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Original Paper

Gamified Physical Rehabilitation for Older Adults With Musculoskeletal Issues: Pilot Noninferiority Randomized Clinical Trial

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Abstract

Background: Resource-rich countries are facing the challenge of aging societies, a high risk of dependence, and a high cost of care. Researchers attempted to address these issues by using cost-efficient, innovative technology to promote healthy aging and regain functionality. After an injury, efficient rehabilitation is crucial to promote returning home and prevent institutionalization. However, there is often a lack of motivation to carry out physical therapies. Consequently, there is a growing interest in testing new approaches like gamified physical rehabilitation to achieve functional targets and prevent rehospitalization.

Objective: The purpose of this study is to assess the effectiveness of a personal mobility device compared with standard care in the rehabilitation treatment of patients with musculoskeletal issues.

Methods: A total of 57 patients aged 67-95 years were randomly assigned to the intervention group (n=35) using the gamified rehabilitation equipment 3 times a week or to the control group (n=22) receiving usual standard care. Due to dropout, only 41 patients were included in the postintervention analysis. Outcome measures included the short physical performance battery (SPPB), isometric hand grip strength (IHGS), functional independence measure (FIM), and the number of steps.

Results: A noninferiority related to the primary outcome (SPPB) was identified during the hospital stay, and no significant differences were found between the control and intervention groups for any of the secondary outcomes (IHGS, FIM, or steps), which demonstrates the potential of the serious game-based intervention to be as effective as the standard physical rehabilitation at the hospital. The analysis by mixed-effects regression on SPPB showed a group×time interaction (SPPB_I_t1=-0.77, 95% CI -2.03 to 0.50, $P=.23$; SPPB_I_t2=0.21, 95% CI -1.07 to 0.48, $P=.75$). Although not significant, a positive IHGS improvement of more than 2 kg (Right: 2.52 kg, 95% CI -0.72 to 5.37, $P=.13$; Left: 2.43 kg, 95% CI -0.18 to 4.23, $P=.07$) for the patient from the intervention group was observed.

Conclusions: Serious game-based rehabilitation could potentially be an effective alternative for older patients to regain their functional capacities.

Trial Registration: ClinicalTrials.gov NCT03847454; <https://clinicaltrials.gov/ct2/show/NCT03847454>

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KEYWORDS

rehabilitation; gamification; emerging technologies; experimental; randomized controlled trial; mobility; device; musculoskeletal; older patients; elderly; aging; functionality; physical therapy; computer-aided; intervention; serious games

Introduction

A globally growing geriatric population emphasizes the importance of providing a healthy aging environment [1]. Rather than the absence of disease, “healthy aging” is defined as a process that enables older people to continue to perform activities of daily living and maintain social contact [2-4]. However, as people age, the prevalence of chronic conditions increases. Due to their polymorbidity, older adults are hospitalized longer and more frequently than younger ones, increasing their risk of functional decline [5]. Therefore, after an acute health problem, a rehabilitation phase is often required to regain functionality before returning home.

Musculoskeletal disorders are one of the main reasons for geriatric hospitalization in Switzerland [6], affecting joints, bones, and muscles. During their hospital stay, patients with musculoskeletal issues follow rehabilitation therapy to regain physical function and the capacity to perform daily tasks such as standing, walking, climbing stairs, or bathing independently. Functionality at discharge is inversely proportional to the risk of rehospitalization [7]. After functional recovery, the hospital-to-home transition is increasingly recognized as a critical period, notably to prevent further functional decline and rehospitalizations [8]. Regular physical activity remains the central point to influence these 2 outcomes, but it needs motivation to be maintained over time [9-11].

Researchers have extensively studied the use of computer-aided physical rehabilitation to promote physical activity. Taylor et al [12] performed a meta-analysis to systematically evaluate whether active video games could improve measures of physical performance in older adults and found positive results related to the improvement of mobility and balance. Idris et al [13] developed specific game scenarios, evaluated them with a panel of patients with musculoskeletal issues, and showed the usefulness of the guidelines and associated games. Serious games coupled with monitoring devices such as Kinect [14] have shown the potential to positively impact patients’ motivation to perform rehabilitation exercises [13,15]. The use of a gamified rehabilitation system in addition to or instead of standard physical rehabilitation will have several potential advantages for the health system, the health professionals, and the patients, such as lower hospital costs, shorter hospital stays, and better access to care.

However, whether such devices would be as effective as standard care rehabilitation in the hospital in engaging older adults to remain active after discharge is still understudied.

The objective of the trial was to compare the effectiveness of a gamified rehabilitation device with the standard of care to help older adult patients regain their functional capacities and maintain them 3 weeks after discharge. We already demonstrated that such an approach improved motivation for therapies in a qualitative paper based on the same study, where the focus was more on acceptance, motivation, and engagement [16]. Our hypothesis is that patients in the intervention group will regain independence as much as those in the control group in terms of strength, speed, and balance and that their abilities will be maintained over time.

Methods

Participants

The study took place at 2 different sites in Switzerland: Loëx Hospital, a 104-bed geriatric post-acute rehabilitation hospital, and Joli-Mont, a 60-bed geriatric rehabilitation clinic. Both are part of the Geneva University Hospitals, where the participants’ recruitment took place.

The eligibility criteria were stipulated as follows: patients (aged 65 years and older) hospitalized in one of the 2 study sites with musculoskeletal issues (pelvic or lower limb fractures, hip prostheses, falls, and low back pain), able to stand upright, and capable of understanding the instructions. Being able to interact with the equipment without any sensory, physical, or mental limitations was necessary. Patients considered too weak to interact with the device or planning to go to a nursing home were excluded. Due to a limitation associated with the device’s size, patients with obesity were not eligible.

Study Design

The study is a 2-arm multicenter noninferiority randomized clinical trial examining the effectiveness of gamified rehabilitation equipment to improve older adults’ functional capacities.

The hospital’s electronic medical records of all newly hospitalized patients were accessed (from February to June 2019) to identify potential participants. All patients fulfilling the eligibility criteria were approached by the researchers. If the patient agreed to participate, researchers asked the patient to sign an informed consent form. Participants were then allocated randomly to one of the 2 arms of the trial. The randomization was based on a single allocation ratio, with no block and no stratification. Due to the type of intervention, the allocation was not masked to the participants in the intervention and control groups or to the researchers who recruited the participants.

Materials

ActivLife (Figure 1) is a multifunctional rehabilitation equipment system with different functionalities such as physical activation, rehabilitation, mobility, bed assistance (eg, transfer), and mental stimulation. The equipment is coupled with a serious game platform called Vast.Rehab, which allows the patients to complete their exercises (lower limbs, upper limbs, or both) while playing games. In addition to the game components, ActivLife is composed of an efficient trunk stabilization that reassures the patients while engaging in different movements such as “cleaning the window,” “guiding an ambulance,” or “flying a dragon” [17]. Figure 2 illustrates an example of a game (the “Stairs” game). The games and instructions are displayed on a screen in front of the patient, who is secured in the ActivLife mechanical platform. The screen has a Kinect sensor that allows the software to determine if the patient is doing the exercise correctly. The software allows the physiotherapist to program and schedule a specific treatment (a series of games) for each patient. Based on the patient’s ability and progress, the physiotherapist can easily adjust the type of movement (Figure

3) to control the game as well as the level of difficulty (by defining the required range of motion for each movement).

The game called “Stairs” is about the creature jumping on the stairs one at a time. To make the creature jump, the patient needs to do a sit-up. The range of movement can be adjusted to the capabilities of the patient.

Stepwatch (Figure 4) [18] is a small (75 mm × 48 mm × 14 mm) and light (41 g) tri-axial accelerometer that can measure the activity of the patient in terms of the number of steps, activity

(low, medium, and high), cadence, and velocity. It has a sampling frequency of 200 Hz, and data can be available in 1-second epochs. The wearable does not display any information and can be worn on the ankle using a Velcro strap. The Stepwatch can capture small changes in step rate (99% accuracy [19,20]), thus it can be used to assess changes in physical activity in individuals who walk slowly or use a walking aid such as a rollator. Furthermore, it allows local data collection, which ensures patient privacy.

Figure 1. ActivLife.

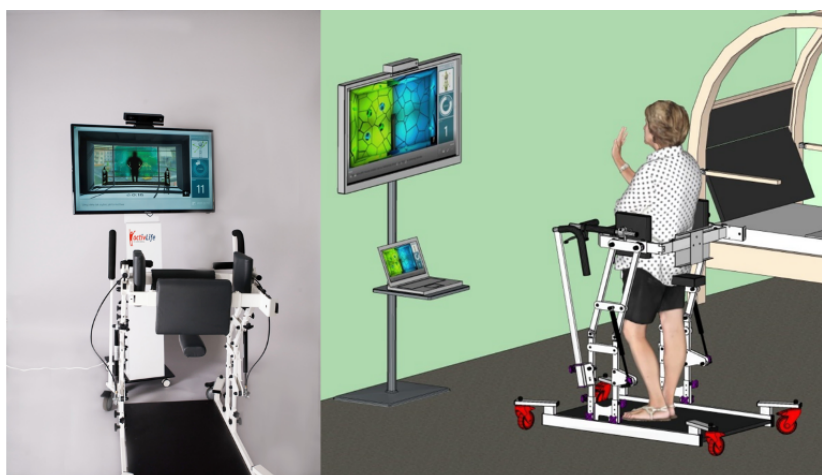


Figure 2. Patient’s interface for “Stairs” game.

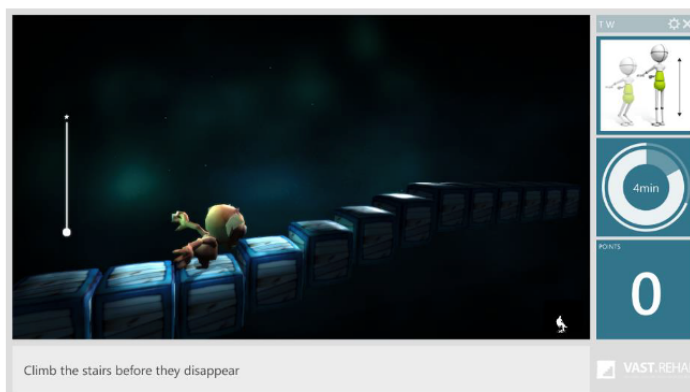


Figure 3. Physiotherapist’s interface—control mode selection.



Figure 4. Stepwatch.

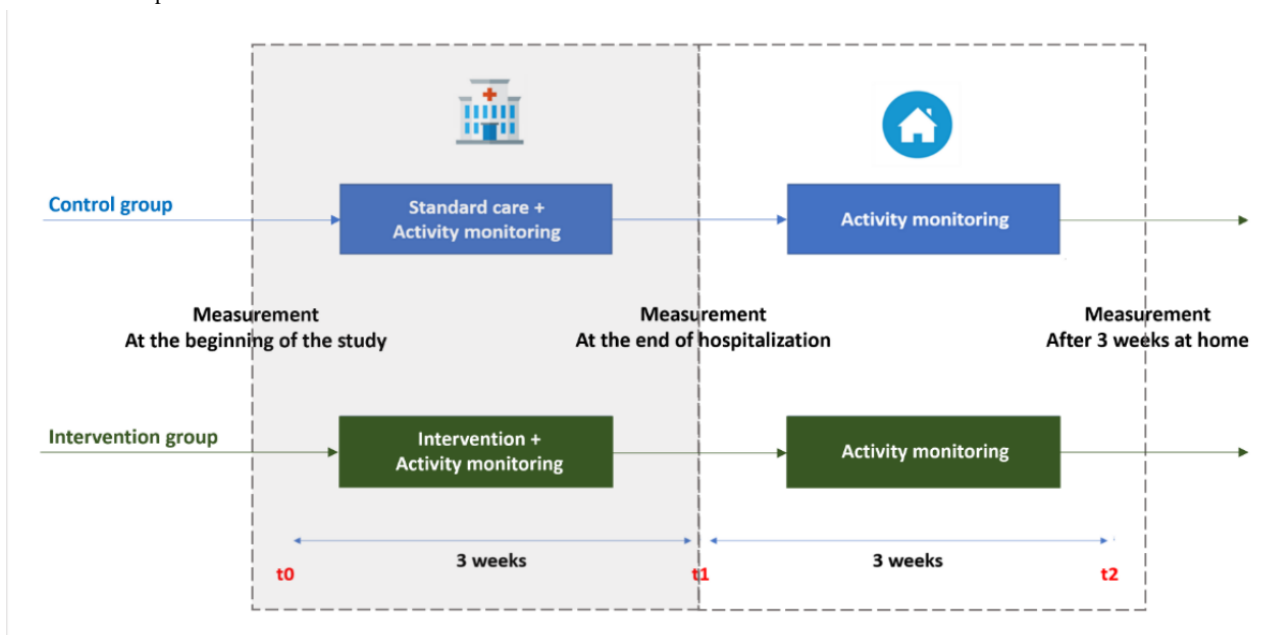


Procedure

For 3 weeks, both intervention and control groups participated in 30-minute training sessions 5 times a week. The intervention group used ActivLife 3 times a week during these sessions, while the control group had all their sessions consist of standard physical therapy sessions. During their hospital stay, the rehabilitation was performed under the supervision of 2 physiotherapists (one at each site). The games played by the patients in the intervention group were selected and defined by the physiotherapist based on the patient’s treatment needs and

abilities. If the patient needed to do an upper limb exercise (eg, moving the right hand up and down, making a 45-degree angle), the physiotherapist was able to choose this movement to control the game. The patients could then play a series of games defined by the physiotherapist during their hospital stay. After discharge (week 3), the patients were assessed at home by the physiotherapist at week 6 (Figure 5). Depending on their state at discharge, some of the patients were recommended to continue physiotherapy at home. All participants in both groups wore the Stepwatch sensor during the 6 weeks.

Figure 5. Research procedure.



Primary and Secondary Outcomes

Used as a primary outcome, the short physical performance battery (SPPB) is an objective tool for assessing lower extremity functioning in older people [21]. This test is associated with the risk of falls, the risk of functional decline, and the risk of death [22-24]. The test consists of 3 parts: balance tests, gait speed tests, and chair stand tests. The SPPB test is based on a point system, with a maximal score of 12 points, meaning an ability to function independently.

As secondary outcomes, we measured:

1. Isometric hand grip strength (IHGS) is a simple and cost-effective method for evaluating overall muscle strength [25]. It is associated with cardiovascular mortality and is a main determinant of sarcopenia (a condition characterized by progressive and generalized loss of skeletal muscle mass and strength) [26,27]. The participant is asked to hold the dynamometer in the hand to be tested, with the arm at a right angle and the elbow next to the body. He or she is asked to tighten the dynamometer with maximum isometric effort, which is maintained for about 5 seconds. The score is expressed in kilograms.

- Functional independence measure (FIM), as a basic indicator of the degree of functionality. This score is associated with the risk of rehospitalization [28]. It is composed of 18 different items scored from 1 (complete assistance required) to 7 (complete independence). The FIM is used to assess functionality in 6 areas, including self-care, continence, mobility, transfers, communication, and social cognition [29]. The FIM is based on a point system, with a maximum of 126 points, meaning an ability to function independently.
- The number of daily steps, assessed by Stepwatch. Patient data were collected at 3 different times: at baseline (t0), after the intervention (t1—end of hospitalization), and 3 weeks after returning home (t2). The SPPB test and the IHGS test were conducted at times t0, t1, and t2. FIM was evaluated at times t0 and t1. Baseline data included age, gender, the Cumulative Illness Rating Score, and the Mini Mental State Evaluation [30,31].

Statistics

The study is a noninferiority trial to test if the gamified rehabilitation concept is at least as effective as standard care with respect to the main outcome measured by SPPB. With a power calculation of 95%, a mean (SD) of 8.8 (1.2), and a noninferiority limit of 0.4, the total sample size needed was 38. Adjusting for a dropout rate of 20%, the sample size needed was increased to 46 patients in total, 23 in each group. To recruit this number of patients, a 6-month inclusion period was anticipated.

The characteristics of subjects are presented as mean (SD) for continuous variables. The normality of the distribution of

continuous variables was verified with Shapiro-Wilks tests. We used a 2-sample *t* test and Fisher exact test to compare baseline data. Mixed-effects multiple linear regression models were used to assess the group and time effects and their interaction on the outcome while taking into account the repeated measure design and adjusting for the presence of a physiotherapist at home and other variables such as the number of sessions, age, and gender. The difference-value was considered significant when $P < .05$. Statistical analyses were performed with STATA (version 16.0; StataCorp).

Ethics Approval and Trial Registration

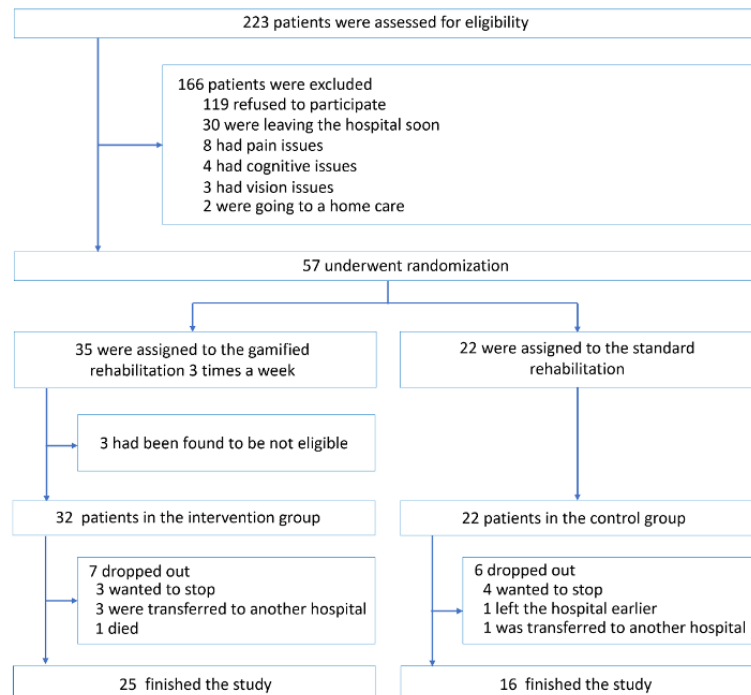
The study has been approved by the Commission Cantonale d'Ethique de la Recherche (CCER) (number 2018-01516). The trial has been registered in the register ClinicalTrials.gov (NCT03847454).

