of usefulness, usability, and other noninstrumental qualities such as esthetics, highlighting the need to take them into account in the design of digital systems. Consequently, assessing the UX of an XR headset will encompass several aspects, including usability, ease of learning, satisfaction, emotions, and other contributory factors.

UX evaluation is essential to the development of innovative technological tools assessing the feasibility of a project, particularly when the user is placed at the center of development [14,25]. By involving users early in the developmental process, it becomes possible to better address their specific needs and promote the adoption of the technology [12,25,26], especially when it is new, one example being AR headsets. User involvement through a participatory design approach, as demonstrated by Eisapour et al [27], facilitates the creation of an exergame that aligns with user preferences while identifying and resolving potential hidden issues. In this study [27], the design process relied on several iterative cycles of testing and revisions based on user feedback, ensuring user-centered development that would optimize the final product's quality and effectiveness.

To enhance this participatory approach and ensure successful adoption, some researchers begin by evaluating healthy participants, the objective is to validate the game's mechanisms and optimize its design before introducing it to clinical populations [28,29]. Indeed, pilot and feasibility studies establish a foundation for future randomized controlled trials involving pathological participants. Free from the confounding effects introduced by pathological variables, the preliminary phase validates the underlying concepts, mechanisms, and design of the game. This approach enables designers to confirm that both

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technically and conceptually, the game functions as intended. Additionally, testing the game on healthy participants establishes a performance baseline, which is crucial to the assessment of the game's actual impact on patients in later stages of development.

This study aims to evaluate UX in terms of usability, emotions, and fatigue in an AR exergame composed of two games targeting typically developing children. Additionally, this study seeks to determine whether there are significant differences between the two AR games in UX outcomes. Our primary hypothesis is that the AR exergame will be easily usable by children, thereby underlining the feasibility of conducting cognitive-motor exercises in AR for this population. We expect the overall UX to be positive. Furthermore, we hypothesize that AR-based sessions will not result in significantly increased physical or mental fatigue. Regarding the secondary hypothesis, we do not anticipate any significant differences between the two AR games.

Methods

Study Design

We recruited children and adolescents from leisure centers in the Haute-Vienne department (France). The inclusion criteria were as follows: children aged between 10 and 16 years with typical development (no diagnosis of developmental disorders, developmental delays, or mental or physical health problems) and sufficient oral comprehension skills. The noninclusion criteria were: children with locomotor disabilities (eg, casts and crutches), contraindications for using XR technologies (eg, photosensitive epilepsy), atypical or uncorrected visual or hearing impairments, unstable medical conditions, or refusal by the child or family, which would prevent inclusion.

Ethical Considerations

This study followed the principles of the Declaration of Helsinki and obtained approval from the ethics commission (IRB00012476-2023-18-10-273). Assent from the child and written informed consent from a legal representative were obtained. Additionally, all participant data were anonymized.

Protocol

Following the MIDE framework proposed by Li et al [21], we used a multidisciplinary approach and an iterative methodology to ensure that our exergame would meet the necessary health objectives while maintaining an attractive and accessible design for its target demographic.

Step 1 of MIDE: Contextual Research

We first established clear objectives for the development of an exergame targeting cognitive-motor rehabilitation of children and adolescents with CP or ABI. This initial phase was grounded in the combined expertise of the project team members and a thorough review of the scientific literature. Rehabilitation needs specific to these young individuals were central to the game's design. To optimize the rehabilitation of motor and cognitive functions, the tasks we designed need to be repetitive, progressive, goal-oriented, and tailored to each individual [30-32], and it is also crucial that the rehabilitation we offer both motivate and engage through gamification. Furthermore, it is necessary to enhance motor and cognitive skills through spatial navigation tasks involving executive functions [5,33].

To ensure the success of this development, we assembled a multidisciplinary team that included specialists in CP and ABI (doctors of physical and rehabilitation medicine), game developers, human-computer interaction experts, XR technology researchers, and UX specialists. Each team member was assigned specific roles based on their expertise, covering all aspects of the development process, from game mechanics to user interface design. For this development, we leveraged our previous experiences with digital technology for cognitive-motor rehabilitation.

In earlier work within our laboratory, we used virtual carpet technology, a projection system, described in an experimental study [34] to develop an exergame for cognitive-motor rehabilitation in older individuals [35]. This prior 2D setup proved cumbersome to implement, requiring various trackers to detect user movements. Building on these findings, we opted to explore an AR system in order to simplify the setup by incorporating motion sensors (ie, accelerometer, gyroscope, and magnetometer) directly into the headset. This approach allows for the design of mobility and interaction scenarios between the real world and 3D holograms.

Step 2 of MIDE: Design and Development of a New AR Exergame

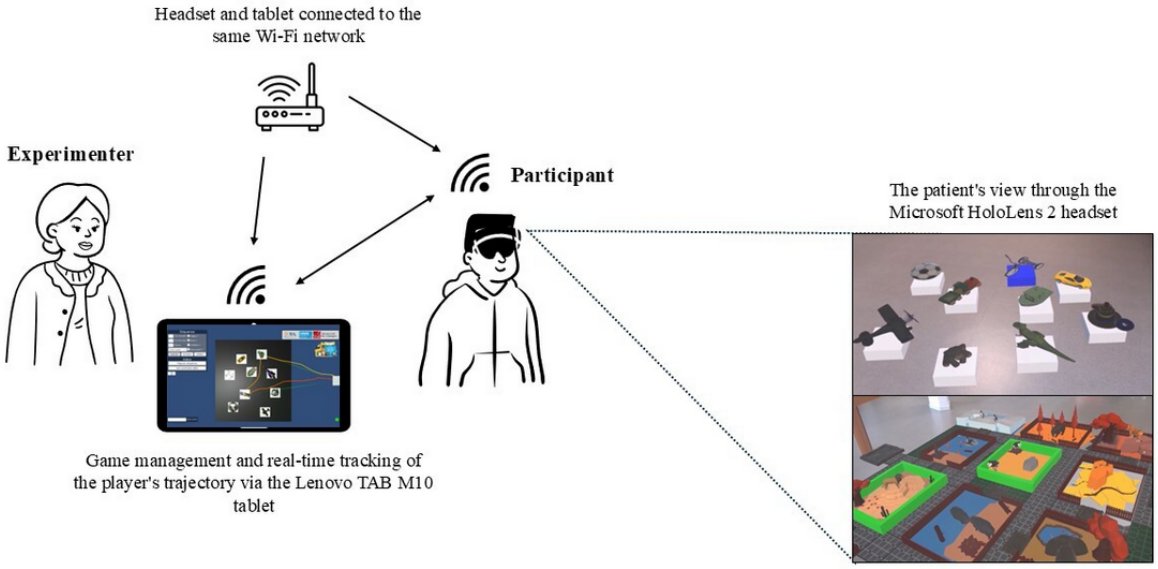
Hardware for AR Exergame

In our exergame, we used the Microsoft HoloLens 2 AR headset, which enables virtual objects to be overlaid in the real environment. This headset indicates the position coordinates (x, y, z) of the participant, allowing for six mechanical degrees of freedom of movement and interaction with the surrounding 3D space. It is portable and lightweight, and due to the seamless integration of holograms, it does not obstruct the user's view of the real world. HoloLens 2 features a resolution of 2048×1080 per eye, a refresh rate of up to 75 Hz, and a 52° diagonal field of view.

To enhance UX, particularly for children, our device is designed in the "Plug and Play" mode. Game management, including condition settings and difficulty levels, is controlled by a therapist using a Lenovo TAB M10 Plus tablet. This tablet runs on the Android 13 operating system and boasts a display resolution of 2000×1200. Communication between the two devices is established via Wi-Fi using an IP4 address. Figure 1 illustrates the interaction between the components of our system, ensuring the instantaneous launching of the game once the connection is established.

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Figure 1. Representation of system interactions.



AR System Software

The AR system (version 2021.3.26f1) and tablet (version 2019.4.21f1) applications were developed using Unity (Unity Technologies Corp) software, using various Unity assets to enhance the UX with key visual and interactive elements for pediatric rehabilitation. Visual Studio (Microsoft Corp) was used for application development and coding. Due to the rapid expansion of the XR headset market in recent years, we have designed our games to be deployable on similar HMD devices, requiring only minimal technical adjustments.

We developed two AR games with innovative variations, one of them entailing the integration of a virtual agent based on the motor learning model [31]. As recommended for this model, these games incorporate a large number of repetitions of functional tasks, visual and auditory feedback, and a gradual increase in task difficulty, all of which are essential to the rehabilitation of children with CP or ABI.

AR Games

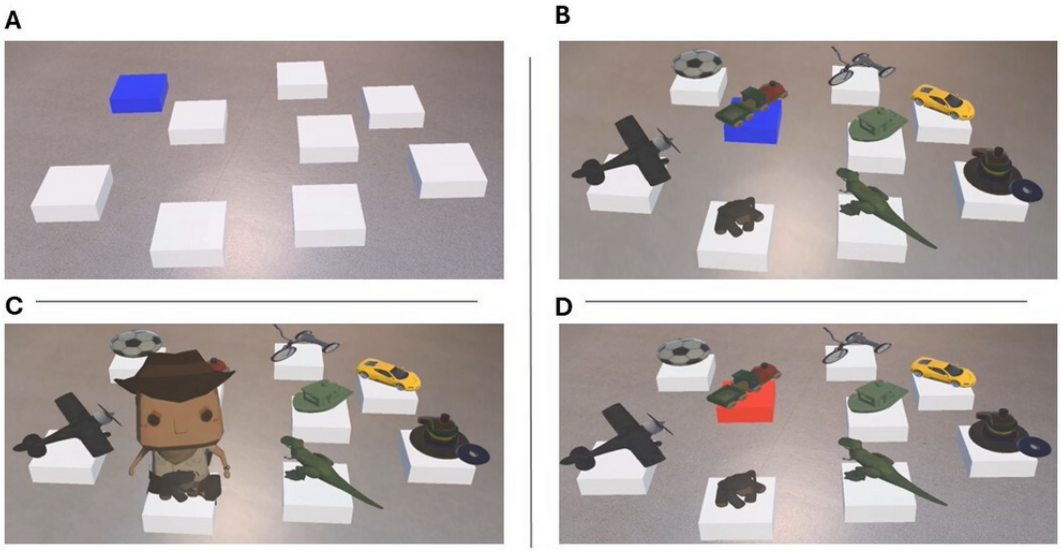
AR Corsi Game

This game draws inspiration from the Magic Carpet (MC) [36-39] and the Virtual Walking Corsi Test [34], both of which are adaptations of the Walking Corsi test [40] for locomotor space. The AR Corsi game was developed to address issues of spatial orientation, visuospatial memory, and cognitive strategies to be deployed during navigation. These tests transpose the Corsi block-tapping task [41] into a format where participants navigate on tiles instead of tapping on cubes. It is one of the most widely used neuropsychological tests assessing visuospatial memory. In this test, participants memorize sequences of increasing length by tapping on small wooden or plastic cubes. By contrast, the MC or Virtual Carpet presents sequences in locomotor space using an electronic device, requiring participants to retrieve them by walking on physical or virtual tiles. The AR Corsi game maintains the same dimensions as the Virtual Walking Corsi Test, featuring nine 3D white square tiles (30 cm×30 cm) arranged in a geometric layout like that of the Corsi block-tapping blocks on a virtual board measuring 300 cm×240 cm. Positioned outside the board, the 10th tile serves as the starting and finishing point. The difficulty levels range from 2 to 9 tiles to navigate.

The AR Corsi game offers four distinct and novelty conditions (Figure 2 and Multimedia Appendix 1).

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Figure 2. AR Corsi game conditions. (A) Condition “Classic.” (B) Condition “Classic with objects.” (C) Condition “Virtual Agent.” (D) Condition “Advanced.”.



- The “Classic” condition (Figure 2A) entails memorizing a sequence of virtual tiles that are illuminated in blue. Players must then reproduce the sequence by navigating the real environment. A sound cue signals the start of the sequence, after which players can commence at their own pace. While navigating, players validate each tile by remaining on it for one second, causing it to illuminate in green and triggering the validation sound signal. Upon completing the sequence, players return to the starting tile.
- The “Classic with objects” (Figure 2B) condition is akin to the first condition but incorporates objects on the tiles. Objectives and instructions remain unchanged, with auditory feedback reproducing the sounds of the objects during the memorization phase. Additionally, spatial cues such as objects will enable participants to develop alternative cognitive strategies for task resolution, as they will be able to use language as well [42].
- In the “Virtual Agent” condition, a virtual agent depicted as an explorer presents the sequence to the player. The virtual agent traverses from one object to another every second, requiring players to memorize its path and reproduce it in accordance with the criteria of the first two conditions. We hypothesize that the integration of this virtual agent will enhance spatial memory and improve player motivation by making the experience more engaging (Figure 2C).
- The final condition, “Advanced,” tasks players with memorizing the order of objects illuminated in blue and inhibiting those illuminated in red. Instructions mirror those of the other conditions (Figure 2D). This condition is more challenging, as it is likely to engage additional executive functions, such as inhibition and cognitive flexibility, in addition to working memory.

AR Zoo Game

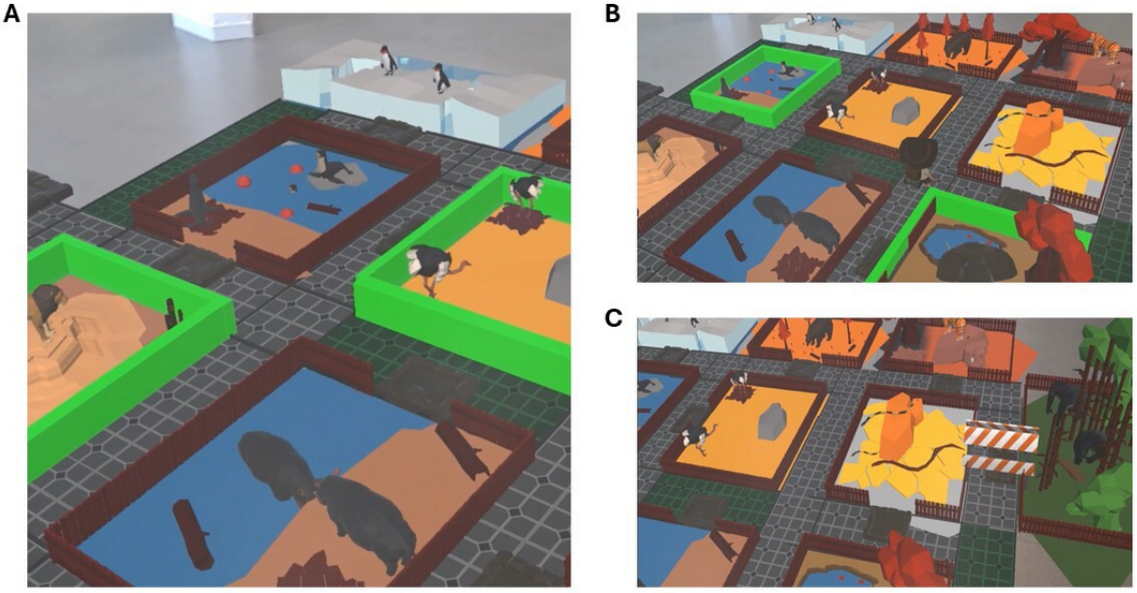
The AR Zoo game is an adaptation of the Zoo Map Test, a commonly used assessment tool evaluating executive functions in children, as part of the Behavioral Assessment of the Dysexecutive Syndrome for Children battery [43-45]. In the traditional neuropsychological test, participants are presented with a map of a zoo on a sheet of paper and tasked with planning a route to visit several animals, adhering to various constraints such as avoiding the retracing of certain paths and selecting the fastest route. The test comprises two conditions: the first emphasizes planning skills, requiring participants to anticipate the order of visiting designated locations in view of minimizing errors, while the second condition is less demanding, simply instructing participants to follow directions in view of completing an error-free journey.

The AR Zoo game aims to address challenges related to spatial orientation, planning, and cognitive strategies to be applied during navigation. We have adapted the fundamental concept by modifying aspects related to the animals, zoo layout, and game conditions while introducing spatial navigation. To enhance accessibility for children, we selected a zoo with 12 easily identifiable animated 3D animal enclosures. The game board measures 500 cm×410 cm, with enclosures measuring 80 cm×75 cm and paths 30 cm wide. Each enclosure is equipped with a validation slab measuring 30 cm×30 cm. The difficulty levels range from two to six animals.

AR Zoo offers three distinct conditions (Figure 3 and Multimedia Appendix 2):

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Figure 3. AR Zoo game conditions. (A) Condition “Classic.” (B) Condition “Virtual Agent.” (C) Condition “Advanced.”.



- In the first condition, known as “Classic,” the player commences on the starting slab and visits the animal enclosures in a chosen order while adhering to specific instructions. They must navigate the quickest route, beginning at the starting slab and concluding at the exit slab. Grey paths are for single use, while green paths can be taken multiple times. To validate a visit to an animal enclosure, the player must remain on the tile in front of the corresponding enclosure for one second (indicated by a green light and the sound of the animal). When the therapist initiates a sequence, the enclosures of the animals to be visited are illuminated in green. Players can take their time planning their itinerary before departing from the starting tile to complete the sequence. Once the player has left the starting tile, the enclosures to visit are no longer highlighted in green, thereby introducing a memory component to the condition. Once the sequence is completed, the player must validate it by ending at the exit slab.
- The second condition, termed “Virtual Agent,” involves a virtual agent demonstrating the optimal route for the player to follow, while adhering to the instructions provided in the “Classic” condition. Positioned on the starting tile, the player observes the virtual explorer navigating the journey. Once the virtual agent reaches the exit slab, the player can commence their journey, attempting to replicate the same route according to the previously stated instructions. Similar to the AR Corsi game, we hypothesize that integration of the virtual agent will facilitate learning by showing the optimal path to the player. This approach may potentially reduce the child’s cognitive load, allowing them to focus not on planning but rather on visuospatial memory.
- The third condition, designated as “Advanced,” focuses on learning the optimal path. Initially, the player follows a sequence as the virtual agent displays the optimal route, which is akin to the “Virtual Agent” condition. Subsequently, similar to the “Classic” condition, the player repeats the same sequence independently. Finally, the player is requested to devise a new route based on memorized information, as obstacles appear on the fastest route following departure from the starting slab. Three obstacles appear simultaneously, and cannot be bypassed by the player. Instructions mirror those of the first two conditions. This condition is more challenging due to the requirement for the player to not only memorize the optimal path but also to demonstrate cognitive flexibility and replanning skills enabling them to navigate around the obstacles having emerged along the route during execution of this type of task [46].

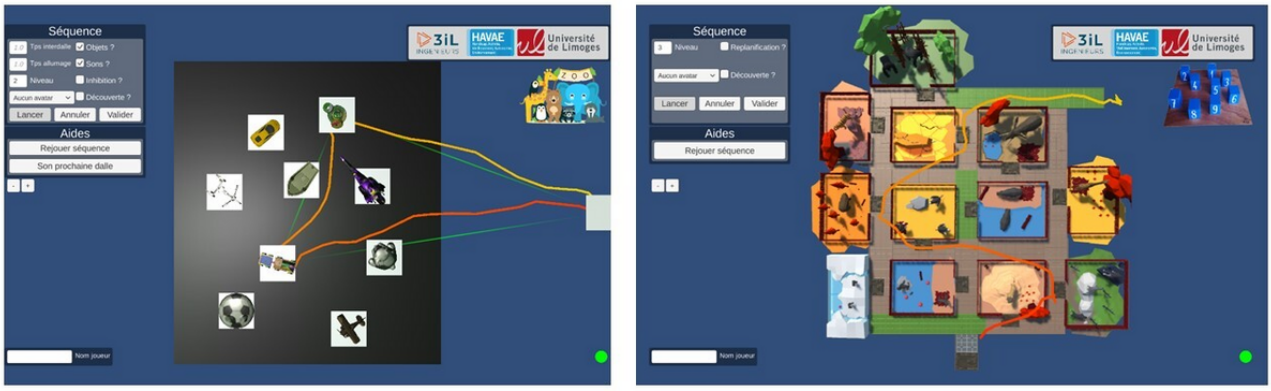
Therapist Interface

Supervision of game progress is essential to ensuring an optimal gaming experience. This involves adjusting difficulty levels, providing assistance, and managing game conditions according to the player’s needs and abilities. For instance, therapists can intervene by replaying a sequence that a child struggles to recall, thereby sustaining motivation and engagement.

Access to specific in-game controls, such as manually starting, validating, or canceling game sequences, offers therapists the flexibility to adapt sessions to unforeseen circumstances. As depicted in Figure 4, trajectory tracking provides therapists with a valuable visual aid for real-time performance assessment and player feedback. This is made possible by real-time tracking of the headset’s x, y, and z trajectory coordinates.

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Figure 4. Tablet interface and traced player trajectory.



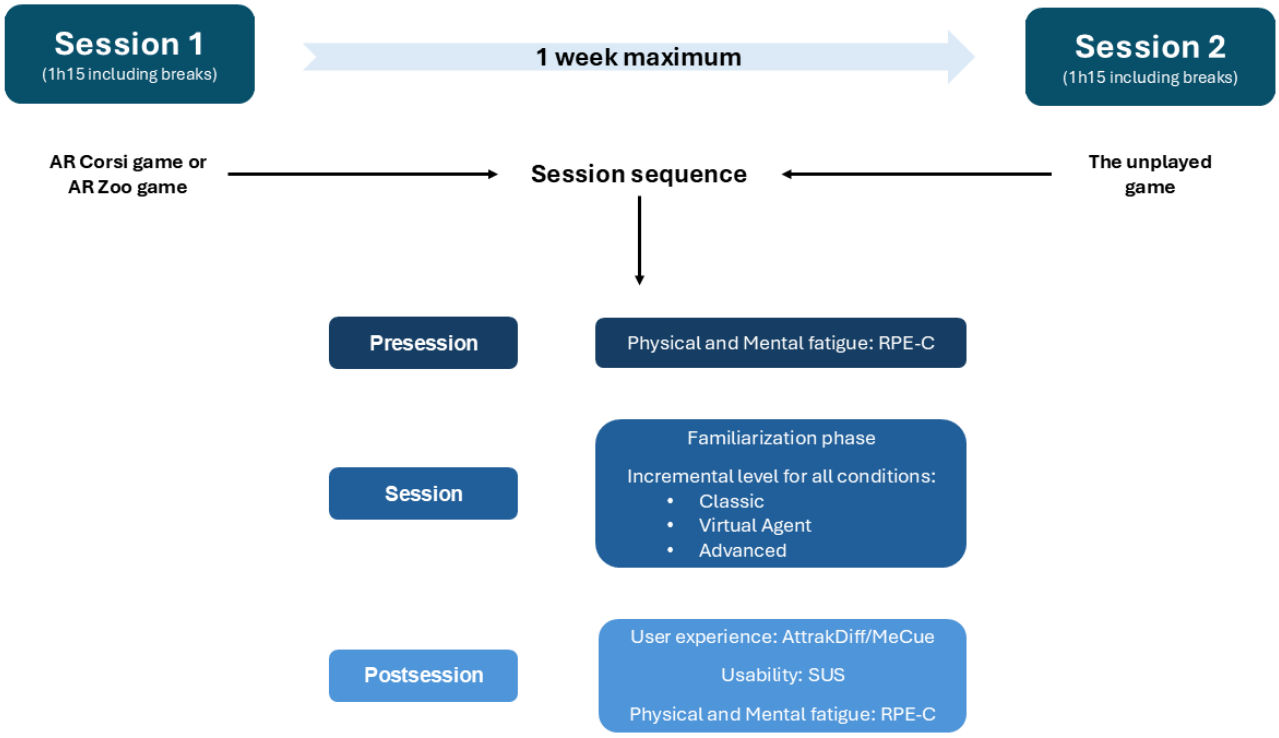
Switching between games is seamless; therapists need only tap the logo at the top right corner of the tablet. In fact, a unified application has been developed, consolidating AR Corsi and AR Zoo games.

Step 3 of MIDE: System Evaluation

Overview

The two-session UX study procedure is displayed in Figure 5. The second session was scheduled no later than one week after the initial session and mirrored its structure. The order of the games was counterbalanced. Each session comprised a familiarization phase and a gameplay phase. The first aimed to acclimate players to the technology, to familiarize them with navigating the AR environment, and to help them comprehend the instructions for each condition. During this phase, players freely explored the virtual elements (objects or animals) and completed an initial "white" sequence of minimal difficulty, accompanied by real-time guidance and instructions from the therapist. The duration of the familiarization period varied according to the child's comprehension level. The actual condition commenced once the player had successfully validated two sequences consecutively at the minimum difficulty level.

Figure 5. The study procedure. RPE-C: Rating scale of Perceived Exertion for Children; SUS: System Usability Scale.



Following this phase, the gameplay phase entailed execution of the different conditions with escalating difficulty levels, starting at the minimum level and progressing to the player-specific maximum level. A child could advance to the next difficulty level upon having successfully completed at least one of the two provided sequences. If unsuccessful, the child had reached their maximum level for that condition. Subsequently, the following condition was similarly explained and launched. To mitigate potential fatigue, which could lead to rejection of the games, the games were designed to be relatively short, with session durations adapted to the individual capacities of the children. A 5-minute break was incorporated before the onset of the third condition for the AR Corsi and AR Zoo games. Additional breaks were permitted if required by the child or deemed necessary by the therapist.

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Each session encompassed three steps: (1) a presession assessment was conducted, comprising a physical and mental fatigability scale (Rating scale of Perceived Exertion for Children [RPE-C]); (2) the main session included a familiarization phase followed by the children's engagement with one of the two AR games; and (3) a postsession evaluation was conducted, incorporating a usability questionnaire (System Usability Scale [SUS]), a UX questionnaire (AttrakDiff/MeCue), and a postsession fatigability questionnaire (RPE-C).

UX Assessment

The usability of the device, a subconcept of UX, was assessed by means of the SUS questionnaire [47]. This questionnaire is a validated tool commonly used in usability studies of new technologies [48], including AR with HoloLens 2 [49]. It consists of 10 statements. Children rate their agreement with each statement using a 5-point Likert scale with anchor points at either end ("Strongly Disagree" to "Strongly Agree"). The results of the SUS questionnaire help to calculate a standardized SUS score. Generally, a score above 85 is considered "excellent," above 75 is "good," and between 50 and 75 is "fair" or "acceptable." A score below 50 indicates low user satisfaction [50].

The UX was assessed by means of the AttrakDiff questionnaire [51,52]. This tool consists of 28 items divided into four dimensions: pragmatic quality, hedonic quality (stimulation), hedonic quality (identity), and overall attractiveness. The 28 items are presented as pairs of contrasted semantic differentiators on a 7-point scale (from –3 to 3). The score for each dimension is analyzed separately. Scores close to the mean (within the 0 to 1 range) are considered standard. The AR device fulfills its purpose without negative impact, but improvements are possible to enhance attractiveness. Scores between 1 and 3 are considered positive points, while scores between –1 and –3 are considered negative points regarding the device, of which the UX was also evaluated using the emotional dimension of the MeCue UX scale [53]. Children rated eight statements (four positive emotions and four negative emotions) using a 7-point Likert scale with anchor points at either end ("Strongly Disagree" to "Strongly Agree").

Secondary effects (mental and physical fatigue) were assessed using the RPE-C visual analog scales before and after the session [54]. Ratings range from 6 (no fatigue) to 20 (extreme fatigue). Pictograms in the form of smiley faces are used to assist children.

Performance Assessment

Performance was assessed by measuring the maximum level reached by the player for each variant of the two games. This approach enabled us to establish a baseline of performance among typically developing participants.

Statistical Analysis

Based on the study by Balani and Tümler [49], with a theoretical SUS good score of 75, an effect size of 0.65, an α risk of 5%, a power of 90%, and a study exit mark-up of 15%, we determined that a sample size of 30 participants was required for this study.

Participant characteristics and performance outcomes were described using descriptive statistics. The SUS questionnaire data were analyzed using a normality test and descriptive statistics for each game. The AttrakDiff questionnaire data and the emotions item of the MeCue questionnaire were analyzed using descriptive statistics (mean or median value of each subscale) for each game, depending on normality. Depending on data distribution, a two-tailed independent samples *t* test or a Mann-Whitney test was used to determine whether or not there are significant differences between the two games. A mixed ANOVA was conducted to investigate the main effects of the "Time" (before and after the session) and "Game" (AR Corsi and AR Zoo) factors, as well as their interactions on physical and mental fatigue. Statistical analyses were conducted using RStudio (Posit Software, PBC) software. The level of statistical significance for all analyses was .05.

Results

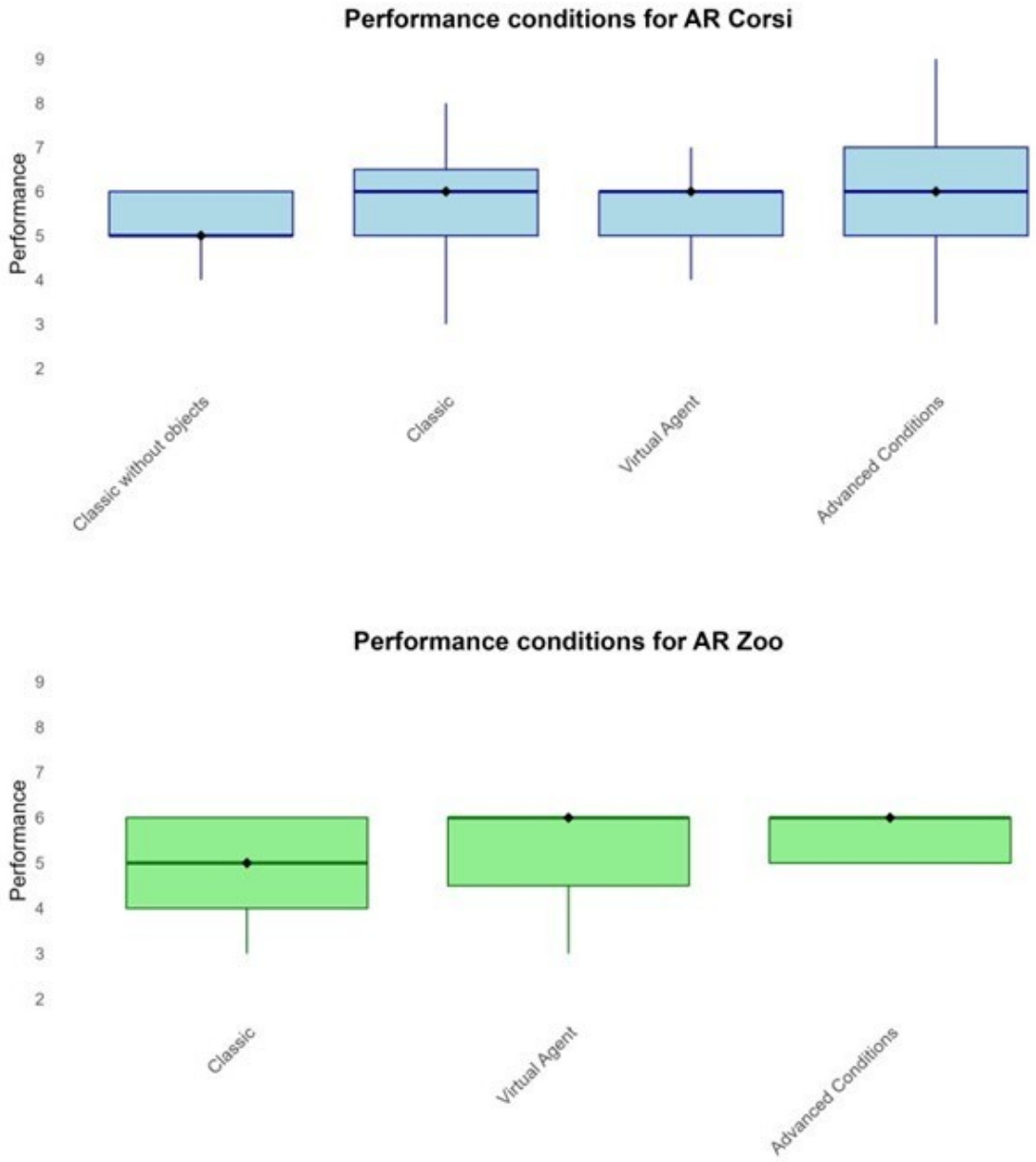
Participants' Score and Performance of AR Games

A total of 30 participants were included in our study. Among them, three participants were excluded due to incomplete questionnaire data. Data from 27 participants, with a distribution of 6 girls and 21 boys, were analyzed. The average age was 11.9 (SD 1.2) years.

The mean effective gameplay durations for the sessions with the AR Corsi and the AR Zoo games were 35.7 (SD 6.1) and 42.9 (SD 8.7) minutes, respectively. The performance results for the AR Corsi and AR Zoo games are visualized in Figure 6, showing the median scores (Q1-Q3) across the different conditions for each game.

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Figure 6. The performance results. Boxplots illustrate the distribution of performance scores for each condition and each game (AR Corsi and AR Zoo). Each plot includes the median (represented by the central line), with the lower quartile (Q1) and upper quartile (Q3) indicated by the edges of the box, as well as the extremes. The maximum level for the AR Corsi game is set at 9, while for the AR Zoo game, it is set at 6.



UX Assessment

The UX results are presented in Table 1 (data tables in Multimedia Appendix 3).

Regarding usability, the mean scores for the Corsi and Zoo games were 79.9 (SD 11.4) and 76.3 (SD 12.1) out of 100, respectively, with no significant difference between the two games (Table 1). For the AR Corsi game, the mean scores for each scale of the AttrakDiff questionnaire were as follows: global attractiveness 1.7 (SD 0.7), pragmatic quality 1.2 (SD 0.8), and hedonic qualities "identity" and "stimulation" 0.6 (SD 0.5) and 1.1 (SD 0.7), respectively. Regarding the AR Zoo game, the mean scores for each scale of the AttrakDiff questionnaire were: global attractiveness 1.8 (SD 0.9), pragmatic quality 1.3 (SD 0.7), and hedonic qualities "identity" and "stimulation" 0.7 (SD 0.8) and 1.1 (SD 0.8), respectively. There was no significant difference between the two AR games for the four AttrakDiff variables (Table 1).

In the emotions module of the MeCue questionnaire, participants had an average score of 5.2 (SD 0.7) for the Corsi game and 5.3 (SD 0.8) for the Zoo game, both of them significantly higher than the theoretical scale value of 4 (P<.001). There was no significant difference between AR Corsi and AR Zoo (Table 1).

The results of the mixed ANOVA demonstrated a statistically significant main effect of the "Time" factor on physical and mental fatigue, with the respective P values of P=.02 and P=.002. In contrast, no significant difference was observed for the "Game" factor on physical and mental fatigue (P=.77 and P=.29). Furthermore, no statistically significant interaction was identified between the type of game and time on physical and mental fatigue scores (P=.54 and P=.28).

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Table 1. Presentation of UX[a] results and comparison between the games.

	AR Corsi, mean (SD)	AR Zoo, mean (SD)	Game comparison, *P* value
SUS[b] (0 to 100)	79.9 (11.4)	76.3 (12.1)	.26
AttrakDiff (–3 to 3)			
Overall attractiveness	1.7 (0.7)	1.8 (0.9)	.49
Identity	0.6 (0.5)	0.7 (0.8)	.66
Pragmatic quality	1.2 (0.8)	1.3 (0.7)	.85
Stimulation	1.1 (0.7)	1.1 (0.8)	.82
MeCue (1 to 7)	5.3 (0.8)	5.4 (0.7)	.73

[a]UX: user experience.

[b]SUS: System Usability Scale.

Discussion

Principal Findings

This study introduces an innovative AR exergame designed for the cognitive-motor rehabilitation of children with CP or ABI. Following a co-design approach based on the MIDE framework, the objective was to test these games with typically developing children in view of gathering initial impressions on UX before offering the game to youth with CP or ABI.

Usability, a subset of UX, is considered a fundamental design criterion, particularly in the field of health technologies, where an adequate level of usability is not only expected but required [55]. In this study, the average SUS scores for the AR Corsi and AR Zoo games were 79.9 (SD 11.4) and 76.3 (SD 12.1) out of 100, respectively. According to the classification established by Bangor et al [50], these results correspond to a usability rating of “good,” which confirms our primary hypothesis regarding the ease of use of our AR exergames. These results are consistent with those obtained by Lauer et al [56], who likewise observed “good” usability (80/100) in their study on HoloLens 2 use. In their research, 47 elementary school children assessed positively the usability of an AR device using Microsoft HoloLens 2, with no reported cybersickness [56]. The absence of cybersickness, which has often been associated with VR, is a significant advantage of AR, particularly insofar as this phenomenon can markedly impair the UX in rehabilitation contexts [57].

We ensured that our exergames not only were user-friendly for typically developing children but also provided a positive UX. UX evaluation by means of the AttrakDiff questionnaire yielded favorable results, with scores ranging between 1 and 3 points for overall attractiveness, pragmatic quality, and stimulation for both the AR Corsi game and the AR Zoo game [51,52]. However, the hedonic quality dimension “identity” received more modest and neutral scores (mean 0.6, SD 0.5) for AR Corsi and (mean 0.7, SD 0.8) for AR Zoo, indicating an area with room for improvement. A similar observation was put forward by Le Roy et al [28] in a pilot study with 14 healthy adult participants, in which a score of 0.67 for hedonic quality (identity) was recorded for a VR device addressed to patients with depression. This result was attributed to the difficulty of their system to reflect the user’s identity in a context where the device was not intended for them. Similarly, in this study, we suggest that the neutral results for this variable could be due to the fact that these exergames, designed for children with CP or ABI, did not meet the expectations or preferences of typically developing children. These children may be less inclined to identify with rehabilitation games, which are quite different from the commercial games to which they are accustomed. It is likely that this dimension of UX would be rated more positively if evaluated by the target population.

Our exergame generated significant emotional engagement among typically developing youth. The results obtained with the MeCue questionnaire for the AR Corsi and AR Zoo games significantly exceeded the theoretical scale average set at 4, indicating the emergence of positive emotions. Consistent with the Mahlke model, these results suggest that UX plays a crucial role in eliciting positive emotional responses [24]. A pleasant UX increases the likelihood of evoking positive emotions in the user. Furthermore, as noted by Dirin and Laine [58], emotional engagement is key to promoting sustained use, particularly in AR mobile apps. Therefore, it will be important to evaluate this aspect with the target population in view of ensuring that the exergame fully meets their needs while remaining emotionally engaging and user-friendly, thereby contributing to the child’s sense of self-value and reinforcing their self-esteem.

While it is known that AR generally does not induce cybersickness, there is a gap in the literature regarding the evaluation of physical and mental fatigue caused by prolonged use of XR technologies among children and adolescents aged 10 to 16 years. We hypothesized that AR-based sessions would not result in a significant additional increase in physical or mental fatigue compared to presession evaluations. However, this study’s results reveal a significant effect of physical fatigue (*P*=.02) and mental fatigue (*P*=.002) between pre- and postsession measurements for both games, a finding contradicting our initial hypothesis.

Regarding observed physical fatigue, it is likely that the weight of the headset played a part. Three participants reported discomfort due to the excessive weight of the headset, leading to neck pain. This can be partially explained by the fact that both games require increased body rotations, especially as the difficulty level rises. Our performance results indicate that, on

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average, typically developing children achieve high maximum levels for each game condition. Belmonti et al [36] made an interesting observation in their study on children with CP using the MC. Short sequences (up to three or four tiles) do not necessarily require a specific strategy, and body rotations are limited. However, as sequences become longer and visual monitoring grows more complex, players need to adopt strategies involving more frequent body rotations to maintain their point of view, a phenomenon that was likely exacerbated in this study by the limited field of view of the Microsoft HoloLens 2. Depending on the strategy chosen, rotations may be more or less frequent, potentially explaining the neck pain associated with headset weight, which is intensified by excessive rotations in some children.

Regarding mental fatigue, even though no significant difference was observed between AR Zoo and AR Corsi, it is likely that the cognitive load induced by the different game variants is too excessive. It bears mentioning that the observations presented here remain hypothetical, as we did not objectively measure the executive functions involved in the various game conditions. For both games, AR Corsi and AR Zoo, we designed variants that simultaneously engage multiple executive functions. For AR Corsi, we followed approaches described in the literature, introducing a simplified version with a virtual agent focused on visuospatial memory, and a more complex version requiring concurrent use of mental inhibition. Similarly, AR Zoo involves multiple executive functions, with sequence completion requiring cognitively demanding tasks: the player must integrate visuospatial memory with planning, replanning, and mental inhibition. The literature suggests that simultaneous activation of several executive functions, such as planning and inhibition in spatial navigation tasks, often results in increased cognitive fatigue and declining performance [59-61]. This cognitive overload is particularly pronounced in contexts where multiple cognitive processes need to be managed concurrently, as is the case in AR Zoo and AR Corsi. Moreover, it is reasonable to assume that the addition of AR intensifies the cognitive effort required, particularly for mental rotation skills and visuospatial memory, due to the movement in 3D space that involves changing perspectives.

In our development, we aimed to design two AR games offering an optimal UX, ensuring no significant differences between them. Our secondary hypothesis was confirmed, showing that typically developing children evaluated both games similarly in terms of UX. A key factor explaining this outcome is adherence to the MIDE model [21] during the exergame design, making sure that the games met user needs and expectations. Additionally, we built both games on a similar core loop, making it easier for young players to understand and engage. The literature emphasizes that a game's primary loop is essential for maintaining motivation and engagement, especially in therapeutic contexts [25]. By providing a consistent foundation while introducing variants to target different executive functions and adjusting difficulty, we made sure that both games remained equally engaging and replayable. This approach could serve as a foundation for future development of pediatric cognitive-motor rehabilitation games.

Limitations

This study has several limitations. First, the measurement tools used are based on scales and questionnaires, which although validated, remain inherently subjective. Additionally, some children's understanding of certain questionnaires proved challenging, requiring rephrasing of certain terms, which may have influenced the results.

Another limitation is related to temporal bias, as not all of the sessions were conducted at the same time of day. Some participants played one exergame in the morning and another in the afternoon on different days. Moreover, participants continued their daily activities (physical, manual, etc) within a youth club or leisure center, which might have affected their level of fatigue. This temporal bias could introduce variations in the results, particularly regarding mental and cognitive fatigue, as factors such as attention and cognitive performance fluctuate throughout the day.

A final limitation concerns the use of the Microsoft HoloLens 2 headset. Some participants reported discomfort regarding the headset's field of view, which they felt was limited. While the second version of the HoloLens 2 offers a field of view expanded by 18 degrees compared to the first version, this limitation had been noted in a previous study involving participants with CP using the first version. To ensure the flexibility of our exergames, we designed them to be easily transferable to other AR devices. In future studies, it would be beneficial to test our exergames on headsets with a wider field of view, which could potentially enhance the UX.

Conclusions

This pilot study demonstrated that our exergame, including the AR Corsi and AR Zoo games, is not only easy to use but also well-received by typically developing youth, eliciting positive emotions. Although some children experienced physical or mental fatigue, the positive evaluation of the UX with this population represents an essential preliminary step in our codevelopment process, particularly regarding the verification of game content and mechanisms. With these methodological aspects having been validated, it is henceforth possible to expand the use of this exergame to children with CP or ABI.

After validating the mechanisms of our games and observing positive UX among typically developing youth, we can now proceed to offer our exergame to young individuals with CP or ABI. In line with the principles of the MIDE design framework [21], it will be crucial in a similar study to evaluate the UX of our exergame in this population. Following this second study, potential modifications may be made to our games based on the performance outcomes and feedback from children with CP and ABI.

In future studies, we plan to incorporate tools such as neuropsychological assessments or electroencephalography measurements to objectively evaluate the neural networks involved and to deepen our understanding of the cognitive processes engaged by the different conditions of our games. To explore the link with executive functions, we will conduct correlations with neuropsychological test batteries, similar to the study by Kronovsek et al [62].

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Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
AR Corsi game video.
[MP4 File (MP4 Video), 74614 KB - rehab_v12i1e69205_app1.mp4]

Multimedia Appendix 2
AR Zoo game video.
[MP4 File (MP4 Video), 73187 KB - rehab_v12i1e69205_app2.mp4]

Multimedia Appendix 3
User experience data tables.
[PDF File (Adobe PDF File), 129 KB - rehab_v12i1e69205_app3.pdf]

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Abbreviations

ABI: acquired brain injury
AR: augmented reality
CP: cerebral palsy
MC: magic carpet
MIDE: Multidisciplinary Iterative Design of Exergame
RPE-C: Rating scale of Perceived Exertion for Children
SUS: System Usability Scale
UX: user experience
VR: virtual reality
XR: extended reality

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The Safety of Telerehabilitation: Systematic Review

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Abstract

Background: Telerehabilitation involves the delivery of rehabilitation services over a distance through communication technologies. In contrast to traditional in-person rehabilitation, telerehabilitation can help overcome barriers including geographic distance and facility use. There is evidence to suggest that telerehabilitation can lead to increased patient engagement and adherence to treatment plans. However, limited research exists on the association of telerehabilitation with adverse events, potentially hindering its broader adoption and use in health care.

Objectives: This systematic review of randomized controlled trials aims to summarize existing research on adverse events related to telerehabilitation delivery.

Methods: This review was conducted according to the methodological framework outlined by the Joanna Briggs Institute. Studies were identified from MEDLINE ALL, Embase, APA PsycINFO, CENTRAL, and CINAHL. Included studies were randomized controlled trials published between 2013 and 2023, written in English, and had no geographic or delivery mode restrictions. Data extraction used the TIDieR (Template for Intervention Description and Replication) framework, along with authors, publication year, sample size, specific telerehabilitation modes, and the incidence, type, severity, and relatedness of reported adverse events. Methodological quality was assessed using the Cochrane risk of bias tool, and the certainty of evidence was evaluated using the Grading of Recommendations Assessment, Development, and Evaluation tool.

Results: Search results identified 9022 references, of which 37 randomized controlled trials met the criteria for inclusion. There were a total of 3166 participants, with a mean age of 57.4 (SD 11.3) years, and 1023 (32.3%) being female participants. Various delivery modes were used, with videoconferencing emerging as the most frequently used method. A total of 201 adverse events were recorded during 65,352 sessions (0.31% or 3.1 per 1000 sessions). These events were predominantly physical (eg, falls and palpitations), nonserious or mild, and not directly attributed to the telerehabilitation intervention. Additionally, 34 (92%) of included studies implemented various safety practices including vital sign monitoring, safety checklists, and scheduled check-ins with study personnel.

Conclusions: This review demonstrates that telerehabilitation exhibits a generally safe profile as an alternative to in-person rehabilitation, with most reported adverse events being rare, nonserious or mild, and unrelated to telerehabilitation protocols. However, more extensive research with detailed reporting on adverse event characteristics is needed. Moreover, future research should evaluate the effectiveness of different safety practices and their association with adverse events. An enhanced understanding of potential risks in telerehabilitation can foster broader adoption while ensuring its safe implementation among health care providers and patients.

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KEYWORDS

telerehabilitation; telehealth; remote health care; safety; exercise; telemedicine; adverse events; rehabilitation; digital health; patient safety; exercise therapy; videoconferencing

Introduction

Telerehabilitation refers to the delivery of rehabilitation services through communication technologies, allowing patients to connect with therapists remotely without needing to be in the same physical space [1,2]. These services can be provided synchronously, with live therapist interactions, or asynchronously, where patients perform therapeutic activities independently [3,4]. Telerehabilitation has been successfully implemented across various rehabilitation fields, including physical therapy, occupational therapy, and speech language therapy, and its benefits have been described in neurological populations as well as during the early stages of the COVID-19 pandemic [5,6].

In recent years, telerehabilitation has gained rapid popularity due to its ability to overcome barriers such as geographic distance, mobility limitations, and scheduling constraints while also reducing costs by minimizing facility and resource use [7,8]. For example, the American Physical Therapy Association found that telerehabilitation is superior to in-person rehabilitation with respect to adherence for certain health conditions [9]. The surge in utility was accelerated by the COVID-19 pandemic, which increased the demand for remote and easily accessible health care solutions [10].

Despite these advantages, telerehabilitation is not without risks. For instance, patients could incur a burn while cooking during a video-based occupational therapy session or sustain soft-tissue injuries from overexercising during an asynchronous text or phone-based physiotherapy session. A mixed methods study on individuals with chronic knee pain found that 36% of participants initially expressed negative feelings about telerehabilitation due to doubts about its effectiveness, the inability of physiotherapists to physically assess them, and concerns about difficulty communicating using technology [11].

Assessing the safety of telerehabilitation is important for guiding decisions made by patients, providers, and funders. For patients, a clearer understanding of its safety can offer reassurance and encourage broader adoption of telerehabilitation [12]. Providers rely on safety data to tailor treatments to individual conditions and refine protocols to minimize adverse events [13]. Funders rely on this information to justify coverage decisions and guide the allocation of resources and financial support [14]. Additionally, patients in rehabilitation often have physical or cognitive deficits (eg, a patient with hemiplegia and memory deficits from brain injury) that make them more vulnerable to risks compared to general telemedicine users, making the evaluation of telerehabilitation safety even more critical for preventing exacerbating existing conditions or for introducing new risks [15].

A scoping review by Yau et al [16] explored the association between telerehabilitation and adverse events. They found that adverse events were reported in 0.3% of sessions, with most being physical, nonserious or mild, and unrelated to the telerehabilitation intervention. While scoping reviews identify broad patterns in the literature, they do not offer in-depth assessments of study outcomes or assess the quality of individual studies. A systematic review can follow a scoping review when a more detailed and specific understanding of outcomes is required. Therefore, the objective of this systematic review is to assess the safety of telerehabilitation by examining the incidence, type, severity, and relatedness of adverse events reported in randomized controlled trials. Moving from a scoping review to a systematic review aligns with the purpose of a scoping review, as it builds on the initial broad exploration by transitioning into a more detailed examination of specific research questions [17].

Methods

This systematic review was registered with PROSPERO (CRD42024518902) and drafted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [18]. A completed PRISMA checklist is shown in Checklist 1.

Eligibility Criteria

The inclusion criteria for this review encompassed randomized controlled trials of any type (eg, parallel, crossover, and cluster) that (1) evaluated telerehabilitation interventions, (2) reported on any adverse events that occurred, and (3) were published between 2013 and 2023, as 2013 marked the beginning of significant advancements and widespread adoption of video communication technologies [19]. Studies that assessed a variety of patient populations (eg, cardiac rehabilitation and postoperative rehabilitation) and modes (eg, asynchronous, synchronous, and hybrid) of telerehabilitation were included. We excluded studies that (1) only provided home-based exercise programs without interactions from a therapist to adjust or monitor the exercise program and (2) were not written in English.

Search Strategy and Information Sources

Literature search strategies were developed by an experienced health sciences librarian with input from the investigators. Search terms included MeSH, EMTREE terms, American Psychological Association thesaurus terms, and CINAHL headings, and text words related to telerehabilitation and adverse events. The search strategy was tested in MEDLINE ALL and reviewed by the research team. Once the MEDLINE ALL test strategy was agreed upon, it was translated using the command language, controlled vocabulary, and appropriate search fields for each database and search platform. Studies were then identified by searching the following databases on the Ovid platform: MEDLINE ALL, Embase, APA PsycINFO, and CENTRAL. The CINAHL database was searched on the EBSCOhost platform. This search strategy was first implemented in the scoping review by Yau et al [16] from January 2013 to June 2023 on June 26, 2023. The current

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research team then identified the randomized controlled trials from the extracted studies and confirmed their eligibility for this systematic review. On January 8, 2024, the search was repeated and extended to include studies published between June 2023 and December 2023. The same search strategy was used, although it was restricted to randomized controlled trials. The search strategy used for each database can be viewed in Multimedia Appendix 1.

Study Selection and Data Extraction

Two reviewers (HS and JC) performed a pilot test and then completed the title and abstract screening independently and in duplicate. The full texts of potentially relevant papers were subsequently retrieved and screened (also independently and in duplicate). At all stages of the review, conflicts were resolved by using discussion to reach consensus or by a third party (TY).

Reviewers HS and JC then independently piloted the extraction form with a random sample of studies and made necessary revisions. Data extracted from publications included study characteristics, participant characteristics, intervention characteristics, and adverse events. Data extraction on intervention characteristics aligned with the TIDieR (Template for Intervention Description and Replication) framework [20]. Information on the incidence, type, severity, and relatedness of adverse events, safety measures implemented for the telerehabilitation interventions, as well as information on adverse events within control groups were also collected.

Data Synthesis

Data from the extraction form were summarized descriptively using counts, proportions, and incidence rates where applicable. Subgroup analyses based on study characteristics (eg, rehabilitation population) were conducted to explore patterns in adverse event reporting. This involved aggregating reported event rates and comparing distributions across categories to identify potential trends in the findings. A meta-analysis was not conducted due to substantial heterogeneity in study populations, interventions, and outcome reporting.

Risk of Bias Assessment

Five reviewers (HS, JC, TY, AK, and MG) independently evaluated the risk of bias in the included studies. Version 2 of the Cochrane risk-of-bias tool for randomized trials was used to appraise all randomized controlled trials [21]. For each included study, reviewers worked through individual domains within the tool and then assigned an overall risk-of-bias judgment. All studies were evaluated based on 5 key methodological elements: randomization process, blinding of participants and assessors, completeness of outcome data, validity of outcome measurement, and selection of reported results.

Certainty of Evidence Evaluation

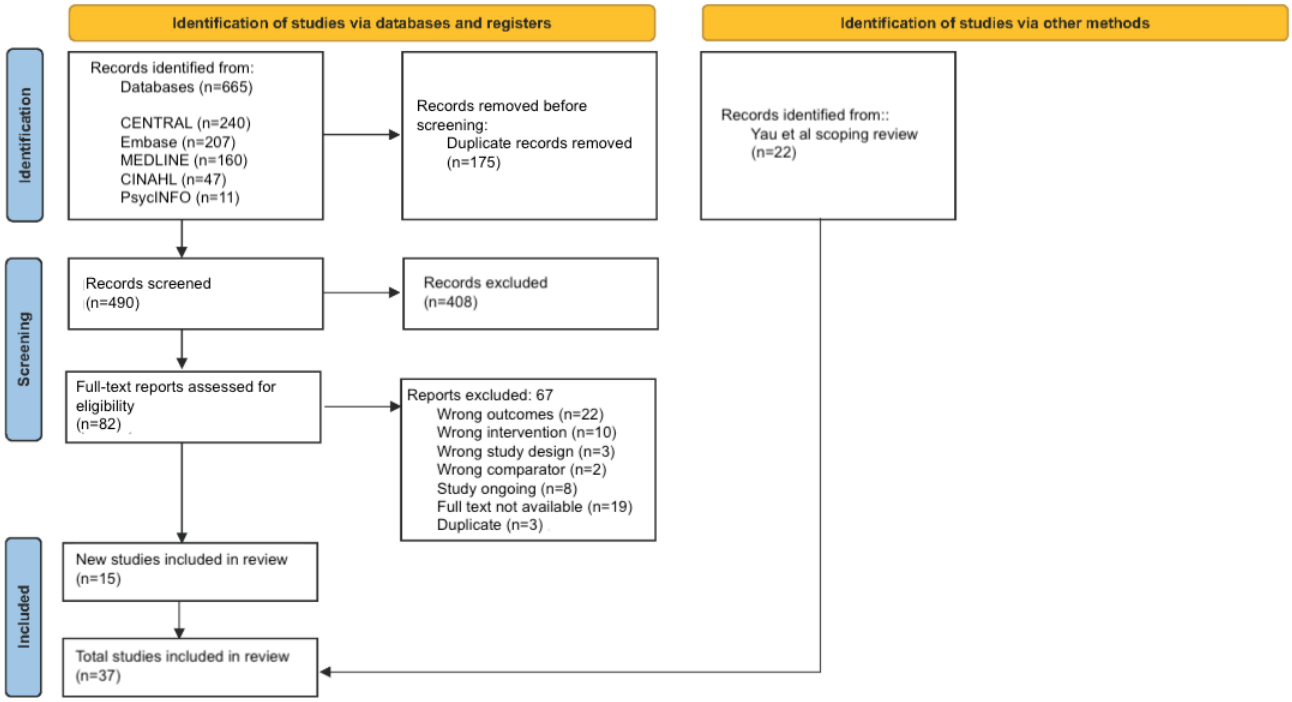
The certainty of the evidence was evaluated by JC using the Grading of Recommendations Assessment, Development, and Evaluation tool, which considers factors including study design, risk of bias, inconsistency in results, indirectness of evidence, imprecision of results, publication bias, effect size, plausible confounding, and dose-response gradient.

Results

Study Selection

The search of all databases resulted in 9022 papers, of which 1008 were removed for duplication. A total of 7754 were excluded following a review of the title and abstract, and 223 were excluded following full-text review. The selection process with reasons for paper exclusion at each stage is presented in Figure 1. Ultimately, 37 papers met the inclusion criteria for data extraction and risk of bias assessment (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



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Description of the Included Studies

All of the included papers were randomized controlled trials. The studies were conducted in 22 countries, with the 3 most common countries being China [22-27], the United States [28-32], and Australia [33-36]. The majority of papers were published following the COVID-19 pandemic, with 30 (81%) published from 2020 onward [22,23,25-32,34-53].

The included studies spanned a number of rehabilitation populations: 11 (30%) focused on musculoskeletal conditions involving interventions like balance, stretching, strengthening, and aerobic exercises [25,29,30,32,37,40,44,50,51,54,55]; 9 (24%) focused on cardiac conditions [23,24,28,33,39,43,46,53,56]; 6 (16%) focused on stroke [26,27,35,38,45,52]; 6 (16%) focused on other areas of neurorehabilitation [41,42,47,49,57,58]; 3 (8%) focused on pulmonary conditions [22,31,34]; 1 (3%) focused on cancer [48]; and 1 (3%) focused on burns [36] (Table 1).

Table . Distribution of rehabilitation populations.

Rehabilitation population	Studies, n (%)
Cardiac	9 (24)
Musculoskeletal	11 (30)
Neurological	6 (16)
Pulmonary	3 (8)
Stroke	6 (16)
Other	2 (6)

A total of 3166 participants were represented across the studies, with 1620 and 1546 in the intervention and control groups, respectively. There were 1023 female participants, accounting for 32% of the overall sample size. The participants in the intervention and control groups were similar at baseline in all studies. The mean age of participants was 57.4 (SD 11.3) years, ranging from 28.2 to 74.9 years. Multimedia Appendix 2 [22-32,34-59] provides a summary of the participant and intervention characteristics.

Intervention Characteristics

In 68% (n=25) of the studies, the rehabilitation intervention was provided exclusively by a physiotherapist, occupational therapist, or their respective assistants. In total, 3 (8%) studies [23,27,48] used a physician to deliver the rehabilitation, which included exercise training and counseling, while 4 (11%) studies involved an interdisciplinary team. In 1 study examining pulmonary rehabilitation in participants with esophageal cancer [22], the interdisciplinary team included the head of the nursing department in thoracic surgery, at least 1 doctor who participated in the surgery, and 3 experienced nurses. Another study investigating cardiac rehabilitation in patients with heart failure in China [24] featured telerehabilitation delivered by a multidisciplinary team comprised of physiotherapists, cardiac nurses, and psychiatric nurses.

In 36 (97%) studies, participants completed therapy sessions from their respective homes, with only 1 study having participants complete rehabilitation at a fitness center [55]. In total, 32 (86%) rehabilitation protocols were entirely telerehabilitation-based, and 5 (13%) [28,34,45,56,57] included an in-person component. In 15 (40%) studies [23,24,26,28,29,31,33,34,36,38,39,41,44,47,51], therapists connected with patients synchronously, while 22 (60%) studies used asynchronous telerehabilitation. The intervention period ranged from 3 weeks to 1 year, with a 3-month protocol being the most common. Of the 27 (73%) studies that reported adherence, 2 achieved a 100% adherence rate [44,47].

In 29 (78%) studies, study personnel tailored the intervention to participants based on factors such as interest in physical exercise, rehabilitation goals, heart rate zones, and functional ability [23-29,31-34,36-39,42,45,47-58]. In total, 2 (5%) interventions carried out standardized testing before the intervention and used these results to personalize the rehabilitation protocol [50,53]. For example, Cerdan de Las Heras et al [50] used a baseline 6-minute walk test and an interview focused on participants' daily activity to individualize the telerehabilitation program for participants with sarcoidosis. In total, 22 (59%) interventions used devices such as smartwatches, heart rate belts, electrocardiograms, blood pressure cuffs, pulse oximeters, pedometers, and various software tools to digitally monitor participants' progress [22-24,27-31,33-35,37,38,40,41,45,46,49-51,54,56]. In 8 of these interventions, therapists used the collected data to adjust the rehabilitation protocol throughout the study period or to ensure that the protocol was being carried out safely [24,27,30,33,40,41,50,51].

Aside from vital sign monitoring, 54% (n=20) of the studies used additional risk mitigation strategies. In total, 11 (30%) studies implemented strategies to mitigate risks including scheduled follow-up times to review adverse events or general questions [22,23,29,30,35,43,46,48,53,55,58], on-call availability of study personnel for addressing concerns [31,39,44,47,52], educational sessions on pain and injury prevention [24,29,32,36], and the presence of caregivers to assist in case of emergencies [24,41]. A study by Capin et al [29], which provided high-intensity strength training and aerobic exercise to 13 survivors of COVID-19, described how the therapists optimized participants' home environments to enhance safety, such as by instructing them to perform balance exercises near a bed to prevent falls.

Control Characteristics

In 30 (81%) studies, the control group received usual care or center-based rehabilitation [22-24,26-28,30-39,42-47,49-56].

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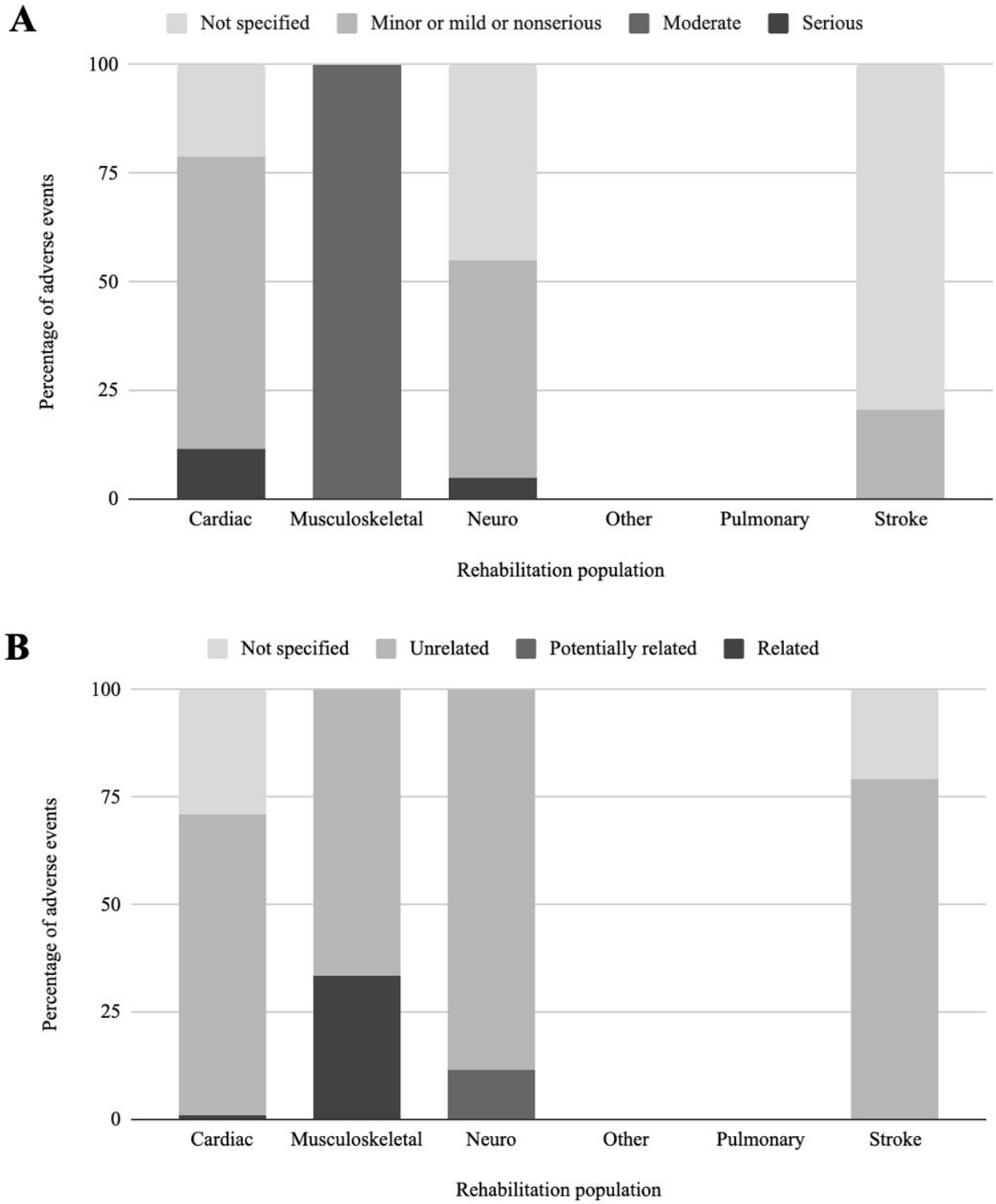
In total, 5 (13%) studies [40,41,48,51,58] provided control participants with booklets offering guidance on independent exercises. A total of 3 (8%) studies included education sessions or scheduled follow-ups with study personnel [25,29,44].

Incidence of Adverse Events

Multimedia Appendix 3 [22-32,34,35,37-49,51,53-59] summarizes the adverse events reported in the included telerehabilitation interventions. A total of 201 adverse events were recorded during 65,352 sessions (0.31 adverse events per 100 sessions). All studies reported information on the incidence of adverse events. In contrast, information on the type, severity, and relatedness of adverse events to the telerehabilitation intervention was infrequently documented. Among the 9 (24%) studies that provided severity details, 7 classified their adverse events as mild or nonserious, while the other 2 classified them as severe or serious. Mild adverse events included dizziness [26], fatigue [26,52], and dry eyes [26], with the most frequently cited being physical issues such as pain [41,51,52,57] and falls [28,41,52,58]. A study by Snoek et al [53], which delivered cardiac telerehabilitation asynchronously to 65 older patients, reported 3 serious adverse events over the intervention period, including vestibular disorder, vasovagal collapse, and knee injury during gardening that required surgery. These adverse events were ultimately determined to be unrelated to the telerehabilitation intervention. Of the 11 (30%) studies that documented relatedness, 8 [27,31,39,41,42,52,56,57] determined that their adverse events were unrelated to the intervention, while 3 studies for cardiac [28], neurological [57], and musculoskeletal [51] rehabilitation populations reported a relation or possible relation. For example, Nuevo et al [51] found a potential link between ReHub, an interactive telerehabilitation system, and a fall. However, no studies reported a serious adverse event that was related to telerehabilitation. A summary of the incidence, severity, and relatedness of adverse events across various rehabilitation populations is illustrated in Table 2 and Figure 2.

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Figure 2. Adverse events. (A) Distribution of adverse event severity across rehabilitation populations. (B) Distribution of adverse event relatedness to the intervention across rehabilitation populations.



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Table . Incidence of adverse events per 100 sessions across rehabilitation populations.

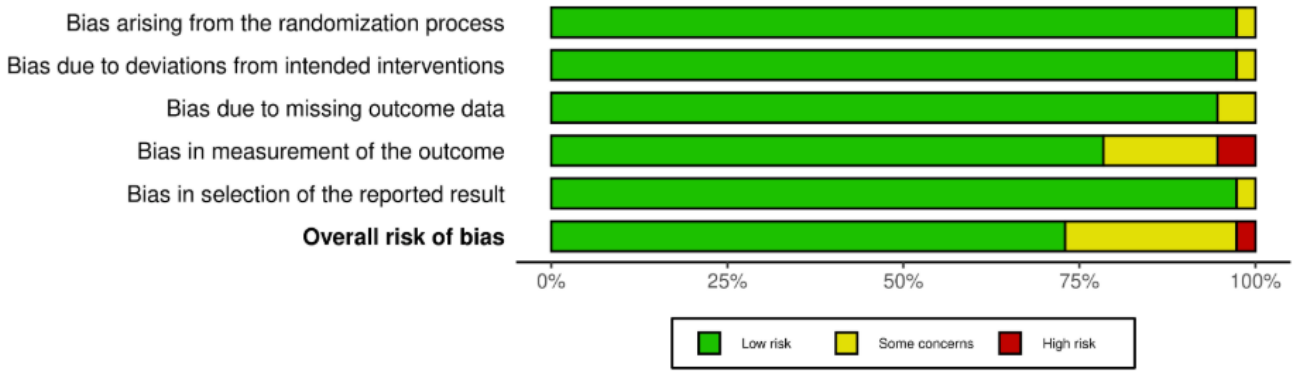
Rehabilitation population	Number of adverse events per 100 sessions
Cardiac	0.28
Musculoskeletal	0.05
Neurological	0.58
Pulmonary	0.00
Stroke	0.61
Other	0.00

Regarding the control groups, a total of 137 adverse events were recorded during 29,688 sessions (0.46 adverse events per 100 sessions). As with the intervention groups, information on the type, severity, and relatedness of adverse events was infrequently provided. Among the 12 (32%) studies that documented adverse events, 9 offered additional details. Most of these adverse events were mild or nonserious, including diaphoresis [33], flu symptoms [41], and pain [41,57]. One study by van der Kolk et al [57], which provided asynchronous telerehabilitation to 23 patients with Parkinson disease, reported 4 serious adverse events: supraventricular tachycardia, hip fracture, fall-related injury, and severe dyskinesia. These events were determined to be unrelated to the control group protocol. Conversely, the same study also identified 4 nonserious adverse events related to back pain, which were found to be potentially related to the control group protocol.

Risk of Bias Assessment

The risk of bias assessment is detailed in Figure 3. In total, 36 (97%) studies demonstrated adequate randomization and allocation concealment, although 1 study [28] did not meet the criteria due to an insufficient description of the randomization process (Multimedia Appendix 4) [22-32,34-59]. Regarding blinding, it is often impractical to blind participants and personnel delivering the intervention in telerehabilitation studies [9]. However, 6 (16%) studies [31,41,47-50] successfully blinded trial personnel to participants' group assignments. In 31 (84%) studies, the absence of blinding did not lead to deviations from the intended interventions. Potential bias was identified in 2 (5%) studies [29,45], where deviations were mainly attributed to missing information. With respect to the availability of outcome data, 34 (92%) studies were rated as low risk. Regarding outcome measurement, 9 (24%) studies [28,33,34,39,44-46,52,55] had potential bias due to either outcome assessors being aware of participant assignments or missing information. In total, 36 (97%) studies had no risk of bias related to the selection of reported results. Overall, 26 (70%) studies were assessed as having a low risk of bias [22-27,29,30,32,34-38,40-43,47-51,54,57,58], 9 (24%) had a moderate risk of bias [31,33,39,44-46,53,55,56], and 2 (5%) had a high risk of bias [28,52].