Results

Patients Flow Diagram

The patients flow diagram is described in Figure 6. A total of 223 patients were screened for eligibility. Of these, 166 were excluded from the study (119 refused to participate, 30 were leaving the hospital shortly, 8 had pain issues, 4 had cognitive issues, 3 had vision issues, and 2 were going to a care home). A total of 57 patients underwent randomization to be allocated to the intervention group ($n=35$) and the control group ($n=22$) and were included in the main analysis. During the follow-up phase, 10 patients dropped out from the intervention group and 6 patients from the control group.

Figure 6. Patients flow diagram.



Baseline Data

The mean age of the total participants was 81.5 (SD 6.8) years, with 68.4% (39/57) female participants. The length of stay at

the hospital was 23.0 (SD 11.6) days on average. The Cumulative Illness Rating Score scored 14.3 (SD 6.4) on average. The Mini-Mental State Evaluation showed a mean

value of 23.4 (SD 5.1). The SPPB showed a mean of 6.36 (SD 2.8) at baseline. FIM at admission was 97.4 (SD 16.1) on average. The IHGS scored 20.7 (SD 9.3) kg on average on the right hand and 21.0 (SD 8.6) kg on average on the left hand.

The mean number of steps was 1402 (SD 1162) steps. Participants' data at baseline are described in Table 1. Comparisons of the groups at baseline showed no evidence of differences between the groups in any of the measures.

Table 1. Patients' baseline data (For the FIM^a, CIRS^b, MMSE^c, SPPB^d, IHGS^e, and steps, higher is better).

	Total (n=57)	Intervention group (n=35)	Control group (n=22)	<i>t</i> test (<i>df</i>)	<i>P</i> value
Age (years), mean (SD)	81.5 (6.8)	82.2 (7.0)	81.5 (6.8)	0.37 (55)	.71
Female gender, n (%)	39 (68.42)	24 (68.57)	15 (68.18)	0.48 (55)	.63
Length of stay (days), mean (SD)	23.0 (11.6)	22.5 (11.1)	23.8 (12.7)	-0.40 (55)	.68
FIM (score), mean (SD)	97.4 (16.1)	98.7 (15.2)	95.3 (17.6)	0.77 (55)	.44
CIRS (score), mean (SD)	14.3 (6.4)	14.4 (5.7)	14.1 (7.5)	0.17 (55)	.86
MMSE (score), mean (SD)	23.4 (5.1)	23.6 (6.1)	23.1 (3.7)	0.35 (55)	.73
SPPB (score), mean (SD)	6.36 (2.78)	6.23 (2.80)	6.58 (2.83)	-0.46 (55)	.65
IHGS right (score), mean (SD)	20.66 (9.3)	19.56 (8.67)	21.77 (9.93)	-0.88 (55)	.38
IHGS left (score), mean (SD)	21 (8.57)	19.71 (8.60)	22.29 (8.54)	-1.11 (55)	.27
Steps (score), mean (SD)	1402 (1162)	1359 (1047)	1468 (1319)	-0.36 (55)	.73
Physiotherapy at home, n (%)	30 (52.63)	17 (48.57)	13 (59.09)	0.28 (55)	.78

^aFIM: functional independence measure.

^bCIRS: Cumulative Illness Rating Score.

^cMMSE: Mini-Mental State Evaluation.

^dSPPB: short physical performance battery.

^eIHGS: isometric hand grip strength.

Outcomes

Overview

Figure 7 and Table 2 summarize the outcomes. The analysis by mixed-effects regression on the primary outcome (SPPB) showed a group×time interaction (SPPB_I_t1=-0.77, 95% CI -2.03 to 0.50, *P*=.23; SPPB_I_t2=0.21, 95% CI -1.07 to 0.48,

P=.75) during hospitalization and at home. Due to our small sample size, the wide CIs made our results inconclusive for most of the defined outcomes. However, although not significant, the group×time interaction between t0 and t1 (SPPB_I_t1=-0.77, 95% CI -2.03 to 0.50, *P*=.23) was <0.4 (noninferiority margin). Additionally, no significant differences in any of the secondary outcomes (IHGS, FIM, or steps) were found between the control and the intervention groups.

Figure 7. Outcomes: SPPB, IHGS—right hand, FIM, and steps. FIM: functional independence measure; IHGS: isometric hand grip strength; SPPB: short physical performance battery.

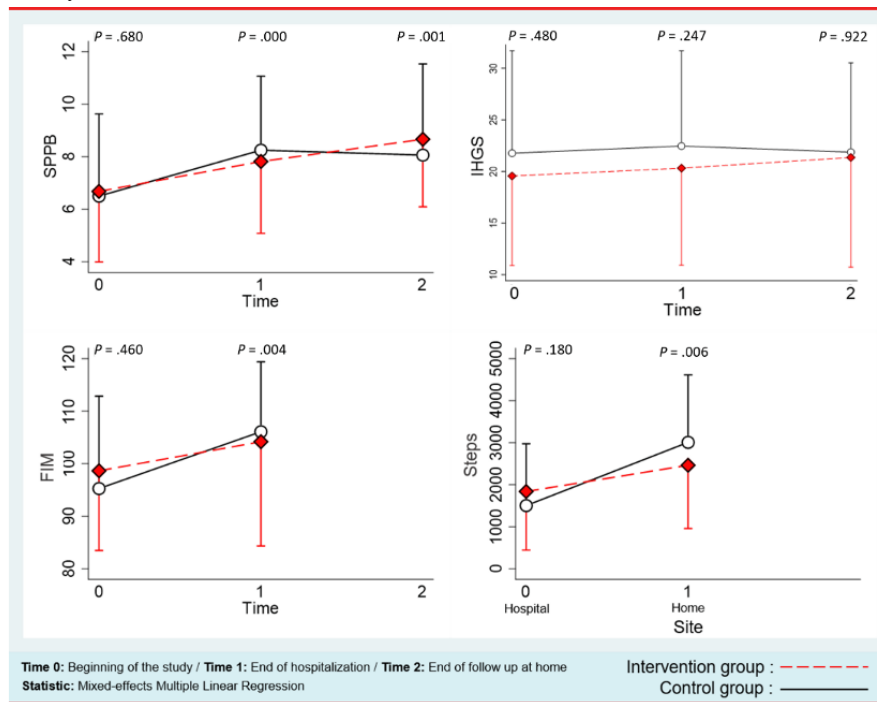


Table 2. Results of mixed-effects regressions.

Outcome variable	SPPB ^a		IHGS ^b (right)		IHGS (left)		FIM ^c		Number of steps	
	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value
Age	-0.10 (-0.21 to 0.01)	.07	-0.30 (-0.56 to -0.04)	.02	-0.23 (-0.53 to 0.06)	.12	-0.62 (-1.15 to -0.10)	.02	-52 (-88 to -16)	.004
Gender(male)	1.37 (-0.19 to 2.93)	.09	12.22 (8.62 to 15.83)	.30	12.78 (8.48 to 17.09)	.60	0.86 (-6.64 to 8.36)	.82	513 (-27 to 1053)	.06
Hospital	0.54 (-1.22 to 2.30)	.55	6.44 (-0.10 to 12.97)	.05	5.80 (-0.17 to 11.78)	.06	N/A ^d	N/A	-692 (-1205 to -178)	.008
Intervention group	-0.65 (-3.12 to 1.83)	.61	-2.62 (-8.31 to 3.08)	.37	-0.23 (-8.63 to 2.16)	.24	4.47 (-4.07 to 13.0)	.31	23 (-664 to 711)	.95
Time 1	1.79 (0.81 to 2.78)	<.001	1.22 (-0.84 to 3.28)	.25	1.24 (-0.31 to 2.80)	.12	10.82 (3.40 to 18.23)	.004	N/A	N/A
Time 2	1.60 (0.62 to 2.59)	.001	-0.12 (-2.62 to 2.37)	.92	0.33 (-1.40 to 2.05)	.71	N/A	N/A	740 (5 to 1474)	.048
Interaction time 1	-0.77 (-2.03 to 0.50)	.23	-0.21 (-2.81 to 2.39)	.88	-0.40 (-2.39 to 1.58)	.69	-5.26 (-14.85 to 4.32)	.28	N/A	N/A
Interaction time 2	0.21 (-1.07 to 1.48)	.75	2.33 (-0.72 to 5.37)	.14	2.03 (-0.18 to 4.23)	.07	N/A	N/A	505 (-448, 1458)	.30
Physio at home	2.43 (0.55 to 4.31)	.01	2.50 (-4.27 to 9.27)	.47	0.94 (-5.51 to 7.40)	.78	N/A	N/A	N/A	N/A
Number of sessions	0.17 (-0.12 to 0.46)	.25	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

^aSPPB: short physical performance battery.

^bIHGS: isometric hand grip strength.

^cFIM: functional independence measure.

^dN/A: not available.

Primary Outcome

Regarding SPPB, there was a main effect of time (SPPB_t1=1.79, 95% CI 0.81-2.78, $P<.001$; SPPB_t2=1.60, 95% CI 0.62-2.59, $P=.001$) reflecting the overall improvement in SPPB score across the 3 measurement points. The main effect of having physiotherapy at home (SPPB=2.43, 95% CI 0.55-4.31, $P=.011$) indicated that remaining active at home has a positive effect on the SPPB score. Although not significant (SPPB_nb_of_sessions=0.17, 95% CI -0.12 to 0.46, $P=.248$), the effect of the number of sessions on the machine tended to be positive. A main effect of gender was also observed (SPPB=1.37, 95% CI -0.19 to 2.93, $P=.09$) indicating that male patients are more active.

Secondary Outcomes

We observed an improvement of more than 2 kg (Right: 2.33 kg, $P=.13$; Left: 2.03 kg, $P=.07$) of IHGS in the intervention group. For the FIM, there was also a main effect of time (FIM_t1=10.8, $P=.004$), reflecting the overall improvement in the FIM score between the 2 measurement points. The mean number of steps (Steps_I=1839; Steps_C=1504) showed that participants in the intervention were somewhat more active at the hospital compared to the control group. However, at home, we failed to observe the same results (Steps_I=2463; Steps_C=3008), while there was a main effect of the site (Steps_hospital=-692, $P=.008$; Steps_home=740, $P=.048$) reflecting an improvement in the number of steps while returning home.

Discussion

Principal Findings

We evaluated the effectiveness of ActivLife, a gamified rehabilitation equipment, for improving functional capacities among older adults with musculoskeletal issues and maintaining them over time. A noninferiority related to the primary outcome (SPPB) was identified during the hospital stay (although it was not significant), and no significant differences were found between the control and intervention groups for any of the secondary outcomes (IHGS, FIM, or steps). These results show the potential of the serious game-based intervention to be as effective as the standard rehabilitation at the hospital.

Comparison to Prior Work

The potential of serious games to improve overall health and specific disease management in older adults has been explored intensively. Parkinson disease [32-34] and stroke rehabilitation [35-37] have been topics of interest for gamified intervention developers. However, a literature review on Kinect-based stroke rehabilitation systems [38] illustrates that previous studies were driven more toward the feasibility and technical effectiveness of such systems than their clinical effectiveness. A similar observation has been found in the use of gamification for cognitive assessment and cognitive training [39].

Additionally, although not statistically significant, it is worth noting that, after 6 weeks, the handgrip strength test improved by 2 kg in the intervention group compared to 0.3 kg in the control group. This effect was likely due to the fact that ActivLife encourages safe upper limb exercises. Knowing that an improvement of 2 kg is considered a minimally significant change in the handgrip test [40], this result demonstrates the potential of gamified rehabilitation to maximize the improvement of older adult patients' muscle strength.

Furthermore, if proven to be as effective as standard care, gamified rehabilitation could potentially induce cost-effectiveness by reducing the time spent by the physiotherapist with the person during a therapy session. Such tools could enable the physiotherapist to manage multiple patients simultaneously, requiring only passive surveillance instead of actively monitoring each one of them. A cost-effectiveness analysis conducted by Rongbo [41] on the use of an intelligent bed system coupled with ActivLife at the hospital showed that relying on the equipment would reduce the time spent by the physiotherapist on one patient from 6 to 2 hours. This would reduce considerably the burden of limited health professionals associated with the increase of musculoskeletal disorders and the prevalence of the aging population [42]. However, as patients value patient-therapist interaction more than the amount or content of therapy during inpatient rehabilitation [43], further investigation is needed to understand the trade-off between those 2 components.

Limitations, Strengths, and Future Directions

Our study presents several limitations. First, the sample size of the study was small, making it difficult to detect moderate effects (eg, differences between groups), especially as we observed several variabilities in the steps' data. Second, due to the subsequent dropouts, some data were missing. Analyses of postintervention results were then adjusted for the remaining participants ($n=41$). Third, the limitations associated with the length of stay of the patients made it difficult to ensure that the intervention group had enough sessions on the machine. However, this experiment also has multiple strengths. First, although based on a small sample size, our study has the benefit of investigating the clinical validity of serious game-based rehabilitation in a real-world setting. Second, the 3-week follow-up at home allowed us to get an overview of patients' improvement after leaving the hospital. To further validate this study, the inclusion of a larger sample size for a longer period is necessary. Another interesting direction could be about understanding and evaluating the potential of using gamified rehabilitation equipment as a hospital-to-home transition tool where the patient will continue to have access to the system (eg, via social institutions) even after discharge.

Conclusions

Our pilot study demonstrated the potential of the ActivLife device, a gamified rehabilitation equipment, to be as effective as standard care (noninferiority) in the treatment of older adults with musculoskeletal issues.

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

CPF is a Section Editor for *JMIR Medical Informatics* at the time of this publication.

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Abbreviations

FIM: functional independence measure

IHGS: isometric hand grip strength

SPPB: short physical performance battery

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Original Paper

Use of the Digital Assistant Vigo in the Home Environment for Stroke Recovery: Focus Group Discussion With Specialists Working in Neurorehabilitation

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Abstract

Background: There is a lack of resources for the provision of adequate rehabilitation after a stroke, thus creating a challenge to provide the necessary high-quality, patient-centered, and cost-efficient rehabilitation services at a time when they are needed the most. Tablet-based therapeutic programs present an alternative way to access rehabilitation services and show a new paradigm for providing therapeutic interventions following a stroke anytime and anywhere. The digital assistant Vigo is an artificial intelligence-based app that provides an opportunity for a new, more integrative way of carrying out a home-based rehabilitation program. Considering the complexity of the stroke recovery process, factors such as a suitable population, appropriate timing, setting, and the necessary patient-specialist support structure need to be thoroughly researched. There is a lack of qualitative research exploring the perspectives of professionals working in neurorehabilitation of the content and usability of the digital tool for the recovery of patients after a stroke.

Objective: The aim of this study is to identify the requirements for a tablet-based home rehabilitation program for stroke recovery from the perspective of a specialist working in stroke rehabilitation.

Methods: The focus group study method was chosen to explore specialists' attitudes, experience, and expectations related to the use of the digital assistant Vigo as a home-based rehabilitation program for stroke recovery in domains of the app's functionality, compliance, usability, and content.

Results: In total, 3 focus groups were conducted with a participant count of 5-6 per group and the duration of the discussion ranging from 70 to 80 minutes. In total, 17 health care professionals participated in the focus group discussions. The participants represented physiotherapists (n=7, 41.2%), occupational therapists (n=7, 41.2%), speech and language therapists (n=2, 11.8%), and physical medicine and rehabilitation physicians (n=1, 5.9%). Audio and video recordings of each discussion were created for further transcription and analysis. In total, 4 themes were identified: (1) the clinician's views on using Vigo as a home-based rehabilitation system, (2) patient-related circumstances facilitating and limiting the use of Vigo; (3) Vigo's functionality and use process (program creation, individual use, remote support); and (4) complementary and alternative Vigo use perspectives. The last 3 themes were divided further into 10 subthemes, and 2 subthemes had 2 sub-subthemes each.

Conclusions: Health care professionals expressed a positive attitude toward the usability of the Vigo app. It is important that the content and use of the app be coherent with the aim to avoid (1) misunderstanding its practical use and the need for integration in practice and (2) misusing the app. In all focus groups, the importance of close involvement of rehabilitation specialists in the process of app development and research was highlighted.

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KEYWORDS

stroke; rehabilitation; digital therapeutic; focus group; home-based rehabilitation; recovery; efficacy; application; rehabilitation program; functionality; usability; development

Introduction

During 2019, in Latvia, 5838 people were hospitalized because of a stroke [1]. More than 80% of these admissions were in stroke units, creating a heavy burden on specialists working in acute stroke care [1,2]. Unfortunately, there is a shortage of rehabilitation providers and a lack of resources for the provision of adequate rehabilitation after a stroke [2-4]. Thus, professionals and organizations are challenged to provide the necessary high-quality, patient-centered, and cost-efficient rehabilitation services at a time when they are needed the most. Increased pressure on hospitals and inpatient centers shows that new rehabilitation approaches need to be considered outside the hospital setting [5,6].