Figure 3. Risk of bias assessment. Red denotes high risk, yellow unclear risk, and green low risk.



Certainty of Evidence Evaluation

For the adverse event outcome, there was serious inconsistency in the results; however, the risk of bias, indirectness of evidence, and imprecision of results were not considered serious. Overall, this led to a moderate certainty of evidence.

Discussion

Principal Findings

The objective of this systematic review was to determine the association between telerehabilitation and adverse events reported in randomized controlled trials. These findings build on a recent scoping review by Yau et al [16] and provide a more in-depth analysis of adverse events and study rigor. To our knowledge, this is the first systematic review to provide a comprehensive summary of adverse events in telerehabilitation across numerous patient populations. Overall, 68% (n=25) of the included studies reported no adverse events in either their telerehabilitation interventions or control groups. Among the studies that did report adverse events, the majority were classified as nonserious or mild and physical in nature. With respect to safety and monitoring, 59% (n=22) of studies used tools such as smartwatches and web-based software to allow digital tracking and monitoring by rehabilitation personnel. Additionally, 54% (n=20) of studies incorporated further

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risk-mitigation strategies, such as patient education sessions and adjustments to activities for safety within the home environment.

Comparison to Prior Work

When comparing these findings to in-person rehabilitation, outcomes vary depending on the type of rehabilitation and patient populations involved. The most frequent form of telerehabilitation in this review was musculoskeletal-related, including strengthening, stretching, and balance exercises. Niemeijer et al [60] conducted a systematic review and meta-analysis of 773 studies that evaluated the relative risk of adverse events for musculoskeletal rehabilitation in various in-person settings, including outpatient centers, hospitals, and long-term care homes. Compared to control groups, in-person rehabilitation did not increase the risk of serious adverse events. However, there was a relative risk of 1.19 (95% CI 1.09-1.30) for nonserious adverse events, translating to a number needed to harm of 6. With respect to cardiac rehabilitation, Dalal et al [61] conducted a systematic review and meta-analysis of 23 randomized controlled trials comparing center-based and home-based cardiac rehabilitation. They found no significant differences in outcomes such as mortality and cardiac events. Other systematic reviews on in-person pulmonary rehabilitation in patients with chronic obstructive pulmonary disease [62] and burn rehabilitation [63] reported comparable findings, including a generally low incidence of adverse events, most of which were mild or nonserious. Therefore, across various patient populations, telerehabilitation appears to have a safety profile similar to that of in-person rehabilitation. Although adverse events are generally infrequent, mild or nonserious incidents cannot be entirely excluded.

The majority of reported adverse events in this systematic review were classified as physical in nature, with 111 of the 201 adverse events falling into this category. The most frequently reported physical adverse events were “falls” and “pain.” These findings align with a systematic review of clinical outcomes in telerehabilitation for individuals with physical disabilities, which also identified “falls” as a common adverse event across 22 studies [64]. This prevalence may stem from the clinical conditions or baseline risk factors of individuals requiring rehabilitation, which heighten susceptibility to incidents like falls. Therefore, regular check-ins focused specifically on pain management and fall prevention strategies may be particularly beneficial in telerehabilitation. It is also important to note that the definition of a “physical” adverse event varied significantly among studies, with some including “fatigue” and “tiredness” within this classification. These symptoms are expected following participation in therapy and exercise and may not be consistently classified as adverse events by investigators across all studies. Future research should establish standardized definitions for adverse events in telerehabilitation to enhance comparability across studies.

Implications of Findings

Adverse events also differed among studies that featured real-time interactions between patients and their therapists compared to those using asynchronous methods, during which therapy and feedback occurred at different times. Specifically, 45 adverse events across 2972 sessions (1.52 per 100 sessions) were reported in synchronous telerehabilitation compared to 156 adverse events across 37,960 sessions (0.41 per 100 sessions) in asynchronous telerehabilitation. This difference may be attributed to the more immediate and direct observation of adverse events in synchronous interventions, where therapists can witness and report events in real time. Additionally, real-time interactions in synchronous sessions may encourage patients to be more active or engage in higher-intensity activities, potentially leading to more frequent adverse events. In contrast, some asynchronous interventions, such as the cardiac telerehabilitation program by Snoek et al [53], relied on scheduled check-ins where patients self-reported adverse events. Other asynchronous interventions, such as a strengthening intervention by Hume et al [37], allowed patients to record adverse events in a notebook at any time. Future research is needed to better understand how the mode of communication in telerehabilitation influences the reporting and recognition of adverse events.

An important consideration in evaluating adverse events is whether they are directly attributable to the intervention or incidental to the patient’s underlying conditions. Of the 12 (32%) interventions reporting adverse events, 9 provided information on their relatedness to the intervention: 1 was deemed related, 3 had mixed causality, and 5 were unrelated. For instance, Keteyian et al [28] reported a fall related to their remote cardiac rehabilitation program, although they did not explore which specific aspects of the intervention may have contributed to this event. van der Kolk et al [57] found that 74% of adverse events in their aerobic exercise telerehabilitation program for patients with Parkinson disease were unrelated to the intervention, though a potential relationship could not be excluded in the remaining cases, as these events may have represented a worsening or recurrence of the patient’s pre-existing conditions. Notably, all potentially related adverse events were classified as nonserious. Further research is needed to clarify which specific components of telerehabilitation interventions may account for the varying relationships observed between the interventions and adverse events. Moreover, standardized reporting frameworks should be implemented in future studies to capture all relevant characteristics of adverse events, including their relatedness and severity.

The included studies used a range of approaches to deliver telerehabilitation, from various technologies to more traditional methods like booklet-based exercise programs. Studies using videoconferencing reported the highest rate of adverse events, with 1.96 events per 100 sessions. This may be due to the real-time nature of videoconferencing, which could lead to increased reporting from therapists compared to methods that rely on patient self-report. The second-highest rate was observed in studies where patients followed independent exercise programs (1.23 events per 100 sessions), possibly due to reduced therapist monitoring of safety. Studies involving technologies such as virtual reality and exergaming software had 0.77 events per 100 sessions, though they were only used in 2 (5%) studies, likely because they are newer technologies. In contrast, studies that implemented monitoring devices (eg, heart rate monitors, electrocardiograms, and motion sensors) and uploaded their

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data to a mobile or web platform for review by rehabilitation personnel had the lowest rate of adverse events (0.31 events per 100 sessions). The abundance of quantitative data these devices provided may have facilitated more thorough monitoring and detection of potential issues, allowing for timely intervention. These findings suggest a potential benefit in using telerehabilitation methods with greater therapist oversight or continuous data monitoring, though further research is needed to fully understand these relationships, especially given the novelty of some technologies.

A significant aspect of reducing adverse events in telerehabilitation is the implementation of safety measures, and 32 (86%) studies provided practical examples of how these were integrated into their interventions. For instance, in a pulmonary telerehabilitation program for survivors of COVID-19, Capin et al [29] required physiotherapists to complete a systematic safety checklist before each session, which included reviewing participants' emergency contact information, vital signs, and any adverse events (eg, emergency room visits, hospitalizations, and new or worsening symptoms) since the last visit. Similarly, Peng et al [24] conducted a 60-minute education session on exercise before rehabilitation and requested that patients' caregivers be present during the sessions. Notably, both of these studies reported 0 adverse events across 1904 telerehabilitation sessions. Among the 11 (30%) studies that implemented scheduled safety check-ins with rehabilitation personnel, only 2 recorded adverse events [53,58]. Additionally, 5 (13%) studies required the on-call availability of personnel, with just 2 reporting any adverse events [39,52]. These findings suggest a potential association between the implementation of defined safety strategies and a reduced number of adverse events during telerehabilitation. However, more research is needed to objectively evaluate the efficacy of these measures. Professional organizations, including the American Physical Therapy Association, have emphasized the need for further research into the effectiveness of specific safety protocols for telerehabilitation, such as standardized assessments and checklists [9]. This underscores the importance of developing and continuously updating evidence-based guidelines to ensure patient safety in telerehabilitation programs as they continue to expand in use.

Strengths and Limitations

The strengths of this study stem from a comprehensive search strategy created in collaboration with a health sciences librarian. The review process adhered to PRISMA best practice guidelines, with all phases, including data screening and extraction, conducted independently and in duplicate by 2 investigators (HS and JC). Additionally, an analysis of study quality using the Cochrane risk of bias 2 tool showed that 70% (n=26) of the included studies had a low risk of bias.

However, this study also has limitations. First, 76% (n=28) of included studies provided insufficient reporting on adverse events, particularly regarding severity and relatedness. This limitation may have hindered our ability to capture a comprehensive understanding of adverse events in telerehabilitation settings. This issue has been well-documented in other reviews [59,65,66]. Therefore, it is essential to emphasize the importance of thorough data collection on adverse events and to develop standardized reporting frameworks. Second, there was a small sample size in some studies, with 5 studies having intervention groups of fewer than 10 participants. The limited statistical power of these studies may have reduced their ability to detect significant differences in adverse event incidence between the intervention and control groups. Future research should prioritize larger, well-powered randomized controlled trials to improve the reliability of findings and allow for more robust conclusions regarding the safety of telerehabilitation. Third, there was an underrepresentation of certain telerehabilitation settings (eg, burn rehabilitation and cancer rehabilitation) as well as younger and older age groups. Notably, only 12 (32%) studies had a mean participant aged 65 years and older, and none had a mean age younger than 18 years. This may limit the generalizability of the findings to specific telerehabilitation settings and age groups. Efforts were made to mitigate this limitation by including telerehabilitation interventions across a range of patient populations. Broadening the search criteria to explore databases specializing in pediatric or geriatric populations may enhance the applicability of the results. Fourth, the participants in randomized controlled trials often represent "ideal" patients without complex health profiles or comorbidities, limiting the applicability of our findings to the general public. This may lead to an overestimation of the safety and effectiveness of telerehabilitation. Fifth, this study did not include a meta-analysis, which may have limited the ability to draw more precise conclusions regarding the safety of telerehabilitation. Future systematic reviews should include meta-analyses to better quantify the incidence, type, severity, and relatedness of adverse events associated with telerehabilitation. Sixth, only studies written in English were included, which may have led to language bias and the exclusion of relevant studies published in other languages. To address this, future research could expand the inclusion criteria to allow for non-English studies or use translation services to capture a broader range of evidence.

Conclusions

This systematic review examining adverse events in telerehabilitation found that telerehabilitation can be a safe alternative to in-person rehabilitation. A total of 37 studies were included, with 25 (68%) reporting 0 adverse events across 24,450 sessions. Among those that did report adverse events, most were physical, nonserious, and unrelated to the telerehabilitation intervention. Additionally, the included studies identified several safety practices that may enhance telerehabilitation delivery. However, further research is needed to determine the impact of specific protocols on telerehabilitation safety. Future studies should also prioritize the development of standardized reporting for adverse events to address the underreporting observed in current randomized controlled trials.

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Authors' Contributions

All the authors (HS, JC, TY, MM, AA, AK, MB, CFL, MG, and SM) have made substantial contributions to the study design, analysis, and interpretation of the paper, drafted and critically revised the paper, and have approved the submitted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File, 49 KB - rehab_v12i1e68681_app1.docx]

Multimedia Appendix 2
Participant and intervention characteristics.
[DOCX File, 45 KB - rehab_v12i1e68681_app2.docx]

Multimedia Appendix 3
Adverse events in the intervention and control groups.
[DOCX File, 28 KB - rehab_v12i1e68681_app3.docx]

Multimedia Appendix 4
Risk of bias assessment of individual studies.
[PDF File, 8595 KB - rehab_v12i1e68681_app4.pdf]

Checklist 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File, 33 KB - rehab_v12i1e68681_app5.docx]

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Abbreviations

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
TIDieR: Template for Intervention Description and Replication

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Smart Device–Based Therapy on Hand Motor Function Improvement in Stroke Survivors During Rehabilitation: Scoping Review

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Abstract

Background: The prevalence of upper limb impairment ranges from 40% to 50% in the chronic phase of stroke, presenting a significant public health challenge. Although traditional therapy effectively improves hand motor function, it often faces accessibility challenges. Telerehabilitation, particularly smart device–based therapy, provides a scalable and engaging alternative, although its effectiveness still requires further investigation.

Objective: This study aimed to identify smart device–based therapy interventions for improving hand motor function in stroke survivors during rehabilitation and to assess their effectiveness in hand motor function improvement in comparison with traditional therapy methods.

Methods: A scoping review was conducted following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines to identify and evaluate smart device–based therapy interventions aimed at improving hand motor function in stroke survivors. A comprehensive literature search was performed across multiple databases, including Web of Science, PubMed (MEDLINE), EBSCO Complete, Google Scholar, Science Direct, ClinicalKey, and Scopus. Studies were screened based on predefined inclusion criteria, focusing on clinical trials that investigated the effectiveness of smart device–based rehabilitation approaches. Data extraction was carried out systematically, capturing key study characteristics, intervention types, and outcome measures. The effectiveness of these interventions was assessed and synthesized to provide a comprehensive overview of their impact on hand motor function recovery in stroke rehabilitation.

Results: A total of 958 studies were identified, of which 17 met the inclusion criteria. The studies encompassed various research designs, including randomized controlled trials (n=9), pilot feasibility studies (n=3), and a comparative nonrandomized trial (n=1). The interventions used diverse digital strategies, including gamified rehabilitation programs (n=14), virtual or mixed reality systems (n=7), Kinect camera or sensor-based approaches (n=6), Jintronix software platforms (n=4), robot-assisted devices (n=3), and tablet- or app-based rehabilitation systems (n=7). Overall, smart device–based therapies were associated with improvements in hand motor function, frequently reaching clinically meaningful thresholds, while also enhancing patient engagement and adherence.

Conclusions: The findings of this scoping study highlight the significant potential of smart device therapies for enhancing hand motor functions among stroke survivors. The development of smart devices is an evolving process, highlighting the need for future studies to assess their long-term effectiveness, optimize intervention designs, and explore their broader application in stroke rehabilitation.

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KEYWORDS

stroke; smart devices; smart device–based therapy; telerehabilitation; hand motor function

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Introduction

Background

Stroke remains a significant global health challenge, ranking as the second leading cause of death and the third leading cause of death and disability combined worldwide. The 2022 Global Stroke Factsheet reveals a 50% increase in the lifetime risk of stroke over the past 17 years, with 1 in 4 individuals now facing this threat [1]. The prevalence of upper limb impairment ranges from 50% to 80% in the acute phase to 40% to 50% in the chronic phase of stroke [2]. This prevalence imposes significant demands on health care systems, with rehabilitation needs far outpacing available resources, as noted by the World Health Organization [3].

Traditional therapy for hand motor recovery is highly effective, offering personalized guidance, feedback, and support for both gross and fine motor deficits. However, it is often inaccessible for patients in remote areas, costly, time-consuming, and constrained by a shortage of professionals. In addition, its repetitive nature can reduce patient motivation and adherence, underscoring the need for more engaging and scalable solutions [4].

Telerehabilitation has emerged as a promising solution, offering scalable and accessible interventions to bridge the gap between demand and supply, especially accelerated by the COVID-19 pandemic, which has catalyzed a rapid technological transformation in post–stroke rehabilitation, driving the adoption of telerehabilitation services delivered directly to the homes of stroke survivors [5]. Among these innovations, smart device–based therapy holds the promise of improving hand motor function through gamified, interactive designs that enhance engagement and adherence [6]. Smart devices, such as wearables, mobile apps, and sensor-integrated equipment, provide real-time feedback, track patient progress, and enable therapists to monitor performance remotely. Such systems often integrated gamification and virtual reality elements to improve engagement and adherence. Studies suggested that these interventions not only enhanced motor outcomes but also positively influenced psychological well-being, such as motivation and satisfaction with therapy [7].

Although there are limited data on the comparative effectiveness of smart device–based therapies, their potential in stroke rehabilitation is promising [8].

Objective

This study aimed to identify smart device–based therapy interventions for improving hand motor function in stroke survivors during rehabilitation and to assess their effectiveness in comparison with traditional therapy methods. Specifically, the study sought to identify and categorize the types of digital hand rehabilitation devices available to stroke patients, including their functionalities and applications; and to compare the effectiveness of remote smart device–based therapies with traditional rehabilitation methods in enhancing hand motor function in stroke survivors.

Research Question

The research questions are as follows: What types of digital hand rehabilitation devices are available for remote use by patients with stroke, and how do their functionalities and effectiveness in improving motor function compare with traditional therapy?

Methods

Overview

The scoping review was performed according to the Joanna Briggs Institute methodology for scoping reviews [9,10] and was reported following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews; Checklist 1) guidelines [11].

The review was registered on the Open Science Framework [12] to promote transparency, enhance reproducibility, and ensure open access to the data, methods, and findings for the broader scientific community.

Search Strategy

This scoping review was conducted to identify smart device–based therapy interventions in clinical trials across 7 databases. The databases searched included Web of Science, MEDLINE (via PubMed), EBSCO Complete, ScienceDirect, and Scopus. In addition, literature was retrieved using the search engine Google Scholar and the publisher platform ClinicalKey. The initial search was conducted in December 2023 for studies published between 2018 and 2023. An updated search was performed on August 10, 2025, extending the coverage to studies published from 2018 to 2025. Additional eligible studies were hand-searched. The available literature was screened to identify smart device–based therapy interventions used to improve hand motor function in stroke survivors during rehabilitation, and their levels of evidence were analyzed.

The search used the following primary keywords and corresponding Medical Subject Headings terms: “Stroke,” “Telerehabilitation,” “Smart devices,” and “Upper extremity.” The primary keywords and corresponding Medical Subject Headings terms are listed in Table 1. The search strategy was tailored to align with the specific indexing and search functionalities of each database. Adjustments were made not only to the keywords but also to the search parameters unique to each platform to ensure comprehensive retrieval of relevant studies. The full search strategy for each database is presented in Multimedia Appendix 1.

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Table . Primary keywords and their corresponding MeSH[a] terms used in database search.

Keyword categories	Keywords
1	"Stroke" OR "Cerebrovascular Accident" OR "CVA"
2	"Telerehabilitation" OR "Tele-rehabilitation" OR "Tele rehabilitation" OR "Remote Rehabilitation" OR "Virtual Rehabilitation" OR "telemedicine" OR "telehealth"
3	"Smart devices" OR "technology" OR "VR" OR "virtual reality"
4	"Hand" OR "upper extremity" OR "upper limb"
Search strategy	((1) AND (2) AND (3) AND (4))

[a]MeSH: Medical Subject Headings.

Study Selection Criteria

The inclusion and exclusion criteria are shown in Textbox 1.

Textbox 1. Inclusion and exclusion criteria

Inclusion criteria for study selection were as follows:

- Population: adult patients diagnosed with stroke
- Condition: upper limb disability or paresis
- Intervention: technology-based interventions (eg, smart devices) used for rehabilitation
- Setting: experimental group—home-based therapy with or without remote supervision or inpatient treatment without substantial assistance involving smart wearable devices, smartphones, tablets, robotic devices, gamified rehabilitation systems, and other similar technologies
- Outcomes: studies reporting on hand function improvement and rehabilitation progress
- Time frame: papers published between 2018 and August 2025
- Language: studies published in English
- Publication type: peer-reviewed papers, reviews, clinical trials, case studies, systematic reviews, and gray literature
- Availability: full-text papers only

Exclusion criteria for study selection were as follows:

- Population: studies involving pediatric patients
- Setting: inpatient treatment settings that required continuous therapist assistance to set up, guide, or complete the intervention
- Diagnosis: patients with diagnoses other than stroke
- Focus: studies unrelated to hand rehabilitation (eg, lower limb rehabilitation, cognitive rehabilitation without a hand-related component)

Selection of Sources of Evidence

All identified references were managed using Mendeley (v 1.19.8; Elsevier), and duplicate records were removed using Covidence systematic review software (Veritas Health Innovation). The study selection process followed a structured multistage approach. First, 2 independent reviewers conducted an initial screening of titles and abstracts to identify potentially relevant studies. Studies deemed ineligible based on predefined inclusion and exclusion criteria were excluded at this stage. Full-text screening was performed on the remaining studies by 2 independent reviewers to determine final eligibility. Any disagreements regarding study inclusion were resolved through discussion, and if necessary, a third reviewer provided adjudication. Covidence systematic review software was used throughout the selection process to ensure accuracy and consistency.

Data Charting and Extraction

A structured data charting framework was developed in Covidence to ensure a systematic and organized approach to data extraction. Two independent reviewers extracted key information from the selected studies, including study characteristics (eg, author, publication year, and country), participant details (eg, sample size, stroke type, and rehabilitation setting), intervention descriptions (eg, technology type and therapy mode), and reported outcomes (eg, functional improvements). To maintain consistency and accuracy, the reviewers engaged in discussions to resolve any discrepancies in the extracted data. If disagreements persisted, a third reviewer provided adjudication. The finalized data were compiled into Microsoft Excel for further synthesis and analysis, enabling a comprehensive comparison of intervention effectiveness across studies.

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Data Items

For each included study, key data points were systematically extracted to facilitate a comprehensive analysis. The extracted data included the study details, study design, participant characteristics, intervention details, outcome measures, and the effectiveness of interventions.

Study Details

This included the author(s), publication year, title, and country of origin.

Study Design

This included the type of study (eg, randomized controlled trial and pilot study), total number of participants, and patient care setting (eg, home-based, outpatient, and inpatient).

Participant Characteristics

This included stroke classification (chronic or subacute), inclusion criteria, and any cognitive assessments performed

Intervention Details

This included the type of smart device–based therapy used (eg, virtualand mixed reality, gamification, sensor-based systems, and robotic-assisted rehabilitation), and mode of delivery (asynchronous, synchronous, or hybrid).

Outcome Measures

This included the primary and secondary measures assessing hand motor function improvement (eg, Fugl-Meyer Assessment for Upper Extremities [FMA-UE], Stroke Impact Scale [SIS], and Wolf Motor Function Test [WMFT]).

Effectiveness of Interventions

These were the findings related to functional recovery and improvements in motor skills.

Data Synthesis

The extracted data were systematically compiled and analyzed to generate a comprehensive overview of the characteristics and findings of the included studies. Data synthesis was carried out in multiple stages to ensure a structured and thorough evaluation. Initially, all relevant data were organized in Microsoft Excel (Microsoft Corporation), where key variables—such as study design, participant demographics, intervention type, outcome measures, and reported effectiveness—were categorized.

Quantitative findings, including the effectiveness of smart device–based therapy on hand motor function improvement, were aggregated based on standardized outcome measures, such as the FMA-UE, SIS, and WMFT. These results were interpreted to determine trends in functional improvements observed among stroke survivors who underwent smart device–based rehabilitation. In addition, variations in intervention designs—such as the use of virtual and mixed reality, gamified rehabilitation platforms, robotic-assisted devices, and wearable sensors—were examined to explore how different technological solutions contribute to rehabilitation outcomes. Consideration was also given to the mode of therapy delivery (asynchronous, synchronous, or hybrid), as well as contextual factors influencing treatment effectiveness, such as study settings (home-based vs inpatient rehabilitation) and patient characteristics (chronic vs subacute stroke).

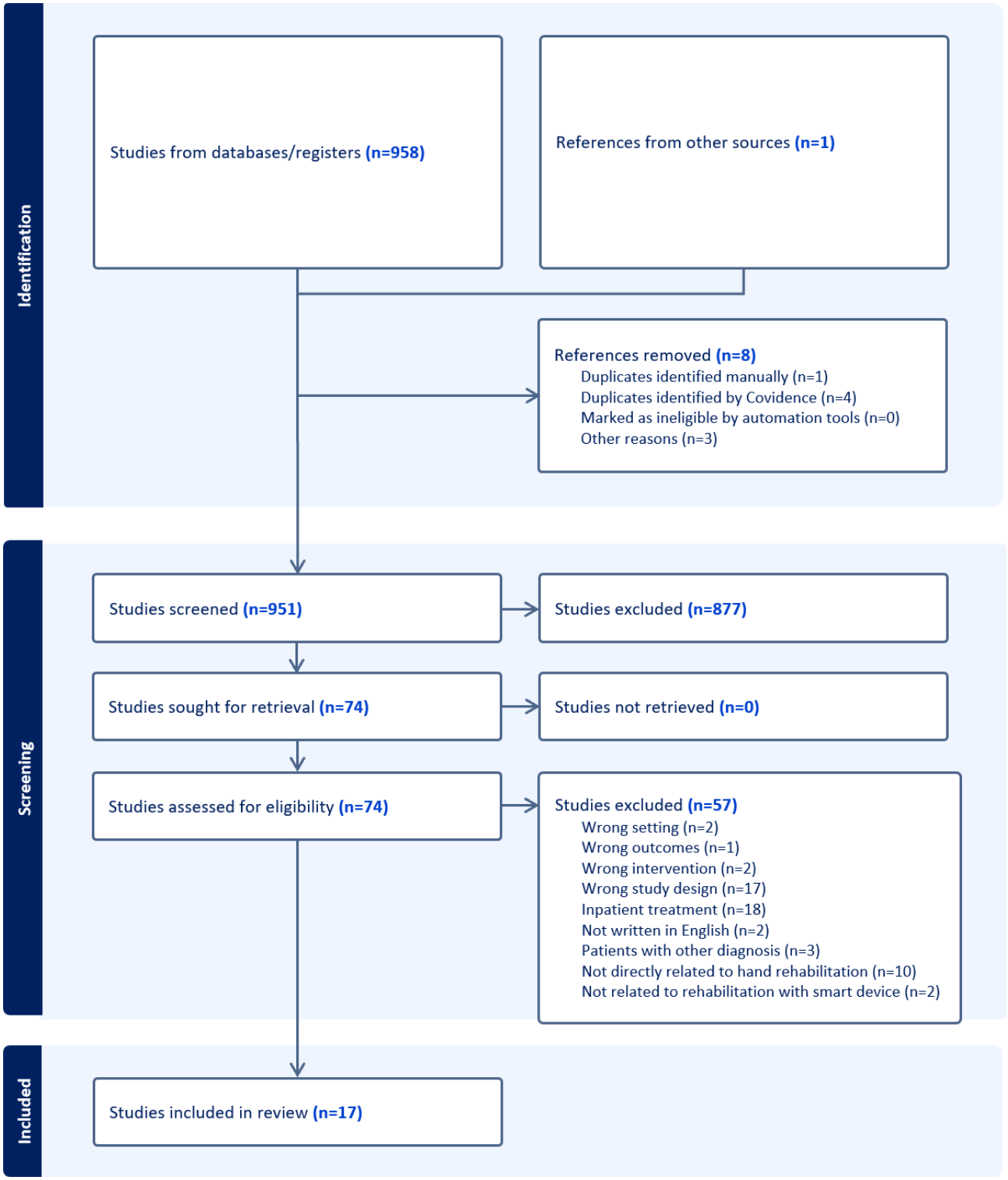
Results

Study Selection

A total of 958 records were identified from databases; after removing duplicates, 951 papers underwent screening, and following a review of titles and abstracts, 877 papers were excluded. Full texts of 74 papers were acquired for further screening. During the full paper text screening, 57 studies were excluded, and the remaining 17 [13-29] studies were selected for extraction. Figure 1 illustrates the process.

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Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for the study selection in the scoping review, depicting the identification of studies via databases and registers.



Of the 958 identified studies, 17 [13-28] met the inclusion criteria. The studies included randomized controlled trials (RCTs; n=9) [13,16,18-23,27-29], non-RCT (feasibility and experimental; n=4) [15,17,26,27], pilot and feasibility studies (n=3) [14,19,20], and comparative non-RCT (n=1) [24]. The interventions used diverse digital strategies, including gamification (n=14) [13-16,18-26,28], virtual and mixed reality devices (n=7) [14-16,18,22,23,25], Kinect camera and sensor (n=6) [13,15,16,22,23,25], Jintronix software (n=4) [15,16,22,23], robot-assisted devices (n=3) [14,20,24], and app or platform based (n=7) [15,16,22,23,25,26,29]. By stroke phase, most studies included chronic cohorts (n=12), with several spanning subacute populations (n=6); we found no acute-only trials. These studies involved 508 participants. Smart device–based interventions were delivered via asynchronous (n=6) [15,16,22,23,25,29], synchronous (n=1) [17], and hybrid (n=10) [13,14,18-21,24,26-28] approaches. Patient care settings were predominantly home-based (n=14) [13,14,16-20,22,24-29], with several studies also involving outpatient components (n=7) [14,15,17,18,23,24,27] and inpatient settings in 2 studies (n=2)

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[21,28]. In 3 studies, cognitive tests were used for outcome measures—Montreal Cognitive Assessment [22,27,29] and Neurobehavioral Functioning Inventory [29].

Study Characteristics and Intervention Effectiveness by Device

An overview of interventions and outcome of each used device of 17 included studies is summarized in Tables 2 and 3.

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Table . Characteristics of included studies.

Author, year	Title	Type of study	Experimental group device type, name	Total participants	Experimental group care setting	Control group interventions in RCT[a]
Adams et al [13], 2023	Telehealth guided virtual reality for recovery of upper extremity function following stroke (GRASP)	RCT	Custom finger sensors+SaeboGlove+GRASP sensor hub (Saebo Inc)+Kinect (Microsoft Corp)	18	Home-based asynchronous HEP[b]+biweekly synchronous telehealth OT[c]	Usual and customary care (no GRASP system)
AguirreOllinger et al [14], 2024	Telerehabilitation using a 2D planar arm rehabilitation robot for hemiparetic stroke: a feasibility study of clinic-to-home exergaming therapy	Prospective pilot feasibility	2D planar end-effector robot (HMan (Articares Pte Ltd), ARTICARES)+home exergaming	12	Clinic onboarding → home (minimally supervised)	—[d]
Allegue et al [15], 2021	Single case evaluation of VirTele (Jintronix+Reacts) for home-based upper limb stroke rehabilitation	Single case study	VirTele[e] (Jintronix (Jintronix Inc)+Reacts (Technomed))	1	Home-based with telesupervision	—
Allegue et al [16], 2022	VirTele: a patient-teletherapist program combining exergames (Jintronix) and videoconferencing (Reacts) for chronic stroke (feasibility trial)	Randomized feasibility trial	Jintronix+Reacts videoconferencing; motivational interviewing	9	Home-based; synchronous telesessions	GRASP home program
Althaf et al [17], 2024	Effectiveness of mirror therapy through telerehabilitation on upper extremity performance in hemiparetic stroke patients: an experimental study	Experimental study	Mirror box setup via telerehabilitation	60	Home-based	Face-to-face mirror therapy
Ase et al [18], 2025	Effects of home-based virtual reality upper extremity rehabilitation in persons with chronic stroke: a randomized controlled trial	RCT	RAPAEL Smart Glove (Neofect)+VR[f] software	14	Home program+weekly outpatient OT	Conventional home exercise program+weekly outpatient OT
Bressi et al [19], 2023	Upper limb home-based robotic rehabilitation in chronic stroke patients: a pilot study	Pilot feasibility study	iCONE (Wearable Robotics srl) end effector planar robot with remote supervision	13	Home-based telerehabilitation	—
Germanotta et al [20], 2025	A robotic rehabilitation intervention in a home setting during the COVID19 outbreak: a feasibility pilot study in patients with stroke	Nonrandomized feasibility pilot	Planar robot (iCONE) with telemonitoring and teleconsultation	18	Home-based telerehabilitation	—

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Author, year	Title	Type of study	Experimental group device type, name	Total participants	Experimental group care setting	Control group interventions in RCT[a]
Guo et al [21], 2023	A remote rehabilitation training system based on wearable devices for stroke inpatients: randomized clinical trial	RCT	Wearable IMU[g] based remote training system+app and cloud	109	Inpatient rehabilitation halls (remoteguided)	Conventional PT or OT[h] without the wearable system
Hernández et al [22], 2022	Feasibility of a virtual reality exergame (Jintronix) versus GRASP for home-based upper extremity stroke rehabilitation	Randomized feasibility trial	Jintronix VR exergaming (Kinect)+remote support	51	Home-based telerehabilitation	GRASP home program
Norouzi Gheidari et al [23], 2020	Supplementary telerehabilitation using Jintronix for outpatients after stroke: pilot randomized trial	Pilot randomized controlled trial	Jintronix VR exergaming platform (Kinect)	18	Outpatient+home telerehabilitation supplement	Standard outpatient rehabilitation without VR supplement
Pavan et al [24], 2024	Effectiveness of two models of telerehabilitation in improving recovery from subacute upper limb disability after stroke: robotic versus non-robotic	Comparative non-RCT	RAPAEL Smart Glove [i]	30	Home-based telerehabilitation (remote supervision)	Nonrobotic telerehabilitation of equivalent dose
Qiu et al [25], 2020	Development and pilot evaluation of the home-based virtual rehabilitation system (HoVRS) for chronic stroke	Feasibility single-arm	HoVRS[j] (developed by University of California Irvine; leap motion–based VR exercises)	15	Home-based with remote monitoring	—
Rozevink et al [26], 2021	Validity of the MERLIN arm weight supporting device for telerehabilitation after stroke	Nonrandomized experimental study	MERLIN[k] (developed by University of Groningen, Netherlands; unactuated arm weight support device)+remote coaching	10	Home-based telerehabilitation context	—
Simpson et al [27], 2024	A randomized control trial of a virtually delivered program for increasing upper limb activity after stroke (VABC)	RCT	Virtual arm boot camp (exercise+TENZR wrist-worn sensor feedback [BioInteractive Technologies]+6 virtual sessions)	73	Fully virtual or home-based	Waitlist or usual care
Toh et al [28], 2024	Effects of a wearable-based intervention on the hemiparetic upper limb in persons with stroke: a randomized controlled trial	RCT	Wrist-worn wearable+reminder app (SRAPP [developed by the Chinese University of Hong Kong]) with remote guidance	40	Home or outpatient telerehabilitation	Usual care without the wearable system

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Author, year	Title	Type of study	Experimental group device type, name	Total participants	Experimental group care setting	Control group interventions in RCT[a]
Wilson et al [29], 2021	Home-based (virtual) rehabilitation improves motor and cognitive function for stroke patients: RCT of the Elements (EDNA22) system	RCT	EDNA22 (Dynamic Neural Arts) tablet-based virtual rehabilitation system	17	Home-based virtual rehabilitation	GRASP home exercise program (active control)

[a]RCT: randomized controlled trial.

[b]HEP: home exercise program.

[c]OT: occupational therapy.

[d]—: not applicable.

[e]VirTele: virtual reality exergames combined with a telerehabilitation app.

[f]VR: virtual reality.

[g]IMU: inertial measurement unit.

[h]PT: physical therapy.

[i]TR: telerehabilitation.

[j]HoVRS: home-based virtual rehabilitation system.

[k]MERLIN: Home care arm rehabilitation.

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Table . Overview of included studies treatment effect.

Author, year	Aim of study	Outcome measure	Treatment effect
Adams et al [13], 2023	Effectiveness of GRASP glove program	• FMA-UE[a] • WMFT-FA[b]	• +10.1 (95% CI 6.7 - 13.5; *P*<.001); 8.6 units greater versus control (95% CI 4.9 - 12.2; *P*<.001) • +0.73 (95% CI 0.26 - 1.19, *P*=.005)
Aguirre-Ollinger et al [14], 2024	Feasibility of H-Man robotic telerehabilitation	• FMA • ARAT[c]	• Change +3.7 (*P*=.02) • Change +4.8 (*P*=.004)
Allegue et al [15], 2021	VirTele[d] feasibility	• FMA-UE • SIS[f] (hand function, ADLs)[g]	• Improved above MCID[e] (4.25 - 7.25) • Gains exceeded MCID (9.4 - 14.1)
Allegue et al [16], 2022	VirTele versus conventional therapy	• FMA-UE • MAL[h]-30 • SIS-16	• 50% improved • 2 participants reached MCID • 1 participant exceeded MCID
Althaf et al [17], 2024	Mirror therapy via telerehabilitation	• FMA-UE • WMFT-FA	• No significant difference between groups, *P*=.673 • No significant difference between groups, *P*=.396
Ase et al [18], 2025	Home-based VR[i] RCT[j]	• FMA-UE • BBT[k] • JTT[l]	• Robotic +8.9 (SD 1.9) versus control +1.7 (SD 1.9), *P*=.027 • Significant difference between groups, *P*=.014 • Significant difference between groups, *P*=.-002
Bressi et al [19], 2023	iCONE robot home-based rehabilitation	• FMA-UE • MAS[m] (elbow) • Robotic indices	• Improved not significant • Significant decrease, *P*=.017 • Independence *P*=.04, size *P*=.019, and duration *P*=.002 all improved
Germanotta et al [20], 2025	Robotic rehabilitation during COVID—iCONE	• FMA-UE	• 11 of 18 patients improved beyond MCID (5.25)
Guo et al [21], 2023	Wearable-based rehabilitation system	• FMA • FMA-UE	• +17.56 (SD 11.65), significant • +11.28 (SD 8.59), significant
Hernández et al [22], 2022	VR serious game versus home exercise	• FMA-UE	• 56% (9/16) reached MCID, *P*=.045
Norouzi-Gheidari et al [23], 2020	VR exergame feasibility	• SIS mobility • SIS physical	• +5.5%, *P*=.017 • +6.7%, *P*=.041
Pavan et al [24], 2024	Robotic versus nonrobotic telerehabilitation	• FMA-UE • ARAT	• Robotic +4.44 (SD 0.79) versus nonrobotic +10.79 (SD 2.17) • Robotic +3.25 (SD 1.68) versus nonrobotic +7.71 (SD 2.05)
Qiu et al [25], 2020	HoVRS[n] feasibility	• FMA-UE	• +5.2 (SE 0.69, 95% CI 3.66 - 6.71; *P*<.001); exceeds MCID 4.25
Rozevink et al [26], 2021	MERLIN[o] training	• WMFT[p] • FMA-UE • ARAT	• +3.8, *P*=.006 • Significant (ηp^2=0.60) • Significant (ηp^2=0.27)

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Author, year	Aim of study	Outcome measure	Treatment effect
Simpson et al [27], 2024	Virtually delivered UL[q] program	• Wearable activity counts	• MD=368, *P*=.046
Toh et al [28], 2024	Wearable-based RCT	• FMA-UE	• MD=2.05, *P*=.036
Wilson et al. [29], 2021	Compare EDNA[r] system with active control for motor, cognitive, and functional outcomes	• BBT • 9HPT[s] • MoCA[t]	• Large effect, g=0.90 • Moderate effect, g=0.55 • Moderate-large effect, g=0.70

[a]FMA-UE: Fugl-Meyer Assessment for Upper Extremities.
[b]WMFT-FA; Wolf Motor Function Test Functional Ability.
[c]ARAT: Action Research Arm Test.
[d]VirTele: virtual reality exergames combined with a telerehabilitation app.
[e]MCID: minimal clinically important difference.
[f]SIS: Stroke Impact Scale.
[g]ADL: activities of daily living.
[h]MAL-30: Motor Activity Log-30.
[i]VR: virtual reality.
[j]RCT: randomized controlled trial.
[k]BBT: Box and Block Test.
[l]JTT: Jebsen-Taylor Hand Function Test.
[m]MAS: Modified Ashworth Scale.
[n]HoVRS: home-based virtual rehabilitation system.
[o]MERLIN: HoMEcare aRm rehabiLItatioN.
[p]WMFT: Wolf Motor Function Test.
[q]UL: upper limb.
[r]EDNA: Elements by Dynamic Neural Art.
[s]9HPT: 9-Hole Pegboard Test.
[t]MoCA: Montreal Cognitive Assessment.

Discussion

Principal Findings

The scoping review highlighted the potential of smart device–based therapies in improving hand motor function among stroke survivors. The review synthesized evidence from 17 studies and identified 5 main types of digital hand rehabilitation devices: virtual and mixed reality systems [15,16,18,22,23,25], which provide immersive environments for interactive training; wearable sensor-based devices, such as motion-tracking gloves [13] and inertial measurement unit–based sensors [21,27,28], enabling real-time feedback and remote monitoring; robotic-assisted rehabilitation devices [14,19,20,24,26], which deliver mechanical support and facilitate guided movement practice; tablet- or app-based rehabilitation platforms [13,15,16,22,23,25,29], offering structured exercise programs with interactive and gamified elements; camera- or Kinect-based motion tracking systems [13,15,16,22,23,25], allowing gesture-based therapy without direct device contact; and mirror therapy device [17], representing a low-tech but adaptable telerehabilitation tool. These smart technologies enhance rehabilitation and can complement or even surpass traditional rehabilitation methods in certain contexts. In line with our findings, several recent trials have further strengthened the evidence on smart device–based and telerehabilitation approaches for upper limb recovery after stroke. For example, Pavan et al [24] demonstrated that both robotic and nonrobotic telerehabilitation models significantly improved motor and cognitive skills in subacute stroke patients, highlighting the feasibility of integrating such solutions into home-based care. Similarly, Simpson et al [27] reported that a virtually delivered program combined with a wearable device increased upper limb activity, emphasizing the role of remote therapist support and objective monitoring. Toh et al [28] further confirmed the efficacy of wearable-based interventions, where a novel *Smart Reminder* device improved upper limb function and adherence in a randomized controlled trial. Taken together, these results reinforce the promise of smart device–based rehabilitation and provide an important context for examining how such approaches compare directly with established traditional therapies.

Comparison With Traditional Therapy

Treatment effectiveness was compared with a variety of conventional or control interventions (hereafter collectively referred to as *traditional therapy*) in 11 studies [13,16-18,21-24,27-29]. These comparators were heterogeneous and included usual care, GRASP home programs, face-to-face mirror therapy, and conventional home exercise programs with outpatient OT or PT. FMA-UE improved across studies, with gains ranging from 6.8 to 17.56 points in experimental groups, frequently exceeding the minimal clinically important difference and indicating clinically meaningful motor recovery. Functional metrics, such as WMFT, Box and Block Test, and Action

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Research Arm Test, showed moderate to large improvements, with effect sizes ranging from g=0.55 to g=0.90. Cognitive outcomes were less frequently assessed, but in the few studies that did, the Montreal Cognitive Assessment demonstrated a moderate-to-large effect [22,27,29].

Limitations and Challenges Identified in the Studies

Our Study Limitations

This review has a few limitations. In this study, only studies in English were reviewed and included, which may have restricted the scope of the findings. The limited number of studies highlighted the potential need to reconsider the exclusion criteria. For instance, our choice to focus solely on remote interventions may have further narrowed the pool of eligible studies. Another limitation is the exclusion of interventions delivered in inpatient settings with substantial assistance. While this approach allowed us to focus on independently usable technologies in home or community environments, it may have reduced the applicability of our findings to individuals with more severe impairments who typically require support during training. As a result, certain devices that demonstrate effectiveness only when used with clinical assistance may be underrepresented in this review. Moreover, inconsistent methodologies and outcome measures across studies hindered direct comparisons, making it challenging to draw robust conclusions from user experience data. In our research, we did not include patient experiences with technologies or usability aspects, as that was not our aim, and these were primarily addressed in separate studies. However, user satisfaction and engagement play a crucial role in enhancing therapy effectiveness [16], highlighting the importance of considering these factors in future research. Moreover, rapid advances in smart technology suggest that findings may require updates as new devices emerge. Several promising smart rehabilitation tools are currently under development, although many remain in early stages, with limited evidence on their clinical efficacy and usability [30].

Limitations of the Included Studies

There were several limitations related to the included studies. First, the included studies differentiated stroke cases by the timing of the event but did not distinguish between ischemic and hemorrhagic strokes. These types vary in recovery mechanisms, potentially affecting device efficacy [31]. Second, in our study, only 1 included cognitive test for outcome measures. Given that cognitive impairments—such as deficits in memory, attention, and executive function—are common among stroke survivors and impact hand motor function recovery and rehabilitation success [32]. Third, the included studies used various outcome measures to assess the effectiveness of the interventions, such as FMA-UE, MAL, SIS, and Box and Block Test, which made it difficult to make direct comparisons.

Implications for Clinical Practice and Rehabilitation Programs

Although the included studies varied in design and sample size, the overall findings indicate that smart device–based interventions are both safe and feasible for telerehabilitation, either delivered independently or in combination with conventional therapy. Several systems already integrated into clinical practice, such as Jintronix [15,16,22,23], have demonstrated that commercial platforms can be effectively adapted for home-based programs, enhancing patient motivation and adherence. Other tools, including the home-based virtual rehabilitation system [25] and wearable sensor-based devices [21,27,28], showed potential to support partially autonomous rehabilitation at home by providing real-time feedback, objective monitoring, and remote therapist supervision. Robotic-assisted devices such as H-Man and iCONE [14,19,20,24] offered mechanical support for patients with more severe impairments and achieved clinically meaningful improvements even with limited therapist input.

Future Research Directions

The findings of this scoping review highlight the significant potential of smart device–based therapy for enhancing hand motor function among stroke survivors. Building on these promising outcomes, several future research directions can help advance the development, implementation, and effectiveness of these interventions. Future research should explore the integration of cognitive and hand motor function rehabilitation to address the multifaceted needs of stroke survivors. Developing comprehensive standardized rehabilitation protocols that include interventions targeting memory, attention, and executive hand function alongside motor recovery could provide a more holistic approach to therapy. In addition, the absence of a single standardized outcome measure for hand motor recovery remains a major limitation of the current evidence base, introducing variability and potential bias across studies. Future work should therefore prioritize the development and adoption of consensus-based, standardized outcome measures to allow more reliable comparison and synthesis of findings across trials.

Emerging innovations in augmented reality and artificial intelligence present exciting opportunities for advancing stroke rehabilitation [33]. Augmented reality can provide immersive, engaging therapy environments, whereas artificial intelligence–driven systems have the potential to deliver adaptive, personalized rehabilitation. In addition, research on more sophisticated sensor and feedback mechanisms can refine therapy delivery and enhance patient outcomes [34], which leads to the crucial future recommendation that technology and innovations should focus on creating user-friendly devices and protocols that empower patients to engage in effective, autonomous rehabilitation from the comfort of their homes, addressing the growing demand for accessible care.

Conclusions

Smart device–based interventions demonstrate possibilities in enhancing hand motor function and overall rehabilitation outcomes in stroke survivors. These results strongly advocate for the integration of smart devices into standard rehabilitation protocols to maximize accessibility and improve patient-specific outcomes. Further research and development are warranted to expand the use of smart technologies, optimize their effectiveness, and integrate them more broadly into stroke rehabilitation practices.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File, 16 KB - rehab_v12i1e73533_app1.docx]

Checklist 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) fillable checklist.
[DOCX File, 111 KB - rehab_v12i1e73533_app2.docx]

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Abbreviations

FMA: Fugl-Meyer assessment
FMA-UE: Fugl-Meyer assessment for upper extremities
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
SIS: Stroke Impact Scale
WMFT: Wolf Motor Function Test

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Internet-Based Telerehabilitation Versus in-Person Therapeutic Exercises in Young Adult Females With Chronic Neck Pain and Forward Head Posture: Randomized Controlled Trial

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Abstract

Background: Neck pain is a common musculoskeletal disorder, often linked to forward head posture (FHP). Studies have shown that exercise interventions can improve pain, craniovertebral angle (CVA), range of motion, and function in individuals with FHP. While telerehabilitation exercise has proven effective for other musculoskeletal conditions, its effectiveness in addressing neck pain and FHP is still being investigated.

Objective: This study aimed to evaluate and compare the effectiveness of an internet-based telerehabilitation therapeutic exercise program with an in-person supervised program in improving clinical outcomes among young adult females with chronic nonspecific neck pain and FHP. The study hypothesized that there would be no significant differences in outcomes between the 2 groups.

Methods: A randomized controlled trial was conducted with 50 participants experiencing chronic neck pain and FHP, recruited through public announcement and voluntary sign-up. Participants were randomly assigned to either a telerehabilitation group or an in-person supervision group. Both groups completed the same 6-week, physiotherapist-supervised therapeutic exercise program, delivered via Zoom (Zoom Video Communications) or in the physiotherapy department laboratory, respectively. Outcome assessments were conducted face-to-face by blinded assessors at baseline, after 4 and 6 weeks of intervention, and at a 2-week follow-up. Outcome measures included pain intensity (assessed using the Visual Analog Scale [VAS]), CVA, neck disability (assessed using the Neck Disability Index [NDI]), and cervical range of motion (CROM). Adherence was monitored using attendance logs.

Results: Of the 50 participants, 48 completed the intervention with 1 dropout from each group. Adherence among completers was 100 percent in both groups. All 50 participants were included in the analysis using the intention-to-treat principle. No differences in effectiveness were found between the telerehabilitation and in-person groups, as no significant interaction effect between group and time was observed across all outcome measures including VAS, CVA, NDI, and CROM (*P* values ranged .07-.61). However, improvements were observed in all outcomes across time, including a 2.2 - to 4.1-cm reduction in VAS, 5°-8.8° increase in CVA, 3.3 - to 7.1-point reduction in NDI (*P*<.001 for all), and 3.5°-22.7° increase in CROM (*P*<.001 to *P*=.04).

Conclusions: Both telerehabilitation and in-person supervision were similarly effective in improving pain, posture, neck disability, and CROM in young adult females with chronic neck pain and FHP. These findings suggest that telerehabilitation may be a feasible and accessible alternative to conventional in-person therapeutic exercise programs for managing chronic neck pain with FHP.

Trial Registration: Thai Clinical Trials Registry TCTR20240326007; https://www.thaiclinicaltrials.org/show/TCTR20240326007

(JMIR Rehabil Assist Technol 2025;12:e74979) doi:10.2196/74979

KEYWORDS

telerehabilitation; chronic neck pain; forward head posture; therapeutic exercise; videoconferencing supervision

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Introduction

Neck pain is one of the most common musculoskeletal disorders and represents a significant public health concern within the general population [1]. Approximately 50% of people experience an essential episode of neck pain at some point in their lives [2]. Notably, female adolescents are particularly susceptible to persistent neck pain [3]. Neck pain is becoming more common due to the widespread use of smartphones [4]. This behavior is associated with increased activity in the neck extensor, erector spinae, and upper trapezius muscles, as well as increased head flexion, tilt angles, and forward head posture (FHP) [5]. This persistent tension on the cervical spine may lead to alterations in spinal curvature. Furthermore, research has linked head and neck posture to neck pain [6], with a negative correlation observed between neck pain and the craniovertebral angle (CVA) [7].

FHP is characterized by hyperextension of the upper cervical spine and increased flexion of the lower cervical and upper thoracic spines. This posture causes the head to shift forward from the gravity line in the sagittal plane [8,9]. Muscle imbalances result from such abnormal spinal alignment, with the deep cervical flexors, rhomboids, lower trapezius, and serratus anterior muscles becoming weakened or lengthened, while the upper trapezius, pectoralis, suboccipital, and levator scapulae muscles become shortened [10-12]. A previous study found that 60% of individuals with neck pain demonstrated FHP [13].

Several studies have reported significant improvements in pain, CVA, neck range of motion (ROM), and function in patients with FHP following in-person exercise interventions [14-16]. The usefulness of telemedicine and telerehabilitation in meeting health care demands during emergencies has become more widely acknowledged by medical professionals since the COVID-19 pandemic. According to recent data, the effectiveness of telerehabilitation, especially for physical therapists, may influence clinical decision-making and improve patient outcomes during and after the pandemic [17]. Previous studies have demonstrated the effectiveness of telerehabilitation for various musculoskeletal conditions, such as patellofemoral pain [18], knee osteoarthritis [19], low back pain [20], musculoskeletal shoulder disorders [21], and musculoskeletal conditions in older adults [22]. Some studies have investigated exercise programs in individuals with chronic neck pain, focusing on improvements in pain, disability, and quality of life [23,24]. However, the effectiveness of a telerehabilitation-based therapeutic exercise program specifically targeting pain, disability, cervical angle, and ROM in patients with neck pain combined with FHP has not yet been clearly established.

This study aims to investigate the effectiveness of an internet-based telerehabilitation exercise program compared with an in-person exercise program for individuals with chronic nonspecific neck pain and FHP. We hypothesize that telerehabilitation will be equally effective as the in-person program in improving pain, cervical angle, ROM, and functional outcomes.

Methods

Study Design

This study used a randomized controlled trial design with a 1:1 allocation ratio to compare 2 groups over 6 weeks with a 2-week follow-up, conducted between January and April 2024. All assessments and in-person interventions were conducted at the Physiotherapy Department Laboratory, Walailak University, Thailand, while the telerehabilitation group received their intervention via Zoom (Zoom Video Communications) platform. The study reporting followed the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) reporting guidelines (the CONSORT-EHEALTH checklist is provided in Checklist 1) [25].

Participants and Randomization

Females aged 18-25 years were eligible to participate in this study and were recruited through public announcement and voluntary sign-up. Inclusion criteria required participants to have nonspecific neck pain that worsened with active neck movement in at least 1 direction. In addition, participants had experienced neck pain for at least 12 weeks and reported a Visual Analog Scale (VAS) score of 3 to 8 out of 10. FHP was defined as a CVA of less than 50°, as established in a previous study [26]. Furthermore, participants in the telerehabilitation group were required to have access to a smartphone or computer with internet connectivity and basic ability to use videoconferencing applications. Exclusion criteria included a history of shoulder or spine injuries or surgeries, spinal deformities (eg, thoracic hyperkyphosis or scoliosis), neurological deficits, infections, inflammatory arthritis in the cervical spine, regular participation in neck and shoulder exercises, or having undergone physical therapy or other medical treatments for neck pain in the previous 6 months. The eligibility criteria and other trial components remained consistent throughout the study, with no major methodological changes made after the trial began.

An a priori power analysis was conducted using G*Power software, version 3.1.9.7 (by Franz Faul, Universität Kiel, Germany) to determine the required sample size. The calculation was based on an *F* test using the effect size reported in a previous study comparing therapeutic exercises with a control group [27]. A total of 42 participants was determined through the calculations. However, a 15% dropout rate was anticipated. As a result, the final target sample size for this study was 50 participants.

Participants were randomly assigned to either the telerehabilitation or in-person group through a concealed allocation process. At the beginning of the program, an independent researcher, not involved in any assessments, prepared 50 small opaque slips labeled “1” and “2.” Each participant drew 1 slip from a container to determine their group assignment. To ensure allocation concealment, sealed and sequentially numbered opaque containers were used, thereby preserving the integrity of the randomization process and minimizing the risk of selection bias. The outcome assessors were blinded to group assignments throughout the study.

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Outcome Measures

Neck pain, CVA, neck disability level, and cervical range of motion (CROM) were evaluated at baseline, after 4 and 6 weeks of intervention, and at a 2-week follow-up. Evaluations were administered in-person in the physiotherapy department laboratory by an assessor who was blinded to group allocation and not involved in the intervention for either group. No modifications were made to the trial outcomes after the commencement of the trial. The outcomes outlined in the protocol remained consistent throughout the study period.

Neck pain was assessed using the VAS within a 24-hour period. The VAS, widely regarded as one of the most reliable and validated methods for self-reporting pain intensity, uses a 10 cm horizontal line. On this scale, 0 cm indicates “no pain,” while 10 cm represents “worst pain” [28].

CVA was measured using photogrammetry in the sitting position. Markers were placed over the right tragus of the ear and the C7 spinous process. Participants were instructed to sit in their neutral resting position with their arms naturally on their knees [29]. A digital camera was positioned on a tripod at shoulder level, 0.8 m away from the participants. Angles were measured using Kinovea, a 2D motion analysis software. CVA was measured from the intersection between a horizontal line through the spinous process of C7 and a line extending to the tragus of the ear. The angle was measured 3 times to enhance data reliability.

Neck disability level was determined using the Neck Disability Index (NDI), Thai version. This self-reported questionnaire determined the disability index of the cervical spine and its impact on daily activities. The NDI has been validated as an effective evaluative tool for patients with neck pain [30].

CROM was measured using a CROM device (Performance Attainment Associates and MedNet Technologies). Active ROM of the cervical spine was assessed in 6 directions, such as flexion, extension, lateral flexion to the left, lateral flexion to the right, rotation to the left, and rotation to the right. The device has demonstrated high intratester reliability (intraclass correlation coefficient [ICC]=0.87 - 0.96) for patients with neck pain [31].

Adherence to the intervention was monitored in both groups using attendance logs and considered as a process outcome. All scheduled sessions were monitored, and participant adherence was defined by session attendance.

Intervention and Control

Following the initial randomization meeting, all participants received patient education regarding postural correction and guidance on avoiding certain activities, particularly rest break guidelines for mobile electronic device and computer use [32]. Both groups received the same exercise program: a combined stretching and strengthening corrective exercise intervention conducted 3 times per week for 6 weeks. The exercise program was designed by a licensed physiotherapist with 18 years of clinical experience in musculoskeletal rehabilitation, based on a synthesis of exercises previously shown to be effective in managing FHP in the literature [27,29,32-34]. Participants were instructed to stretch each muscle, including the pectoralis, sternocleidomastoid, upper trapezius, and levator scapulae, to the end of its range without inducing pain or discomfort, following standard protocols. Each stretch was held for 30 seconds and repeated twice for each muscle on both the right and left sides, with a 30-second rest period between repetitions and between muscles. Four strengthening corrective exercises were performed: sitting chin tuck, standing W-to-Y, wall slide with shoulder flexion while facing the wall, and wall slide with shoulder abduction and external rotation while positioned with the back against the wall. Each exercise consisted of 10 repetitions per set, with 3 sets completed for each exercise. A 1-minute rest period was provided between sets, and a 2-second rest was allowed between exercises. Each session lasted approximately 40 minutes. The exercise protocol and remote supervision model remained unchanged throughout the trial. Participants in both groups received weekly reminders via the LINE application before each scheduled session. The detailed exercise prescription for the strengthening corrective exercises is provided in Multimedia Appendix 1.

The telerehabilitation group performed the exercise program individually under real-time remote supervision in their home environment via secure, password-protected Zoom links. No sessions were recorded, and the Zoom platform remained stable and unchanged during the study. The researcher monitored movement patterns and provided verbal feedback to correct exercises, ensuring both proper technique and compliance with the prescribed exercise schedule.

The in-person group completed the same program under supervision at a physiotherapy laboratory. Another researcher monitored the movement patterns and provided both verbal instructions and manual correction when necessary. This difference in feedback modality was intentional and designed to reflect real-world remote rehabilitation settings, where tactile feedback is not feasible. Therapists followed a standardized session checklist to ensure consistent feedback and technique correction.

During the 6-week intervention period and 2-week follow-up, all participants were instructed to refrain from engaging in any neck-related exercises or receiving physical therapy or other medical treatments for neck pain.

Statistical Analysis

Statistical analysis was conducted using SPSS for Windows (version 23, IBM Corp). A *P* value of .05 was considered statistically significant. Descriptive statistics, including the mean, SD, and 95% CI values, were reported. Intervention effects on outcome measures were assessed via repeated-measures analysis of variance with a 2-by-4 design (2 groups and 4 time points). The effect size was indicated by partial eta squared (η^2). In the case of significant group-by-time interactions, post hoc pairwise comparisons with Bonferroni correction were used to adjust for multiple comparisons. Intention-to-treat analysis was applied to account for altered results from baseline if data were lost during follow-up. No interim analyses were performed during the trial, and stopping guidelines were not relevant. The trial adhered strictly to the

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predetermined protocol without any deviations concerning interim analyses or early termination.

Ethical Considerations

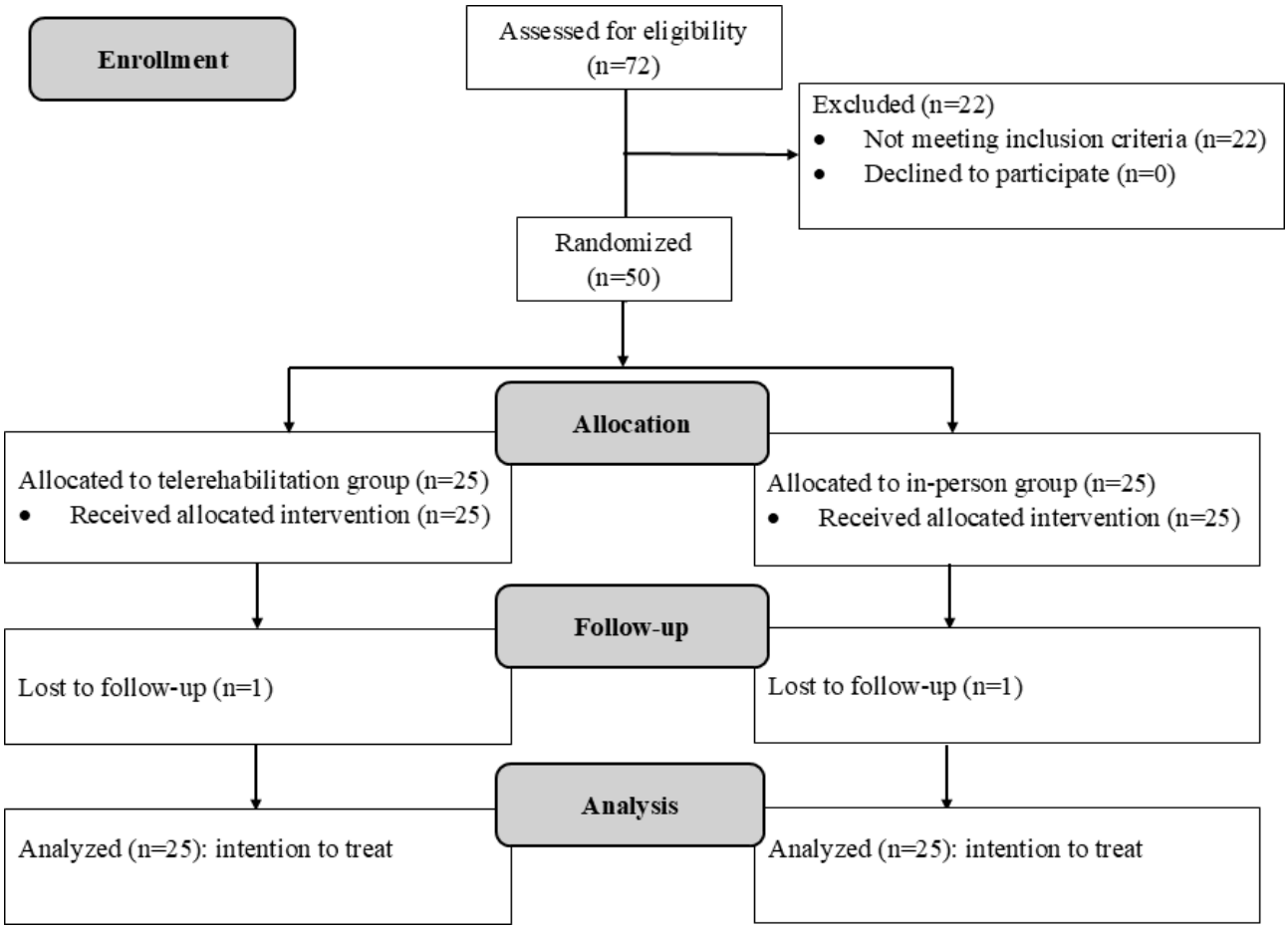
The study protocol was approved by the Human Research Ethics Committee of Walailak University, Thailand (approval number: WUEC-23-335-02), and the trial was registered with the Thai Clinical Trials Registry (registration number: TCTR20240326007). The data were deidentified, and no compensation was provided. Before the study began, all participants were informed about the study's purpose, procedures, potential risks and benefits, their right to withdraw at any time without consequences, and how their personal data would be protected. Written informed consent was obtained from all participants.

Results

This study initially recruited 72 participants for screening, of which 22 were disqualified, leaving 50 participants enrolled. A total of 50 participants were randomized into telerehabilitation and in-person groups. A depiction of a participant in the trial is presented in Figure 1.

The participants' characteristics are presented in Table 1. One participant from the telerehabilitation group and another participant from the in-person group withdrew, leading to a dropout. Among the 48 participants who completed the intervention, adherence was 100% (48/48), with all participants attending every scheduled session over the 6-week period. The intention-to-treat principle was used, and all 50 participants were included in the analysis (Figure 1). The baseline characteristics were similar between the groups for all variables. No harm or unintended effects were observed in either group. The participants reported no adverse events during the treatment period, nor were any identified during the 2-week follow-up. No additional analyses, such as subgroup analyses or adjusted analyses, were conducted.

Figure 1. Consolidated Standards of Reporting Trials diagram for the randomized clinical trial.



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Table . Demographic characteristics of participants in the telerehabilitation and in-person groups.

Characteristics	Telerehabilitation (n=25), mean (SD)	In-person (n=25), mean (SD)	*P* value[a]
Age (years)	19.80 (1.29)	19.76 (1.27)	.91
BMI (kg/m^2)	22.77 (3.91)	23.15 (4.13)	.74
Pain duration (months)	12.20 (9.59)	16.16 (9.40)	.15

[a]*P* values were calculated using independent *t* tests.

Mean (SD) of VAS, CVA, NDI, and CROM at baseline, after 4 weeks of intervention, after 6 weeks of intervention, and during a 2-week follow-up period of both telerehabilitation and in-person groups were presented in Table 2 and Figures 2 and 3.

Table 3 presents the mean change from baseline with 95% CI values for all outcomes within each group over time. The multivariate test demonstrated that the main effect of group-by-time interaction had no significant difference of all variables including VAS ($F_{3,46}$=1.001; *P*=.40; η^2=0.061), CVA ($F_{3,46}$=1.554; *P*=.21; η^2=0.092), NDI ($F_{3,46}$=1.489; *P*=.23; η^2=0.089), CROM of flexion ($F_{3,46}$=0.610; *P*=.61; η^2=0.038), CROM of extension ($F_{3,46}$=2.181; *P*=.10; η^2=0.125), CROM of lateral flexion to left ($F_{3,46}$=1.633; *P*=.19; η^2=0.096), CROM of lateral flexion to right ($F_{3,46}$=2.529; *P*=.07; η^2=0.142), CROM of rotation to left ($F_{3,46}$=1.102; *P*=.36; η^2=0.067), and CROM of rotation to right ($F_{3,46}$=1.048; *P*=.38; η^2=0.064).

However, the main effect of time was statistically significant in all parameters; VAS ($F_{3,46}$=85.673; *P*<.001; η^2=0.848), CVA ($F_{3,46}$=69.383; *P*<.001; η^2=0.819), NDI ($F_{3,46}$=49.704; *P*<.001; η^2=0.764), CROM of flexion ($F_{3,46}$=61.035; *P*<.001; η^2=0.799), CROM of extension ($F_{3,46}$=35.699; *P*<.001; η^2=0.700), CROM of lateral flexion to left ($F_{3,46}$=86.050; *P*<.001; η^2=0.849), CROM of lateral flexion to right ($F_{3,46}$=62.989; *P*<.001; η^2=0.804), CROM of rotation to left ($F_{3,46}$=57.219; *P*<.001; η^2=0.789), and CROM of rotation to right ($F_{3,46}$=140.378; *P*<.001; η^2=0.902).

Pairwise comparisons using Bonferroni correction revealed statistically significant improvements from baseline (week 0) at all subsequent time points (weeks 4-, 6-, and 2-week follow-up) in both the telerehabilitation and in-person groups. Significant improvements from baseline were observed in all outcomes, including VAS (*P*<.001), CVA (*P*<.001), NDI (*P*<.001), and CROM in flexion, extension, lateral flexion, and rotation (*P*<.001-*P*=.04, depending on direction and group).

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Table . Mean (SD) score by group over time.

Outcome measure	Week 0 (baseline), mean (SD)		4-week treatment, mean (SD)		6-week treatment, mean (SD)		2-week follow-up, mean (SD)	
	[a]TR (n=25)	[b]IP (n=25)	TR (n=25)	IP (n=25)	TR (n=25)	IP (n=25)	TR (n=25)	IP (n=25)
[c]VAS (cm)	4.51 (1.23)	5.14 (1.54)	1.78 (1.30)	2.30 (1.72)	1.28 (1.15)	1.32 (1.19)	1.14 (1.28)	1.38 (1.04)
[d]CVA (°)	40.75 (4.21)	41.54 (3.45)	45.76 (4.22)	48.37 (3.96)	47.63 (4.08)	50.32 (4.19)	46.76 (4.39)	50.02 (4.20)
[e]NDI (score)	8.84 (4.12)	10.84 (4.93)	5.56 (4.36)	6.44 (4.48)	3.92 (3.88)	4.28 (3.49)	2.80 (3.72)	3.76 (3.62)
[f]CROM-Flexion (°)	51.93 (8.29)	51.64 (7.82)	61.49 (9.64)	59.17 (9.30)	65.40 (8.27)	65.07 (6.78)	59.90 (7.75)	62.21 (7.85)
CROM-Extension (°)	54.25 (9.10)	55.48 (12.37)	61.07 (9.74)	58.97 (13.26)	67.47 (6.86)	67.14 (12.22)	63.49 (6.87)	60.91 (12.36)
CROM-Lateral flexion to left (°)	36.13 (3.07)	36.79 (3.36)	40.15 (2.91)	41.07 (2.95)	41.99 (2.10)	43.89 (2.74)	40.61 (2.01)	42.07 (2.65)
CROM-Lateral flexion to right (°)	36.16 (3.05)	36.63 (3.42)	40.37 (2.27)	40.55 (2.61)	41.29 (2.36)	41.81 (2.78)	40.73 (2.39)	42.21 (2.47)
CROM-Rotation to left (°)	55.17 (7.17)	55.29 (7.67)	61.22 (5.93)	63.07 (6.93)	64.51 (5.48)	65.07 (5.05)	62.48 (4.66)	62.59 (5.26)
CROM-Rotation to right (°)	41.14 (6.67)	41.68 (8.31)	58.16 (8.32)	57.55 (9.24)	62.45 (8.03)	63.36 (7.20)	60.75 (9.13)	63.84 (8.19)

[a]TR: telerehabilitation group.

[b]IP: in-person group.