Home-based rehabilitation has the benefit of treating clients in a familiar environment, which stimulates mental and physical activity and prevents problems with transferring learned skills to their daily lives [4]. Research shows that home-based interventions can provide more cost-efficient services [7,8]. In recent years, the use of information and communication technologies (ICT) has been a research area of interest due to its potential to improve the efficiency, quality, and availability of rehabilitation care [9,10]. Tablet-based therapeutic programs present an alternative way to access rehabilitation services anytime and everywhere through the internet and technology under remote guidance of the therapist [11-13]. Tablet-based rehabilitation programs show a new paradigm for providing therapeutic interventions following a stroke [14]. Considering the complexity of the stroke recovery process, factors such as a suitable population, appropriate timing, setting, and the necessary patient-specialist support structure need to be thoroughly researched [15,16]. Research shows that personalized apps could give health professionals a better overview of patients' rehabilitation process and provide follow-up after the patients are discharged from the inpatient rehabilitation center or stroke unit, with the condition that the apps would contain information about patients' health status and functional impairment and the content would support the person-centered rehabilitation process [17,18].

At the time of discharge from the hospital or inpatient rehabilitation center, approximately 74% of physical and occupational therapists hand out a written home program. Even though written recommendations are a widely used approach for continuing rehabilitation at home, they lack 2 key components, adherence and feedback [14,19]. The digital assistant Vigo provides an opportunity for a new, more integrative way of carrying out a home-based rehabilitation program compared to traditional written recommendations. Previous research shows that patients have a positive attitude toward the use of the digital assistant Vigo as a tool for therapeutic home-based programs [20]. To integrate the digital assistant into practice, it is of utmost importance to research the use of the program, not only from a patient perspective, but also from the perspective of health care professionals working in neurorehabilitation. The aim of this study is to identify the requirements for a tablet-based home rehabilitation program for stroke recovery from the perspective of a specialist working in stroke rehabilitation.

Methods

Study Design

A qualitative exploratory study was conducted to identify the eligibility requirements of the tablet-based home rehabilitation program Vigo for stroke recovery from a specialist perspective. The focus group study method was chosen since this method is useful to gather information about the beliefs of a specific subgroup [21]. The main interest of concern is a better understanding of specialists' attitudes, experience, and expectations related to the use of the digital assistant Vigo as a home-based rehabilitation program for stroke recovery in domains of the app's functionality, compliance, usability, and content.

Digital Assistant Vigo

The digital assistant Vigo is an artificial intelligence-based app suitable for installation on Apple iPad. The main goal of the app is to be a digital assistant to patients recovering from a stroke. It is intended to educate and give practical advice and exercises on stroke-related issues, rehabilitation, and care useful for both the patient and their family. The app is designed using chatbot and gamification elements to encourage participation in the patients' individual daily plan that is adapted according to their functional status. Vigo comprises 3 modules: knowledge, skills, and motivation. Additionally, standardized cognitive behavioral therapy (CBT) methods and exercises are used to overcome anxiety, lack of motivation, and depressed mood [22].

Developers of the app describe Vigo as a tool that gives the patient an opportunity to immediately receive interventions intended to be part of stroke rehabilitation medical services (physiotherapy, speech and language therapy, occupational therapy, and psychological support) that are adjusted to be received through a digital device. Exercises provided in the program are in prerecorded video format. It is also stated that to use the app, most of the time the patient does not require help from another person and specialist consultations are needed to solve specific problems [23].

Participants

Participants in this study were selected using a purposeful sampling strategy [24]. Health care specialists were invited to participate in the study if they met the following inclusion criteria: representing 1 of the rehabilitation professions (physiotherapist, occupational therapist, speech and language therapist, physical medicine, and rehabilitation physician) and being employed at a health care facility providing rehabilitation services after a stroke in the acute or subacute phase. Prospective participants were contacted directly or through a contact person at their workplace to provide an introduction to the study and an invitation to participate. Those who accepted the invitation and were eligible to participate received further information regarding the procedures of focus group discussions and confidentiality concerns of the study. Each participant was asked to get acquainted with publicly available information, as well as a manufacturer-provided description and demonstration video about Vigo. Participants were provided an opportunity to try

Vigo on an Apple iPad mini with a manufacturer-provided demo patient profile.

Data Collection

The data in this study were obtained by conducting remote focus group discussions via Zoom videoconferencing software during September and October 2022. The focus groups were moderated by the coauthor (AG), who has previous experience in conducting focus groups for health care research according to a previously designed focus group plan. The moderator of the discussions had no previous experience with the app and had no personal assumptions about the main questions of interest to ensure clarity of gathered data. Discussions were observed by the lead author (KE) assisting, where necessary, and taking notes about the process of the discussion. The lead author played the role of an observer due to their previous qualitative research experience in the usability of the app. A total of 3 focus groups were conducted, with a participant count of 5-6 per group and the duration of the discussion ranging from 70 to 80 minutes. Audio and video recordings of each discussion were created for further transcription and analysis.

Discussions were conducted based on a premade focus group guide containing open-ended questions regarding the Vigo app content, functionality, and user experience. The first focus group was considered as a pilot, and the selected focus group guide questions were modified based on observed participants' responses in order to facilitate data collection.

Ethical Considerations

The study complied with the General Data Protection Regulation and the Declaration of Helsinki and was approved by the Ethics Committee of Riga Stradins University, Latvia (no. 2-PĒK-4/487/2022).

Participants were informed about confidentiality concerns regarding their participation in the study before and at the start of each focus group and provided informed consent by expressing their intention to continue with the discussions.

Data Analyses

Discussion recordings were transcribed verbatim according to predefined transcription rules. All sensitive information, such as participants' names, workplace names, job positions, and locations, that could potentially reveal participants' identity was edited out or replaced by more generic information. Transcripts and original recordings were imported in MaxQDA software, with each speech contribution coded by the participant's ID, recording timestamp, and consecutive number within the focus group.

Data coding was performed in several iterations using an inductive approach to identify and systematically organize themes of the discussion according to the needs of the study. Data coding was performed by 1 of the coauthors.

Thematic data were extracted from all coded segments by rephrasing and summarizing a theme within the speech contribution according to designated codes. Such thematic extracts from all focus groups were organized within the structure of the main themes. Similarly, themed extracts were summarized within the structure of subthemes of the main themes. The resulting summary of themes and subthemes, with references to the original participants' contributions, was used to describe the results of the study. The themes and summaries were discussed and reviewed between all authors of the study.

Results

Participant Characteristics

A total of 29 health care professionals working in neurorehabilitation were invited to participate in the study, 17 (58.6%) of whom accepted the invitation and participated in the focus group discussions. All participants were females. They represented physiotherapists (n=7, 41.2%), occupational therapists (n=7, 41.2%), speech and language therapists (n=2, 11.8%), and physical medicine and rehabilitation physicians (n=1, 5.9%). They were employed in inpatient rehabilitation centers (n=10, 58.8%) or hospital stroke units (n=7, 41.2%), with an additional job at an outpatient clinic in 2 (11.8%) cases. Most of the participants had a professional work experience of 2-5 years (n=5, 29.4%) or 5-10 years (n=5, 29.4%), fewer participants indicated 0-2 years (n=4, 23.5%) and more than 10 years (n=2, 11.8%) of work experience, and 1 (5.9%) participant did not specify any work experience. The majority of participants provided inpatient rehabilitation services (n=13, 76.5%), some provided day-hospital (n=8, 47.1%) and outpatient services (n=9, 52.9%), a few were involved in home-based rehabilitation services (n=4, 23.5%), and 2 (11.8%) of the participants did not specify any type of rehabilitation service they provide. Detailed information about the study participants is provided in [Table 1](#). Most of the participants (n=15, 88.25%), except for 2 (11.8%) who did not provide feedback, felt that they were able to express their views and opinions during the discussion. Most of the participants who provided feedback (n=13, 86.7%) stated that they did not have any technical problems that disturbed their participation in the discussion. In addition, 1 (5.9%) of the participants had internet connection problems and 1 (5.9%) was disturbed by someone outside of the focus group, which hindered their ability to participate.

Table 1. Basic characteristics of study participants (N=17).

ID	Profession	Institution	Time working in stroke rehabilitation (years)	Type of rehabilitation service			
				Outpatient	Day hospital	Inpatient	Home based
1.1	Physiotherapist	Hospital	2-5	Yes	Yes	Yes	No
1.2	Occupational therapist	Hospital	<10	No	No	Yes	Yes
1.3	Speech and language therapist	Hospital	5-10	No	No	Yes	No
1.4	Physiotherapist	Hospital	5-10	No	No	Yes	No
1.5	Physiotherapist	Hospital	2 - 5	No	No	Yes	No
1.6	Physical medicine and rehabilitation physician	Hospital	0 - 2	No	No	No	No
2.1	Occupational therapist	Rehabilitation center	5-10	Yes	Yes	Yes	No
2.2	Occupational therapist	Rehabilitation center	0-2	Yes	Yes	Yes	Yes
2.3	Speech and language therapist	Rehabilitation center	0-2	No	Yes	Yes	No
2.4	Physiotherapist	Rehabilitation center	2-5	Yes	Yes	No	No
2.5	Occupational therapist	Rehabilitation center	5-10	Yes	Yes	Yes	No
3.1	Occupational therapist	Hospital	5-10	No	No	Yes	Yes
3.2	Occupational therapist	Outpatient clinic	2-5	Yes	No	Yes	No
3.3	Physiotherapist	Rehabilitation center	2-5	Yes	Yes	Yes	No
3.4	Occupational therapist	Rehabilitation center	<10	Yes	Yes	Yes	No
3.5	Physiotherapist	Rehabilitation center	0-2	Yes	Yes	Yes	No
3.6	Physiotherapist	Outpatient clinic	5-10	Yes	No	No	Yes

Focus Groups

As outlined in [Textbox 1](#) and [Tables 2-4](#), 4 main groups of themes were identified: (1) the clinician's views on using Vigo as a home-based rehabilitation system, (2) patient-related circumstances facilitating and limiting the use of Vigo, (3)

Vigo's functionality and use process (program creation, individual use, remote support), and (4) complementary and alternative Vigo use perspectives. The last 3 themes were further divided into 10 subthemes, and 2 of those subthemes had 2 sub-subthemes each.

Textbox 1. Coding framework matrix for theme 1 ("clinician's views on using Vigo as a home-based rehabilitation system").

<p>Strengths</p> <ul style="list-style-type: none"> • The use of Vigo potentially can partially compensate for the problems related to the availability of rehabilitation services and the lack of specialists. • Reduce patient costs for rehabilitation, promote patient participation in rehabilitation activities at home, and reduce the involvement of specialists in the home environment. • The goal of the rehabilitation process is to solve the patient's problems through therapeutic activities rather than the patient's involvement in activities. <p>Limitation</p> <ul style="list-style-type: none"> • Effective and targeted use of Vigo currently may only be possible for a small proportion of patients with stroke. <p>Suggestions</p> <ul style="list-style-type: none"> • In the development of Vigo, it could be important to determine the patients' selection process and criteria so that the application of the method would be targeted and effective. • A specialist could recommend the use of Vigo when they are sure that this method will be appropriate and effective for the target population. • Involvement of a specialist with expertise in neurorehabilitation in further product development and research is required to prove Vigo's effectiveness, appropriateness, and usefulness for rehabilitation purposes.

Table 2. Coding framework matrix for theme 2 (“patient-related circumstances facilitating and limiting the use of Vigo”).

Subtheme	Description
Personal factors	<p>Strength:</p> <ul style="list-style-type: none"> • Previous rehabilitation experience can add to motivation and knowledge. <p>Limitations:</p> <ul style="list-style-type: none"> • Age. • Skills and habits of using smart devices. • Lack of motivation for active involvement in therapy. • Language skills. • Health literacy.
Level of functioning	<p>Limitations:</p> <ul style="list-style-type: none"> • The level of independence in carrying out activities is a potential barrier to being able to use Vigo. • Impairment of structures and movement functions. • Patients with cognitive, sensory, and mood disorders would not be able to use the app independently. <p>Suggestions:</p> <ul style="list-style-type: none"> • Unsupervised use could be dangerous for patients with the risk of falls. • A modified level of independence of functioning is most appropriate for the target audience. • The use of the app is limited due to the need to read and understand the text.
Environmental factors	<p>Limitations:</p> <ul style="list-style-type: none"> • Home environment and availability of amenities. • Access to the internet and quality of the connection significantly affect user experience. <p>Suggestions:</p> <ul style="list-style-type: none"> • Involvement of support persons for patients with greater functional impairment broadens the range of potential users. • Involvement of specialists to assess the patient’s home and adjust the home environment. • Possibility to download the content and use it without an internet connection.

Table 3. Coding framework matrix for theme 3 (“Vigo’s functionality and use process [program creation, individual use, remote support]”).

Subtheme: sub-subtheme	Description
The process of creating an individual therapy program: assessment of the patient’s situation	<p>Suggestions:</p> <ul style="list-style-type: none"> To create a rehabilitation program that meets the patient’s needs and abilities, specialist evaluation of the patient is required. Carrying out intermediate evaluations, assessing the dynamics of the patient’s condition, checking the compliance of tasks, and adapting the individual program to the current needs of the patient are equally important. An interim assessment could be conducted with the video call function built into the app.
The process of creating an individual therapy program: options of creating an individual therapy program	<p>Limitations:</p> <ul style="list-style-type: none"> Specialists are not clear on how the assessment of a patient’s functioning impacts the process of creating an individual program and its results. After getting acquainted with the demo version of the app, specialists have concluded that the selection of available exercises and tasks limits the realization of possible rehabilitation goals and is suitable for patients with mild impairment. Bilateral movement exercises, supine position, stable posture, and exercises for voice and dysphagia management are not included. Combining exercises into thematic modules, which are not modifiable, limits the possibility of adapting the program to the patient’s individual abilities and needs. <p>Suggestion:</p> <ul style="list-style-type: none"> A practical way to test the patient’s ability and motivation to use the device is to give it a trial run.
The process of executing the individual therapy program: information and communication in text format	<p>Limitations:</p> <ul style="list-style-type: none"> The communication of the digital assistant with the patient in the form of short message correspondence and the large volume of textual information place additional demands on the patient’s abilities and motivation to use Vigo. Patients with left hemisphere damage, confusion, and visual or perceptual impairment may have difficulties reading and keeping up with the information. There is no option to review the conversation on previous topics of conversation. <p>Suggestion:</p> <ul style="list-style-type: none"> Specialists suggest replacing text message correspondence with voice communication using multimedia content instead of text to inform the patient. Simplification of information and instructions, as well of adaptation of the app interface, would provide the possibility to adapt Vigo for use for patients with different abilities and needs.
The process of executing the individual therapy program: instructions and exercises in video format	<p>Limitations:</p> <ul style="list-style-type: none"> Specialists believe that the patient will not be able to perform the activity correctly without the supervision of a specialist. The demonstrations of exercises do not illustrate how they would be performed by a person with mobility limitations. Therefore, the perception of the exercises can be difficult for patients. There is no option to adjust the speed of the exercise demonstration, which is not appropriate for all patients. If a patient cannot perform or keep up with the exercise video, it might have a negative effect on the patient’s confidence and motivation. The patient must perform the exercises within several minutes without motivational stimuli and warning of the remaining time. The patient must be given the option of being able to choose to skip, modify, or stop the planned activity if they get bored or there is a change in feeling.
Remote support and related considerations	<p>Strength:</p> <ul style="list-style-type: none"> Remote patient counseling could be suitable for solving technical issues related to the app, but adjustment of exercises could require on-site consultation. <p>Limitation:</p> <ul style="list-style-type: none"> Specialists believe that remote assessment cannot be as high quality as meeting with a specialist in person. <p>Suggestions:</p> <ul style="list-style-type: none"> Remote support could be suitable for patients without cognitive impairment and with a milder course of stroke. The specialist should be in regular contact with the patient to perform an assessment and monitor changes in the patient’s condition.

Table 4. Coding framework matrix for theme 4 (“complementary and alternative Vigo use perspectives”).

Subtheme: sub-subtheme	Description
Application in the context of existing rehabilitation services	<p>Strength:</p> <ul style="list-style-type: none"> The use of Vigo as part of home rehabilitation services would allow the specialist to use the device in a targeted way to ensure the patient’s therapy needs, reducing the number of contact hours or increasing the intensity of therapy due to the patient’s independent involvement in the process. <p>Suggestions:</p> <ul style="list-style-type: none"> The use of Vigo in the home environment should be connected to home rehabilitation services. The specialists’ role would be to adjust the program, train the patient and caregiver to use the app, and monitor the therapy process.
Ensuring continuity of care	<p>Strengths:</p> <ul style="list-style-type: none"> Vigo could help ensure the continuity of rehabilitation specialists by giving recommendations on continuing the therapy process at home. Compared to printed recommendation materials, multimedia content can more transparently explain the activities to be performed, promote the patient’s motivation to engage in therapy, and cannot be damaged. <p>Suggestions:</p> <ul style="list-style-type: none"> By supplementing Vigo with information about the prevention of stroke complications and the availability of various support services, it would be possible to provide timely information to the patient when there is no immediate possibility to receive rehabilitation services. Consolidating the recommendations into 1 resource could make them easier to access and less likely to be lost. It is necessary to supplement Vigo’s content and functions so that it becomes a tool that professionals can use at work
Monitoring of therapy	<p>Suggestions:</p> <ul style="list-style-type: none"> Collecting data on the patient’s compliance with therapy could help assess the patient’s performance and progress, determine the presence of problems, and determine the need for support. Vigo has the potential to provide the patient with feedback after they have received rehabilitation services, which could imply new opportunities for research, service improvement, and coordination. It would be beneficial to add a medication schedule, provide an opportunity to film the patient performing tasks for use in the app, and broaden the daily schedule plan.
Support persons as primary users	<p>Suggestions:</p> <ul style="list-style-type: none"> Depending on the required level of assistance, relatives could be the ones who would assist with daily activities or provide the necessary care to prevent the risks of complications with the help of Vigo. Creating a section of the app for support persons as primary users would allow Vigo to be also usefully for patients with major functional impairment. It is necessary to inform the patient’s relatives about the possibility of receiving the necessary psychoemotional or social support services for themselves.