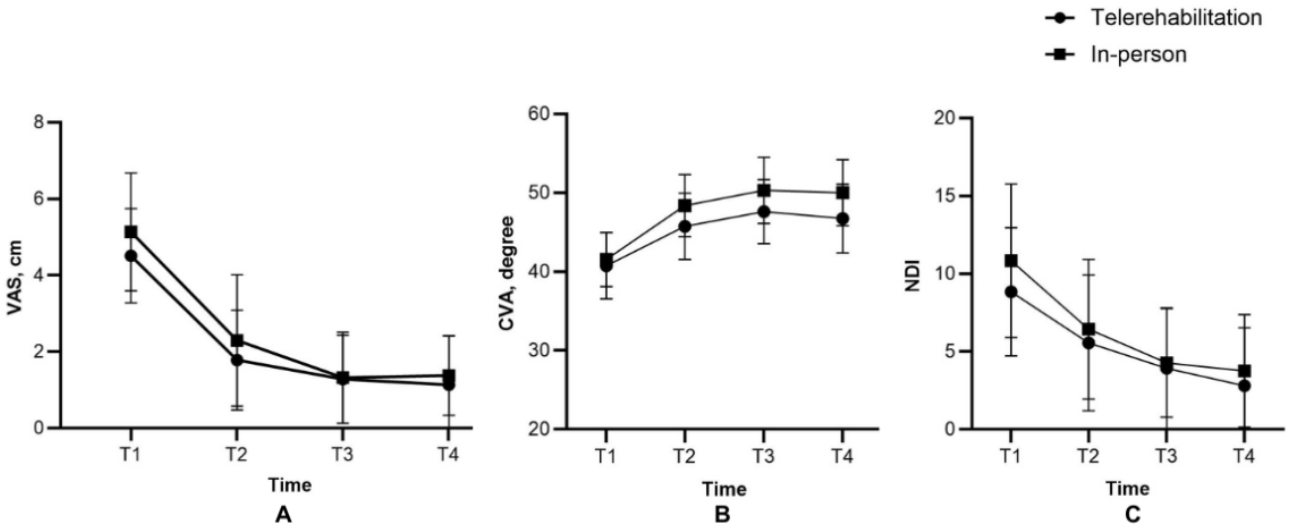
[c]VAS: visual analog scale.

[d]CVA: craniovertebral angle.

[e]NDI: neck disability index.

[f]CROM: cervical range of motion.

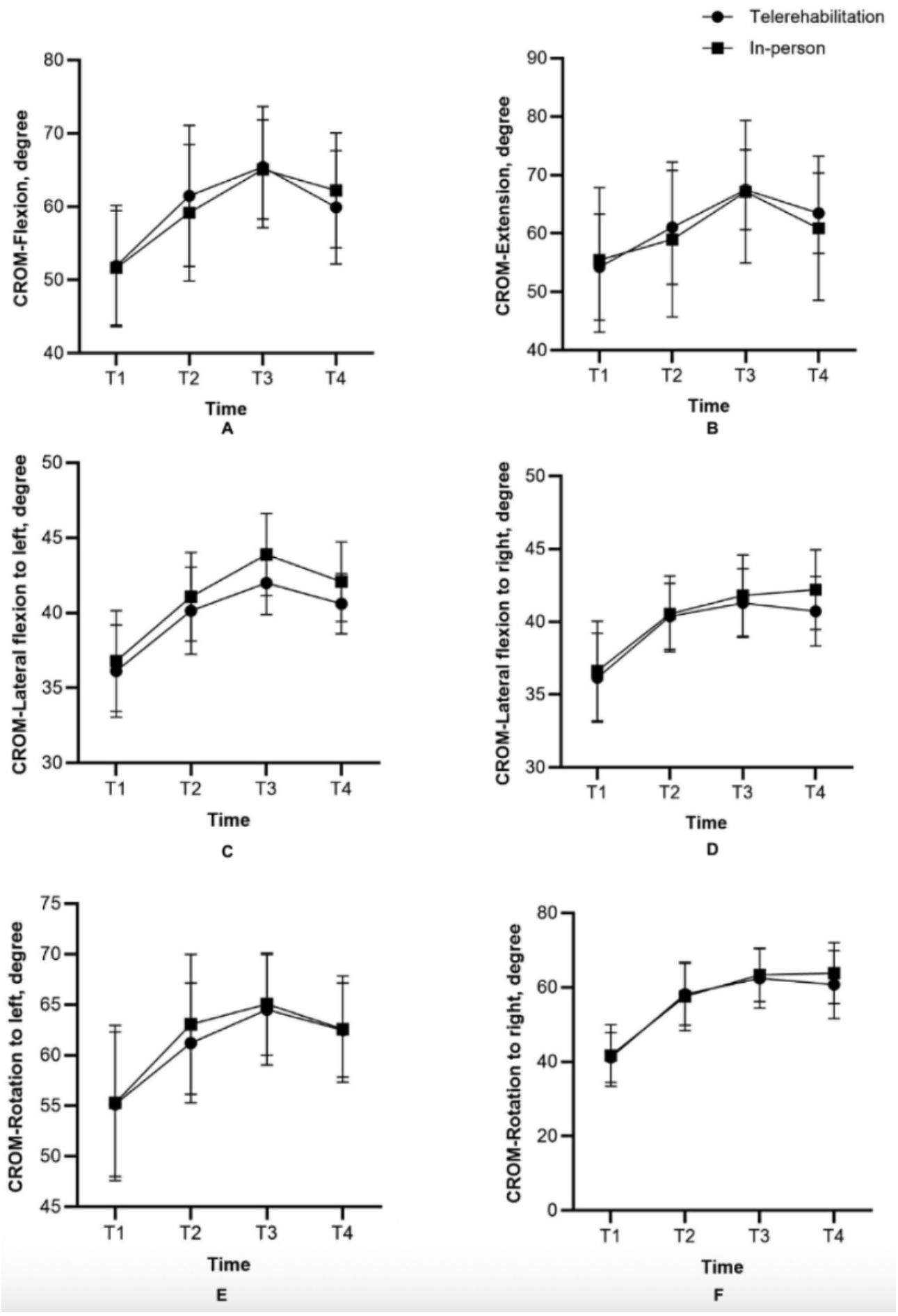
Figure 2. Visual analog scale (A), craniovertebral angle (B), and neck disability index (C) at 4-time points (baseline, after 4-week and 6-week of intervention, and during 2-week of follow-up). T1=week0, T2=4-week treatment, T3=6-week treatment, and T4=2-week follow-up. CVA: craniovertebral angle; NDI: neck disability index; VAS: visual analog scale.



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Figure 3. Cervical range of motion: flexion (A), extension (B), lateral flexion to left (C), lateral flexion to right (D), rotation to left (E), and rotation to right (F) at 4-time points (baseline, after 4-week and 6-week of intervention, and during 2-week of follow-up). T1=week0, T2=4-week treatment, T3=6-week treatment, T4=2-week follow-up. CROM: cervical range of motion.

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Table . Mean (95% CI) change within group over time.

Outcome measure	Mean (95% CI) change within group					
	Week 4−week 0		Week 6−week 0		F/U 2 week−week 0	
	TR[a] (n=25)	IP[b] (n=25)	TR (n=25)	IP (n=25)	TR (n=25)	IP (n=25)
VAS[c] (cm)	2.188 (1.26 to 3.11)	2.812 (1.88 to 3.74)	3.104 (2.26 to 3.95)	3.876 (3.03 to 4.72)	3.428 (2.51 to 4.35)	4.140 (3.22 to 5.06)
CVA[d] (°)	−5.012 (−7.33 to −2.69)	−6.832 (−9.15 to −4.51)	−6.884 (−9.29 to −4.48)	−8.784 (−11.19 to −6.38)	−6.012 (−8.49 to −3.54)	−8.488 (−10.96 to −6.01)
NDI[e] (score)	3.280 (1.34 to 5.22)	4.40 (2.46 to 6.34)	4.920 (2.93 to 6.91)	6.56 (4.57 to 8.55)	6.04 (3.97 to 8.11)	7.08 (5.01 to 9.15)
CROM-Flexion[f] (°)	−9.56 (−13.96 to −5.16)	−7.53 (−11.93 to −3.14)	−13.47 (−17.29 to −9.64)	−13.43 (−17.25 to −9.60)	−10.28 (−14.28 to −6.28)	−8.27 (−12.27 to −4.27)
CROM-Extension (°)	−6.81 (−11.23 to −2.40)	−3.49 (−7.91 to 0.92)	−13.23 (−18.07 to −8.38)	−11.67 (−16.51 to −6.82)	−9.24 (−13.26 to −5.22)	−5.43 (−9.15 to −1.41)
CROM- Lateral flexion to left (°)	−4.01 (−5.66 to −2.37)	−4.28 (−5.93 to −2.63)	−5.87 (−5.66 to −2.37)	−7.11 (−8.75 to −5.46)	−4.48 (−6.05 to −2.91)	−5.28 (−6.82 to −3.71)
CROM- Lateral flexion to right (°)	−4.21 (−5.66 to −2.77)	−3.92 (−5.36 to −2.48)	−5.13 (−7.05 to −3.21)	−5.19 (−7.11 to −3.27)	−4.57 (−5.98 to −3.17)	−5.59 (−6.99 to −4.18)
CROM- Rotation to left (°)	−6.05 (−8.29 to −3.82)	−7.77 (−10.01 to −5.54)	−9.33 (−12.94 to −5.73)	−9.77 (−13.38 to −6.17)	−7.31 (−10.42 to −4.19)	−7.29 (−10.41 to −4.18)
CROM- Rotation to right (°)	−17.01 (−21.75 to −12.27)	−15.87 (−20.61 to −11.13)	−21.31 (−25.44 to −17.18)	−21.68 (−25.81 to −17.55)	−22.69 (−27.95 to −17.43)	−19.07 (−24.33 to −13.81)

[a]TR: telerehabilitation group.

[b]IP: in-person group.

[c]VAS: visual analog scale.

[d]CVA: craniovertebral angle.

[e]NDI: neck disability index.

[f]CROM: cervical range of motion.

Discussion

Principal Findings

The major finding of this study is that there were no significant differences in neck pain intensity (VAS), CVA, NDI, and CROM between the telerehabilitation and in-person groups, indicating comparable effectiveness of both delivery methods. The partial eta squared values supported the overall interpretation that both telerehabilitation and in-person exercise produced clinically meaningful improvements. The consistently large effect sizes observed for the main effect of time further emphasize the effectiveness of the intervention across both delivery methods. In addition, adherence to the intervention was excellent, with all participants who completed the program attending all scheduled sessions. This high adherence rate demonstrates the feasibility and acceptance of both approaches among participants. These findings support the clinical viability of remote rehabilitation models when implemented with appropriate supervision and technological support.

This exercise program can be effectively delivered via telemedicine using real-time videoconferencing for young adult females with FHP and nonspecific chronic neck pain. The intervention led to improvements in neck pain management, cervical alignment, neck disability, and ROM. Furthermore, physical therapy services delivered through real-time interactive communication provide significant benefits for patients who are geographically isolated, reduce travel distances, and require more timely responses for care [35].

In this study, both the telerehabilitation and in-person groups, which followed an identical exercise protocol, demonstrated comparable improvements in neck pain. This supports the effectiveness of a combined stretching and corrective strengthening program delivered over 4-6 weeks in reducing pain intensity. A previous study reported that neck pain is often associated with poor posture and FHP, both of which are linked to muscle imbalances [36]. Therefore, therapeutic exercises can effectively address potential muscle imbalances [37]. Iqbal et al [38] emphasized the clinical importance of deep cervical flexor training for managing neck pain and improving functional disability. Letafatkar et al [27] revealed that corrective exercises targeting the neck and upper body can effectively reduce neck pain. Furthermore, changes in CVA have been identified as being strongly associated with variations in pain levels [39]. In this study, the difference in VAS from baseline in both groups exceeded the minimum clinically important difference (MCID) of 2.14 cm [40], indicating a clinically significant effect of the therapeutic exercise program, regardless of whether it was delivered through in-person supervision or real-time videoconferencing. In contrast, previous internet-based interventions for chronic neck pain have shown statistically significant improvements in pain; however, the mean change in VAS did not exceed the MCID threshold [41].

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To correct the FHP in this study was achieved by increasing the CVA. The exercise program aimed to restore normal muscle balance between opposing muscle groups. Training the deep neck flexor muscles (longus colli and capitis) resulted in a reduction in the mechanosensitivity of specific neural, muscular, and articular structures [42], thereby improving the ability to maintain a neutral cervical position [43]. In addition, increasing the activation of the lower trapezius and serratus anterior muscles, which are critical for scapular stabilization, contributed to reducing abnormal posture [44]. Most studies, including this one, have used a combination of stretching and strengthening exercises with varying characteristics to improve CVA [45,46]. A meta-analysis demonstrated significant improvements in CVA across participants of diverse age ranges and socioeconomic groups when various therapeutic exercises were applied. Specifically, individuals with neck pain experienced a mean improvement in CVA of 4.58° [39]. These findings suggest that both telerehabilitation and in-person exercise programs could enhance CVA outcomes beyond previously reported levels.

Both the telerehabilitation and in-person groups demonstrated a statistically significant improvement in neck-related functional disability, as measured by the NDI. Following a 6-week intervention, the NDI reached the minimum detectable change threshold of at least 5 points but did not surpass the MCID of a 7-point reduction required to confirm meaningful clinical improvement [47]. This suggests that, while the intervention had a measurable effect on disability, the extent of change may not have been large enough for participants to perceive a substantial functional benefit. This limitation should be considered when interpreting the clinical relevance of the NDI findings. Nonetheless, a previous study reported that therapeutic exercises for the neck achieved a faster reduction in neck disability compared with manual therapy [48].

CROM in all directions improved in both groups, potentially due to pain relief. A previous study showed that patients with mechanical neck pain could enhance CROM by improving joint mobility and reducing soft tissue adhesions [49]. Similarly, Anderson et al [50] reported that a 6-week cervical stretching and strengthening exercise program improved neck ROM in young adults, regardless of whether they experienced neck pain.

Telerehabilitation delivered through real-time videoconferencing offers practical benefits for patients familiar with digital tools. In this study, all participants were able to access the Zoom-based exercise sessions without difficulty. Previous research has shown that factors, such as age, cognitive reserve, and therapist support can influence satisfaction and engagement with telerehabilitation [51,52]. Therapists play a key role in guiding patients through technology use and providing motivational support to maximize treatment adherence. One notable difference between groups was the mode of therapist feedback. While the in-person group received occasional manual corrections, the telerehabilitation group relied solely on verbal and visual guidance. Despite this difference, both groups demonstrated comparable improvements, suggesting that effective exercise instruction and correction can be achieved through telerehabilitation without the need for tactile feedback. This supports the clinical use of remote physiotherapy models, especially in settings where physical interaction is limited.

Importantly, our findings demonstrate that telerehabilitation is clinically equivalent to in-person supervision in improving pain, posture, neck disability, and CROM in individuals with chronic neck pain and FHP. This equivalence supports its use as a valid alternative to in-person care. With comparable outcomes in both groups, telerehabilitation may help expand access to effective physiotherapy, especially for individuals living in remote or underserved areas. As digital literacy improves, remote physiotherapy models may become more sustainable in routine clinical practice.

Limitations and Future Research

This study had some limitations. First, exercises performed in a lying position were excluded because telerehabilitation required participants to remain in front of a mobile device or laptop for the physiotherapist to observe and provide feedback effectively. Second, although corrective strengthening exercises were included, cervical and upper body muscle strength was not assessed. This limits interpretation regarding whether observed improvements were linked to actual strength gains. Including muscle strength assessment would have provided a more comprehensive understanding of treatment effects. Third, participant blinding was not feasible due to the nature of the intervention, a common constraint in exercise studies. However, assessor blinding and concealed allocation were used to minimize bias. Fourth, participant satisfaction was not evaluated, restricting insight into the user experience with telerehabilitation. Finally, the study focused on young adult females, limiting generalizability to other sexes and age groups. These limitations indicate that findings should be applied cautiously to broader populations, particularly males, older adults, or those requiring long-term care.

Furthermore, understanding the cost-effectiveness and satisfaction associated with telerehabilitation is essential for guiding future clinical implementation. Future research should explore the long-term sustainability of treatment effects, cost-effectiveness, and broader applicability of telerehabilitation across diverse populations and clinical settings. To better understand treatment response and optimize intervention strategies, future studies should incorporate subgroup analyses based on baseline characteristics such as pain duration and include objective measures of cervical and upper body muscle strength to more accurately assess the physiological impact of corrective exercises.

Conclusions

This study demonstrates that real-time supervised telerehabilitation can achieve clinical outcomes comparable to in-person physiotherapy in improving pain, posture, disability, and cervical range of motion among young adult females with chronic neck pain and forward head posture. These findings provide strong support for the use of telerehabilitation as a clinically effective, feasible, and accessible treatment option, particularly in settings where in-person care is not readily available.

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Acknowledgments

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Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed exercise prescription for strengthening corrective exercises.
[DOCX File, 2087 KB - rehab_v12i1e74979_app1.docx]

Checklist 1
CONSORT-EHEALTH checklist (V1.6.1).
[PDF File, 4251 KB - rehab_v12i1e74979_app2.pdf]

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Abbreviation

CONSORT-EHEALTH : Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
CROM: cervical range of motion
CVA: craniovertebral angle
FHP: forward head posture
MCID: minimum clinically important difference
NDI: Neck Disability Index
ROM: range of motion
VAS: Visual Analog Scale

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Investigating a Telerehabilitation Platform Integrated With a Rehabilitation Robot Using Microsoft HoloLens 2 for Upper-Limb Therapy: Pilot Usability Study

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Abstract

Background: Upper-limb impairments following conditions such as stroke and spinal cord injury contribute significantly to long-term disability. Many survivors of stroke face limited access to rehabilitation due to geographical, financial, or scheduling barriers, leaving unmet therapeutic needs.

Objective: This study conducted a preliminary evaluation of the usability of a novel telerehabilitation platform integrating a portable, desktop-mounted robot (DMRbotV3) with a mixed reality HoloLens 2 application to support accessible and adaptive upper-limb neurorehabilitation.

Methods: This was a pilot usability study. Six participants, 3 (50%) stroke survivors (≥3 months after the event) recruited from a hospital stroke registry and 3 (50%) occupational therapists (≥1 year of clinical experience) recruited through convenience sampling in the Greater Milwaukee region, completed a single 2-hour session using the telerehabilitation platform in the BioRobotics laboratory at the University of Wisconsin-Milwaukee. Participants tried out the system, which delivered passive, active, and resistive exercises through DMRbotV3 combined with interactive mixed reality displays, and then completed a customized usability questionnaire. Data collected included (1) robotic parameters from onboard sensors (joint position, velocity, and interaction forces); (2) participant usability feedback from questionnaires to assess usability, satisfaction, and user engagement; and (3) documentation of adverse events and safety concerns. Descriptive statistics (mean scores and ranges) were used to analyze usability ratings and performance parameters.

Results: The system was safe and well tolerated, with no adverse events reported. All participants completed the session, and usability scores averaged ≥4.0 across all items, reflecting high satisfaction and engagement with mixed reality integration. The robotic system demonstrated smooth performance, with controlled joint velocity profiles (–10 m/s to +10 m/s) and adaptive interaction forces up to approximately 25 N.

Conclusions: This preliminary study supports the usability of combining robotics and mixed reality technologies into a telerehabilitation platform for upper-limb neurorehabilitation. Participant feedback also identified opportunities for refinement to enhance adaptability and personalization of therapy.

(JMIR Rehabil Assist Technol 2025;12:e75907) doi:10.2196/75907

KEYWORDS

Azure IoT; Internet of Things; digital twin; HoloLens 2; mixed reality; robot-aided therapy; telerehabilitation; upper-limb dysfunction

Introduction

Upper-limb dysfunction is a frequent consequence of neurological and musculoskeletal conditions such as stroke, spinal cord injury, cerebral palsy, multiple sclerosis, amyotrophic lateral sclerosis, trauma, occupational injuries, and age-related disorders [1]. Among these conditions, stroke accounts for the highest proportion of upper-limb dysfunction

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cases (approximately 34%), followed by spinal cord injury (27%), multiple sclerosis (19%), and cerebral palsy (8%) [2]. Restoration of upper-limb motor function is essential for performing daily activities, with rehabilitation serving as the cornerstone of functional recovery for patients with upper-limb dysfunction. Conventional rehabilitation typically involves intensive, one-on-one engagement with qualified therapists in clinical settings over extended periods [3]. However, this approach poses significant challenges, including high costs, limited availability of therapy sessions, and logistical barriers such as transportation difficulties, making sustained rehabilitation unattainable for many patients [4,5]. These challenges are further impacted by a shortage of therapists capable of providing personalized, long-term care, particularly in underserved areas [6]. Consequently, many patients often experience premature discharge and insufficient follow-up care, depriving them of the consistent rehabilitation needed for optimal recovery [7].

Robot-aided therapy has demonstrated promise in improving upper-limb rehabilitation outcomes by providing high-intensity, repetitive, and personalized training that supports motor relearning [8-11]. Taveggia et al [12] demonstrated that patients using robotic therapy experienced significantly improved strength, reduced spasticity, and better pain management. Their findings support the use of robotic assistance to alleviate the physical demands on therapists and provide patients with higher-intensity sessions [12]. The integration of machine learning algorithms into robotic systems has further improved the adaptability of these devices. Ai et al [13] reviewed various machine learning applications in robotic upper-limb rehabilitation, finding that algorithms capable of real-time learning can enhance robot-patient interaction, predicting patient needs and adjusting support accordingly. This advance increases the personalization of therapy, aligning it more closely with the fluctuating needs of stroke survivors [13].

The development of technologies for remote rehabilitation has revolutionized the management of poststroke upper-limb impairments, mainly through advancements in telerehabilitation, mixed reality applications, and robotic assistance. Several studies highlight the impact of telerehabilitation on improving access and sustaining engagement among poststroke patients. For example, Housley et al [14] explored telerehabilitation robotics as a promising adjunct to conventional therapies, integrating telehealth and robotic systems to enhance upper-limb function remotely. They found that telerehabilitation significantly increased therapy accessibility and patient adherence, providing an option for continuous care beyond the clinical setting [14]. A notable advancement in telerehabilitation is integrating gamification and remote feedback features. Rodriguez-de-Pablo et al [15] conducted a study on the ArmAssist system, a low-cost robotic system equipped with serious games for upper-limb rehabilitation, which allowed therapists to monitor patient progress remotely. Their findings demonstrated that gamified environments improved patient motivation and engagement and enabled the remote assessment of motor performance, which is crucial for adjusting therapy as patients progress [15]. However, telerehabilitation faces challenges related to communication delays and the limited capacity for real-time, in-depth sensory feedback, which is necessary for more effective motor recovery [16].

Mixed reality technologies, notably Microsoft's HoloLens 2, have transformed telerehabilitation by creating immersive virtual environments that enhance patient engagement and spatial awareness during physical therapy exercises. MR combines augmented reality and virtual reality (VR), allowing users to interact with holographic projections in real-world settings, which has shown potential in upper-limb rehabilitation by immersing patients in task-oriented training. Palumbo [17] examined HoloLens applications across various health care fields, emphasizing its value in creating interactive, digitally enriched environments conducive to motor rehabilitation. Their study suggested that HoloLens fosters a sense of patient presence and focus, thereby increasing the motivation for continuous practice [17]. Pillai et al [18] implemented a mixed reality–based gamified rehabilitation system on the HoloLens 2 specifically designed to make upper-limb exercises more engaging; their results showed that patients adhered to therapy regimens and improved motor skills [18]. Furthermore, mixed reality technologies in rehabilitation facilitate patient feedback and movement tracking. Vona et al [19] integrated speech-based virtual assistants into mixed reality environments to aid patients in completing rehabilitation exercises, finding that virtual assistants enhanced patient autonomy in home-based settings [19].

Existing commercially available devices such as continuous passive motion devices primarily offer passive therapy, which is limited in adaptability and lacks the active, responsive interactions needed for effective upper-limb rehabilitation in stroke survivors [20]. Robotic rehabilitation devices such as CLEVERarm [21] and Harmony [22] were created to enable home-based rehabilitation; however, these systems are still under development and do not always work well for full-spectrum therapy, limiting their use [23]. Commercially available devices such as ArmeoPower [24], InMotion ARM [25], and ReoGo [26] are mostly used in clinical settings and only support a few motion modes or 2D movements, making them less useful for conducting 3D exercises that target specific joints and are needed for full recovery [27]. Furthermore, many existing systems such as Tyromotion's AMADEO [28] are designed for specific tasks and lack broad upper-limb training capabilities. Another limitation is the absence of telerehabilitation functions, which restricts these devices to in-clinic use and limits access for patients who require remote support [29].

Recent advancements in home-based telerehabilitation have introduced transformative technologies, including artificial intelligence, VR, and digital twin (DT) frameworks, which offer adaptive and interactive solutions tailored to individual patient needs. VR-based systems integrated with collaborative robotics have significantly enhanced patient engagement and therapeutic outcomes through gamified exercises that promote active participation [30]. Home-based platforms such as the telepresence rehabilitation system have demonstrated the potential for remote therapy by incorporating therapist-in-the-loop designs with VR-enhanced environments and haptic feedback for interactive training [31]. Systems such

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as GARMI exemplify the seamless integration of robotics with telemedicine by offering dynamic and adaptive rehabilitation modes supported by optimal control and game theory, along with user-friendly interfaces and real-time communication features [32]. Similarly, the MERLIN system leverages serious gaming to boost patient engagement, although ergonomic challenges affect user satisfaction [33]. Other systems, such as the PVSED exoskeleton [34] and Hand Mentor Pro [35], offer advanced haptic feedback and innovative training modules but face limitations related to cost, portability, and accessibility. DT technology further facilitates remote monitoring and real-time customization of therapy, enabling therapists to deliver highly personalized interventions [36,37]. Similarly, the xArm-5 integrates industrial Internet of Things (IoT) and augmented reality to deliver remote therapy programs with real-time visualization and feedback [37]. Despite these advancements, key challenges remain, including the absence of seamless real-time data transfer and visualization and the inability to offer passive, active, and resistive therapies that deliver personalized and adaptive treatment remotely.

The aim of this study was to conduct a preliminary evaluation of the usability of a novel telerehabilitation platform integrating a portable, desktop-mounted robot (DMRbotV3) with a mixed reality HoloLens 2 application to support accessible and adaptive upper-limb neurorehabilitation. Participants interacted with the device (tryout session) and provided feedback through a customized usability questionnaire to assess usability of and satisfaction and user engagement with the system.

Methods

Study Sample

To evaluate the usability of the device, two participant groups were recruited: (1) survivors of stroke, representing the end users who would directly engage with the upper-limb rehabilitation system; and (2) occupational therapists, representing the potential operators and clinical supervisors who may adopt the device for rehabilitation in future practice. Survivors of stroke were recruited from the Stroke Survivor Recruitment Database at Froedtert Hospital (Milwaukee, Wisconsin). Eligible participants were required to be aged ≥18 years at the time of enrollment, have had a radiologically confirmed stroke due to ischemia or intracerebral hemorrhage, and have experienced stroke onset more than 3 months before recruitment. Occupational therapists were recruited through convenience sampling in the Greater Milwaukee area. Eligible therapists were required to have at least one year of professional rehabilitation experience.

System Trial and Feedback Loop

Each participant completed a single 2-hour session in the BioRobotics laboratory at the University of Wisconsin–Milwaukee using the telerehabilitation platform, where they first interacted with the device in a tryout session and then provided structured feedback through a customized questionnaire assessing the usability of and satisfaction and engagement with the system.

Each session began with an introduction to the telerehabilitation platform, and participants were familiarized with the robotic rehabilitation system and mixed reality interface. Participants were seated in a chair and positioned to hold the DMRbotV3 handle while the therapist controlled the system using a HoloLens 2 mixed reality interface, as shown in Figures 1 and 2, to ensure that the rehabilitation routine was aligned with individual needs and safety requirements. The therapy commenced with passive exercises, where the operator (the person controlling the device) guided the participant's arm through controlled motions tailored to their range of motion to enhance joint mobility with minimal exertion. Subsequently, participants wore the HoloLens 2 to engage in mixed reality–based active game levels designed to simulate real-world tasks such as reaching for objects and performing repetitive hand movements, as shown in Figure 3. Depending on their abilities, participants performed active tasks with or without robotic assistance. The operator dynamically adjusted resistance levels to match the participant's progress, adding appropriate challenges to the tasks and enabling strength training through controlled resistance adjustments via the robotic rehabilitation system. Throughout the session, the operator monitored real-time data, including force exertion, robotic parameters, hand positioning, and motion trajectories, to adapt therapy settings for optimal challenge and safety. These metrics were recorded in real time and transmitted via a cloud-based system, allowing for detailed analysis of the participant's performance and interaction with the system. Real-time feedback was provided via live video communication, guiding participants on posture, movement quality, and task execution.

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Figure 1. Therapist controlling DMRbotV3 via the HoloLens 2 mixed reality interface, accessing real-time robot data, the participant's view, and a video call for seamless therapy interaction.

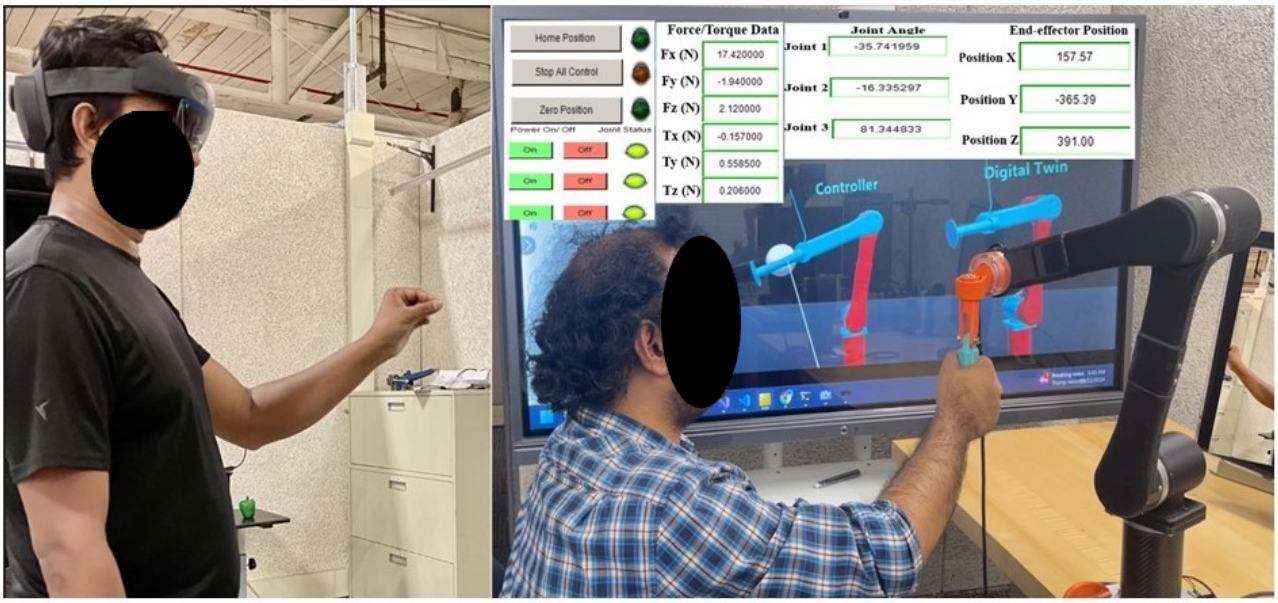
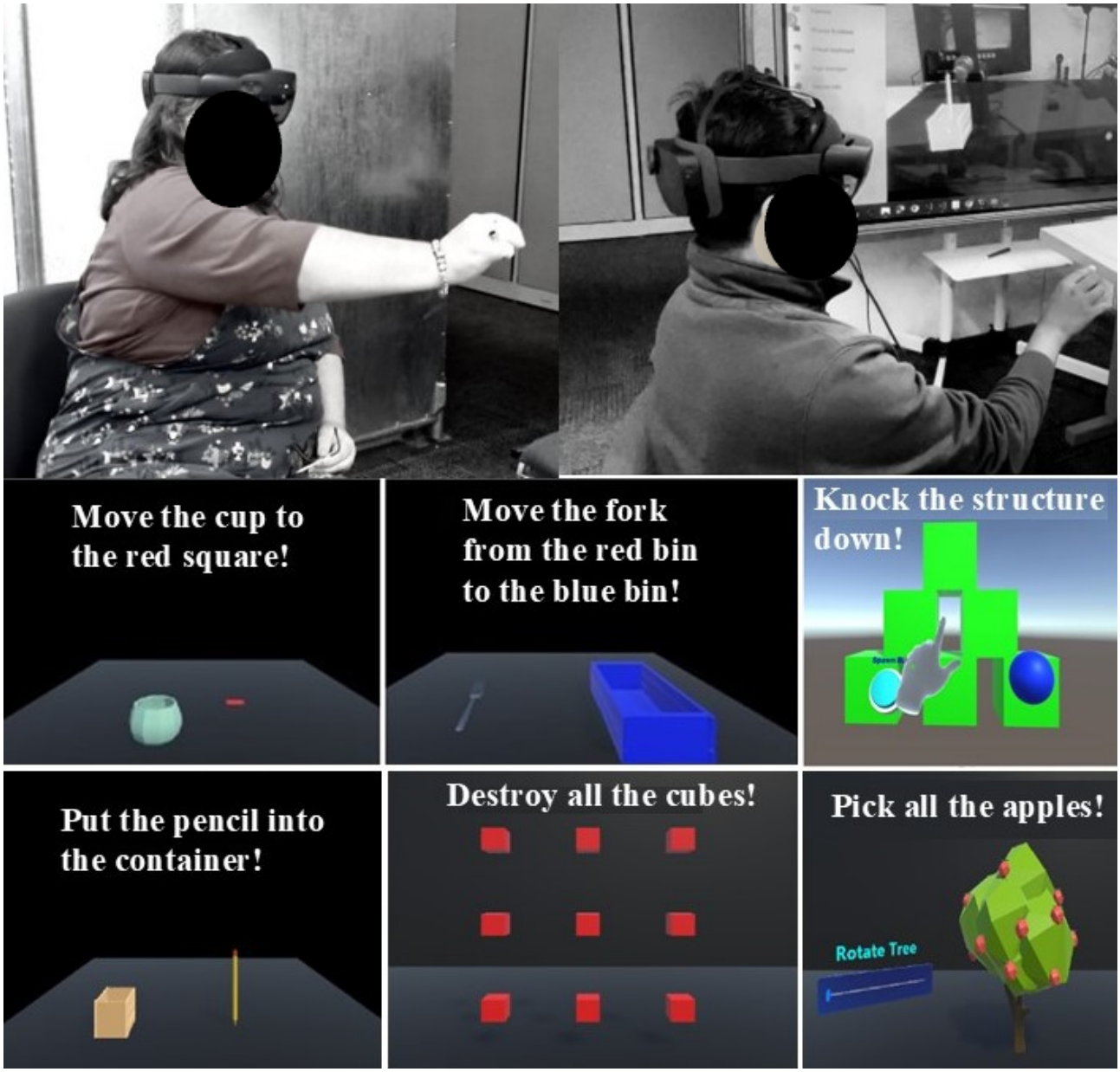


Figure 2. Participants in a remote therapy session within a simulated home environment, communicating with the therapist via video call to provide real-time feedback on the therapy session.



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Figure 3. Participants actively engaged in therapy sessions, using the HoloLens 2 to progress through various game levels.



After the tryout session, participants completed a customized 15-item usability questionnaire using a 5-point Likert scale to evaluate the platform's ease of use, usability, satisfaction, and user engagement. Items assessed multiple domains, including perceived effectiveness and usefulness, comfort and satisfaction with adjustability, and flexibility of use. Additional items focused on ease of use, such as following instructions, performing exercises, personalizing settings, and operating controls, as well as safety perceptions. Items were rated on a 5-point Likert scale (1="strongly disagree"; 5="strongly agree"). Established usability questionnaires were not adopted fully because several items were not directly relevant to the unique features and operational demands of an upper-limb robotic rehabilitation device.

In addition, participants provided subjective verbal feedback during sessions and engaged in open discussions with the operator. Integrating these qualitative insights with quantitative measures captured both the system's technical performance and user experience, yielding actionable feedback to refine the telerehabilitation platform for future applications.

Overview of the Telerehabilitation Platform

The architecture of the telerehabilitation platform consists of four main components: (1) hardware elements, including the DMRbotV3 and HoloLens 2; (2) software applications for mixed reality interaction and therapy control; (3) cloud-based IoT communication and data storage infrastructure; and (4) the exercise module, including passive, active, and resistive therapy games designed to adapt to user needs and deliver personalized upper-limb rehabilitation.

Hardware Elements

The telerehabilitation platform integrates a DMRbotV3 with a mixed reality HoloLens 2 application to deliver personalized therapy in a remote format. The configuration includes a mixed reality interface that enables precise control of the robotic rehabilitation system, real-time monitoring of therapy sessions,

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guidance of the DMRbotV3, and on-the-fly adjustments to therapy (exercise games) parameters. Specifically, the DMRbotV3 is a portable rehabilitation robot specifically designed for delivering physical therapy exercises. Equipped with a force sensor in its handle, it provides real-time feedback on the patient's arm stiffness, which helps the therapist assess and adjust exercises remotely. This force feedback enhances therapy customization and supports adaptive rehabilitation by allowing therapists to monitor patient response actively during sessions. The DMRbotV3 administers passive, active, and resistive therapy, whereas video communication tools support continuous feedback and instruction.

The HoloLens 2 [38] serves as a vital component of the telerehabilitation platform, providing an advanced mixed reality interface that enables immersive and hands-free rehabilitation. With its sophisticated sensors for hand tracking, eye tracking, and depth sensing, the device allows patients to interact with holographic guides and video game levels that provide precise instructions for therapeutic exercises. The headset can seamlessly integrate real-time feedback from the platform's data systems and offer immediate visual insights on metrics such as joint angles and range of motion, helping patients refine their movements for optimal rehabilitation outcomes. By incorporating gamified elements such as timed objectives and progress indicators, HoloLens 2 enhances engagement and motivation, making it an indispensable tool for effective remote rehabilitation.

Software Applications

Unity (Unity Technologies) is used to create the mixed reality environment and support 3D model import, enabling immersive user interfaces. The TwinCAT software (Beckhoff Automation) running on a PC interfaces with the DMRbotV3 to execute control commands and stream telemetry data. In addition, a Mixed Reality Toolkit 3 (MRTK3; Microsoft Corp)–based application on the HoloLens 2 manages therapy modes, facilitates user interaction, and provides real-time visualization.

Unity and Visual Studio (Microsoft Corp) [39] are essential components of the telerehabilitation platform, working together effectively to enable the development and deployment of immersive mixed reality applications. Unity, a versatile and powerful game engine, serves as the foundation for designing dynamic and interactive rehabilitation environments, integrating holographic elements with real-world interactions to emulate engaging user experiences. Visual Studio, a robust integrated development environment, enhances this process with advanced coding, debugging, and deployment tools optimized for HoloLens 2 compatibility. The synergy between Unity and Visual Studio ensures a streamlined workflow, allowing developers to build responsive and user-friendly applications that meet the platform's requirements for precision, adaptability, and patient engagement.

MRTK3 [40] is a critical component of the telerehabilitation platform, providing the foundational framework for developing immersive and interactive applications on HoloLens 2. This open-source toolkit from Microsoft offers a robust set of features, including prebuilt user interface elements, game objects, and scripts that enable robust interaction between patients and their mixed reality environment. MRTK3 simplifies the development process and allows for the creation of engaging, user-friendly interfaces tailored to rehabilitation needs. Its flexibility and customization options make it an indispensable tool for building gamified applications that improve patient engagement, ensure ease of use, and support the dynamic requirements of telerehabilitation.

Cloud-Based IoT Infrastructure and Data Storage

The telerehabilitation platform uses a cloud-connected IoT architecture built on Microsoft Azure to enable secure, real-time communication; data storage; and dynamic therapy adaptation. Azure IoT Hub serves as the central gateway for bidirectional messaging between the HoloLens 2 application and the DMRbotV3. When therapy commands are issued through the HoloLens 2 mixed reality interface, they are transmitted via Azure IoT Hub to a TwinCAT PC, which drives the robotic arm's therapeutic actions. Conversely, telemetry from the DMRbotV3, including joint states, force feedback, and movement data, is streamed back to Azure IoT Hub and securely logged in Azure Storage. This continuous data flow supports both live visualization on the HoloLens 2 interface and the creation of a DT of the DMRbotV3 within Unity, allowing therapists to monitor performance, adjust therapy parameters in real time, and ensure precise execution of exercises. By integrating authentication, data management, and session logging, the Azure cloud infrastructure provides a reliable foundation for adaptive, safe, and personalized upper-limb rehabilitation (Figure 4).

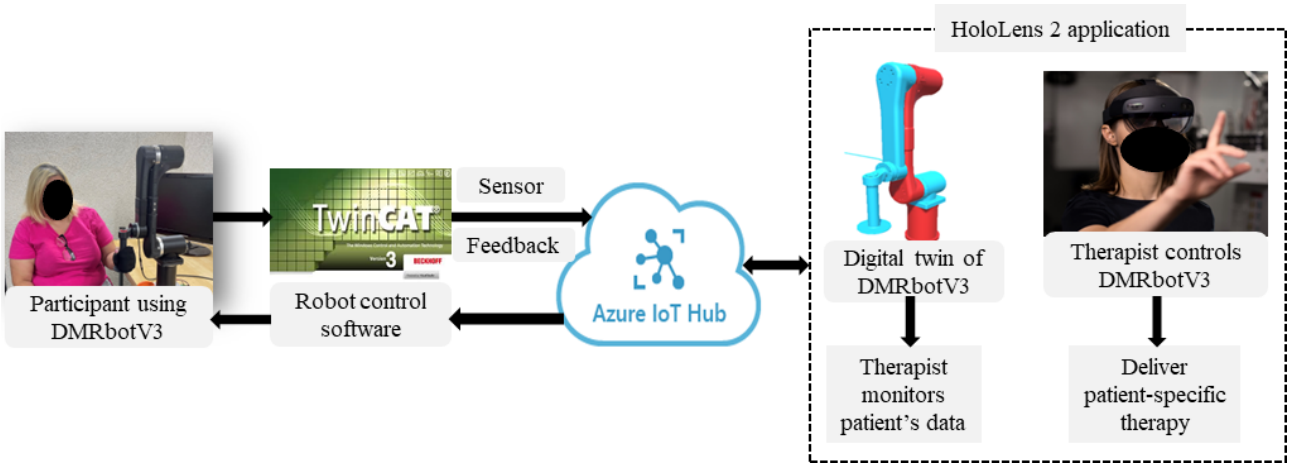
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Figure 4. Conceptual architecture of the Azure IoT–enabled telerehabilitation platform with Microsoft HoloLens 2 and Azure services.



A key feature of this system is the DT, which links a 3D model of the DMRbotV3 (developed in Unity) to live telemetry from the Azure IoT Hub. This integration allows for real-time synchronization between the physical robot and its virtual counterpart, enabling therapists to visualize the device's state, monitor patient performance, and adjust therapy parameters dynamically. By leveraging Azure's authentication, messaging, and storage services, the telerehabilitation platform cloud framework ensures seamless connectivity between operator and patient endpoints while maintaining high standards of data security, responsiveness, and clinical reliability (Figure 5).

Figure 5. Data flow diagram illustrating the integration of a robotic rehabilitation system with a telerehabilitation platform. IoT: Internet of Things.



System Development Summary

In summary, the telerehabilitation platform integrates multiple hardware, software, and cloud components into a seamless rehabilitation system. The DMRbotV3 serves as the robotic hardware delivering passive, active, and resistive exercise modules. The Microsoft HoloLens 2, running an MRTK3-based application, provides the mixed reality interface for therapist control, patient interaction, and visualization. This application is built in Unity, which also supports 3D model import, immersive environments, and integration of the DT of the DMRbotV3. The TwinCAT PC acts as the local controller, executing commands received from the HoloLens 2 via the Azure IoT Hub and streaming telemetry (forces and joint states) back through the same channel. Azure Cloud Services, including Azure Storage, manages authentication, secure data transfer, and session logging. The DT links Unity with live IoT telemetry, enabling real-time monitoring and adaptive adjustments. Finally, the exercise modules, covering passive, active, and resistive therapy, were developed within Unity and deployed through the HoloLens 2 application, ensuring synchronized execution by the DMRbotV3.

Therapy Modalities

Passive Therapy

Passive therapy is crucial for managing movement limitations and motor dysfunctions in survivors of stroke using therapist- or device-assisted movements to maintain joint flexibility and muscle elasticity while preventing stiffness and contractures. Techniques such as passive range-of-motion exercises help preserve mobility and reduce muscle atrophy, supporting long-term recovery potential [41]. The telerehabilitation platform leverages a HoloLens 2 control to implement passive therapy effectively for patients with stroke. Through HoloLens 2 control, operators (or therapists controlling the device) can manually guide the DMRbotV3 to perform specific passive range-of-motion stretching exercises, precisely adjusting the speed, direction, and range of motion. This control enables therapists to customize movements to the patient's needs, allowing for slow, controlled exercises that accommodate limited range of motion in the early stages of recovery. For

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remote sessions, the HoloLens 2 mixed reality interface offers a hands-free, interactive alternative where therapists can adjust the DMRbotV3's trajectory using holographic controls. This approach ensures that patients experience safe, consistent, and responsive movement guidance tailored to their rehabilitative needs.

Active Therapy

Active therapy is a critical component of poststroke recovery, enhancing motor control, functional independence, and psychological well-being through patient-driven movements [42]. The telerehabilitation platform incorporates MRTK3 game levels to facilitate active therapy, offering an engaging and interactive experience that motivates patients to participate in their rehabilitation either independently or with the assistance of DMRbotV3. This patient-centric mode includes 2 types of levels. The *eye–activities of daily living* levels involve practical activities such as moving a pencil, fork, and cup to designated areas in a virtual environment and simulating real-life actions to help patients practice essential movements. The *challenge* levels introduce playful elements such as picking apples from a tree, shooting targets, and knocking down structures with virtual objects in the HoloLens 2 environment, making therapy more enjoyable. These MRTK3 game levels are carefully tailored to the patient's abilities and designed to replicate real-world tasks such as reaching, grasping, and manipulating objects, fostering functional recovery through gamified interventions [18]. In this mode, patients rely on their own abilities to complete exercises, with the game levels dynamically changing based on their level completion. The mixed reality interface provides visual feedback, reinforcing proper movement patterns and enabling patients to monitor their progress. The game levels provide a structured progression that allows patients to start with basic tasks and advance to more complex movements as their abilities improve.

Resistive Therapy

Resistive therapy, a strength training approach that incorporates resistance against muscle contractions, is a critical component of poststroke rehabilitation [43]. In the telerehabilitation platform, resistive therapy is implemented through MRTK3 game levels, allowing patients to engage in familiar, interactive tasks while the DMRbotV3 applies moderate resistance to motion. This resistance requires patients to exert more force, actively engaging their muscles as they complete each task. By making the exercises progressively more challenging (changing the resistance level), the DMRbotV3 fosters muscle growth and improves functional strength, preparing patients for more physically demanding activities. The adjustable resistance levels allow for the provision of a tailored strength-building regimen aligned with each patient's specific recovery goals and capabilities [44].

Data Analysis

Data from three sources were analyzed: (1) sensor-based performance metrics from the DMRbotV3, including joint position, velocity, and interaction forces; (2) self-reported usability feedback from a customized usability questionnaire; and (3) observation of adverse events or concerns.

Sensor data were summarized using descriptive statistics (eg, means and ranges) to characterize the robotic system's performance during passive, active, and resistive exercises. Usability questionnaire responses were analyzed using descriptive statistics, with item-level mean scores and ranges calculated to evaluate overall usability and user satisfaction. Safety data were reviewed qualitatively to determine whether any adverse events or safety concerns arose during the study session.

The Mann-Whitney *U* test was applied as an exploratory analysis to compare usability scores between the groups of survivors of stroke and therapists.

Ethical Considerations

This study was approved by the Institutional Review Board at the University of Wisconsin–Milwaukee (application 22.220). All procedures complied with the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment following a thorough explanation of the study objectives, procedures, potential risks, and benefits. Participants were assured of confidentiality and their right to withdraw at any time without consequence.

Results

Sample Characteristics

This study included 6 participants: 3 (50%) stroke survivors and 3 (50%) occupational therapists. Survivors of stroke ranged in age from 57 to 73 years (all female), had had right- or left-brain stroke, had varying levels of education (elementary school to university), and were from diverse racial backgrounds (Hispanic and African American). Occupational therapists were younger (aged 23 - 29 years), represented both genders, and had education at the university or graduate level. Their racial backgrounds included Asian and non-Hispanic White. Table 1 provides the demographic characteristics of the study sample.

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Table . Demographic data of the participants.

ID[a]	Age (y)	Side of the brain affected	Sex	Dominant hand	Educational level	Race
PS1	57	Right	Female	Left	University	Hispanic
PS2	73	Left	Female	Right	Elementary school	Hispanic
PS3	69	Left	Female	Right	High school	African American
OT1	29	—[b]	Male	Right	Graduate school	Asian
OT2	23	—	Female	Right	University	Non-Hispanic White
OT3	24	—	Female	Right	University	Asian

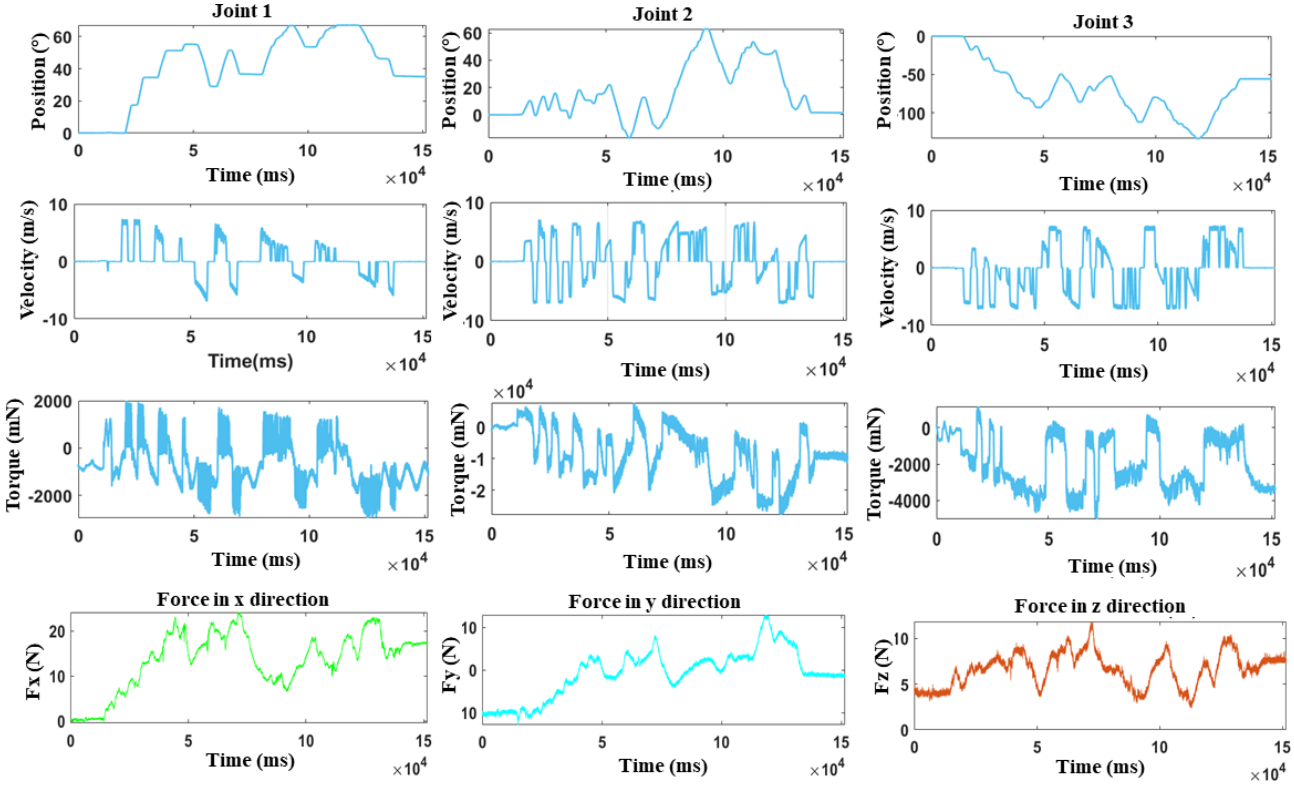
[a]"PS" refers to patients with stroke, and "OT" refers to occupational therapists.

[b]Not applicable.

Robot Parameters

The robot metrics, which include joint position, velocity, and torque, demonstrate the system's smooth and accurate performance during the multijoint upper-limb workout (Figure 6). Positions for joint 1, joint 2, and joint 3 varied from 0° to 65°, 0° to 60°, and 0 to −120°, indicating a regulated and acceptable range of motion for therapeutic purposes. Velocity profiles across the 3 joints showed comparable oscillatory patterns, with joint 1 to joint 3 functioning in the −10 to +10 m/s range, demonstrating dynamic flexibility. The torque data showed that joint 1 and joint 3 maintained torque levels ranging from −2000 to +2000 mN, but joint 2 had larger torque changes between −4000 and +4000 mN, indicating its function in managing more strenuous lateral and stabilizing activities. These robotic parameters supported the system's capacity to move precisely, steadily, and smoothly, indicating its appropriateness for therapeutic applications.

Figure 6. DMRbotV3's joint position, velocity, torque, and participant force data profiles during HoloLens 2 control for multijoint upper-limb exercises, showcasing smooth robotic movements.



The participant force data collected in the x-, y-, and z-axes showed active engagement and physical interaction with the robotic system. Forces applied in the x direction varied from 0 to +25 N, showing that participants exerted substantial effort when moving forward and backward. Forces in the y direction ranged from −10 N to +12 N, representing dynamic lateral motion, whereas forces in the z direction ranged from 0 to +15 N, indicating modest participation in vertical motions such as raising or lowering. The oscillatory patterns in all force directions demonstrated persistent participation, which is essential for motor recovery and strengthening. These results show that the system may provide robot-assisted motions, which are critical for accomplishing rehabilitation goals, including increased strength, coordination, and range of motion.

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Participant Usability Feedback

Overall, mean scores across items ranged from 3.66 to 4.83 (average SD 0.70), indicating high levels of usability, satisfaction, and perceived safety (Table 2). Participants provided consistently high ratings for the device's effectiveness and usefulness, with mean scores of 4.66 (SD 0.51) for assisting rehabilitation needs (question 1) and 4.83 (SD 0.40) for its overall usefulness (question 2). These findings indicate a strong confidence in the device's ability to support rehabilitation goals. Comfort during rehabilitation sessions (question 3; mean 4.00, SD 1.26) and satisfaction with the device's range of motion and adjustability (question 4; mean 4.66, SD 0.51) were also highly rated, reflecting the device's capacity to accommodate a variety of movement requirements effectively.

Table . Experience evaluation questions, including the mean, SD, and *P* value for each item response from all participants, with each score ranging from 0 to 5.

Item	Question	Score, mean (SD)	*P* value
1	"How effective do you feel the rehab device is in assisting your rehabilitation needs?"	4.66 (0.51)	.60
2	"How useful do you think this rehab device is?"	4.83 (0.40)	.26
3	"How comfortable did you feel using the rehab device during your rehabilitation sessions?"	4.00 (1.26)	.44
4	"How satisfied are you with the range of motion and adjustability provided by the rehab device during your rehabilitation exercises?"	4.66 (0.51)	.60
5	"How would you rate the durability and reliability of the rehab device for long-term use in your rehabilitation journey?"	4.50 (0.54)	.60
6	"How do you rate the flexibility of using this rehab device?"	4.16 (0.75)	.26
7	"How easy was it to follow the instructions provided while using the rehab robot?"	4.66 (0.51)	>.99
8	"How easy was it to engage in the upper limb exercises facilitated by the rehab robot?"	4.50 (0.54)	.69
9	"How easy was it to personalize the settings and parameters of the rehab robot to suit your needs?"	3.66 (1.21)	.26
10	"How easy was it to operate the controls and interfaces of the rehab robot?"	4.50 (0.54)	.09
11	"How easy was it to adjust the rehab robot's range of motion or movement patterns?"	4.66 (0.51)	>.99
12	"How easy was it to adjust the resistance levels of the rehab robot according to your abilities?"	4.33 (0.51)	.60
13	"How would you rate the ease of use and user-friendliness of the rehab device?"	4.50 (0.54)	.69
14	"How do you rate the safety of this rehab device?"	4.33 (1.21)	>.99
15	"How comfortable did you feel using the rehab device during your rehabilitation sessions?"	4.23 (0.89)	.55

The durability and reliability of the device for long-term use were favorably perceived, with a mean score of 4.50 (SD 0.54), highlighting participants' trust in the device's construction for extended use. The flexibility (question 6; mean 4.16, SD 0.75)

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and user-friendliness (question 13; mean 4.50, SD 0.54) scores further underscored its ability to cater to diverse user needs. The device's controls and interfaces were deemed easy to operate (question 10; mean 4.50, SD 0.54), although some participants indicated that personalizing the settings (question 9; mean 3.66, SD 1.21) could require additional support or training. The device's adjustability for movement patterns (question 11; mean 4.66, SD 0.51) and resistance levels (question 12; mean 4.33, SD 0.51) was positively rated, demonstrating its adaptability to different rehabilitation exercises and user abilities. In addition, participants expressed high satisfaction with the device's safety (question 14; mean 4.33, SD 1.21) and overall comfort during use (question 15; mean 4.23, SD 0.89), indicating trust and comfort during rehabilitation sessions.

Discussion

Principal Findings

This study conducted a preliminary evaluation of the usability of a telerehabilitation platform in upper-limb neurorehabilitation. Overall, the results indicated that the system was safe and well tolerated, with no adverse events reported. All participants completed the session, and usability scores averaged ≥4.0 across all items, reflecting high satisfaction and strong engagement with mixed reality integration. The robot demonstrated smooth joint movements within a defined speed range in both directions and could apply resisting forces up to approximately 25 N (2.5 kg). In practice, this means that, if a patient is weak, the robot provides greater assistance, whereas if the patient is strong, it increases resistance to provide a greater challenge. This adaptability is critical for progressive therapy, ensuring that patients are neither under- nor overchallenged.

This study investigated the integration of the DMRbotV3 telerehabilitation platform with HoloLens 2, focusing on its potential to provide upper-limb therapy to survivors of stroke. The findings highlight the transformational effects of merging mixed reality technology with a robotic rehabilitation system, notably increasing patient involvement and encouraging autonomy during therapy. By allowing for personalized therapies in home-based settings, the system solves essential obstacles such as geographical constraints and restricted mobility, considerably enhancing accessibility. Participants expressed great satisfaction with the system's operation, as evidenced by an exceptional experience assessment score, and emphasized its potential to aid in long-term rehabilitation. The DMRbotV3 system demonstrated exceptional safety, with no adverse incidents reported. Although this study was conducted under therapist supervision in a simulated home environment and did not test unsupervised self-installation, the good performance observed of the system underscores that prioritizing safety (eg, bounded workspaces, responsive stops, and clear feedback) is central to designing home-deployable robotic systems. This emphasis aligns with broader trends toward improving health care accessibility, reducing supervision burden, and advancing patient-centered care.

Our findings are directionally consistent with evidence that robot-assisted upper-limb rehabilitation can deliver high-intensity, repetitive, task-specific practice associated with functional gains in stroke populations while reducing therapist physical burden when appropriately dosed [8-11]. Mixed reality guidance using HoloLens has demonstrated feasibility for spatial cues, hands-free visualization, and improved engagement in rehabilitation contexts [8-11]; this study extended this by coupling mixed reality tasking directly with instrumented, multimode robotic assistance and live telemetry for on-the-fly tuning. Previous telerehabilitation efforts and serious game platforms have reported enhanced motivation and remote monitoring [8-11]; in this study, the combination of mixed reality guidance and graded robotic support and resistance allowed us to preserve safety envelopes—defined as the predefined limits on kinematics and interaction forces that the system will not exceed (eg, workspace/range-of-motion boundaries and velocity)—while keeping sessions interactive. Finally, emerging DT frameworks emphasize remote visualization, logging, and data-driven personalization [8-11]; our cloud-synchronized twin mirrored joint states and interaction forces in real time, enabling therapist visibility and rapid parameter adjustments during the session. The unique value of the telerehabilitation platform lies in its innovative combination of DMRbotV3, mixed reality environments, and real-time data monitoring through DT technology. The system's seamless integration allows for remote therapy sessions with therapist-guided adjustments via HoloLens 2 supported by low latency (approximately 90 ms) [45]. Gamified, task-oriented exercises in the mixed reality environment provide an engaging therapeutic experience while delivering quantitative feedback to both therapists and patients, enabling data-driven adjustments tailored to individual recovery needs. With dynamic, bidirectional communication facilitated by the Azure IoT Hub, the telerehabilitation platform offers a level of adaptability and responsiveness that distinguishes it from conventional rehabilitation systems.

The DMRbotV3 ensures user safety through multiple hardware and software features. Hardware safety features include adjustable mechanical stoppers for personalized joint limits; software safety features are added in the controller that include limiting the joints' ranges of movements depending on the participant's requirements and limiting the joints' speed, torques, and voltage values, which are the final output of the controller and the command values to the motor. To take advantage of a secure cloud platform and support minimally supervised operation, the system was deployed on HIPAA (Health Insurance Portability and Accountability Act)-eligible Microsoft Azure services, using a data minimization strategy in which only deidentified device telemetry (forces, kinematics, and system events) was stored in Azure, and the reidentification key was maintained off-cloud on an encrypted, access-restricted drive [46]. Data were protected in transit via Transport Layer Security 1.2 and at rest via 256-bit Advanced Encryption Standard with HTTPS-only end points; access was governed by role-based access control on a least-privileged basis with multifactor authentication [47]. Device- and message-level security used distinct IoT identities and time-limited shared access signature tokens. Storage firewalls and private end points limited network exposure, and Azure Monitor provided continuous auditing and alerts. HoloLens 2 needs calibration,

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which is done automatically in seconds (<10 seconds) when a user wears it. When the internet connection was lost during a rehabilitation exercise, the connection between HoloLens 2 and DMRbotV3 was interrupted; the session stopped, and DMRbotV3 returned to its home position at a slow, controlled speed to ensure patient safety. After reconnecting to the internet, the connection between HoloLens 2 and the DMRbotV3 was re-established automatically, and the patient and therapist were notified. We tested the Azure cloud with a Microsoft server in the eastern United States (in Virginia, 1376 km from the BioRobotics laboratory in Milwaukee) to execute bidirectional data transfer between DMRbotV3 and HoloLens 2 in real time. The robotic rehabilitation system facilitates safe and controlled movement execution, providing real-time feedback on critical metrics such as patient arm force and robotic parameters. This dynamic feedback mechanism fosters a highly adaptable and responsive rehabilitation environment, effectively accommodating a wide range of recovery needs.

Unlike many commercial or laboratory-stage systems that emphasize single-mode assistance, 2D movements, or strictly in-clinic operation, our platform integrates 3 therapy modes (passive, active, and resistive) with mixed reality task guidance and a cloud-synchronized DT in a portable, desktop-mounted robot, explicitly designed for remotely supervised care. This end-to-end integration reduces the gap between engaging interfaces and precise physical assistance and addresses common gaps in prior systems (limited mode sets, constrained workspaces, and lack of telerehabilitation functionality) highlighted in the Introduction section [8-11]. Participants' confidence in safety and their reports of autonomy and flexibility speak to the promise of minimally supervised or home-based use. Nonetheless, this study did not evaluate unsupervised patient or caregiver self-installation.

This study's strengths include its innovative system design, which bridges critical gaps in traditional and emerging rehabilitation methods, and its focus on user-centered evaluation. This study assessed the system's functionality and impact by collecting both qualitative feedback and quantitative data. However, the limited sample size and single-session design are notable weaknesses as they restrict the generalizability of the findings and preclude analysis of long-term therapeutic outcomes. Future studies should aim to conduct longitudinal evaluations with more extensive and diverse participant groups to validate the system's effectiveness and usability over extended periods. Further research could explore the integration of artificial intelligence to enable adaptive learning based on patient progress, enhancing the system's ability to deliver personalized therapy.

This study has several limitations that should be considered when interpreting the findings. First, the sample size was small and limited to a single site, which restricts the generalizability of the results to broader populations of survivors of stroke and rehabilitation practitioners. Second, the evaluation was conducted in a simulated laboratory environment rather than in patients' homes or clinical settings, meaning that real-world usability, accessibility, and logistical challenges may not have been fully captured. Third, this study focused primarily on short-term usability during a single 2-hour session; longer-term use is necessary to evaluate sustained engagement, adherence, and potential therapeutic benefits. Fourth, while the customized usability questionnaire provided device-specific insights, the absence of standardized scales such as the System Usability Scale or Quebec User Evaluation of Satisfaction With Assistive Technology limits comparability with other studies in the field. Finally, this study emphasized subjective usability and safety outcomes but did not include objective clinical measures of motor recovery or functional improvement, which will be essential for future trials assessing therapeutic efficacy.

Conclusions

This study introduced an innovative telerehabilitation platform integrated with a robotic rehabilitation system to provide a comprehensive framework for remote upper-limb therapy. The proposed system leverages advanced technologies, including mixed reality through HoloLens 2, gamification for engagement, and DT technology for real-time data monitoring and therapist interaction. A key strength of this system is its ability to deliver diverse therapy modes, such as passive, active, and resistive, allowing for tailored rehabilitation routines that adapt to individual patient needs and recovery stages. The experimental results demonstrated that the telerehabilitation platform offers a promising alternative to traditional in-person rehabilitation, addressing common barriers such as geographical and logistical constraints. Participant feedback reflected high satisfaction with the device's usability, adaptability, and safety, suggesting the telerehabilitation platform's potential to enhance engagement and adherence in home-based rehabilitation. Further research with a larger and more diverse participant sample, including control groups and extended intervention periods, would provide valuable insights into the system's long-term effectiveness and comparative performance against traditional rehabilitation methods while identifying factors to enhance neurorehabilitation outcomes. In addition, integrating machine learning algorithms to analyze patient data and optimize therapy delivery presents an exciting opportunity to advance personalization and improve therapeutic efficacy, paving the way for more precise and impactful rehabilitation solutions.

Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

DT: digital twin
HIPAA: Health Insurance Portability and Accountability Act
IoT: Internet of Things
MRTK3: Mixed Reality Toolkit 3
VR: virtual reality

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Review

Telerehabilitation in Postoperative Breast Cancer Care: Systematic Review and Meta-Analysis

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Abstract

Background: Postoperative rehabilitation is essential to improve quality of life (QoL), pain control, and upper limb function in women undergoing surgery for breast cancer (BC). Telerehabilitation has emerged as a promising alternative to conventional rehabilitation, especially in patients with limited access to care, but its comparative efficacy remains uncertain.

Objective: This study aimed to evaluate the effectiveness of telerehabilitation compared with standard care or no treatment in improving QoL, pain, handgrip strength, and upper limb function in women undergoing BC surgery.

Methods: We conducted a systematic review and meta-analysis following PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 guidelines. We included 11 randomized controlled trials, of which 5 were eligible for quantitative synthesis. Risk of bias was assessed using the Cochrane risk-of-bias tool for randomized trials version 2 (RoB2), and the certainty of evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation approach. Outcomes assessed included QoL, pain, grip strength, and upper limb function.

Results: Telerehabilitation significantly improved QoL (standardized mean difference [SMD] 0.59; 95% CI 0.24-0.95; moderate certainty) and grip strength (mean difference [MD] 2.93; 95% CI 0.82-5.04 kg; low certainty), and significantly reduced pain (SMD –0.50; 95% CI –0.79 to –0.22; low certainty). No significant difference was observed for upper limb function (SMD –0.86; 95% CI –2.02 to 0.31; low certainty).

Conclusions: Telerehabilitation is an effective and viable intervention for improving QoL, reducing pain, and enhancing grip strength in women following BC surgery. However, its impact on upper limb function remains inconclusive and requires further investigation.

Trial Registration: PROSPERO CRD42024545075; https://www.crd.york.ac.uk/PROSPERO/view/CRD42024545075

(JMIR Rehabil Assist Technol 2025;12:e77161) doi:10.2196/77161

KEYWORDS

telerehabilitation; physiotherapy; breast cancer; postoperative care; quality of life; pain; upper limb function; randomized controlled trial

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Introduction

Breast cancer (BC) is the most frequently diagnosed cancer in women: an incidence analysis of 2020 reported that BC became the most frequently diagnosed cancer worldwide, with an estimation of 2.26 million of new cases [1]. In Italy, it is the neoplasm with the highest incidence and represents the main cause of death from cancer in women [2]. Therefore, some recent predictions and analyses [3,4] suggested that the incidence of new cases will increase to over 3 million cases annually by 2040. Due to its high incidence and future predictions, BC is considered a cause for global concern.

Advances in early diagnosis and treatment have led to increased survival after diagnosis, resulting in many more women living with the outcomes of surgical treatment of the condition. The disorders most frequently encountered after breast surgery are postoperative pain (68% of patients), followed by musculoskeletal problems and functional limitations in the shoulder (59% of the population after mastectomy and quadrantectomy) and a reduction in range of motion (ROM) and muscle strength in 24%-53% [5]. Other complications reported include "axillary web syndrome," which can cause pain and movement limitations [6]; lymphedema reported with a prevalence of 6%-52% especially after axillary lymph node dissection; kinematic alterations that may contribute to the future development of rotator cuff tendinopathy [7]; scapulohumeral dyskinesia, proprioception deficit, postural alterations and reduction in perceived quality of life (QoL) [8].

Literature suggests that early postoperative exercise is safe and can improve shoulder function; however, uncertainty remains regarding the optimal type and dosage, timing of delivery, and effectiveness in terms of cost-benefit ratio of the rehabilitation intervention [9-11].

Among the various rehabilitation approaches, telerehabilitation has shown its effectiveness in ensuring continuity in the care of fragile patients, and after BC surgery during the SARS COVID-19 pandemic period [12]. However, telerehabilitation seems to represent an alternative for all those patients who have difficulty reaching treatment locations, minimizing barriers, such as distance, time, and costs, and facilitating rapid and reducing costs, even after the pandemic era [13,14].

Recent systematic reviews (SRs) have investigated the use of telerehabilitation [15] or eHealth systems [16], such as videoconferencing or counseling and their impact on patients: in the review with meta-analysis conducted by Peng et al [15], telerehabilitation seems to have a significantly positive effect on physical activity (PA), performance, fatigue, and QoL compared with the usual care. Therefore, it is important to highlight that anthropometric body composition and pain did not differ significantly between the 2 groups: these data could confirm the noninferiority of telerehabilitation compared with usual care.

Therefore, eHealth seems to also have a positive impact on psychosocial domains: Wen et al [16] highlight that patients undergoing eHealth have a significantly higher QoL and an improvement in physical and social roles and emotional domains of QoL, even if these subitems have not reached statistical significance.

However, SRs [15-18] have not analyzed the effectiveness of this treatment in improving pain, QoL, or function in this population, despite several studies having been published on the topic [12,19,20]. Therefore, summarizing the results obtained from the studies becomes fundamental to verify the possibility of using this approach as a rehabilitation method for patients post BC surgery.

The main goal of this SR is to investigate the effects of telerehabilitation treatment in women undergoing surgery for BC, in the recovery of QoL. The primary aim is to determine whether telerehabilitation improves QoL compared with (1) conventional, center-based rehabilitation and (2) no rehabilitation. Secondary aims are to assess the effects of telerehabilitation on pain, upper-limb function, shoulder ROM, body composition or weight, and postoperative complication rate, relative to (1) conventional rehabilitation and (2) no rehabilitation.