Theme 1: Clinician’s Views on Using Vigo as a Home-Based Rehabilitation System

When researching the opinions of specialists about Vigo, it was assumed that the main way to use the program was for the patient to use it independently (not including technical support, if needed) and the involvement of professionals during the development of the individualized program and interim assessment. Results from the discussions conducted showed that the relevance and potential benefits of using Vigo are as follows:

- Availability of services: The use of Vigo as an alternative to conventional rehabilitation services could be relevant for a patient whose functional impairment is mild enough to not interfere with the use of the device and would be more convenient than receiving rehabilitation services at home or in an outpatient setting. It is assumed that the use of a digital assistant could potentially help partially solve the lack of human resources in the rehabilitation sector under the condition that the specialists will not be excluded

- from the process of using Vigo, and it would also be a way to increase the intensity of therapy.
- Cost reduction: The possibilities to reduce the involvement of specialists in rehabilitation at home, saving the time of the patient and their caregivers’ travel expenses to receive the necessary services, could reduce the total costs of ensuring the rehabilitation process.
- Promotion of the patient’s independent involvement in therapy: Specialists positively evaluate the idea of the possibility for the patient to be involved in the rehabilitation process at home. Participants in the discussions expressed concerns that the technology without the involvement of a specialist could provide an opportunity to fully perform tasks. The daily individual therapy plan and the possibility to perform exercises along with the video demonstration could promote the patient’s compliance with the therapy. Better activity of the patient at home could lead to greater improvements in their functioning, which would reduce the amount of necessary care or assistance and the burden of support persons.

Participants of the focus group discussions identified the appropriateness of using Vigo for the rehabilitation process, indicating that it is necessary to pay attention to the purposefulness and usefulness of the product:

Rehabilitation activities do not take place to provide the patient with the opportunity to “do something.”

The adaption of the new technology must be aimed at improving the patient's functional status at some point of using the program, and the effectiveness must be proven. Specialists believe that there should be a clearly defined target population and selection criteria and that only a small proportion of patients with stroke will be able to use Vigo at home for rehabilitation interventions. Patients with the potential for independent and purposeful use of a digital assistant must be motivated, cooperative, and critical of their condition. They cannot have severe cognitive impairment, neglect, aphasia, and sensory and motor impairments that would significantly limit their ability to use a smart device. In addition, selection criteria should be sensitive to all aspects of functioning, and therapy should be targeted and effective. Therefore, specialists from the field of neurorehabilitation should be involved in the definition and application of the criteria. One participant noted that they would not risk their professional reputation by recommending a therapy method that they were unsure of. It is suggested that further development of Vigo could include expert discussions on needs, iterative development of new features, and content with feedback from experts on the results of the practical application of the program.

Theme 2: Patient-Related Circumstances Facilitating and Limiting the Use of Vigo

According to the results of the study, the following factors were identified as facilitators of or barriers to the use of Vigo for patients: personal factors, level of functioning, and environmental factors.

Personal Factors

Personal factors, such as age, skills in using smart devices, motivation for active involvement in therapy, language skills, previous rehabilitation experience, and health literacy, were mentioned. One physiotherapist shared the experience of using Vigo with two patients, one of whom was 90 years old and the other was middle-aged. The elderly patient could not keep up with the text message correspondence with the digital assistant and had difficulty understanding how the communication was happening with a chatbot, not a real person. However, for the younger patient, “Everything was too slow.”

Another factor mentioned multiple times was motivation for active involvement in therapy. Many perceived rehabilitation as a passive process, gladly receiving a massage or other passive procedures.

A large part of those who request recommendations for doing exercises at home do not follow them.

Vigo could not be used for patients whose language of communication is not Latvian. One of the specialists mentioned that in their institution, “99% are Russian-speaking patients.” The use of Vigo might be easier for a patient who has already

received rehabilitation and has the knowledge of how to perform the exercises. Performing tasks independently at home could then be done correctly if there is a limited opportunity to receive rehabilitation services. The health literacy of the patient and their support persons may affect their ability to participate in the therapy process in an informed manner. The way of providing information should correspond to the patient's ability to perceive information, and it can also affect participation in the therapy process. Educational information should be presented in a simple way.

Level of Functioning

The functional status of the patient affects the use of Vigo, depending on the stage of rehabilitation, the level of independence of the patient, disorders of body structure and functions, the presence of risk of falls, and cognitive, sensory, and mood disorders. Specialists recognized that a patient's functional status and not stage of rehabilitation of the disease will determine the patient's abilities. The modified independence level of functioning refers to the patient's ability to perform daily activities with necessary adjustments independently, which would also be the most appropriate target audience for Vigo use. Unsupervised exercise could be dangerous for patients with increased risk of falls. The limitations in patient functioning that were most frequently cited as an absolute or potential barrier to a patient's ability to use Vigo were related to patients' sensory and cognitive abilities. A patient who is uncritical of their condition or has neglected their paretic side will not be able to perform exercises without a specialist or caregiver. One specialist noted that none of the patients with stroke they worked with during the week would be able to use Vigo independently due to cognitive impairment. The use of Vigo is limited by the need to read and understand text to interact with the digital assistant. This could be difficult for patients with vision problems or cognitive impairment associated with damage to the left hemisphere of the brain.

Environmental Factors

The home environment and the involvement of caregivers were mentioned as important environmental factors. Participants mentioned that the involvement of specialists would be necessary to assess and adjust the home environment, when necessary:

Sometimes the patient doesn't even have a chair at home to sit down to do the exercises.

The availability of the internet and the quality of the connection can significantly affect the user experience or make the patient stop using the digital assistant if they must wait “for some spinning circle” while doing exercises. It was recommended to offer the possibility to download Vigo content to the device so that its user experience does not depend on the quality of the internet connection. By involving relatives in assisting in the use of the device for patients with greater functional impairment, the device could be used for a larger number of patients.

Theme 3: Vigo's Functionality and Use Process (Program Creation, Individual Use, Remote Support)

Based on our results, the aspects of using Vigo can be divided into 3 subtopics: the process of creating individual therapy, the

process of its execution, and remote support and related considerations.

Process of Creating an Individual Therapy Program

The process of creating an individual therapy program and related considerations include the assessment of the patient and adapting an individual therapy program, which must be carried out by a specialist in the field of neurorehabilitation to create a rehabilitation program that matches the patient's needs and abilities. Without understanding the medical perspective of the problem, loved ones may think that the stroke made the person lazy:

Yeah, they think it's the willpower that's missing. He just doesn't want to get out of those diapers, or he doesn't want to talk.

For the successful application of Vigo, it would be equally important to meet with the patient again to make an interim assessment. The specialist should evaluate the dynamics of the patient's condition, check that the patient performs the tasks correctly, and check that the created program is appropriate and adjust it, if needed. Specialists assumed that the partial assessment of the situation could be implemented using the video call function built into the app.

Specialists noted that the best way to check the patient's ability to use the device is to use it for a few days under the supervision of a specialist. This would also allow the testing of the patient's motivation and ability to use a digital device. Several specialists have concluded that they found exercises only for patients with mild functional impairment. Exercises with bilateral movements and a supine position and exercises for voice development and dysphagia management are not included. One occupational therapist noted that attention should be paid to assuming a safe and stable posture with which activities should be started. The specialist's ability to customize the exercise program is limited by the fact that the exercises in the app are grouped into thematic modules, which cannot be changed by excluding an exercise from them if the patient cannot perform it. It is necessary to be able to adjust the speed of exercise demonstration, determine the number of repetitions, and modify the intensity according to the needs of the patient.

Process of Executing the Individual Therapy Program

Considerations of the individual rehabilitation program implementation process are mainly related to the text format of the content, as well as instructions and exercises in video format. One of the specialists noted that without cognitive impairment, they had difficulty reading the many explanatory text messages. A patient with confusion and visual or perceptual impairment, especially with left hemisphere damage, may have difficulty reading and understanding the educational information or instructions. Another disadvantage of the chat correspondence format is that previously provided information disappears and the patient cannot review the topics of previous informational conversations.

The educational information about the home environment is very long, so long that when you read it you forget what was written before.

However, "The information given before disappears." By selecting specific topics that would be relevant individually for the patient, for example, basing their selection on screening questions, the amount of information provided could be reduced. Possible solutions for overcoming obstacles related to the perception of information would be to play the text in voice, to replace the educational text with a short video, to assist loved ones in reading the text, to simplify the instructions and content, and to adapt the visual interface.

Regarding the exercise process, specialists were concerned that without specialist supervision, the patient may not be able to perform the tasks correctly, even if they are suitable for them.

The exercises are demonstrated at the same speed for both sides of the body, which makes it difficult to understand which limb is paretic.

It was also noted that the initial familiarization information for the patient is "horribly long" and overwhelming and that during an exercise block that might last 10 minutes, the patient has no option to stop the activity if they are tired or bored; during the exercise process, the patient is not encouraged or warned about the remaining exercise time. One of the speech and language therapists noted that the exercises to improve the function of the structures involved in articulation and mimicry were demonstrated at a faster rate than the patient would normally be able to follow.

The application is difficult at the moment.

If the patient is motivated but cannot perform the tasks, then this could make the patient feel bad about themselves and stop using the device. Participants indicated that the patient could be bothered by not being able to skip exercises, follow video instructions for exercises they already know, change the order of exercises, and adjust the speed of the exercise demonstration and would need the ability to modify the exercise program, depending on how they are feeling.

Remote Support and Related Considerations

The participants believed that remote assessment of a patient cannot be as high quality as in-person assessment. However, the condition of patients is prone to change, so it is necessary to communicate with specialists at least remotely. Providing remote support requires additional resources and targeted work organization, as specialists working in inpatient or outpatient institutions are not able to respond to patients' video call requests because they do not have time. For technical support, when a patient needs an explanation about the functions or use of the app, a phone conversation could also be sufficient.

Theme 4: Complementary and Alternative Vigo Use Perspectives

Application in the Context of Existing Rehabilitation Services

Specialists believed that Vigo could be used not as an independent rehabilitation method that tries to replace a functional specialist but as an aid for relatives or an additional tool for rehabilitation specialists. The use of Vigo should be connected with rehabilitation services at home, in the framework of which the specialist's task would be to adjust the device,

educate the patient and their relatives about its use, and regularly monitor the therapy process. It could also help compensate for the lack of human resources by reducing the number of specialist contact hours required.

Ensuring Continuity of Care

The use of smart devices could be a great tool and the next step in the use of technology in rehabilitation. Vigo could help ensure continuity of service after discharge from the hospital and prior to and after discharge from inpatient rehabilitation. By adding information about bedsores, other possible complications, and where to find medical assistance, the doctor could use this app to ensure timely and high-quality patient information. In addition, instructions in video format have an advantage over printed visuals, as they can provide a better idea of the required movements, as well as promote patient motivation.

Monitoring of Therapy

Specialists concluded that Vigo's content should be supplemented and suggested creating an opportunity for the specialist to film the patient performing tasks so that the patient can use these materials in the app. In addition, the app should provide an opportunity to enter the necessary medication schedule so that the patient can receive reminders when the medication needs to be taken and an opportunity to create a wider daily plan for daily activities with their performance times. Vigo has the potential to provide therapy monitoring both by following the patient's response during therapy and by evaluating the results (follow-up).

Support Persons as Primary Users

It is difficult for specialists to imagine that a patient in the acute phase of the disease could practice dressing, washing, and other activities without the support of caregivers. It is possible that a person who can use a smart device will also be able to perform the mentioned daily activities. Therefore, the participants suggested that the patients' relatives could be the target users. This would be a suitable use for patients with severe stroke who require moderate assistance or patients with cognitive impairment. Timely involvement of relatives could help ensure that a patient with a more severe course of stroke would not end up in a rehabilitation service with additional complications, because they would have simply slept at home without receiving the necessary care. The loved ones themselves may need psychoemotional support to overcome the effects of their relative's illness and caregiving experience.

Discussion

Principal Findings

This study explored health care professionals' opinions on the use of the digital assistant Vigo for patients recovering from stroke. Qualitative research on the adaptation of stroke rehabilitation technologies shows that stakeholders have identified that key points, such as access to technologies, ease of use, supported self-management, evidence of effectiveness, value for money, knowledgeable staff, and feedback, are important with regard to successful adaptation of the use of technologies in stroke rehabilitation [10]. Results of this study show that health care professionals have similar opinions about

aspects important for meaningful use of the digital assistant Vigo. Findings of this study are also consistent with our previous research on patient perspectives on the use of the digital assistant Vigo, where the main results showed that patients have a positive attitude toward the use of technologies at home, and highlighted the importance of the simplicity of app design, flexibility of content, and benefits on the individual level. Some common points from patients and professionals were about the amount of text in the chatbot, complexity of the information, variety and difficulty of exercises, and practical use in the home environment [20]. Specialists suggested that it would be less demanding for the patient if there was a voiceover option and if the information was illustrated and simplified. It would also be beneficial if the person demonstrating exercises would be someone who has had a stroke and if the user would have the ability to adjust the speed and repetition of the exercises.

The literature shows that the user-centered approach is required to meet the requirements of intended users (health care professionals, patients, and their caregivers) [25-27]. Although there are mixed findings about the opportunities and benefits of home-based technologies, some studies show that home-based rehabilitation technologies offer interventions that are equivalent to conventional interventions [11]. Specialists agree that the digital assistant could partly compensate the shortage of specialists and availability of rehabilitation services, reduce costs, and promote patient participation. Both patients and professionals have shown acceptance of and satisfaction with telerehabilitation interventions, but there are still many barriers [28]. One of the themes that emerged in all the discussions was assessment. Rehabilitation specialists expressed that an important step for development of the app is defining the inclusion process and criteria for patients to use the program purposefully and effectively, with the main concern being that, currently, there is a small group of patients with stroke that would benefit from the use of the tool in the home environment.

Considering the aspects mentioned about defining inclusion criteria and assessment, the process of developing an individual program requires direct involvement of the therapist. The only way the health care professional can be certain that the program is appropriate is to test the program together with the patient. There needs to be an assessment of the patient's functional status, not only at the beginning, but also in the interim, to check whether any adjustments are required. Telerehabilitation services through video calls could be applicable for patients without cognitive impairment and mild functional impairment, as well as addressing technical issues. Specialists believe that remote functional assessment of the patient will not be as accurate as in-person assessment.

Our results also add to the research on the barriers to and opportunities of assistive technology transitions into stroke rehabilitation where the key barriers are knowledge, education, awareness, and access [29,30]. Specialists mentioned that the following patient-related conditions are important for the use of the app: patients' personal factors, functional status, and environmental factors. All the mentioned factors can be barriers, but if addressed correctly, they can become facilitators. Training and good knowledge of professionals, patients, and their caregivers can potentially eliminate some of the barriers

regarding uncertainty about the use of the app in the home environment. Additionally, a secure and strong internet connection plays the most important role, because issues with a poor internet connection can lead to poor quality of videos and a longer waiting time for loading content, thus negatively affecting motivation for regular use of the program [31].

ICT has the potential to effectively provide home-based telerehabilitation services, improve patient education, and provide a means of interaction [32]. Reduction in the availability of poststroke rehabilitation caused by SARS-CoV-2 has serious consequences, indicating that telerehabilitation could be 1 of the solutions as an alternative for therapeutic interventions [28,33]. Health care professionals proposed that the app could also be not only a digital assistant but also a tool to reduce the number of contact hours or increase the intensity of home-based rehabilitation, provide an alternative format to traditional written recommendations for continuing rehabilitation at home, provide feedback, and serve as a guide for the caregivers of patients with stroke.

In summary, health care professionals highlighted the important aspects related to the process of using Vigo in relation to the functionality of the app and patient conditions. The possible barriers and facilitators described indicate that the perspectives of all end users (patients, caregivers, health care professionals) need to be considered in the process of developing a home-based stroke rehabilitation tool. Results of this study shows the complexity of ICT use in the context of stroke rehabilitation. These results outline important key points that developers need to consider in the process of designing home-based e-rehabilitation tools for patients with stroke.

Limitations

There is a lot of quantitative research on the efficacy of different digital tools and technologies used in stroke rehabilitation and qualitative data about patient experience, but there is a lack of information about health care specialists' opinions about specific

program relevance to the target population [11,16,34]. Most of the specialists working in rehabilitation in Latvia are females; thus, there were no male participants in the study. The digital assistant Vigo is a relatively new application, and specialists have had limited opportunities to test the program with patients with stroke. Although each participant in the study was provided with a description of the program and an opportunity to test it, only a few had experience with adjusting the content of the app according to patients' individual needs and functional status. Therefore, specialists had a lot of suggestions and questions about the process of creating an individual program and patients' ability to use it independently at home. Developers need to consider providing more possibilities for specialists to learn more detailed information about the app, its content, and practical use. Some of the participants had a lot of practical considerations about implementing the app in practice that indicates the need for specific training.

Conclusion

Overall, health care professionals expressed a positive attitude toward the usability of the Vigo app, but the app is still a work in progress to show any improvements in patients' functional outcomes. The digital assistant has the potential to partly compensate for the problems of the availability of rehabilitation services and lack of specialists if the program is adjusted appropriately and the patients' functional status allows the use of the app independently. Developers' biggest challenge is to create an app that is adjustable to each patient's individual factors and abilities. It is important that the content and use of the app be coherent with the aim and description defined by the developers. Otherwise, there is a risk of misunderstanding its practical use, not understanding the need for integration in practice, and misuse of the app. To use the app not only to engage the patient in some sort of activities but also to have a therapeutic effect, close involvement of rehabilitation specialists is needed in the process of app development and research.

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Data Availability

Anonymized focus group transcripts in the original language are available as [Multimedia Appendices 1-3](#), and the interview guide for the focus groups is available as [Multimedia Appendix 4](#).

Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group transcript 1.

[[PDF File \(Adobe PDF File\), 122 KB - rehab_v10i1e44285_app1.pdf](#)]

Multimedia Appendix 2

Focus group transcript 2.

[[PDF File \(Adobe PDF File\), 89 KB - rehab_v10i1e44285_app2.pdf](#)]

Multimedia Appendix 3

Focus group transcript 3.

[\[PDF File \(Adobe PDF File\), 85 KB - rehab_v10i1e44285_app3.pdf \]](#)

Multimedia Appendix 4

Interview guide for the focus groups.

[\[PDF File \(Adobe PDF File\), 112 KB - rehab_v10i1e44285_app4.pdf \]](#)

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Abbreviations

ICT: information and communication technologies

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Original Paper

Perspectives of Rehabilitation Professionals on Implementing a Validated Home Telerehabilitation Intervention for Older Adults in Geriatric Rehabilitation: Multisite Focus Group Study

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Abstract

Background: Owing to demographic trends and increasing health care costs, quick discharge with geriatric rehabilitation at home is advised and recommended for older adults. Telerehabilitation has been identified as a promising tool to support rehabilitation at home. However, there is insufficient knowledge about how to implement a validated home telerehabilitation system in other contexts. One of the major challenges for rehabilitation professionals is transitioning to a blended work process in which human coaching is supplemented via digital care.

Objective: The study aimed to gain an in-depth understanding of the factors that influence the implementation of an evidence-based sensor monitoring intervention (SMI) for older adults by analyzing the perspectives of rehabilitation professionals working in 2 different health ecosystems and mapping SMI barriers and facilitators.

Methods: We adopted a qualitative study design to conduct 2 focus groups, 1 in person in the Netherlands during winter of 2017 and 1 on the web via Zoom (Zoom Video Communications; owing to the COVID-19 pandemic) in Canada during winter of 2022, to explore rehabilitation providers' perspectives about implementing SMI. Qualitative data obtained were analyzed using thematic analysis. Participants were a group of rehabilitation professionals in the Netherlands who have previously worked with the SMI and a group of rehabilitation professionals in the province of Manitoba (Canada) who have not previously worked with the SMI but who were introduced to the intervention through a 30-minute web-based presentation before the focus group.

Results: The participants expressed different characteristics of the telerehabilitation intervention that contributed to making the intervention successful for at-home rehabilitation: focus on future participation goals, technology support provides the rehabilitation professionals with objective and additional insight into the daily functioning of the older adults at home, SMI can be used as a goal-setting tool, and SMI deepens their contact with older adults. The analysis showed facilitators of and barriers to the implementation of the telerehabilitation intervention. These included personal or client-related, therapist-related, and technology-related aspects.

Conclusions: Rehabilitation professionals believed that telerehabilitation could be suitable for monitoring and supporting older adults' rehabilitation at home. To better guide the implementation of telerehabilitation in the daily practice of rehabilitation professionals, the following steps are needed: ensuring that technology is feasible for communities with limited digital health literacy and cognitive impairments, developing instruction tools and guidelines, and training and coaching of rehabilitation professionals.

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KEYWORDS

aging in place; aging well; digital technology; remote monitoring; activity; sensor; mobile phone

Introduction

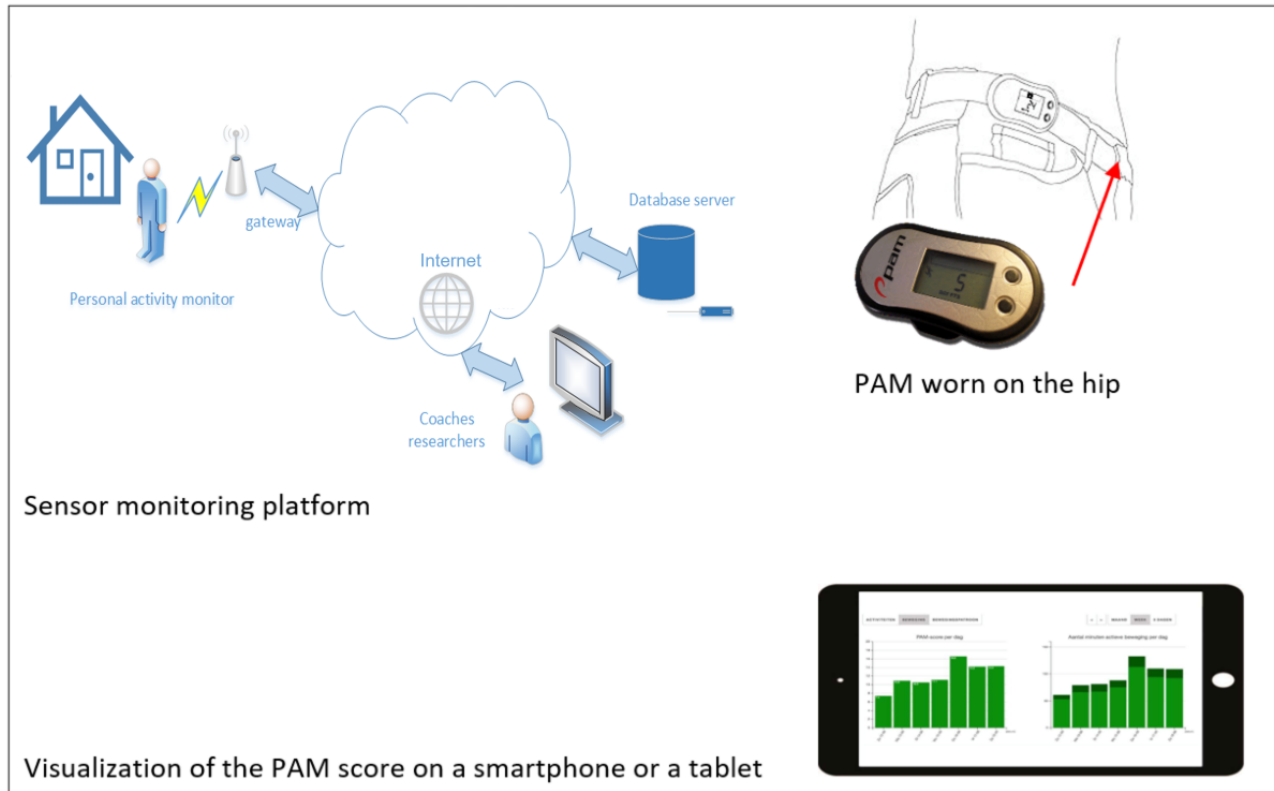
The worldwide aging revolution has put the rehabilitation of older adults high on the agenda of both health care policy and research [1]. The 2 critical policies in many resource-limited countries, aging and reducing hospitalization, which particularly affect older people who are frail, have stimulated the search for appropriate and cost-effective use of rehabilitation resources. It is crucial to increase the adoption of digital health care technologies to support the stakeholders (e, rehabilitation professionals and older adults and their families) in care pathways [2,3].

Geriatric rehabilitation (GR) is defined as “a multidimensional approach of diagnostic and therapeutic interventions, the purpose of which is to optimize functional capacity, promote activity and preserve functional reserve and social participation in older people with disabling impairments” [4]. GR consists of multidisciplinary care with a focus on function and participation after acute illness or functional decline [5,6]. In GR, people over the age of 75 years living with multiple comorbidities are often categorized into four groups: people with (1) stroke (21% of people); (2) traumatic orthopedic problems (19% of people); (3) elective orthopedic surgery (14% of people); and (4) other conditions (38% of people), for example, cardiac, neurological, or oncological problems [5,7]. Depending on national policies and local availability, GR may be offered community service, hospital service, skilled nursing facility, or intensive day program. This results in different patient journeys. The aim of GR is to return home. Once it is safe, based on the condition of the person and social environment, people are encouraged to be discharged home [8,9]. This decision does not mean that these older adults are fully rehabilitated and have reached their rehabilitation potential. They are often restricted in daily functioning and still dependent on ongoing support by rehabilitation professionals and informal care [10-12].

Owing to demographic trends, quick discharge with GR at home is advised and recommended. Moreover, rehabilitation at home is more realistic, and older adults report high satisfaction levels [13]. Therefore, optimal rehabilitation care beyond discharge is crucial, with particular attention to the everyday activities that are meaningful for individuals [12,14]. However, the smooth transition from inpatient GR to home is challenging [15]. The first challenge is that only a minority of older adults receive home-care rehabilitation services after discharge [12]. Second,

the therapist providing in-home rehabilitation is rarely the same therapist at the institution from which the person received initial care, which undermines the continuity of the rehabilitation process. Third, working in the community differs from working in an inpatient setting and requires other skills and work routines. Being discharged from inpatient GR to home with a rehabilitation plan but without continuous support negatively influences the rehabilitation process. The lack of support has, for example, negative consequences for adherence to prescribed exercise routines [16] and leads to a sense of insecurity in older adults [12]. A fourth challenge is the lack of involvement of the older adult in decision-making related to home rehabilitation [17].

In this context, telerehabilitation has been identified as a promising tool in GR [2]. Previous studies investigating telerehabilitation in different conditions have yielded encouraging results [16,18]. A promising and effective home telerehabilitation intervention is a sensor monitoring intervention (SMI) for older individuals rehabilitating after hip fracture, developed at the University of Amsterdam and the Amsterdam University of Applied Sciences [19-21]. The intervention consists of a rehabilitation protocol of coaching supported by sensor monitoring. The coaching is based on the principles of a cognitive behavioral therapy program concerning falls and focuses on setting realistic goals for increasing performance in meaningful daily functioning at home. The sensor technology consists of a wearable sensor worn on the hip that was used to assist older adults in obtaining feedback about their daily physical functioning and as a tool to assist therapists in coaching [22,23]. The wearable activity monitor (physical activity monitor [PAM]; [24]) comprises a 3D accelerometer worn on the hip (68 × 33 × 10 mm). The sensor measures the activity level per day, expressed as a PAM score, which is the ratio between the amount of energy used while active and the amount of energy used while at rest, multiplied by 100. Furthermore, the sensor gives the number of minutes of daily regular and vigorous activity [25]. The data collected by the PAM sensor are stored in the PAM itself and are synchronized with the gateway using Bluetooth when the client is near the gateway. The PAM sensor can collect data for 64 days without synchronization and runs on a single battery for 7 months [23]. This transitional rehabilitation starts within the geriatric care facility with a follow-up rehabilitation at home. [Figure 1](#) shows the sensor monitoring platform's components and system interactions diagram.

Figure 1. The sensor monitoring platform. PAM: physical activity monitor.

The results from a randomized controlled trial (RCT) were positive. In an RCT including 240 community-dwelling older adults after hip fracture, older adults in the sensor monitoring group perceived greater improvements in daily functioning than those in the care-as-usual group [22]. Although the findings from the RCT for the SMI are positive for older adults after hip fracture, there is insufficient knowledge about how to implement a validated home telerehabilitation system in other contexts. One of the major challenges for rehabilitation professionals is the transition to a blended work process in which human coaching is supplemented by digital care. A systematic implementation approach will be crucial to understand its fit within current transitional rehabilitation from different stakeholder perspectives [26]. Therefore, the purpose of this study was to depict the factors that influence the implementation of an evidence-based home telerehabilitation intervention for older adults from the perspectives of rehabilitation professionals working in two different health ecosystems—(1) rehabilitation professionals in the Netherlands who have previously worked with the SMI and (2) rehabilitation professionals in the province of Manitoba (Canada) who have not previously worked with the SMI—by mapping of the barriers to and facilitators of using the intervention. For the sake of clarity for international readers, the term “Canada” will refer to the province of Manitoba in this paper. Our study attempts to answer the following research questions:

1. From the rehabilitation professionals’ perspectives in both contexts (the Netherlands and Canada), what are the characteristics of a successful telerehabilitation intervention in the transition from inpatient to home rehabilitation?

2. What are the needs and expected roles of technology-enabled solutions in GR at home in Canada, and what is the Dutch experience?
3. To what extent are Canada and the Netherlands’ health ecosystems ready to adopt the SMI?
4. From the rehabilitation professionals’ perspectives in both contexts, what are the barriers to and facilitators of using SMI at home?
5. What are the possible next steps to implement SMI in other contexts in Canada and the Netherlands?

Methods

Design

For this exploratory study, we conducted 2 focus groups (FGs), 1 in person in the Netherlands (winter of 2017) and 1 on the web via Zoom (Zoom Video Communications; owing to the COVID-19 pandemic) in Canada (winter of 2022) to explore rehabilitation professionals’ perspectives about implementing SMI. This qualitative research approach allows to gain an in - depth understanding of the barriers to and facilitators of using SMI in the Netherlands (FG 1) or introducing SMI in the Canadian context (FG 2) [27]. The COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist for reporting qualitative research was followed [28].

Context

This study was part of an ongoing study of the development, effectiveness, and implementation of an SMI following the Medical Research Council framework, a framework for the development and evaluation of complex interventions [29]. The first phases of the framework (the development of the

intervention, feasibility, and evaluation) were conducted earlier [30]. This study focused on the stage of implementation and was built on the knowledge gained from the RCT and process evaluation that we conducted alongside the RCT. There was a worldwide surge in the use of telerehabilitation technologies during the COVID-19 pandemic. Therefore, our study secondarily explored the effect of the pandemic on the rehabilitation professionals' perspectives about telerehabilitation before and during the pandemic and using technology to support remote care.

We conducted this study in 2 international contexts. FG 1 was conducted in the Netherlands at the Amsterdam University of Applied Sciences, located in Amsterdam. Participants in this FG worked at 6 different health care organizations for GR in the Netherlands' middle and northwest regions. FG 2 was conducted in Canada at the University of Manitoba located in Winnipeg, Manitoba. All participants in this FG work at a public rehabilitation and long-term care facility.

Participants

Focus Group 1

We purposefully sampled occupational therapists (OTs) who delivered the intervention in the RCT (n=34) [22]. Participants were approached by the main researcher via a recruitment mail including an information letter.

Focus Group 2

Participants were approached via a recruitment email sent by the Deer Lodge Centre Foundation to the Deer Lodge Centre clinical staff. A research team member then contacted the individuals interested in participating in the study. Eligibility criteria for this FG were being an OT or physical therapist (PT) with experience in GR.

Ethics Approval

FG 1 was approved by the Medical Ethics Committee of the Amsterdam University Medical Center located in the Netherlands (ID AMC 2015_169). FG 2 was approved by the University of Manitoba Human Research Ethics Board (HS24220 [H2020:390]).

FG Sessions

The FG sessions followed the guidelines as described by Kruger et al [31].

FG 1 was moderated by an experienced independent moderator and coauthor, MP. The FG lasted 90 minutes. We developed and tested a topic guide to explore therapists' experiences and opinions regarding the use of the telerehabilitation intervention (Multimedia Appendix 1).

First, participants were asked to introduce themselves and share their years of experience, where they currently work, and what type of older adults they deal with. Second, the FG discussion goals were shared with all the participants. Third, brainstorming with stick notes was conducted to collect the most important

topics, and questions and discussions were followed according to the topic guide.

FG 2 was moderated by 2 coauthors (MAC and AQ), was conducted via Zoom, and lasted 1 hour. The researchers followed an FG guide (Multimedia Appendix 1). The discussion started with a general introduction of MAC and AQ. Participants were also asked to introduce themselves and share their years of experience, where they currently work, what type of older adults they deal with, and the focus of their work. Then, the purpose of the FG discussion was shared with all the participants, followed by an introduction to SMI. A 5-minute presentation video was also shown to the participants to give an overview of the SMI technology, its functionalities, how it can be used to monitor older adults, and how it can help OTs and PTs to monitor and coach their older adults.

Data Analysis

Both interviews were audiotaped, transcribed verbatim, and anonymized before analysis. The transcripts were analyzed using thematic analysis [31,32]. We used thematic analysis to understand the barriers to and facilitators of implementing or introducing SMI. The first stage was familiarization with the data, followed by initial coding. Codes were organized in categories (theme identification) and recurring themes (refer to Multimedia Appendix 2 for an overview of themes, categories, and some example quotes). The coding, theme identification, and themes were discussed with MP and MvH (FG 1) and MAC and AQ (FG 2). Discrepancies were resolved until agreement was reached. The final themes were discussed with and agreed upon by the whole research team. The final themes were not shared with the participants owing to feasibility considerations.