The hypothesis is that telerehabilitation will be noninferior to conventional rehabilitation and superior to no rehabilitation for QoL; for secondary outcomes, effects will be comparable with conventional care and greater than no rehabilitation, with similar complication rates between telerehabilitation and conventional care, and higher where no rehabilitation is provided.

Methods

A comprehensive literature review was conducted, accompanied by a meta-analysis, in accordance with the methodological principles set forth in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist (Multimedia Appendix 1) [21].

Search Strategies

A bibliographic search was performed on July 23, 2024, using the following databases: US National Library of Medicine (PubMed or MEDLINE), SCOPUS, Web of Science, and the Cochrane Database of Systematic Reviews. No temporal restrictions were applied for the inclusion of articles. The study question was framed using the Population, Intervention, Comparison, and Outcome (PICO) model [22] available in Table 1. Medical Subject Headings terms and keywords were used for the search string, in accordance with the specifications of each consulted database (Multimedia Appendix 2). To strengthen the research, reference lists from both the selected studies and pertinent literature reviews on the subject were examined as well. The primary goal was to investigate the effects of telerehabilitation treatment compared with other forms of treatment and with no treatment in terms of pain, upper limb functionality, and QoL. The secondary goal was to determine if there is a difference in the rate of complications among those who underwent telerehabilitation treatment, other forms of treatment, or no treatment.

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Table 1. Population, Intervention, Comparison, and Outcome model.

Domain	Description
Population	Women undergoing surgery for breast cancer
Intervention	Tele-rehabilitation treatment
Comparison	Other treatments, no treatment
Outcomes	Improvement in terms of QoL[a], pain, function, complications incidence, and body weight composition

[a]QoL: quality of life.

Eligibility Criteria

This SR included (1) articles in English and Italian; (2) randomized controlled trials (RCTs); (3) studies that included a population of adult women (age >18 y) who underwent surgery for BC; (4) telerehabilitation treatment versus other types of treatment or no treatment; and (5) studies that measured the effects of the treatments in the domains of QoL, pain, function, complications incidence, and body weight composition.

All RCT studies that included a group undergoing telerehabilitation treatment compared with one or more groups undergoing other types of treatment or no treatment were included. Telerehabilitation treatment refers to all rehabilitation interventions delivered remotely, even without direct supervision by health care personnel. Telemonitoring interventions (eg, monitoring of symptom variations such as pain and exercise-related fatigue) were also included.

All publications that had one or more of these elements were excluded: (1) articles written in languages other than English or Italian; (2) non-RCT studies, observational studies, case reports, case series, narrative reviews and overviews, study protocols, SRs, meta-analyses, and gray literature; (3) pediatric population (age <18 y); and (4) conference papers.

Selection Process

Duplicates were initially identified and removed using the Rayyan web app for SRs [23]. Two reviewers (FS and BC) independently assessed the titles and abstracts to determine their eligibility. At the end of this phase, the 2 reviewers examined, always independently, the full text of the articles to verify their eligibility criteria. After selecting the studies to include, data were extracted. Any discrepancies or disagreements between the 2 reviewers in the previous phases were discussed and resolved with the help of a third reviewer (MB).

Study Risk of Bias Assessment

The Cochrane risk-of-bias tool for randomized trials version 2 (RoB 2) [24] was used to assess articles included in this SR. To consider all potential areas of bias, the 5 items of the tool (the randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result) were evaluated as “low,” “some concerns,” or “high.” A proposed judgment about the risk of bias arising from each domain is generated by an algorithm based on answers to the signaling questions. Two authors (FS and BC) independently evaluated the RCTs included. Any disagreements that arose between the primary 2 reviewers were resolved through discussion or with a third reviewer (MB).

Statistical Analysis

For continuous variables, the mean was calculated according to the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions version 6.3 [25]. If the results were reported as median, IQR, mean value, or 95% CI, a conversion was applied. For studies with incomplete or not directly accessible data, an attempt was made to contact the corresponding author for feedback. In case of no response or inability to provide further data, the articles were excluded from the review. A random-effects model was used a priori due to anticipated clinical and methodological heterogeneity among included studies, including differences in intervention duration and outcome measures. This choice is consistent with recommendations that the use of random-effects models should be based not only on statistical heterogeneity, but also on conceptual considerations [26]. We prespecified subgroup analyses for follow-up time (end of treatment, approximately 12 weeks and 24 weeks) in outcomes reported at multiple timepoints. Where sufficient data were available (≥3 studies per subgroup), we also planned subgroups by outcome instrument family (eg, Functional Assessment of Cancer Therapy vs European Organisation for Research and Treatment of Cancer [EORTC] for QoL) to examine whether the choice of measurement tool influenced pooled effects. Additional subgroup or sensitivity analyses (eg, by comparator type—standard care vs no rehabilitation and by telerehabilitation delivery mode—synchronous, asynchronous, and hybrid) were considered exploratory and conducted only when ≥2 studies informed each category. All analyses were performed using Review Manager (RevMan) version 5.4 (Cochrane Collaboration, 2020), which was used for meta-analyses, forest plots, and chi-square tests for subgroup differences. GRADEpro (guideline development tool; Evidence Prime) was used to generate evidence profiles and a summary of findings.

Certainty of Evidence

The certainty of evidence for each outcome was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [27]. In total, 5 domains were considered: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Evidence profiles and summary of findings tables were generated with the GRADEpro guideline development tool.

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Results

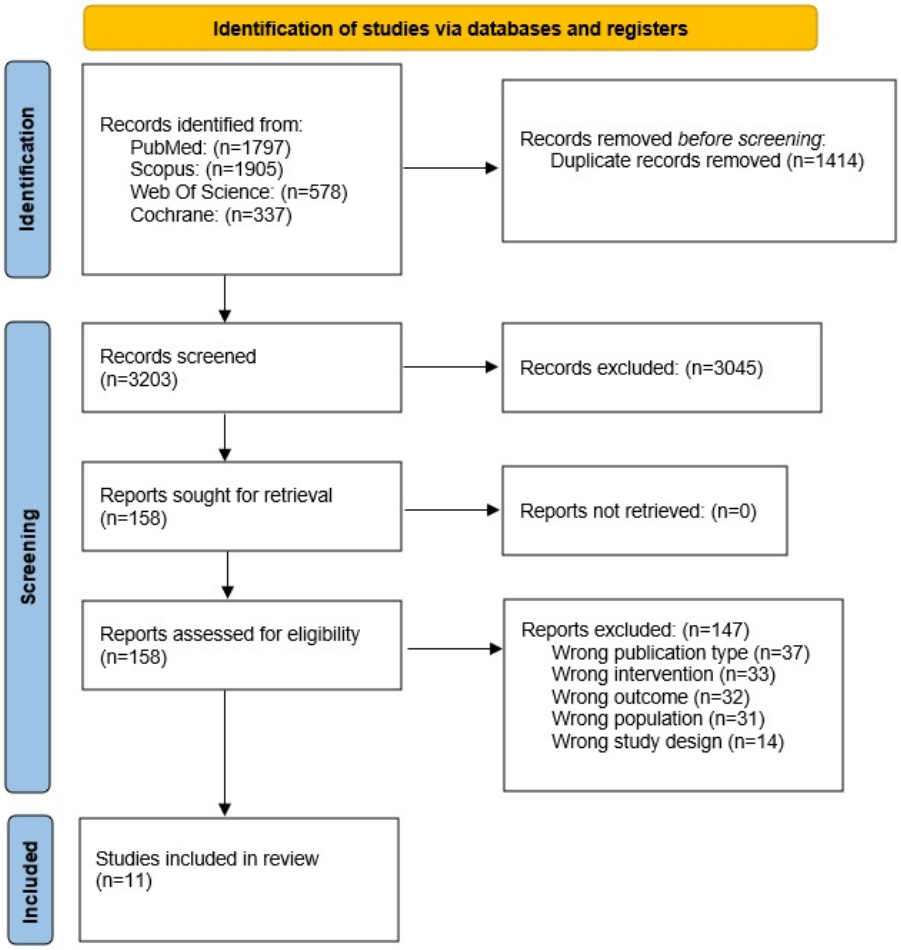
Study Selection

A total of 4617 studies were found after the systematic search of online databases. From duplicate analysis conducted using Rayyan online software, 1414 articles were deleted.

After the analysis of title, abstract, and keywords, 3045 articles were excluded since they did not meet the inclusion criteria (background article: 1777, wrong outcome: 527, wrong publication type: 383, wrong study design: 253, wrong population: 133, wrong drug: 43, and foreign language: 11). Therefore, 158 articles were analyzed in detail through full text screening to verify their eligibility: 37 studies were excluded due to the publication type (ie, study protocol), 14 were excluded because the study design did not meet the inclusion criteria, 31 articles were excluded because their population was different from patients undergoing BC surgery, 33 articles were excluded because their intervention did not meet the PICO question, and 32 articles were excluded because the outcomes did not meet the PICO question and the inclusion criteria. At the end of the screening process, 11 RCTs [28-38] were selected as they met all the eligibility criteria.

The study selection process and the included trials are reported in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



Study Characteristics

A total of 11 RCT studies [28-38] were included and summarized in this SR.

The articles were published between 2016 [30] and 2023 [36,37]. A total of 748 women who underwent BC surgery were enrolled in the control and experimental groups. Table 2 summarizes the sociodemographic and clinical characteristics of participants across the included studies.

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Table 2. Sociodemographic characteristics.

Study	Country	N		Age (y), mean (SD)		Gender	Cancer stage, n (%)	Surgery type, n (%)
		Intervention	Control	Intervention	Control			
Çınar et al [28]	Turkey	31	33	45.7 (9.0)	45.9 (8.3)	Women only	• 1: 9 (29) vs 12 (36.4) • 2: 12 (38.7) vs 12 (36.4) • 3: 10 (32.3) vs 9 (27.2)	• Mastectomy 38.7% (12/31) vs 36.4% (12/33) • BCSa 61.3% (19/31) vs 63.6% (21/33)
de Aviz et al [38]	Brazil	24	20	48 (6)	52 (7)	Women only	• 1-3 (eligibility)	• Mostly quadrantectomy • Axillary dissection frequent
Dong et al [29]	China	26	24	48.0 (5.5)	51.6 (7.5)	Women only	• 1: 6 (23.1) vs 10 (41.7) • 2: 18 (69.2) vs 10 (41.7) • 3: 2 (7.7) vs 4 (16.7)	• Not specified
Galiano-Castillo et al [30]	Spain	40	41	47 (10)	46 (10)	Women only	• 1: 28 (34.6) • 2: 42 (51.9) • 3A: 10 (13.5)	• Lumpectomy 42% (34/81) • Quadrantectomy 34.6% (28/81) • Mastectomy 23.5% (19/81)
Galiano-Castillo et al [31]	Spain	40	41	47 (10)	46 (10)	Women only	• 1: 28 (34.6) • 2: 42 (51.9) • 3A: 10 (13.5)	• Lumpectomy 42% (34/81) • Quadrantectomy 34.6% (28/81) • Mastectomy 23.5% (19/81)
Hou et al [32]	Taiwan	53	59	—[b]	—	Women only	• 2 (most frequent): 44 (39.3)	• BCS 67.9% (76/112) • Chemo 65.2% (73/112) • RTb 66.1% (74/112) • Endocrine 53.6% (60/112)
Loubani et al [33]	Israel	18	17	48.0 (11.1)	52.1 (12.8)	Women only	• 1: 2 (11.1) vs 6 (35.3) • 2: 10 (55.6) vs 5 (29.4) • 3: 6 (33.3) vs 6 (35.3)	• Lumpectomy 55.6% (10/35) vs 76.5% (13/35) • Mastectomy 44.4% (8/35) vs 23.5% (4/35)
Ochi et al [34]	Japan	25	25	48 (6)	49 (5)	Women only	• 1: 36 (72) • 2A: 14 (28)	• Not specified
Park et al [35]	South Korea	50	50	42.6 (9.1)	47.3 (8.6)	Women only	• Not reported	• ALNDc 44% (22/100) vs 34% (17/100) • Immediate reconstruction 78% (78/100) both groups
Swartz et al [36]	United States	10	10	63.8 (6.4)	63.8 (6.4)	Women only	• Stage 0: 2 (11.1) • 1: 8 (44.4) • 2: 4 (22.2) • 3: 4 (22.2)	• Mixed, not detailed (with adjuvant CTd/RT)
Zhou et al [37]	China	56	55	49.84 (8.8)	49.98 (9.8)	Women only	• 1: 34 (30.6) • 2: 59 (53.2) • 3: 18 (16.2)	• MRMe 36% (40/111) • Total mastectomy 45.9% (51/111)

[a]BCS: breast-conserving surgery.

[b]Not available.

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[b]RT: radiotherapy.

[c]ALND: axillary lymph node dissection.

[d]CT: chemotherapy.

[e]MRM: modified radical mastectomy.

The interventions analyzed were highly heterogeneous regarding the types of instruments used, training frequency, intensity, and duration. However, they can be classified according to the method of therapy delivery.

In total, 5 studies [28,29,32,34,38] based their interventions on mobile apps, albeit in different therapeutic approaches. For instance, Çınar et al [28] designed a mobile app that offered information, advice, and consultations from qualified nurses, alongside daily reminders. In contrast, Dong et al [29] used a step-tracking app for monitoring PA, complemented by remote video instructions for muscle training and supportive messages via social media, while de Aviz et al [38] performed an asynchronous treatment with the sending of exercises via instant messaging app, in order to induce physical improvements, in the QoL and reduce fatigue and pain in postoperative patients with BC.

Only the studies of Galiano-Castillo et al [30,31] focused on a web-based intervention, using the e-CUIDATE system, which provided a personalized exercise program accessible through a secure online interface, while Zhou et al [37] used a multimodal care program via WeChat (Tencent Holdings Limited), including relaxation training, expression of feelings, and social support.

The remaining studies [33,35] combined several rehabilitation interventions: Park et al [35] used the Xbox One Kinect (Microsoft), integrating it with virtual reality experiences; Loubani et al [33] blended clinical sessions with home-based telerehabilitation through the Kinect-based CogniMotion system (ReAbility Online, Gertner Institute, Sheba Medical Center, Ramat Gan, Israel) for both motor and cognitive exercises, while Swartz et al [36] combined virtual exergaming via SecureVideo with PA behavioral coaching.

It is important to highlight that nearly all the studies provided patient education within their interventions. This may include individualized information delivered through online coaching sessions [36], content available via mobile apps [28,29,32] or instant messaging apps [38], or combined methods using email and apps [34], as well as online consultations using platforms such as WeChat [37], exercise guidelines, or written recommendations [35]. Galiano-Castillo [30,31] reported having conveyed the significance of the exercise program in the context of post-BC rehabilitation to the study cohort.

Therefore, the studies proposed a variety of exercises as part of their rehabilitative interventions for women with BC. Among these, the main types include video game–based PA [36], specific exercises for the upper limbs [29,33,35,37,38] or lower limbs, cardiorespiratory training [29], high-intensity interval training [34], relaxation exercises and guided imagination [28], and both resistance and aerobic training [30,31]. Naturally, the choice of exercises depends on the specific objectives of the study, such as improving physical function, QoL, or ROM.

Table 3 provides a comprehensive summary of the RCTs included in this review, detailing study design, sample characteristics, type and duration of interventions, comparators, outcome measures, and main findings.

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Table 3. Summary table for randomized controlled trials.

Study	Design and aim	Participants		Intervention		Outcome	Results
		Exp[a]	Ctrl[b]	Exp	Ctrl		
Çinar et al [28]	• Design: RCTc. • Aim: To determine the effect of mobile app–based training on the QoLd in women with breast cancer using endocrine hormonal therapy (EHT).	n=31; mean age 46 (SD 8) y	n=33; mean age 45 (SD 9) y	Routine care plus the access to the educational contents and relaxation exercises and guided imagery applications on the mobile app whenever they wished. The treatment group received supportive care for 12 weeks including symptom management and specialist nurse counseling.	Routine care.	• Timepoints: baseline, before intervention (T0), and after 12 weeks (T1). • QoL: FACT-ESe Quality of Life Scale; Distress Thermometer Scores	• Exp improved QoL after intervention (*P*=.001) while ctrl decreased (*P*=.003). • Similarly, distress improved in exp group and between group significant difference was found (*P*=.03).
de Aviz et al [38]	• Design: RCT. • Aim: To test the effects of telerehabilitation on upper limb functionality, muscle strength, shoulder range of motion (ROM), QoL, pain and fatigue against an in-person rehabilitation in postoperative patients with breast cancer.	n=24; mean age 48 (SD 6) y	n=20; mean age 52 (SD 7) y	Patients received exercise videos (same exercises as ctrl) via instant messaging apps including active-free shoulder exercises (flexion, extension, abduction, adduction, and rotations), use of ball and wall support (early postoperative 0-15 days). Afterwards, patients received a structured telerehabilitation protocol, also via instant messaging including active-free and resistance exercises for upper and lower limbs, and aerobic exercises. Weekly video calls were implemented to monitor adherence, answer questions, and check for adverse events. Intervention duration: 4 weeks. Frequency: 2 sessions per week (8 sessions total).	Patients received a printed explanatory leaflet with guidelines for postoperative care, including home exercises (same as exp), recommendations for arm care on the surgical side (early postoperative 0-15 days). Afterwards, patients began face-to-face physiotherapy sessions, which included active-free and resistance exercises for upper and lower limbs, aerobic exercises. Intervention duration: 4 weeks. Frequency: 2 sessions per week (8 sessions total).	• Timepoints: baseline (T0), and at 4 weeks (end of treatment; T1). • QoL: FACT-Gf. • Pain: VASg • Upper-extremity functioning: DASHh, shoulder muscle strength tested with an isometric dynamometer. • Fatigue: FACT-Fi	• Between-group comparison showed better results in exp for FACT-G (*P*=.002), pain (*P*=.004), DASH (*P*=.001), FACT-F (*P*=.001), shoulder flexion (*P*=.01), and abduction (*P*=.03). • No between group differences for the other muscle strength tested.

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Study	Design and aim	Participants		Intervention		Outcome	Results
		Exp[a]	Ctrl[b]	Exp	Ctrl		
Dong et al [29]	• Design: RCT. • Aim: To estimate the effects of a combined exercise intervention based on internet and social media software (CEIBISMS) on QoL, muscle strength and cardiorespiratory capacity in postoperative patients with breast cancer.	n=26; mean age 48 (SD 6) y	n=24; mean age 52 (SD 7) y	Muscle training consisting of face-to-face televideo instruction on physical exercise rehabilitation was performed 3 times per week in 30-min sessions, including 5 min warm-up, 20 min muscle training, and 5 min relaxation. Each time; cardiorespiratory training (4 sessions/week, step-recording app); rehabilitation knowledge pushed daily via social media apps. Started after surgery but not specified the exact day of initiation. Intervention duration: 12 weeks.	Traditional treatment and rehabilitation according to daily specifications of the hospital. Started after surgery but not specified the exact day of initiation. Intervention duration: 12 weeks.	• Timepoints: baseline (T0) and after 12 weeks (T1). • QoL: SF-36j. • Functional: SPSD-CTk; • Muscle strength: ALTl; • Cardiorespiratory capacity: VO2maxm.	• Exp group improves significantly respect to ctrl in SF-36 subdomain of vitality (*P*=.009), mental health (*P*=.001), and reported health transition (*P*=.048). • Similarly, exp group improves significantly in SPSDCT at T1 with respect to ctrl group (*P*=.001) in ALT (*P*=.02). • No between group differences for VO2max (*P*=.15).
Galiano-Castillo et al [30]	• Design: RCT. • Aim: To compare a telerehabilitation program with usual care in breast cancer survivors.	n=40; mean age 47 (SD 10) y	n=41; mean age 46 (SD 10) y	Telerehabilitation program through the e-CUIDATE system, an online system that facilities the development of remote rehabilitation. The intervention was managed by CUIDATE research staff to assign and check different exercise programs. The schedule consisted of 3 sessions/wk (on nonconsecutive days) that lasted nearly 90 min/d. The intensity and volume of the physical exercise training were established following the recommendations of the American College of Sports Medicine for cancer survivors. Each session contained a battery of specific exercises that were divided into 3 sections: (1) warm-up, (2) resistance and aerobic exercise training, and (3) cooldown. Intervention duration: 8 weeks.	Basic recommendations for exercise in written format. Started after surgery. The exact day of initiation not specified. Intervention duration: 8 weeks.	• Timepoints: baseline (T0), after 8-weeks (T1), and after 6 months (T2). • QoL: EORTCn QLQ-C30o • Pain: Brief pain inventory • Upper-extremity functioning: hand grip dynamometer strength test. • Fatigue: R-PFSp	

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Study	Design and aim	Participants		Intervention		Outcome	Results
		Exp[a]	Ctrl[b]	Exp	Ctrl		
							• Exp showed significantly higher improvements in QoL of the domain of global health status, physical functioning (both *P*=.001), role functioning (*P*=.001), cognitive functioning, and arm symptoms (both *P*=.002) compared with the ctrl at T1. At T2 was observed a maintenance of effects (all *P*=.05) except for role functioning (*P*=.17). • At T1, the exp group reported significantly lower pain severity (*P*=.001) and pain interference (*P*=.045) than the ctrl group. At T2, significant results were maintained only for pain interference (*P*=.008). • At T1, exp handgrip strength on the affected and nonaffected sides improved significantly (both *P*=.006) compared with the ctrl. This improvement was only maintained at the 6-month follow-up assessment on the affected side (*P*=.03) • At T1, exp improved total fatigue perception significantly (*P*=.001) compared with the ctrl. This improvement was at T2 (*P*=.002).
Galiano-Castillo et al [31]	• Design: Secondary analysis of RCT. • Aim: To compare a telerehabilitation program with usual care in breast cancer survivors.	n=40; mean age 47 (SD 10) y	n=41; mean age 46 (SD 10) y	Basic recommendations for exercise in written format. Started after surgery. The exact day of initiation not specified. Intervention duration: 8 weeks.		• Timepoints: baseline (T0), after 8-weeks (T1), and after 6 months (T2). • Functional capacity: 6MWTq	• Exp group had significantly improved distances (*P*<.001) compared with the ctrl group at T1. At T2, the effect was maintained (*P*=.001).

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Study	Design and aim	Participants		Intervention		Outcome	Results
		Exp[a]	Ctrl[b]	Exp	Ctrl		
				Telerehabilitation program through the e-CUIDATE system, an online system that facilities the development of remote rehabilitation. The intervention was managed by CUIDATE research staff to assign and check different exercise programs. The schedule consisted of 3 sessions/wk (on nonconsecutive days) that lasted nearly 90 min/d. The intensity and volume of the physical exercise training were established following the recommendations of the American College of Sports Medicine for cancer survivors. Each session contained a battery of specific exercises that were divided into 3 sections: (1) warm-up, (2) resistance and aerobic exercise training, and (3) cooldown. Intervention duration: 8 weeks.			
Hou et al [32]	• Design: RCT. • Aim: To evaluate the effectiveness of a breast cancer self-management support (BCSMS) app on the QoL of women with breast cancer.	n=53; mean age 50-64 y	n=59; mean age 50-64 y	BCSMS[r] mobile app, started after pretest data collection (baseline). Participants could use the app any time as needed. The app was developed with 8 main features, feature number 2 was "exercise and rehabilitation" after surgery. Intervention duration: 3 months.	Received the same care from health care professionals as the experimental group. Intervention duration: 3 months.	• Timepoints: baseline (T0), 1.5 months (T1), and 3 months (T2). • QoL: EORTC QLQ-C30 and EORTC QLQ-BR23s.	• Exp showed significantly higher mean total QoL summary scores from the EORTC QLQ-C30 (83.45 vs 82.23, *P*=.03) and the QLQ-BR23 (65.53 vs 63.13, *P*=.04) at T2 compared with the ctrl. • Both groups showed improvements in QoL and symptom scores.
Loubani et al [33]	• Design: RCT. • Aim: To examine the effectiveness of a hybrid occupation-based intervention (MaP-BC) on improving daily participation upper limb function and QoL.	n=18; mean age 48 (SD 11.1) y	n=17; mean age 52 (SD 12.8) y	Hybrid managing participation with breast cancer (MaP-BC[t]) consisting of 12 alternating weekly in-clinic and telerehabilitation sessions. Started 3-24 months post-BC[u] diagnosis. Intervention duration: 6 weeks.	Standard care only. Intervention duration: 6 weeks.	• Timepoints: baseline (T1), 6 weeks (T2), and 12 weeks (T3). • Participation: COPMv. • Activity levels: ACSw. • QoL: FACT-Bx. • Upper-extremity functioning: DASH; grip strength	

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Study	Design and aim	Participants		Intervention		Outcome	Results
		Exp[a]	Ctrl[b]	Exp	Ctrl		
							• Significant interaction (group×time) effects were found for the primary outcome in COPM performance (*P*=.001) and performance satisfaction (*P*=.02). • Exp had greater improvement between T1 and T2 in performance and QoL compared with the ctrl group. • Both groups improved DASH over time (P<0.001) but with no group×time effect (*P*=.16). Grip strength showed no time (*P*=.17) and no group×time (*P*=.21) effect.
Ochi et al [34]	• Design: RCT. • Aim: To determine whether a home-based smartphone-supported high intensity interval training (HIIT) improves cardiorespiratory fitness (CRF) in early- stage breast cancer survivors.	n=25; mean age 48 (SD 6) y	n=25; mean age 49 (SD 5) y	Home-based HIIT[y] and behavioral modification (Habit-b) with counseling or exercise guidance and support provided via personalized email and a newly developed smartphone app. Intervention duration: 12 weeks (3/week).	Self-monitoring using the wearable device, a smart-watch (Fitbit Versa [Google]).	• Timepoints: baseline (T0) and 12 weeks (T1). • QoL: EQ-5D total score. • Upper-extremity functioning: • Grip strength: assessed through a dynamometer. • Body composition: BMI; body mass (kg)	• No between-group differences in QoL at T1 (*P*=.25). Both groups show improvements in QoL (exp: –0.03; ctrl –0.06). • No between-group differences in body composition both for body mass and BMI at T1 (*P*=.25) and for grip strength (*P*=.53).
Park et al [35]	• Design: Multicenter RCT. • Aim: To evaluate the effectiveness in improving shoulder ROM, pain, function and QoL of a telerehabilitation therapy using an ARz-based, real-time interactive digital health care system (UINCARE Home+) with a brochure-based home rehabilitation program in postoperative patients with breast cancer.	n=50; mean age 43 (SD 9) y	n=50; mean age 47 (SD 9) y	Telerehabilitation was provided through the AR-based UINCARE Home and rehabilitation system which uses the Xbox One Kinect for Windows. The exercise program consisted of 2 parts with 2 difficulty levels each (total of 4 levels). Each exercise level was composed of warm-up, main workouts, and cool-down components. The exercise level was determined according to the results obtained over the first 4 weeks. Intervention duration 8 weeks.	Brochure detailing the same daily exercise program used for the exp group. The brochure included pictures and brief descriptions of each exercise. The exercise difficulty level was determined according to the results obtained over the first 4 weeks. Intervention duration 8 weeks.	• Timepoints: baseline (T0), 4 weeks (T1), 8 weeks (T2), and 12 weeks (T3). • QoL: FACT-B; EQ-5D-5L scores • Upper-extremity functioning: Shoulder abduction and flexion ROM; QuickDASHaa score • Pain: NRSab	

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Study	Design and aim	Participants		Intervention		Outcome	Results
		Exp[a]	Ctrl[b]	Exp	Ctrl		
							• All outcomes improved over time. • No between-group (group×time) differences for shoulder active and passive ROM: active (*P*=.15) and passive flexion (*P*=.68); and active (*P*=.41) and passive abduction (*P*=.44). • Similarly, Quick-DASH revealed no between group differences (*P*=.97). • No significant group differences were observed for pain (*P*=.56) and for most intense pain (*P*=.64). • Similarly, no significant group differences were detected in the EQ-5D-5L or FACT-B scores (*P*=.14 and *P*=.24, respectively)
Swartz et al [36]	• Design: Pilot RCT. • Aim: To determine feasibility, acceptability and estimate the effects on physical activity (PA) and physical function of an Active Video Game–Based Physical Activity (AVG-PA) intervention in breast cancer survivors.	n=10; mean age 64.9 (SD 8) y	n=10; mean age 62.6 (SD 4.2) y	12 weekly virtual sessions consisting of AVG-PA[ac] (Pink Warrior 2), PA[ad] behavioral coaching, and survivorship navigation discussions.	12 weekly telephone-based breast cancer support group discussions. Participants were provided a Xiaomi Mi Band 3 which delivered progressive step goal notifications and a "reach goal" badge when a person reaches the step goal.	• Timepoints: at baseline, week 6, and week 13. • Physical activity: average daily steps, average minutes of MVPAae measured by accelerometers. • Physical Function: gait speed, SPPBaf, TUGag test, and 2-minute step.	• Exp showed moderate effect sizes for (1) SPPB: Cohen d=1.06 and (2) 2-minute step test Cohen d=0.61; and small effect sizes for (1) gait speed Cohen d=0.46, (2) TUG Cohen d=0.43, and (3) MVPA Cohen d= 0.27. • ActiGraph data from both groups showed higher MVPA, but lower step counts were found among the exp group participants.
Zhou et al [37]	• Design: RCT. • Aim: To investigate the benefits of a WeChat-based multimodal nursing program on health-related quality of life (HRQoL) in postoperative women with breast cancer.	n=56; mean age 49.84 (SD 8.85) y	n=55; mean age 49.98 (SD 9.84) y	WeChat-based multimodal nursing program, including individualized information, surgical side upper limb exercise, psychological guidance, and social support, starting from hospital admission to 6 months post surgery.	Routine nursing care including health education, monitoring, and drainage tube care.	• Timepoints: at presurgery, 1-, 3-, and 6-months post surgery • QoL: FACT-Bv4.0ah • Pain: NRS • Fatigue: NRS • Sleep: NRS	• Exp showed higher improvement than ctrl in total FACT-Bv4.0 scores: *P*<.001 (group), and *P*=.001 (group×time). Pain had only a group-time interaction effect (*P*=.01). • No differences for fatigue (*P*=.24) and sleep (*P*=.70).

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[a]Exp: experimental group.
[b]Ctrl: control group.
[c]RCT: randomized controlled trial.
[d]QoL: quality of life.
[e]FACT-ES: Functional Assessment of Cancer Therapy-Endocrine Subscale.
[f]FACT-G: Functional Assessment of Cancer Therapy-General.
[g]VAS: visual analog scale.
[h]DASH: Disability of Arm Shoulder and Hand Questionnaire.
[i]FACT-F: Functional Assessment of Cancer Therapy-Fatigue.
[j]SF-36: Short Form Health Survey 36.
[k]SPSDCT: stand-up and sit-down chair test.
[l]ALT: arm lifting test.
[m]VO2max: maximal oxygen consumption.
[n]EORTC: European Organisation for Research and Treatment of Cancer.
[o]QLQ-C30: Quality-of-Life Questionnaire Core 30.
[p]R-PFS: Piper Fatigue Scale revised.
[q]6MWT: 6-Minute Walk Test.
[r]BCSMS: breast cancer self-management support.
[s]QLQ-BR23: Breast Cancer–Specific Quality-of-Life Questionnaire.
[t]MaP-BC: hybrid managing participation with breast cancer.
[u]BC: breast cancer.
[v]COPM: Canadian Occupational Performance Measure.
[w]ACS: Activity Card Sort.
[x]FACT-B: Functional Assessment of Cancer Therapy-Breast.
[y]HIIT: high intensity interval training.
[z]AR: augmented reality.
[aa]QuickDASH: Quick Version of Disability of Arm Shoulder and Hand Questionnaire.
[ab]NRS: numeric rating scale.
[ac]AVG-PA: active video game–based physical activity.
[ad]PA: physical activity.
[ae]MVPA: moderate to vigorous physical activity.
[af]SPPB: Short Physical Performance Battery.
[ag]TUG: Timed Up and Go.
[ah]FACT-Bv4.0: Functional Assessment of Cancer Therapy-Breast version 4.0.

The characteristics of the included interventions were further synthesized according to the Frequency, Intensity, Time, and Type framework, as reported in Table 4. While frequency and time or duration were consistently described across studies, intensity was often poorly defined or heterogeneous. Notably, in the study by Park et al [35], intensity was not expressed through quantitative measures (eg, load, percentage of one-repetition maximum, or rating of perceived exertion [RPE]) but only described in terms of progression in ROM and the introduction of active movements with or without dumbbells.

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Table 4. Frequency, intensity, time, and type summary of telerehabilitation interventions across the included randomized controlled trials. The table reports the delivery mode or technology, exercise type, frequency, intensity, duration, supervision or adherence strategies, and comparator for each study.

Study	Delivery mode or technology	Type	Frequency	Intensity	Time or duration	Supervision or adherence	Comparator
Çınar et al [28]	mHealth[a] app and nurse support	Education, lifestyle, relaxation	On-demand	—[b]	12 weeks	Nurse support; app logs	Routine care
de Aviz et al [38]	Instant message app (exercise video or exercise protocol)	ROM[c] upper and lower limbs, resistance, and aerobic training	2 times per week	Moderate (Borg 0-10)	Approximately 40 min/session; 8 weeks	Weekly video call	Printed manual + in-person rehabilitation
Dong et al [29]	Face-to-face televideo and social media app	Education, strengthening, endurance, muscle function, and cardiorespiratory training	Daily	RPE[d] to assess the cardiorespiratory training	30-40 min/day; 12 weeks	Daily remote check	Traditional treatment and rehabilitation
Galiano-Castillo et al [30]	e-CUIDATE system (online system)	Aerobic, resistance, and flexibility	3 times per week	Following recommendations of the ACSM[e] for cancer survivors	Approximately 90 min/session; 8 weeks	Live supervision and adherence	Printed information on stress management and physical fitness
Galiano-Castillo et al [31]	e-CUIDATE system (online system)	Aerobic, resistance, and flexibility	3 times per week	Following recommendations of the ACSM for cancer survivors	Approximately 90 min/session; 8 weeks	Live supervision and adherence	Printed information on stress management and physical fitness
Hou et al [32]	Mobile app and weekly video calls	ROM, stretching, and strengthening	5 times per week	Low	Approximately 30 min/session; 12 weeks	Weekly check	Printed exercises
Loubani et al [33]	Videoconference (CogniMotion telesystem) and in-clinic session	ROM, stretching, resistance, cognitive abilities	Daily + 2 weekly check	Moderate	Approximately 45 min/session; 6 weeks	Live supervision	Standard care
Ochi et al [34]	Habit-B app, tracker, and email	HIIT[f] training and education	Daily + weekly check	High	20-30 min/day; 12 weeks	App and wearable logs	Self-monitoring using the wearable device
Park et al [35]	UINCARE Home and rehabilitation system (app and motion sensor)	ROM, strengthening, posture	5 times per week	No information	Approximately 30-40 min/session; 8 weeks	Wearable logs and feedback	Leaflet
Swartz et al [36]	Zoom (Zoom Communications) live sessions and HR[g] tracker	behavioral coaching, exergames-based activity (“Mind-body” “e-fitness–based”), and BC[h] support	3 times per week	Moderate to high	Approximately 45-60 min/session; 12 weeks	Live supervision	Telephone-based support group discussions
Zhou et al [37]	WeChat and routine nursing care	ROM, stretching, strengthening, education	Daily	Low to moderate	6 months	Weekly calls; app logs	Routine nursing care

[a]mHealth: mobile health.

[b]Not applicable.

[c]ROM: range of motion.

[d]RPE: rating of perceived exertion.

[e]ACSM: American College of Sport Medicine.

[f]HIIT: high intensity interval training.

[g]HR: heart rate.

[h]BC: breast cancer.