Results

Focus Group 1

Overview

Participants were 9 female OTs, with a median practice experience of 10 (range 1-18) years (Table 1). Before beginning the FG session, participants signed an informed consent form. The participants shared their experiences with the SMI and their reflections and opinions about delivering the intervention. The analysis led to five themes:

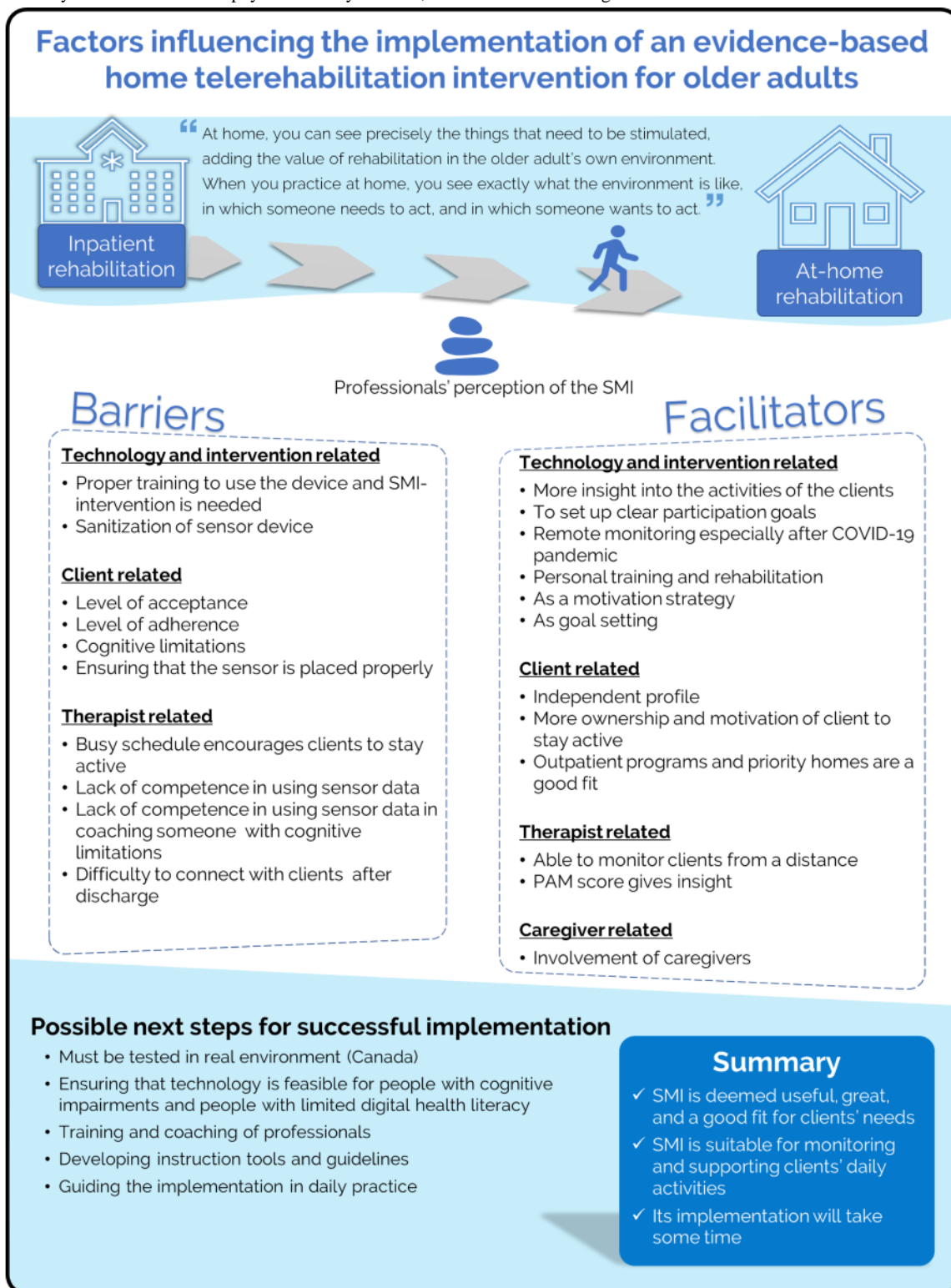
1. The transition from inpatient rehabilitation to home rehabilitation
2. Content of the SMI
3. Facilitators of implementing an SMI for rehabilitation
4. Barriers to implementing an SMI for rehabilitation
5. Recommendations for further implementation

Anonymous quotes from participants will be used with the code of the participant. Table 1 shows the codes and background information of the participants of the FGs, and Figure 2 provides a visual summary of the results.

Table 1. Characteristics of participants in focus groups 1 and 2.

Focus group and participant ID	Experience (years)	Profession	Type of older adults	Work location
1				
A	8	Occupational therapist	Older adults with orthopedic (trauma and elective), neurological, and complex health problems	Geriatric rehabilitation center A
B	14	Occupational therapist	Older adults with orthopedic (trauma and elective), neurological, and complex health problems	Geriatric rehabilitation center A
C	1	Occupational therapist	Older adults with orthopedic (trauma) and neurological problems	Geriatric rehabilitation center B
D	18	Occupational therapist	Older adults with orthopedic (trauma and elective), neurological, and complex health problems	Geriatric rehabilitation center B
E	14	Occupational therapist	Older adults with orthopedic (trauma and elective) problems	Geriatric rehabilitation center C
F	9	Occupational therapist	Older adults with orthopedic (trauma and elective) and complex health problems	Geriatric rehabilitation center A
G	6	Occupational therapist	Older adults with orthopedic (trauma and elective), neurological, and complex health problems	Geriatric rehabilitation center D
H	7	Occupational therapist	Older adults with orthopedic (trauma and elective), neurological, and complex health problems	Geriatric rehabilitation center E
I	12	Occupational therapist	Older adults with orthopedic (trauma and elective), neurological, and complex health problems	Geriatric rehabilitation center F
2				
J	26	Physiotherapist	Older adults with fractures and neurologic conditions	Geriatric rehabilitation
K	30	Occupational therapist	Geriatric older adults	Geriatric rehabilitation
L	10	Occupational therapist	Geriatric older adults	Geriatric rehabilitation (previously, acute care and private practice)
M	22	Occupational therapist	Geriatric older adults	Geriatric rehabilitation
N	11	Manager of PRIME Care and former clinical service lead for occupational therapy	Geriatric older adults	Deer Lodge Centre

Figure 2. Summary of the results. PAM: physical activity monitor; SMI: sensor monitoring intervention.



Transition From Inpatient Rehabilitation to Home Rehabilitation

The participants generally focused on the added value of at-home rehabilitation, after discharge. They expressed that they were used to only providing inpatient rehabilitation, and by conducting this SMI at home, they experienced the added value of at-home rehabilitation. Participant E said the following:

You can apply some part you practiced in the clinic at home. There [at home] you can see the bottlenecks, precisely the things that need to be stimulated. Then you can apply things much better with someone.

Participant B added the following:

You can practice the task of going to the bathroom in a rehabilitation department that has been made as

ideal as possible with a lot of space and adjustments, but it is often different at home.

Participants stated that they became more aware of the added value of treating the clients in their own environment also, for the target group orthopedic rehabilitation. Participant B said the following:

SMI has made me more aware that, I think, with this target group after hip fracture, it is perhaps just as important as with the stroke target group. In the past, we used to see almost no one at home. Still, the idea of continuing the home-based treatment after rehabilitation was more common among people with cognitive problems and stroke older adults because there were more generalization problems. Now, you can see more going on at home than you might have initially expected.

Content of the SMI

After focusing on the benefits of at-home rehabilitation in general, participants mentioned different aspects of the content of the SMI specifically.

Most participants indicated that the SMI helped to focus more on future participation goals that focus on what people want to do again in the future, rather than focusing on primary activities of daily living, as illustrated by participant G:

In our regular work, we are much more focused on practical daily functioning, such as getting in and out of bed and going to the toilet. The goals in the SMI are much more oriented towards the future, a few steps further. For example, revisiting family, traveling, or cooking, extensive cooking, it is a different branch of "sport."

Most participants mentioned that the added value of the intervention helped to get the clients more involved and take more ownership. Participant F stated the following:

The coaching procedure; actively return to those goals each time during the therapy session; where are we now, and how can we take another step forward? I thought that worked well to get someone more involved and in charge of their rehabilitation process.

Participant H noted the following:

I notice a more responsibility on the client's part and more client control. And I notice that the motivation comes more from the client.

Participants mentioned different aspects of the added value of the sensor monitoring data that provide them additional insight and make it more concrete. Participant I said the following:

I liked the sensor- score. Because without the sensor-score, I sometimes found it quite challenging to shape coaching properly. The moment you made certain things clear with the sensor-score, also for the client, I found it a perfect aid because you could look at it and say: look here, you did almost nothing for two days, and on Wednesday, you suddenly did a lot. What

did you do on Wednesday? And how did you make sure you get more done on the other days? The objective data makes it more concrete for me. Just a little more concrete and insightful.

Participant E added the positive value of the sensor data to the therapist as having more upfront information:

You can very well take that sensor information into a conversation. The sensors give additional objective information instead of just a perception. That's also very important.

Some of the participants explained that the SMI contributed to more involvement, motivation, and taking control of the client, as participant I said the following:

I like it because I had a man who was also cognitively impaired, and who became very enthusiastic about the sensor score and asked: "can I log in at home and keep track of my score?" That motivated him. And not only to start exercising but also to keep himself busy with his rehabilitation. I visited him, and he said: "well, yesterday I had a dip in my graph, because...but the day before I went there and there, I needed to rest."

The visualization of the sensor data was helpful for therapists to connect to the goals of the client, as participant E illustrated the following:

Well, if someone has a goal, e.g., I want to exercise more, I want to build up my condition, then you can show that to someone, and then you can also say: gosh, I see that you are indeed building up, you have planned a rest day, or you have taken a rest day, well that's also good for recovery.

Participants experienced the coaching with sensors as providing a deepening in their contact with the clients, as participant G explained the following:

I found it does tighten the contact with someone, where you would otherwise remain more superficial: can you manage to go to the toilet and wash yourself and dress, and maybe it is helpful if there is a shower chair in the shower; you now go more deeply into the conversation with people I think: gosh, what makes it so that you can't do it now or that you have moved more that day.

Barriers to Implementing an SMI for Rehabilitation

The FG discussion identified some barriers to implementing an SMI. The barriers identified were categorized into 2 groups: client-related and therapist-related barriers.

The client-related barriers were (1) the level of vulnerability of the clients, (2) cognitive limitations, and (3) client's level of acceptance and adherence. Most participants experienced difficulties in conducting the intervention with people with cognitive limitations, as illustrated by participant G:

I found it very difficult to coach someone with cognitive limitations. A bit of self-reflection is difficult

to stimulate, so realistic goal setting is challenging if one has no insight into his functioning.

Participant B added the following:

Initiative, I think. There are people who at a certain point in time became very passive sitting in a chair and couldn't think of their own way to do their daily activities and then usually say: "you tell me what I have to do." Then it becomes challenging to let someone be really active with his rehabilitation and to start thinking about it: how can I do that?

Moreover, participant A mentioned the client's level of acceptance or adherence:

Sometimes the client does not understand why they are wearing a sensor.

The therapist-related barriers were focused on the competence in using the sensor data in coaching the client. Participant E said the following:

Yes, I did start thinking very consciously about how I use the data. If you indeed see that someone has done a lot one day and very little the next, then you need to know...how I can discuss this with someone without sounding like: why did you do so little that day? Because that is not at all what you want to say.

Facilitators of Implementing an SMI for Rehabilitation

Apart from the barriers, some facilitators of implementing an SMI for rehabilitation were identified in the FG discussion. These facilitators were categorized into two groups: (1) client-related and (2) informal care-related facilitators. The client-related facilitators were people who were already interested and motivated and had good cognition. Participant B said the following:

Some clients were very interested and motivated in the SMI.

The level of cognitive functioning was mentioned as a facilitator:

The intervention was easy to apply when people had good cognitive functioning.

Participants stated that they see a shift in seeing more vulnerable people who did not function independently before admission. People who were independent before admission found the intervention easy to apply. Participant C said the following:

The intervention was easy to use with people who were independent before admission.

Participants mentioned that the involvement of family or informal caregivers makes SMI easy to use. Participant H said the following:

The intervention was easy to use when family or informal caregivers were involved.

Recommendations for Further Implementation

The recommendations for further implementation emanating from the FG discussion were categorized into three groups: (1) organization, (2) involvement of the multidisciplinary team, and (3) training of therapists.

Participant G said the following:

In practice, who is responsible for the technology? How do you arrange that, the technical part, the ICT part? That gives much peace when you have some clarity on that.

Regarding the involvement of the multidisciplinary team, participant H said the following:

In terms of implementation, I also think that you have to take the team with you because, as a multidisciplinary team, you give advice and direction to the process with the client.

Regarding the training, participant G mentioned the following:

And I really liked that training of the SMI. I would have liked to see more examples, something with videos or something like that.

Participant E told the following:

And on the follow-up training day, there was also a section on cognitive problems, I found that very useful. I think that should also be included in the basic training because that makes up a large part of this target group.

Focus Group 2

Overview

FG 2 involved 5 participants (n=3, 60% women and n=2, 40% men) with 10 to 30 years of experience in GR, including 4 (80%) OTs and 1 (20%) PT (Table 1), who agreed to participate in the FG study and gave their written consent to participate. They all signed consent forms electronically before gathering for the FG. All the participants (5/5, 100%) had experience in the field of rehabilitation and GR. The thematic analysis enabled patterns (themes and resulting categories) across the data set to be constantly compared and drawn together to describe users' perceptions and perspectives about the usability of the devices [33]. Primary themes that emerged from the data were categorized into 2 groups: advantages and barriers. These groups were further subdivided as follows.

Overall, 8 final categories or subthemes were identified as advantages of using SMI technology and 7 final categories or subthemes were identified as barriers to using SMI in Manitoba. The advantages of using the SMI technology were categorized into three groups: (1) motivation, (2) other programs, and (3) client monitoring. The barriers to using SMI technology were categorized into 3 groups: devices or materials-related, therapy-related, and personal or client-related barriers.

FG group successfully analyzed the technology and gave valuable feedback regarding the barriers to and facilitators of using SMI technology in Manitoba. They effectively provided information about the current practice and if the new intervention will be successful in this community. The following sections show the advantages of and barriers to using SMI.

Advantages of Using SMI

The advantages identified in the FG discussion were categorized into three groups: (1) motivation, (2) fit with existing programs, and (3) monitoring clients.

Motivation

The views of our FG participants about the implementation of SMI technology in Manitoba and its barriers and facilitators indicated that this technology has the potential to be useful for older adults in terms of motivation and goal setting, as stated by participant N who “sees this technology as a goal-setting tool” and participant J who mentioned that older adults “could monitor the activity level that’d be beneficial as a motivator.” According to them, this intervention is suitable for the younger population of older adults (aged 65-75 years). They will be able to see and know how active or inactive they are. The intervention was found to be suitable as the OTs and PTs will be able to monitor their clients. OTs and PTs agreed that this intervention would be easy to implement in the younger population of older adults and those who are active in terms of walking and have the habit of staying active. Ensuring that the older adults walk could be a challenge in the absence of a caregiver or supporting family member. Nevertheless, this intervention can be used as a goal-setting approach.

Fit With Existing Programs

Some ongoing programs such as “outpatient programs” and “priority homes” can benefit from this technology. The technology was also found to be suitable for personal training and rehabilitation in general. Those outpatient programs that see older adults for extended periods and can invest time in monitoring older adults for long term can benefit from this intervention. Priority home is another type of rehabilitation program in Winnipeg, which offers at-home care, and they can use this technology for GR and monitoring of older adults at home. They continue to monitor older adults for months after discharge. Participant K stated that she “could see it definitely being useful in that type of setting where you are kind of personal training/rehabbing people.”

Monitoring Clients

Before the COVID-19 pandemic, people used to stay in rehabilitation centers for months and had time for improvement. However, now, owing to the COVID-19 context, changes have been made, and older adults do not stay in rehabilitation centers for extended periods. The intervention could be helpful in terms of monitoring older adults after discharge. Furthermore, this technology will be suitable for specific populations such as the younger population of older adults and people who live with their family members to support them. Participant M thinks that “it might be worth exploring for the right patient like people, maybe, who are some of our younger geriatrics, maybe more tech-savvy or have a supportive caregiver.” Moreover, it would be essential to know the patient history. Implementing this intervention to monitor older adults can aid in developing the patient’s history over time. OTs and PTs will know whether the person is active or inactive and, then, will be able to work with the person accordingly using the SMI. Using SMI technology, good awareness of a person’s history can help OTs and PTs

monitor the clients. The intervention was found to be good for monitoring people by the OTs. Participant M enthusiastically stated the following:

The idea of being able to monitor how much are people doing every day is great; we would love that.

Barriers to Using SMI

Apart from the advantages of using SMI technology, some barriers were also identified during the FG discussion. The barriers identified in the FG discussion were categorized into three groups: (1) device or material-related, (2) OT-related, and (3) patient-related barriers.

Device or Material-Related Barriers

An important point raised during the discussion was that, given the COVID-19 situation, it would be critical to ensure that the intervention belt remained sanitized, as the older adults would be wearing it daily and performing all their daily activities while wearing the SMI intervention belt. The sensor score states that one will get a PAM score of 6 with half an hour of walking, which means a PAM score of 1 will be for 5 minutes of walking. Ensuring that the person walks for 5 minutes straight to get a PAM score of 1 could be a challenge. A person might be active with intervals, for 2 to 3 minutes, probably going from one room to another, but that might not give the PAM score. Understanding the scores and numbers could be a challenge. Moreover, it could be a challenge for OTs and PTs to ensure that the belt has been placed correctly. Using SMI will not be a challenge for the younger population of older adults, but for the older population and those with cognitive impairment, this could be a challenge; they also need to consider whether the device is missing.

OTs and PTs—Related Barriers

According to our participants, OTs and PTs need time to monitor the older adults after discharge and to read graphs of their daily activities while also seeing or monitoring the people who are physically present. This will require extra time, and the schedule of OTs and PTs is usually very busy. In addition, it is difficult to track and stay in contact with the patient on day-to-day basis after the patient is discharged. Ensuring that older adults stay in touch with their OTs in regular basis will be a challenge. Participant K stated the following:

Once the patient is gone from us that bed gets filled with somebody else, and we don’t have any interaction with them. Once they’ve been discharged from Deer Lodge.

Participant K also noted the following:

Days are usually filled, doing a lot of assessments, so, when the beds are full to the day is filled with and you’d have to like things like how long this monitoring would continue.

Another challenge that emerged from our FG discussion is that SMI will be difficult to use for those older adults who live independently with no family member or caregiver. Another challenge that the FG participants stated during the discussion was the challenge with the older adults with cognitive impairment. Participant M stated the following:

It would be difficult to use them with clients with cognitive impairment, or people have no supports, to make sure it's being done properly, etc. those sorts of things.

Personal or Client-Related Barriers

Another challenge that emerged from our FG discussion is that the sensor technology will be difficult to use for those clients who live independently with no family member or caregiver. A substantial challenge that the FG participants stated during the discussion was the challenge with the older adults with cognitive impairment. Participant M stated the following:

It would be difficult to use them with clients with cognitive impairment, or people have no supports, to make sure it's being done properly etc. those sorts of things.