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Sociodemographic Characteristics

Across the 11 RCTs, a total of 748 women were included (373 allocated to telerehabilitation and 375 to control arms). The mean age of participants spanned from the early 40s to the mid-60s, with most cohorts representing middle-aged women, although the US trial (Swartz et al [36]) recruited an older sample (mean 63.8 y). Cancer stage was predominantly early disease (stages 1-2), although several trials [36] also included patients at stage 3 or 3A. Surgical management varied: breast-conserving surgery predominated in Taiwan (76/112, 67.9%) [32], whereas Turkish and Israeli cohorts [28,33] reported mixed lumpectomy and mastectomy distributions, and immediate reconstruction was frequent in the Korean multicenter trial (78/100, 78%) [35]. Axillary lymph node dissection was reported in the intervention group in the study by Park et al [35]. The 2 Spanish trials [30,31] recruited BC survivors who had completed adjuvant therapy, with a balanced distribution of lumpectomy, quadrantectomy, and mastectomy. In other cohorts, details of surgical procedures were often sparse. Beyond age, sex, stage, and surgery, additional sociodemographic descriptors (eg, education, employment, marital status, ethnicity) were underreported. Where available, most participants were married (69.1%), had a basic educational level (45.7%), and were housewives or on medical leave [31]. Overall, baseline characteristics were generally well balanced between intervention and control groups within studies, supporting internal validity. A full study-level summary is provided in Table 2.

QoL

In total, 9 articles [28-30,32-35,37,38] assessed QoL as part of their research. The most frequently used assessment was the Functional Assessment of Cancer Therapy-Breast (FACT-B). However, the specific version of the scale varied across studies. For instance, Zhou et al [37] used version 4 of the FACT-B scale, while Loubani et al [33] and Park et al [35] used the original version. Meanwhile, Çınar et al [28] opted for a different approach, using the Functional Assessment of Cancer Therapy-Endocrine Subscale QoL scale, which is tailored for endocrine symptoms and de Aviz et al [38] administered Functional Assessment of Cancer Therapy-General (FACT-G).

The EORTC QoL questionnaires were used in 2 articles [30,32]. Galiano-Castillo et al [30] administered the EORTC Quality-of-Life Questionnaire Core 30 (EORTC QLQ-C30). Similarly, Hou et al [32] also used the EORTC QLQ-C30, but supplemented it with the EORTC Breast Cancer–Specific Quality-Of-Life Questionnaire, a module specifically designed for patients with BC.

The EQ-5D was another instrument used in 2 studies. Ochi et al [34] assessed participants using the standard EQ-5D total score, while Park et al [35] opted for the EQ-5D-5L version.

Only 1 study, conducted by Dong et al [29], used the Short Form Health Survey 36 to evaluate QoL.

As illustrated in Table 3, the majority of studies [28-30,32,33,37,38] reported significant improvements in QoL among participants in the intervention groups. However, not all findings were consistent. Of the total, 2 studies [34,35] did not observe statistically significant differences between the intervention and control groups, even though both groups experienced some degree of improvement.

Functional and PA

All articles analyzed function and PA, albeit using different evaluation and assessment methods. In general, PA was measured using accelerometers, assessing mean daily steps and mean minutes of moderate to vigorous PA only by Swartz et al [36].

Additionally, Swartz et al [36] used various performance tests to evaluate the effect of their intervention on physical function, including the Short Physical Performance Battery, gait speed, Timed Up and Go test, and 2-minute step test.

Furthermore, 2 other articles used performance tests to measure PA, in particular, Dong et al [29] used the Stand-Up and Sit-Down Chair Test, while Galiano-Castillo et al [31] used the 6-Minute Walk Test (6MWT).

In addition, 3 studies [33,35,38] used questionnaires to assess upper limb function. Specifically, Loubani et al [33] and de Aviz et al [38] used the Disability of Arm, Shoulder, Hand (DASH) questionnaire, while Park et al [35] administered the Quick Version of the Disability of Arm, Shoulder, Hand (QuickDASH) questionnaire score.

Despite the methodologies, results indicated a moderate effect size for the Short Physical Performance Battery and 2-minute step test, along with small effect sizes for gait speed, Timed Up and Go test, and moderate to vigorous PA. Significant improvements were noted in the experimental groups as reported by Dong et al [29], Loubani et al [33], and Galiano-Castillo et al [31].

In contrast, Park et al [35] documented improvements over time without significant differences between the 2 groups.

In total, 5 articles analyzed muscle strength. Specifically, Dong et al [29] evaluated the upper limb strength using the arm lifting test, while De Aviz et al [38] used a digital dynamometer to measure shoulder joint flexion, extension, abduction, external rotation, and internal rotation. Additionally, Loubani et al [33], Ochi et al [34], and Galiano-Castillo et al [30] assessed handgrip strength using a dynamometer.

Strength assessment results indicated significant improvements in the experimental group as reported by Dong et al [29], while de Aviz et al [38] found enhancements in both groups pertaining to upper limb strength, without a statistical difference. Regarding handgrip strength, Galiano-Castillo et al [30] reported significant enhancement solely in the experimental group, which was maintained at the 6-month follow-up. Ochi et al [34] showed no significant differences in between-group analyses.

Of the total, 2 studies [29,31] examined the cardiorespiratory capability: Dong et al [29] used the maximal oxygen consumption, while Galiano-Castillo et al [31] used the 6-Minute Walk Test to evaluate the functional capability. The results were inconsistent; the study by Galiano-Castillo et al [31] showed significant improvements in the intervention group during both T1 and T2 evaluations compared with the control group, while

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Dong et al [29] found no differences between the groups at the end of the intervention.

ROM was assessed by Park et al [35], specifically focusing on shoulder abduction and flexion and by de Aviz et el [38] for shoulder joint flexion, extension, abduction, external rotation, and internal rotation.

Only Ochi et al [34] evaluated BMI and body mass in kilograms. Both studies reported no significant differences in between-group analyses.

Table 3 presents the results of functional and physical assessments.

Pain, Fatigue, and Kinesiophobia

In total, 4 articles [30,35,37,38] evaluated pain as an outcome measure. Zhou et al [37] and Park et al [35] used the numerical rating scale (NRS), while de Aviz et al [38] used the visual analog scale, and Galiano-Castillo et al [30] applied the brief pain inventory.

The findings across these studies were variable: 3 studies [30,37,38] reported significantly lower pain in the experimental group than the control group. It is important to underline that, although the results did not present a statistically significant difference between the groups, in the study by de Aviz et al [38], the patients in the experimental group did not present pain at the intermediate and final evaluation.

In contrast, Park et al [35] found no significant differences between the groups.

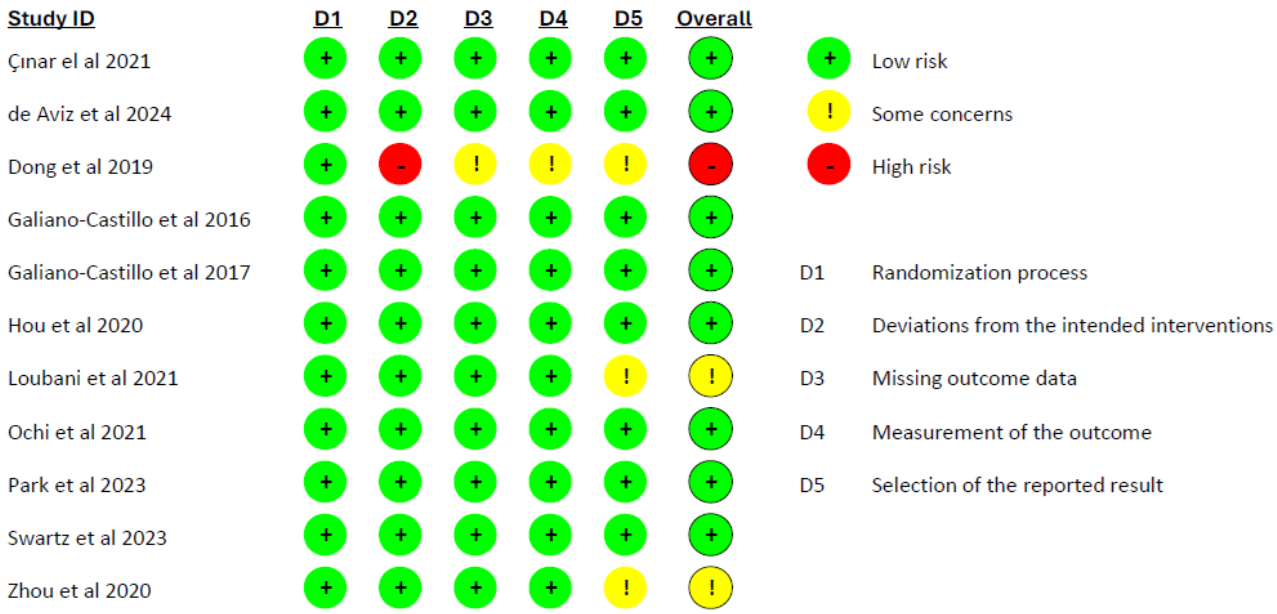
Fatigue was assessed by Zhou et al [37] using the NRS, Galiano-Castillo et al [30] using the revised Piper Fatigue Scale, and de Aviz et al [38] using the Functional Assessment of Cancer Therapy-Fatigue. Zhou et al [37] reported no significant differences between the groups, while Galiano-Castillo et al [30] and de Aviz et al [38] demonstrated a significant improvement in total fatigue perception in the intervention group compared with the control group, with this effect maintained at follow-up (T2).

Table 3 presents the results of the assessments for pain, fatigue, and kinesiophobia.

Risk of Bias in Studies

The risk of bias assessment with RoB2 [24] across the included studies revealed variability in methodological quality (Figure 2). Most studies, in the overall assessment, are at low risk of bias, while 1 study [33] raises some concerns, and 1 study [29] is at high risk of bias.

Figure 2. Risk of Bias with Cochrane risk-of-bias tool for randomized trials version 2 [28-38].



Most studies demonstrated a low risk of bias in terms of randomization and allocation concealment, suggesting robust methodological designs. However, 1 study [29] seems to have adopted a per-protocol analysis without a clear balancing of dropouts, raising doubts regarding domain D2, deviations from intended intervention, thus resulting in a high risk of bias. A major limitation across multiple studies was the lack of blinding for both participants and intervention providers, which is particularly relevant given the reliance on patient-reported outcomes in telerehabilitation interventions. This raises concerns about performance and detection bias, potentially influencing the reported effectiveness of interventions. Incomplete outcome data and selective reporting were generally well-managed, with most studies showing a low risk of bias in these domains, ensuring transparency and data integrity. Nonetheless, other biases, such as small sample sizes [36], lack of preregistered protocols in English [33,37], and possible confounding factors, were present in some studies, warranting caution in interpreting their results. Overall, while the included studies provide valuable insights into telerehabilitation for patients post BC surgery, future research should prioritize improved blinding strategies, objective outcome measures, and standardized reporting protocols to enhance methodological rigor and reliability of findings.

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Results of Synthesis

Overview

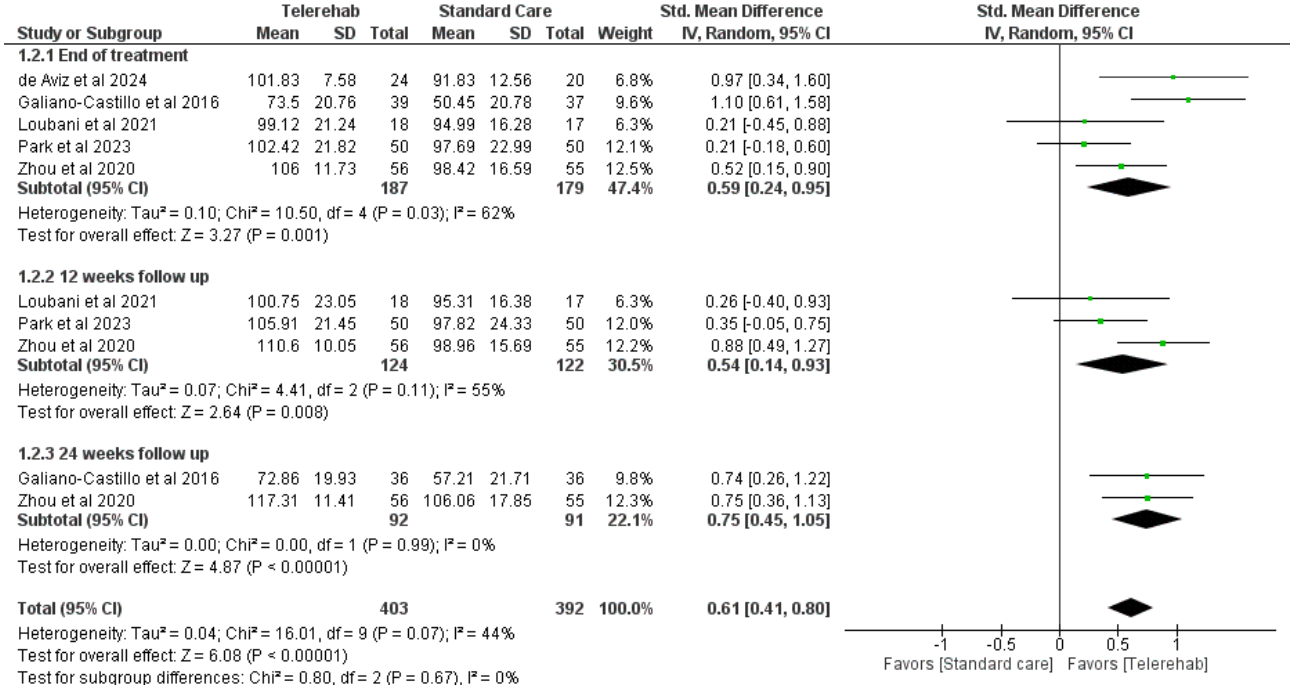
In this meta-analysis, we included only studies [30,33,35,37,38] that evaluated the effectiveness of upper limb muscle strength training via telerehabilitation compared with standard care in patients undergoing surgery for BC. The rigorous selection of articles ensured that only interventions using homogeneous treatment modalities (upper limb muscle strength training) were analyzed, thereby enhancing methodological consistency across the included studies. Regarding standard care groups (control groups), results highlight a significant effect of telerehabilitation based on upper limb muscle strength training on QoL, pain, function, and handgrip strength, demonstrating a clinically relevant improvement compared with standard care at the end of treatment. As for the outcomes related to QoL and pain only, it was possible to analyze long-term effects through follow-up data.

QoL

QoL was assessed in 4 studies [30,33,35,37,38] using the FACT-B [33,35,37], FACT-G [38], and EORTC QLQ-C30 [30] at different follow-up points (end of treatment, 12 weeks, and 24 weeks). One additional study [29] was excluded from the meta-analysis due to the use of a noncomparable outcome measure (Short Form Health Survey 36).

The overall effect across all time points showed a statistically significant improvement in favor of telerehabilitation compared with standard care (standardized mean difference [SMD] 0.61; 95% CI 0.41 to 0.80; P<.001), indicating a moderate effect size. Subgroup analysis based on follow-up time (end of treatment, 12 weeks, and 24 weeks) revealed no statistically significant differences between subgroups (χ^2_2=0.8, P=.67). Each time-point analysis showed statistically significant results in favor of telerehabilitation (Figure 3).

Figure 3. Forest plot of standardized mean differences for the outcome "quality of life" between telerehabilitation and standard care. Results are stratified by time of follow-up assessment. A random-effects model was applied [30,33,35,37,38].

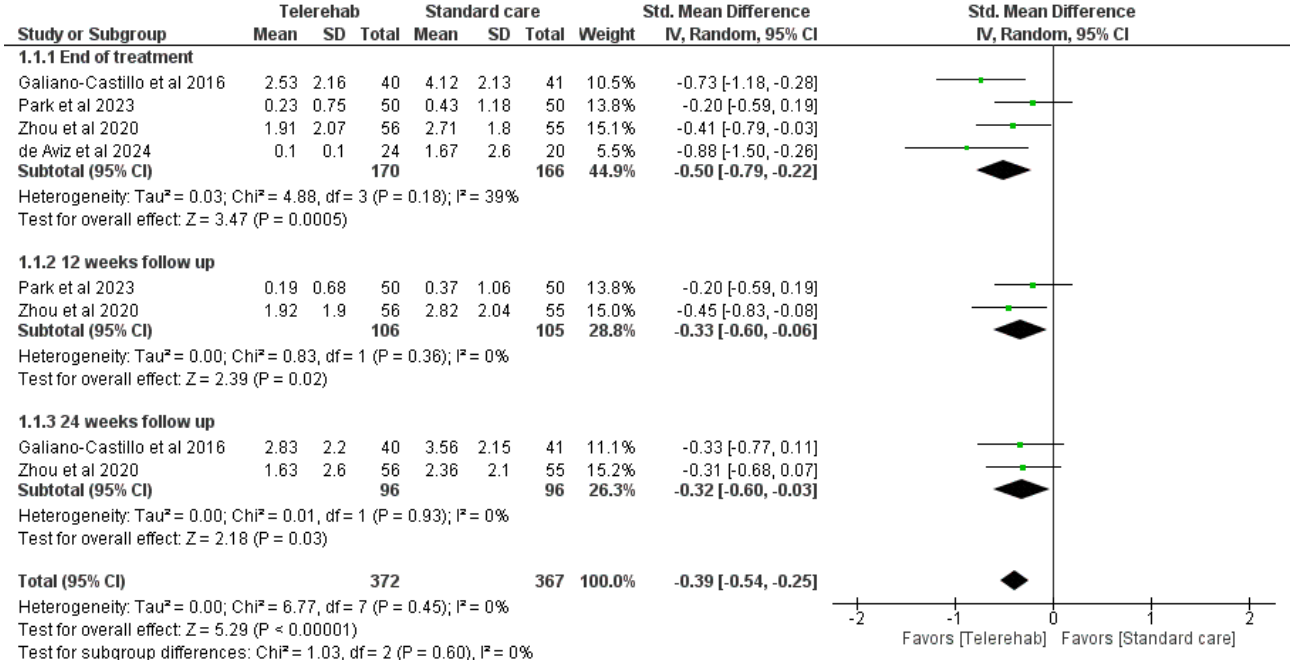


Pain

In total, 4 studies (n=731) [30,35,37,38] assessed pain using validated measures such as the visual analog scale [38], brief pain inventory [30], and NRS [35,37] at various time points (end of treatment, 12 weeks, and 24 weeks). The overall analysis showed a statistically significant reduction in pain intensity in favor of telerehabilitation compared with standard care (SMD –0.39; 95% CI –0.54 to –0.25; P<.001), indicating a small to moderate effect size. Subgroup analysis by follow-up time showed consistent results, with no statistically significant differences between subgroups (χ^2_2=1.0; P=.60). Each subgroup showed a statistically significant effect of telerehabilitation (Figure 4).

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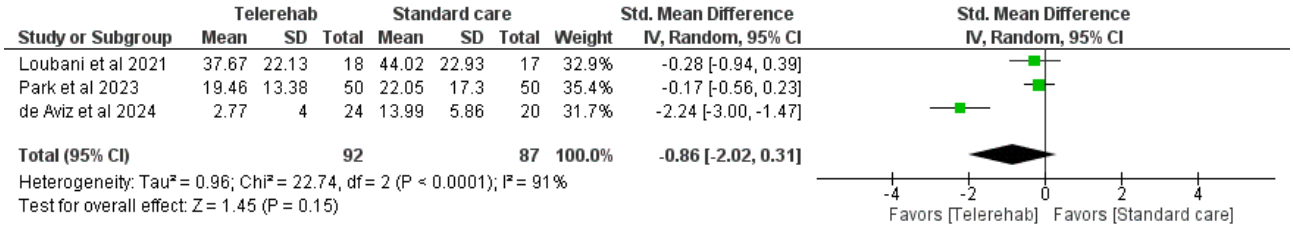
Figure 4. Forest plot of the standardized mean differences for the outcome "pain intensity" between telerehabilitation and standard care. Results are grouped by time of follow-up assessment. A random-effects model was used [30,35,37,38].



Upper Limb Function

Upper limb function was evaluated in 3 studies (n=171) [33,35,38] at the end of the intervention using DASH [35,38] and QuickDASH scores [33]. The meta-analysis showed no statistically significant difference between telerehabilitation and standard care (SMD –0.86; 95% CI –2.02 to 0.31; *P*=.15), indicating a small and nonsignificant effect in favor of telerehabilitation (Figure 5).

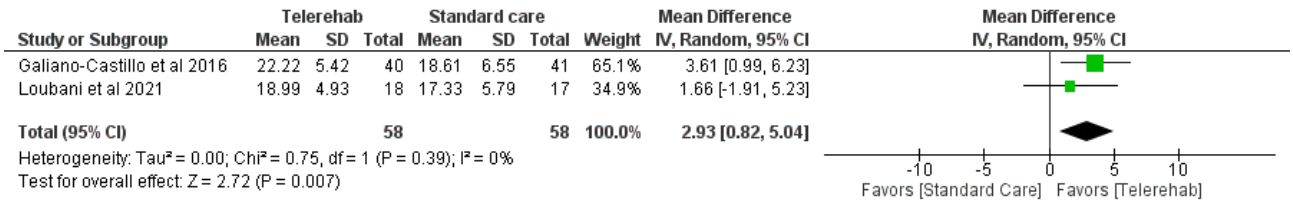
Figure 5. Forest plot of standardized mean difference for the outcome "upper limb function" between telerehabilitation and standard care at the end of the treatment. A random-effects model was applied [33,35,38].



Handgrip Strength

In total, 2 studies (n=116) [30,33] examined the effect of telerehabilitation on handgrip strength. Handgrip strength was assessed through a handheld dynamometer at the end of treatment. The overall effect was statistically significant in favor of telerehabilitation (mean difference [MD] 2.93; 95% CI 0.82-5.04; *P*=.006), indicating a moderate improvement (Figure 6).

Figure 6. Forest plot of standardized mean difference for the outcome "handgrip strength" between telerehabilitation and standard care. A random-effects model was used [30,33].



Certainty of Evidence

The GRADE summary of findings (Table 5) for the main outcomes at different time points showed that at the end of treatment moderate evidence suggests that telerehabilitation was associated with a statistically significant improvement in QoL compared with standard care (SMD 0.59, 95% CI 0.24-0.95; moderate certainty); similarly regarding to handgrip strength (MD 2.93 kg, 95% CI 0.82-5.04; low certainty). A moderate reduction in pain was also observed (SMD 0.50 lower, 95% CI 0.79-0.22 lower; low certainty). No relevant effects were found for upper limb function (SMD 0.86 lower, 95% CI

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–2.02 to 0.31; low certainty). During the 12-week follow-up, telerehabilitation maintained a beneficial effect on QoL (SMD 0.54 higher, 95% CI 0.14-0.93; low certainty) and was associated with a reduction in pain intensity (SMD 0.33 lower, 95% CI –0.60 to –0.06; low certainty). At 24 weeks follow-up, the improvement in QoL was further increased (SMD 0.75 higher, 95% CI 0.45-1.05; low certainty), while pain reduction remained modest (SMD 0.32 lower, 95% CI –0.60 to –0.03; low certainty). The certainty of evidence ranged from low to moderate, mainly due to limitations in study design and imprecision related to small sample sizes and wide CIs.

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Table 5. Grading of Recommendations Assessment, Development and Evaluation summary of findings.

Outcomes	Assessment tool	Number of participants, n (studies)	Certainty of the evidence (GRADE[a])	Anticipated absolute effects (95% CI), mean value with standard care	MD[b] or SMD[c] with telerehabilitation (95% CI)
End of treatment					
QoL[d]	FACT-B[e]; FACT-B V4.0[f]; EORTC[g] QLQ-C30[h]; FACT-G[i]	366 (5 RCTs[j])	⊗ Moderate[k,l]	NE[m]	SMD 0.59 (0.24 to 0.95)
Pain	VAS[n]; NPRS[o]; BPI[p]	336 (4 RCTs)	⊗ Low[l,q]	NE	SMD –0.50 (–0.79 to –0.22)
Upper limb function	DASH[r]; quickDASH[s]	179 (3 RCTs)	⊗ Low[k,l]	NE	SMD –0.86 (–2.02 to 0.31)
Handgrip strength	Handheld dynamometer	116 (58 RCTs)	⊗ Low[k,l]	The mean handgrip strength was **17.97** kg	MD 2.93 (0.82 to 5.04)
12 weeks follow-up					
QoL	FACT-B; FACT-B V4.0; EORTC QLQ-C30	246 (3 RCTs)	⊗ Low[k,l]	NE	SMD 0.54 (0.14 to 0.93)
Pain	NPRS	211 (2 RCTs)	⊗ Low[k,l]	NE	SMD –0.33 (–0.6 to –0.06)
24 weeks follow-up					
QoL	FACT-B V4.0; EORTC QLQ-C30	183 (2 RCTs)	⊗ Low[k,l]	NE	SMD 0.75 (0.45 to 1.05)
Pain	NPRS; BPI	192 (2 RCTs)	⊗ Low[k,l]	NE	SMD –0.32 (–0.6 to –0.03)

[a]GRADE: Grading of Recommendations Assessment, Development and Evaluation. GRADE Working Group grades of evidence. High certainty: we are very confident that the true effect lies close to that of the estimate of the effect. Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[b]MD: mean difference.

[c]SMD: standardized mean difference.

[d]QoL: quality of life.

[e]FACT-B: Functional Assessment of Cancer Therapy-Breast.

[f]FACT-B V4.0: Functional Assessment of Cancer Therapy-Breast version 4.0.

[g]EORTC: European Organisation for Research and Treatment of Cancer.

[h]QLQ-C30: Quality-of-Life Questionnaire Core 30.

[i]FACT-G: Functional Assessment of Cancer Therapy-General.

[j]RCT: randomized controlled trial.

[k]Lack of details on randomization, allocation concealment, and masking in 1 or + studies.

[l]Total sample size < 400.

[m]NE: not estimable.

[n]VAS: visual analog scale.

[o]NPRS: numeric pain rating scale.

[p]BPI: brief pain inventory.

[q]Lack details on reported results in 1 or + studies.

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[r]DASH: Disability of Arm Shoulder and Hand Questionnaire.

[s]quickDASH: Quick Version of Disability of Arm Shoulder and Hand Questionnaire.

Discussion

Principal Results

This SR with meta-analysis evaluated the clinical effectiveness of telerehabilitation in women undergoing BC surgery, focusing on 4 core outcomes: QoL, pain, upper limb function, and handgrip strength. A total of 11 RCTs were included in the qualitative synthesis, of which 5 were eligible for meta-analysis. The overall findings support the use of telerehabilitation as a valid, safe, and in some cases superior alternative to routine care, especially in improving QoL and muscular strength, while some functional outcomes require further investigation.

The most consistent benefit of telerehabilitation across included studies was its effect on QoL. The meta-analysis showed a moderate, statistically significant improvement (SMD 0.59) with moderate certainty of evidence. This effect was maintained across multiple follow-up points and QoL instruments, including FACT-B, FACT-G, and EORTC QLQ-C30. These findings align with those reported by Wen et al [16], who observed that eHealth-based interventions significantly improved general and subdomain QoL metrics in women with BC. Similarly, Peng et al [15] noted improvements in fatigue and functional domains in patients with BC who engaged in structured tele-exercise programs.

Specific interventions, such as the e-CUIDATE system studied by Galiano-Castillo et al [30], showed both QoL gains and durability of effects over a 6-month follow-up, supporting the long-term potential of well-structured telerehabilitation protocols.

In contrast, Scaturro et al [12] found that synchronous telerehabilitation, delivered through a web-meeting platform, was effective, but face-to-face rehabilitation yielded greater QoL improvements, potentially due to individualized adjustment and closer supervision. This observation underscores the role of patient-physiotherapist interaction and feedback loops, which are harder to replicate in remote formats.

Pain control emerged as another area where telerehabilitation was effective. The pooled analysis showed a significant reduction in pain (SMD –0.50). In literature, the beneficial effects of rehabilitation and physical exercise on pain reduction in patients undergoing BC surgery are well-established [39]. However, to date, no SRs have comprehensively evaluated this specific outcome in the context of telerehabilitation in this specific population. To the best of our knowledge, this is the first SR with meta-analysis to demonstrate the reduction of pain in patients receiving telerehabilitation following BC surgery.

Generally, the efficacy of telerehabilitation in alleviating pain is documented for both acute [40,41] and chronic pain, short-term and long-term [41], in patients following cancer surgery. The findings of our SR are thus consistent with existing literature on this subject.

Handgrip strength improved significantly (MD 2.93 kg); nevertheless, given the low certainty of evidence and reference values for minimal clinically important differences reported in the literature, this change is unlikely to be clinically meaningful [42,43]. Grip strength is an important functional indicator post mastectomy or quadrantectomy and is correlated with patient independence and upper limb integrity [44].

Upper limb function did not significantly improve in the meta-analysis (SMD –0.86, 95% CI –2.02 to 0.31). This may be due to substantial variability in the tools used (DASH and Quick-DASH), the intensity of training, or baseline impairments. Scaturro et al [12] found outpatient rehabilitation to be more effective than telerehabilitation in improving upper limb functional scores, possibly due to the capacity for individualized correction and targeted kinematic feedback.

Park et al [35] attempted to overcome this by using virtual reality–based telerehabilitation with the Xbox Kinect, achieving encouraging improvements in shoulder function and patient engagement.

The clinical implications of these findings are substantial. Telerehabilitation overcomes several barriers that hamper access to rehabilitation services, including geographic isolation, transportation challenges, financial burdens, and caregiver constraints. Studies such as those by Keikha et al [17] and Anik et al [45] emphasize that telerehabilitation can significantly enhance service reach and continuity of care, particularly for underserved populations.

Furthermore, its cost-effectiveness is becoming increasingly recognized [46-48]. Remote protocols may reduce direct and indirect costs, a hypothesis supported by implementation studies showing decreased health care usage when telerehabilitation is adopted as part of routine cancer recovery [12].

Several trials also incorporated patient education and behavioral coaching components [28,34,36] via messaging apps or interactive video calls (eg, WeChat-based multimodal nursing by Zhou et al [37]), highlighting how multidomain interventions can reinforce adherence and long-term engagement.

The sociodemographic and clinical profiles of participants in the included trials provide important context for interpreting the findings of this SR. Most samples consisted of middle-aged women, with mean ages ranging from the early 40s to the mid-60s. Cancer stage was predominantly early (1-2), although several studies included stage 3 cases, while surgical management varied between breast-conserving surgery, mastectomy, and immediate reconstruction. These characteristics reflect the typical population of BC survivors eligible for rehabilitation, but also highlight potential limitations in generalizability.

A relevant aspect emerging from the FIIT analysis concerns exercise intensity. Unlike frequency and duration, which were usually well defined, intensity was rarely standardized across studies. Some trials referred to perceived exertion scales (eg, Borg and RPE) or to international recommendations (eg, American College of Sport Medicine), while others, such as Park et al [35], described progression exclusively in terms of

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ROM and the transition from passive to active movements with or without dumbbells, without specifying external load. This heterogeneity, and in some cases the total absence of information, hinders direct comparison between protocols and limits clinical reproducibility. From a methodological perspective, the lack of clear criteria for load progression makes it difficult to determine whether observed improvements were due to training frequency, total volume, or actual modulation of intensity. Future telerehabilitation trials should therefore adopt shared and explicit parameters for defining exercise intensity (eg, percentage of one-repetition maximum, RPE, or progressive load adjustments), in order to ensure greater standardization and clinical transferability.

Limitations

Despite promising results, this review presents some limitations. Only 5 studies were included in the meta-analysis due to heterogeneity in intervention types, duration, and outcome measures. Sample sizes were often small, and blinding was generally not feasible, increasing the risk of performance and detection bias. Furthermore, most studies lacked long-term follow-up data, making it difficult to assess the sustainability of effects beyond 3-6 months. The GRADE approach revealed moderate certainty for QoL but low certainty for other outcomes, primarily due to methodological limitations and imprecision.

One relevant limitation of this meta-analysis is the heterogeneity among the included telerehabilitation interventions in terms of delivery mode (eg, mobile app, videoconferencing, and SMS text messaging), session frequency, intensity, and duration. Additionally, the standard care comparator varied across studies, encompassing different rehabilitation strategies and intensities. This clinical and methodological variability may have influenced the estimated effect sizes. The use of a random-effects model was a deliberate methodological choice to account for and mitigate such heterogeneity. Future trials should aim to harmonize both intervention and comparator protocols to enhance comparability and validity. Furthermore, the underreporting of sociodemographic variables such as education, employment, or ethnicity in many trials limits our ability to fully explore how social context may interact with the effectiveness of telerehabilitation. Future research should systematically report these descriptors to improve external validity and allow stratified analyses.

Future Perspectives

From a clinical perspective, these findings support the integration of telerehabilitation into standard postoperative care for women after BC surgery. In particular, telerehabilitation appears to be a valuable complement to in-person rehabilitation, especially for patients who face barriers such as distance, limited mobility, or time constraints. To maximize its effectiveness, clinical programs should be individualized, taking into account disease stage, type of surgery, functional status, and patients' access to and familiarity with digital technologies. From a research perspective, future trials should prioritize the use of standardized and validated outcome measures to ensure comparability across studies and to strengthen the evidence base for meta-analyses. Furthermore, consistent and detailed reporting of sociodemographic variables is needed, as these factors may significantly influence adherence to telerehabilitation and treatment effectiveness, ultimately affecting the external validity of the findings. Addressing these aspects will enhance both the robustness of future evidence and its applicability in clinical practice. Finally, while this review did not include formal cost-effectiveness analyses, the potential economic implications of telerehabilitation deserve attention. Telerehabilitation may reduce indirect costs related to travel, time, and health care resource usage, making it an attractive option for both patients and health care systems. However, these assumptions require confirmation through well-designed economic evaluations alongside clinical trials. Future studies should therefore integrate cost-effectiveness analyses to determine whether the clinical benefits of telerehabilitation are accompanied by sustainable economic advantages.

Conclusions

This SR and meta-analysis confirm that telerehabilitation is an effective and viable approach for postoperative care in women undergoing BC surgery. It significantly improves QoL, reduces pain, and enhances grip strength compared with standard care, with moderate to low certainty of evidence. No significant improvement was observed in the upper limb function, although the direction of effect favors telerehabilitation. The variability across interventions and outcome measures suggests a need for more standardized, high-quality trials. Further research should focus on long-term outcomes, technological enhancements, and cost-effectiveness to support broader implementation.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA 2020 checklist.
[PDF File (Adobe PDF File), 166 KB - rehab_v12i1e77161_app1.pdf]

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Multimedia Appendix 2
Search strategy.
[DOCX File , 18 KB - rehab_v12i1e77161_app2.docx]

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Abbreviations

BC: breast cancer
DASH: Disability of Arm, Shoulder, and Hand
EORTC: European Organisation for Research and Treatment of Cancer
EORTC QLQ-C30: EORTC Quality-Of-Life Questionnaire Core 30
FACT-B: Functional Assessment Of Cancer Therapy-Breast
FACT-G: Functional Assessment of Cancer Therapy-General
GRADE: Grading of Recommendations Assessment, Development and Evaluation
MD: mean difference
NRS: numeric rating scale
PA: physical activity
PICO: Population, Intervention, Comparison, and Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QoL: Quality of life
Quick-DASH: Quick Version of Disability of Arm, Shoulder, and Hand Questionnaire
RCT: randomized controlled trial
RoB2: Cochrane risk-of-bias tool for randomized trials version 2
ROM: range of motion
RPE: rating of perceived exertion
SMD: standardized mean difference
SR: systematic review

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