A general challenge that emerged from our FG was the practicality of SMI. Participant N thinks that “consistency and having sensors put on clients” should be considered. In addition, “not having gone missing” is another challenge according to participant N. Older adults sometimes might forget to wear the belt. In that case, OTs and PTs might be unable to monitor their clients daily. Moreover, the older adults will be discharged and will be at home, not at the rehabilitation centers; thus, it will be a challenge to ensure that those people wear the intervention belt so that the OTs and PTs can monitor them regularly. This is more of a challenge for people with cognitive impairment.

Figure 2 depicts the factors influencing the implementation of the SMI. It summarizes the barriers to and facilitators of implementing SMI for at-home rehabilitation. The figure also suggests a list of possible next steps to be considered to support the implementation of SMI.

Discussion

Principal Findings

This study aimed to depict the factors that influence the implementation of an evidence-based home telerehabilitation intervention for older adults (SMI). The information gathered was mapped as barriers to and facilitators of using SMI. We gathered the perspectives of rehabilitation professionals working in two different health ecosystems: (1) rehabilitation professionals in the Netherlands who have previously worked with SMI (FG 1) and (2) rehabilitation professionals in Manitoba (Canada) who attended a 30-minute web-based presentation of SMI before the beginning of the FG but who have not previously worked and did not have experience in working with SMI (FG 2). The qualitative information collected in both contexts provided information about their perceptions of SMI characteristics and the determinants of successful implementation of this telerehabilitation intervention. The information also allowed us to identify the barriers to and facilitators of using SMI.

The participants expressed different characteristics of the telerehabilitation intervention that contributed to making the intervention successful in the Netherlands for the at-home

rehabilitation of older adults and potentially successful in Manitoba:

1. The focus of at-home telerehabilitation intervention is on future participation goals rather than focusing on primary activities of daily living.
2. The technology support provides the rehabilitation professionals with objective and additional insight into the daily functioning of the older adults at home, and rehabilitation professionals from both countries find this promising.
3. The technology contributes to more involvement of the person in rehabilitation and can be used as a goal-setting tool underpinning motivation in clients.
4. The coaching, combined with the sensors' information, deepens their contact with older adults.

According to the rehabilitation professionals, these intervention characteristics facilitated the mechanisms supporting older adults' recovery at home. This result is consistent with previous studies of the experiences and perspectives of older adults after hip fracture [12]. The interviewed older people positively valued SMI and indicated that the technology served as a strategy to enable independent living. The participants perceived that the system contributed to their sense of safety as an important premise for independent living [12]. Older adults mentioned resources for their recovery, such as coaching, motivation, and technology, that supported them to become more active in developing motivation for engaging more fully in their rehabilitation process [12]. However, different factors influence the implementation. A recent Cochrane review of people after hip fracture [34] recommends to continuously evaluate the effectiveness of the various strategies used for rehabilitating people with hip fractures. They found little to no difference between supported discharge and multidisciplinary home rehabilitation versus usual care for people living in their own homes and no or minimal difference between multidisciplinary rehabilitation versus usual care for nursing home residents. Moreover, a recent systematic review, especially for people in GR [35], concludes that outpatient GR was as effective as usual care and possibly more cost-effective. However, in both reviews, no strategies supported by technology were included.

Digital telerehabilitation solutions such as SMI can allow older adults to get discharged soon from the facility while their therapists will still be able to monitor and coach the older adults from a distance. In the Dutch and Canadian contexts, this study shows the need for—and interest in—using this technology to support older adults in their rehabilitation at home. Rehabilitation professionals stated that they became more aware of the added value of rehabilitating the clients in their environment and using this technology to adapt to the pandemic and postpandemic contexts and demographic trends. Previous researchers also have identified the benefit of telerehabilitation in delivering cost-effective home-based interventions, thus encouraging the transfer and maintenance of the rehabilitation achievements to the home context [36].

As expected, the COVID-19 pandemic emerged as an accelerator for adopting technologies to support remote care, particularly telerehabilitation. Before the COVID-19 pandemic,

telerehabilitation had already gained popularity in rehabilitation and occupational therapy services, enabling independence at home through person-centered intervention [35]. Therefore, we are expecting digital technology to take more place to support telerehabilitation. Therefore, in this study, we inquired about the role that SMI would play in at-home telerehabilitation and its acceptance and implementability. Participants in the Netherlands experienced the added value of using SMI to gain more insight into the functioning and participation of the older adult at home. However, the opinions of FG-2 participants about the acceptance of this technology were mixed. Some found it helpful, whereas others liked the opportunity of monitoring the older adults and checking in on them every day. According to FG 2, the technology can be implemented in some running programs, such as the “Outpatient Program” and “Priority Home,” which monitor people in the community after discharge. “Priority Home” is a person-centered collaborative philosophy focused on keeping people—specifically older adults with high needs—safe in their homes for as long as possible with community support [37].

Before the COVID-19 pandemic, in Canada, older adults used to stay for more extended periods at rehabilitation centers and had time for treatment and improvement. Moreover, OTs are used to ensure that the older adult is physically well before leaving the facility. This is similar to the context in the Netherlands. Emerging literature mentions that health care providers turned to technology to stay in touch with older adults [2,38,39]. Older adults were discharged sooner than before to avoid close contact during the COVID-19 pandemic. All the FG participants in Canada perceived monitoring and coaching older adults after being discharged as a valuable idea and a safe practice to standardize beyond the pandemic. They believe it to be an excellent time to have such technology; older adults want to be at home, and if that is possible with the help of portable technology that will connect the older adults to their health care providers, that technology deserves to undergo an implementation trial [40]. In Canada, FG participants stated that while older adults are in the rehabilitation center, they have a team to monitor them, but once the person is discharged, therapists have little consistent interaction with their clients. Therefore, it is beneficial to use telerehabilitation to stay connected after discharge to ensure that people are doing well, as experienced during the COVID-19 pandemic. Following the pandemic, this novel practice should be regarded as a new standard.

The analysis showed facilitators of and barriers to the implementation of the telerehabilitation intervention. These included (1) personal or client-related, (2) therapist-related, and (3) technology-related aspects. All FG participants noted that SMI implementation is feasible if therapists can monitor clients remotely, especially as part of existing programs (eg, outpatient programs) and if the clients are independent and willing to engage in a technology-enabled remote monitoring program. The involvement of a family caregiver has also been noted as a facilitator of implementing SMI. In terms of the intervention, it appears that setting up clear participation goals and a motivational strategy is a key facilitator of remote monitoring. It is well established that motivation promotes better

telerehabilitation outcomes, as does patient involvement in decision-making centered on goal setting [41]. Client participation in telerehabilitation is viewed as a facilitator of their adherence to the programs, which determines rehabilitation success. According to the literature, the success of physical rehabilitation programs depends on clients completing the planned therapeutic exercises [42]. SMI provides insight into daily activity, which is thought to promote adherence among independent clients. The results of the RCT were positive for the intervention group [22], and the older adults indicated that the technology served as a strategy to enable independent living [12]. However, both FG participants noted that client’s level of vulnerability, cognitive limitations, and level of acceptance and adherence are the most critical barriers to implementation. Most participants indicated that older adults with cognitive impairment would have difficulty in adapting to technology. However, now and in the future, there will be more people with complex diagnoses, with a mix of cognitive and physical deficits, and more people will stay and return to the community. Therefore, it is important that the technology should be accessible and easy to use by people with limited digital health literacy [43].

Previous studies demonstrated that older adults with limited experience could be taught to use technology successfully [44]. Rehabilitation professionals felt less confident and competent in delivering a telerehabilitation intervention to these older adults. Our findings are consistent with those of other studies that found that some rehabilitation professionals perceived older adults’ lack of confidence in a technology or their old age as a barrier to using that technology and, as a result, may be hesitant to incorporate telerehabilitation into their practice with older adults [45]. These findings must be balanced between the 2 sites in terms of years of clinical experience and technological use. A cross-sectional survey was conducted across Canada to determine Canadian OTs’ knowledge and practice of information and communication technology (ICT) with older adults and factors associated with its recommendation [46]. Of 387 OTs, only 12.4% reported recommending ICT in practice. According to the findings, clinicians with more clinical experience were more likely to recommend ICT. Surprisingly, Canadian participants had more experience than their Dutch counterparts but were more hesitant or reluctant to use the technology with older adults and people with cognitive limitations. The difference between the 2 sites could be owing to environmental differences. According to the same Canadian survey, clinician services, work environments, and client diagnoses were all factors associated with ICT recommendation [46]. The Dutch National Institute for Public Health and the Environment (*Rijksinstituut voor Volksgezondheid en Milieu*) conducted the 2021 eHealth monitor survey to monitor the development and uptake of eHealth across the Netherlands [47]. In comparison with 2019, an increase in the use of eHealth was reported. For example, the use of video calling increased greatly in 2021, and more organizations now have so-called patient portals, apps, or secured websites for their clients. Although the use of eHealth has increased substantially, the COVID-19 pandemic has given it an extra boost. One of the conclusions of the annual report was that clients and care providers are optimistic about this increase, but they also mention some concerns. Clients are often unaware about eHealth options, and rehabilitation professionals

found that eHealth creates a heavy workload. Better knowledge and change in working methods are needed to improve this situation [47]. This is consistent with this study, where the FG participants suggested proper training on the use of SMI in their practice [48].

Regarding technology-related barriers, SMI technology does not tell us the number of steps a person walks, but the PAM score on SMI technology indicates how much a person moved per day. The PAM score provides insight into the overall activity and how well a person is progressing. This information helps create achievable goals for speedy recovery. PAM sensor registers the amount of activity and provides insight into the intensity of the activity performed throughout the day. This information was perceived as valuable by the rehabilitation professionals of both FGs. Activity monitors may not accurately detect steps in older adults who walk slowly, as stated in the literature [49], but SMI quantifies the intensity of movement, making it capable of monitoring the activity regardless of the walking speed. According to literature, long walks last longer in hospitals than at home after discharge, whereas short walks are usually more frequent and short at home [50]. It was mentioned by the FG participants that the therapists would want the older adults to be active after getting discharged, but once they leave the facility, they do not do that often. Overall, all the FG participants believed that telerehabilitation could be helpful for older adults. It will help OTs and PTs to have more insight into the daily physical activities of the individuals after getting discharged and allow older adults to be treated in their own homes.

Making telerehabilitation beneficial, functional, and feasible for people with cognitive impairment could be the next important step in making the telerehabilitation technology better and more suitable for such a population. We should further develop the graphs of the sensor technology to give better information to therapists to help them understand what the sensor scores mean and how the scores are situated versus the rehabilitation goals already set up with the older adult. Training on how to use the telerehabilitation intervention with people with cognitive impairment and implementing the intervention in their daily practice is needed. Therefore, we must develop instructional tools and guidelines with the rehabilitation professionals and older adults to ensure implementation in their working routines. Collaboration among all stakeholders in further developing the telerehabilitation intervention is essential for its implementation [29]. Our results indicate that the adoption of telerehabilitation technology may take time. It will be good

to implement this technology not only for the younger population of older adults (aged 65-75 years) but also to make it feasible for all different groups of the older population, including those with low digital health literacy. Although there will be barriers with some specific populations, such as older adults with cognitive impairment, the technology can be implemented successfully in practice with the proper approaches.

Strengths and Limitations

One of the strengths of our study was the generation of a valuable understanding of rehabilitation professionals' experiences and perspectives about implementing a telerehabilitation intervention and the factors contributing to its implementation. Another strength is that we included data from 2 different international contexts, before and after the COVID-19 pandemic, and collected data from participants who had hands-on experience with an SMI and from participants who had not. Internationally, GR is offered as different services; therefore, we can only make general recommendations for implementing an SMI, as obtained from the FG discussions. It is necessary to test the SMI in a specific context. The 2 studies did not include the perspectives of older people, their family members, or decision makers about the SMI technology. However, we investigated the perspectives of older adults in the Netherlands previously [12]. The studies concentrated on rehabilitation professionals because they are involved in both the individual (care delivery to older adults) and system levels. However, more studies are needed to understand the factors influencing SMI implementation from organizational perspectives (eg, policy makers and decision makers) and perspectives of older adults and their family members in Canada.

Conclusions

Rehabilitation professionals believed that telerehabilitation could be suitable for monitoring and supporting older adults' rehabilitation at home. The analysis showed facilitators of and barriers to the implementation of the telerehabilitation intervention. These included (1) personal or client-related, (2) therapist-related, and (3) technology-related aspects. To better guide the implementation of telerehabilitation in the daily practice of rehabilitation professionals, the following steps are needed: (1) ensuring that technology is feasible for a population with limited digital health literacy or cognitive impairments, (2) developing instruction tools and guidelines, and (3) training and coaching of rehabilitation professionals.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Topic guide for focus group for exploring occupational therapists' experience with and opinions about delivering the sensor monitoring intervention for rehabilitation after hip fracture (SO-HIP).

[[DOCX File, 17 KB - rehab_v10i1e44498_app1.docx](#)]

Multimedia Appendix 2

Overview of themes, categories, and quotes from the focus group interviews.

[[DOCX File, 25 KB - rehab_v10i1e44498_app2.docx](#)]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

FG: focus group

GR: geriatric rehabilitation

ICT: information and communication technology

OT: occupational therapist

PAM: physical activity monitor

PT: physical therapist

RCT: randomized controlled trial

SMI: sensor monitoring intervention

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Original Paper

Experiences With In-Person and Virtual Health Care Services for People With Chronic Obstructive Pulmonary Disease: Qualitative Study

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Abstract

Background: The World Health Organization and the European Commission predict increased use of health technologies in the future care for patients in Europe. Studies have shown that services based on telehealth, which includes components of education, as well as rehabilitation initiatives can support the self-management of individuals living with COPD. This raises an interest in how virtual and in-person interactions and roles can best be organized in a way that suits people living with COPD in relation to their treatment and rehabilitation.

Objective: This study aims to investigate how individuals living with COPD experience different combinations of virtual and in-person care, to help us better understand what aspects are valued and how to best combine elements of these services in future care.

Methods: Two rounds of semistructured interviews were conducted with 13 and 4 informants, respectively. The individuals were all recruited in relation to a research project led by the telehealth initiative Epital Health. The first round of interviews included 11 informants, as 2 dropped out. Of these, 7 received the telemedicine service provided by Epital Health, 3 participated in a 12-week COPD program provided by their respective municipality, and 1 did not receive any supplementary service besides the usual care. In the second round, which included 4 informants, all had at one point received the telemedicine service and participated in a municipality-based rehabilitation program. A content analysis of the interviews was performed based on deductive coding with 4 categories, namely, (1) Self-management, (2) Health-related support, (3) Digital context, and (4) Well-being.

Results: Medical and emotional support from health care professionals is a key aspect of care for individuals with COPD. Acute treatment with at-home medicine, monitoring one's own condition through technology, and having easy access and close contact with health care professionals familiar to them can promote self-management and well-being, as well as provide a feeling of security. Having regular meetings with a network of peers and health care professionals provides education, support, and tools to cope with the condition and improve own health. Furthermore, group-based activity motivates and increases the activity level of the individuals. Continued offers of services are desired as many experience a decrease in achieved benefits after the service ends. More emphasis is placed on the importance of the therapeutic and medical elements of care compared with factors such as technology. The identified barriers related to optimal utilization of the virtual service were related to differentiation in levels of contact depending on disease severity and skills related to the practical use of equipment.

Conclusions: A combination of virtual and in-person services providing lasting medical and social support is suggested for the future. This should build upon the preferences and needs of individuals living with COPD and support relationships to caregivers and peers.

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KEYWORDS

chronic obstructive pulmonary disease; telemedicine; telehealth; virtual RCC service; rehabilitation; self-management; eHealth literacy; social support; well-being

Introduction

Background

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death globally with 3.23 million deaths reported in 2019 [1]. The condition is characterized by breathlessness (dyspnea), coughing, increased sputum, and tiredness [1]. This often results in reduced physical activity, sleep disturbances, the experience of social isolation, anxiety, and depression [2-5]. The World Health Organization Regional Office for Europe (WHO/Europe) and the European Commission predict an increase in the integration of telemedicine and health technologies for the treatment of patients in Europe. Following the approval of the Regional Digital Health Action Plan for 2023-2030 by the Ministers of Health at the WHO Regional Committee for Europe in September 2022 [6,7], there is an expectation for a new way of collaborative management between health care professionals (HCPs) and patients. This makes it more relevant than ever to gain insights into what expectations patients have for their treatment and what they value in already experienced treatment programs. This knowledge can contribute to an understanding of what elements of care should be considered when designing and providing new ways of caring for patients with COPD, and how the use of technology can help to alleviate current shortcomings in treatment as experienced today by patients globally.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommends pulmonary rehabilitation as part of integrated patient management [8]. Pulmonary rehabilitation, as defined by an expert group from the American Thoracic Society together with the European Respiratory Society, is “a comprehensive intervention based on thorough patient assessment followed by a patient-tailored therapy that includes, but is not limited to, exercise training, education, self-management intervention aiming at behavior change, designed to improve the physical and psychological condition of people with chronic respiratory disease and to improve the long-term adherence to health-enhancing behaviors” [9].

The GOLD recommends that rehabilitation programs should last from 6 to 8 weeks and include a range of HCPs to cover the different aspects of patient education [8].

The motivation for this study originated from our previous work concerning the development and implementation of a 24/7 telemedicine service for individuals with COPD [10]. In this work we, among others, discuss the extent, as well as the related challenges, to which virtual and in-person services can most efficiently be combined to offer a digitally assisted active and independent living that meets the needs, preferences, and values of people with COPD [10,11]. To better understand this concept, we will build on a recently developed model, the Readiness and Enablement Index for Health Technology (READHY) [12-14], as a theoretical framework that helps us to enlighten aspects of the role of support by peers and professionals, their digital health

literacy, and their ability to self-manage. By using this lens in interviews with a group of individuals having an experience that covers a range of combinations of exposures to virtual and in-person medical treatment and rehabilitation services, it is anticipated to help us better understand how to best combine services that are offered virtually or in-person, which may create better support from peers and professionals and increase ease of access to technology, increase self-management, and achieve a higher level of well-being.

Role of a Supportive Network in COPD

Social support may be a factor for the improvement of self-care behavior, treatment adherence, and self-efficacy among patients with COPD. It may also help maintain or improve their overall functioning (covering 6 domains as defined by the World Health Organization Disability Assessment Schedule 2.0 [WHODAS II] score) [15,16]. Further, a higher degree of social support is associated with lower levels of depression and anxiety, as measured by The Beck Depression Inventory (BDI) and The State-Trait Anxiety Inventory (FormX-2, Trait Anxiety). Likewise, negative social support (eg, an unsympathetic response and the feeling of being let down by social network members) is associated with higher levels of depression and anxiety [17,18]. Anxiety, in turn, is associated with poor health-related outcomes, such as poor physical health status and performance, risk of COPD-specific deterioration and exacerbations, functional limitation, and lower disease-specific quality of life [17-19]. Interventions aimed at increasing social support, fostering self-efficacy, and reducing anxiety can help maintain overall functioning among patients with a chronic condition [16].

Role of Technology

It is generally believed that digital tools can promote patient empowerment by enhancing the one's ability to understand and influence their own health status, enabling distant clinical support, and increasing the ability to manage the disease in an at-home setting [11,20]. This is in contrast to our recent study, where we found that participants in a 24/7 accessible virtual response and coordination center (RCC) service felt less active over time in managing their health [21]. This may indicate a decrease in independence, but could also be an indicator of the virtual RCC service easing the management of their health.

With the prospect of increased use of telemedicine and health technologies in the future care for individuals with COPD [6,7], it is important to understand the individual preferences and values in relation to virtual and in-person services for successful planning of future health services. To meet this need for information, we herein report on the problems individuals with COPD experience in their care today, and how this can be managed by virtual and in-person services. The main objective is to identify the elements of the different services explored in this study, namely, a virtual RCC service, in-person municipality-based rehabilitation programs, and no specific initiatives besides regular care, informants value in their care,

and those that would be important to maintain in a future care model. To obtain this information an analytical framework inspired by READHY [12] will be adopted with increased mental well-being as a goal.

Self-management

Self-management has been defined in many ways, but in the context of living with a chronic condition it is referred to as the ability to deal with all that a chronic illness entails, including symptoms, treatment, physical and social consequences, and lifestyle changes [22]. It is essential to improve both general and mental health, which in this context is “a state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively, and is able to make a contribution to his or her community” [23]. A review from 2022 reported that interventions to improve self-management in patients with COPD are associated with improved outcomes including improvements in health-related quality of life (measured by the Saint George Respiratory Questionnaire), lower probability of respiratory-related hospital admissions, and no excess respiratory-related and all-cause mortality risks [24]. It may also improve physical activity and performance, as well as emotional function, and reduce the number of emergency room visits [25-28].

Interventions aimed at improving mental health as well as symptom management prove more effective than those solely aimed toward symptom management [27]. This is supported by the WHO, which defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” [23]. Examples of self-management strategies are breathing exercises, physical activity, and techniques to perform daily activities [29].

A Norwegian study from 2018, using the Health Education Impact Questionnaire (HeiQ) to assess the ability of patients with COPD to manage their condition and how this affects their condition, found that a higher symptom burden from COPD was associated with a lower level of self-reported ability to manage their own condition. This was related to t-scores in 6 out of 8 scales [30].

Many patients with COPD have limited knowledge about their condition, including the cause of the disease, the consequences of inadequate therapy, and the management and prevention of exacerbations [31]. Insufficient knowledge is related to poor adherence to medical treatment and as a consequence a lack of experience of its benefits [15].

Methods

Study Overview

This study is reported according to the COREQ (Consolidated Criteria for Reporting Qualitative Research) [32] and follows the recommendations by Connelly [33] and Lee [34] to ensure trustworthiness.

Study Setting and Context

Alles Lægehus is an organization providing primary health care in 17 general practice centers in Denmark.

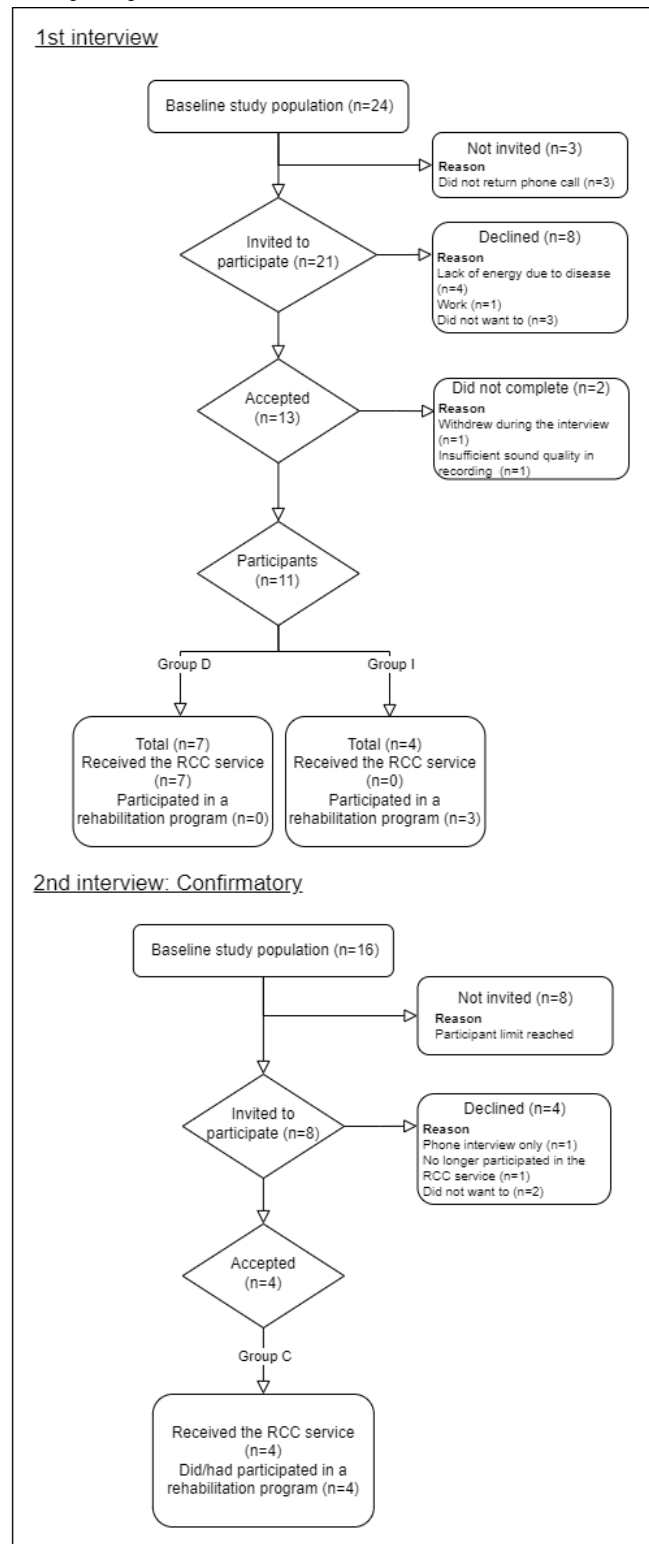
In Denmark, visits to the general practitioner (GP) are normally free of charge for the patients, as the GPs are reimbursed by 1 of the 5 Danish regions. The GPs are either working alone or organized in joint GP centers, where typically 3-8 physicians work together and are assisted by registered nurses and medical secretaries. In some areas of Denmark, it is difficult to recruit GPs. In these areas, the GP services are offered by medical doctors employed by either the Danish regions or private organizations. They can be former GPs or recruited from hospitals and are employed full-time, part-time, or are temporarily visiting. They can be located in either individual practices or GP centers.

Study Design and Interview Participants

The informants for this study are recruited among those participating in an ongoing randomized controlled trial, the TEMOCAP study (Telemonitoring of COPD in General Practice), which was initiated in September 2020 by KP and LK. The informants had, in the original informed consent form, allowed being contacted for substudies. The TEMOCAP study is conducted in collaboration with the University of Copenhagen, Epital Health Ltd, and Alles Lægehus. In the TEMOCAP study, 186/200 individuals with COPD were randomized either to usual care (services from GPs) or to a virtual RCC service in addition to their usual care. The RCC service, provided by Epital Health, is based on the principles of the Epital Care Model (ECM), which is a Danish telehealth initiative developed as a cocreative process involving all stakeholders participating in COPD treatment and care [35]. The model is designed to promote integrated people-centered health service and facilitate engagement, self-management, and empowerment of patients, and has been iteratively developed and tested since 2012. The ECM is described in more detail elsewhere [11,21,35]. The current implementation of the ECM has focused on the medical treatment of COPD and less on rehabilitation and services from allied health professionals such as occupational therapists, physical therapists, dietitians, and health coaches, despite all these being part of the conceptual framework of the ECM [10]. When enrolled in Epital Health as part of the TEMOCAP study, the participants are recruited from 1 out of 4 selected GP centers, organized by Alles Lægehus. The 4 centers were selected to ensure a geographical spread in the inclusion of participants, so there is population heterogeneity.

Via the TEMOCAP study, we were able to recruit 13 informants in April 2021 for the first round of interviews, and 4 informants in November 2021 for an additional round of interviews. Figure 1 illustrates the recruitment process for the interview participants.

Figure 1. Recruitment process for interview participants.



Reasons for declining were not requested. However, some mentioned declining participation due to undergoing or having undergone severe illness and therefore not having the capacity to participate.

In total, 24 individuals were invited to this study by the principal investigator of the TEMOCAP study (KP) from the included participants (on the top of the list based on inclusion date) from 2 GP centers. The participants were recruited from 2 different municipalities; 11 females and 13 males (12 in the category of

receiving the virtual RCC service and 12 in the category of not receiving the RCC service, respectively) were invited via phone to participate in the first semistructured interview (Multimedia Appendix 1). Of these, 13 (3 females and 10 males) accepted the invitation. However, data from 2 of the interviews were not included for the following reasons: informant did not complete the interview (n=1) and quality of the recording was not sufficient for transcription (n=1). The remaining 11 informants ranged in age from 48 to 81 years; 7 of those who accepted the

invitation received the virtual RCC service and 4 did not. The second interview was a confirmatory interview with a focus on the combined experience of physical and virtual services. Here, 4 new informants (age range 46-87 years), 2 females and 2 males, had all received the virtual RCC service and had at one point participated in a rehabilitation program. The purpose of the confirmatory interview was to present the results from the first interview to informants exposed to both virtual and physical services and clarify whether our findings matched their experience ([Multimedia Appendix 2](#)). The duration of rehabilitation programs lasted from once a week for 5 weeks to twice a week for 12 weeks.

The interview was conducted virtually because of COVID-19, and to facilitate the inclusion of informants living in various locations. The first interviews took place in April 2021 and the second confirmatory interviews took place in November 2021. The first author (TK, female) and the second author (EHJ, female) performed 9 and 6 of the interviews, respectively. Both authors are finalizing their bachelor's degree in health informatics with this study at the University of Copenhagen, qualified in performing qualitative and quantitative methods during their study, and for this final project were trained and supervised by author LK, who is experienced in performing qualitative methods and an associate professor at the Department of Public Health, University of Copenhagen. The interviewers followed an interview guide ([Multimedia Appendix 1](#)), where

the questions were based on themes inspired by the READHY model [12] and the WHO-5 Well-being Index [36-38]. The interview guide was pilot tested before the interviews.

The interviews were performed over Zoom (Zoom Video Communications, Inc.) or via a phone call, as some participants had technical difficulties with using Zoom. Informants joined from home, and the interview was scheduled for a duration of 30 minutes. For some, the interviews lasted for 20 minutes, whereas for others it lasted up to an hour. The duration of the interviews was related to the number and kinds of services the informant had experienced and their ability to express themselves. The informants were not invited to review transcripts or data after data collection.

The education level among the informants ranged from only school education (n=4) to professional training (n=7) and academic training (n=2). For 2 informants, this information was not obtained.

Informants' statements related to other self-services such as apps or additional self-monitoring equipment acquired will not be included in the reporting of results.

[Table 1](#) presents the components of the 3 services and their correlation with the WHO recommendations. These are based on information from the WHO's global strategy on people-centered and integrated health services [39].

Table 1. COPD^a service alignment with GOLD^b-related aims.

Service	Telehealth	Rehabilitation programs (Municipality)	Other (eg, general practitioner, outpatient clinic)
GOLD-related aims	Self-management education, pharmacotherapy, preventing exacerbations	Programs lasting 6-8 weeks, self-management education to improve the physical and psychological condition, active lifestyle and exercise, offer to participate in smoking cessation course, variety of HCPs ^c	Variety of HCPs, regular assessment, influenza and pneumococcal vaccination, pharmacotherapy
Description	24-hour individual service with daily monitoring and assessment of the condition	Group-based rehabilitation course with education and physical activity with attendance 2 times per week	Annual visitation or when needed
Duration	As long as registered	6-8 weeks	Permanent
Components	Self-reported outcome measures	Physical exercise, smoking cessation, nutritional counseling, training in daily activities, and patient education; additionally, network and exchange of knowledge	Annual checks, vaccinations, medication
Personnel	HCPs and staff (response and coordination center staff)	Nurses, nutritionists, and physiotherapists	Doctors and other HCPs

^aCOPD: chronic obstructive pulmonary disease.

^bGOLD: Global Initiative for Chronic Obstructive Lung Disease.

^cHCP: health care professional.

Data Analysis

Interviews and analysis were conducted in Danish, which is the native language of the researchers and informants. In the "Results" section, selected quotes are presented, which were translated by the first author (TK) and verified by authors EHJ and LK. The translated selected quotes are used to illustrate our analysis and arguments.

The interviews were transcribed, read through, coded, and analyzed using deductive content analysis in close collaboration between the 2 interviewers TK and EHJ. They were discussed with LK biweekly [40]. A codebook [41] was constructed with 4 categories based on the 3 themes from READHY (ie, Health-related support, Digital context, and Self-management [12]) and the focus on the informants well-being, as this is a recommended outcome of health defined by the WHO [2].

NVivo 12 (QSR International) was used to organize and code the data based on the codebook. For alignment and insurance of the relevance of codes, the coding of the first interviews was discussed by the authors and the new codes that evolved from the coding and discussion were added to the codebook.

In the “Results” section, we present the results based on the content analysis applied for coding, which were stratified into the following 4 categories: Health-related support, Digital context, Self-management, and Well-being. Health-related support is divided into 2 subcategories: Medical, provided by formal caregivers (HCPs), and social network provided by informal caregivers (spouses, relatives, and friends). Although there can be an overlap between different responsibilities and roles, we chose, for the sake of a later discussion, to make this distinction in the presentation.

We here report on patients’ ability to manage their COPD-related condition, how they feel supported, and to what extent the services impact their well-being.

Ethical Considerations

The informants were given information about the study, researchers, and the collection and handling of data in

accordance with the Helsinki Declaration in both written and oral forms. They were also informed that their participation was voluntary and anonymous and that they at any point could withdraw their consent without changing their role in the randomized controlled trial. Informed consent was obtained before the interview. During the recorded interview, the consent was documented. As no biological material was used in the study, review, approval, or exemption from the Danish National Center for Ethics was not required, according to Danish legislation [42]. Furthermore, local institutional committees do not exist in Denmark. The interviews were performed and recorded over an encrypted version of Zoom licensed by the University of Copenhagen. All data from the informants are considered personal health data and stored on safe drives and handled in accordance with Danish legislation (General Data Protection Regulation). The informants were not compensated for participation and were not invited to review transcripts or data after data collection.

Results

Table 2 presents the demographics of the informants.

Table 2. Characteristics of the informants.

ID	Sex	Age (years)	Years lived with chronic obstructive pulmonary disease	Marital status
D1 ^a	Male	81	16	Married
D2	Male	75	15	Married
D3	Female	64	10	Married
D4	Male	70	5-6	Single
D5	Male	72	10-15	Married
D6	Male	69	5-10	Single
D7	Male	63	10	Single
I8 ^b	Male	48	7	Single
I9	Female	75	N/A ^c	Single
I10	Male	56	1	In a relationship
I11	Female	69	10	Single
C12 ^d	Female	46	5	Single
C13	Male	87	6	Married
C14	Male	65	9 (20 with symptoms)	Single
C15	Female	65	8	Married

^aD: Was part of the first round of interviews and participated in the virtual response and coordination center service.

^bI: Was part of the first round of interviews and was not offered the virtual response and coordination center service.

^cN/A: not applicable.

^dC: Was part of the second confirmatory interview and participated in the virtual response and coordination center service and attended a chronic obstructive pulmonary disease rehabilitation program.

Health-Related Support

Medical

For many, a medical doctor is more than a professional treating a disease. This was reflected equally in both rounds of the

interviews: when dealing with a chronic condition, many wish for the doctor to become a close source of support who not only treats symptoms and prescribes medication. Based on informants’ statements, it emerges that there is a wish for what many would describe as coherent care. More specifically, it is important for individuals with COPD to be treated by GPs who

are familiar with their medical history and involved and show interest in their diagnosis-related well-being both medically and emotionally.

Feeling sufficiently medicated and having time to be listened to and understood by the GP is an important aspect of care as described by the informants of this study. When asked about what could be improved in one's care, one of the informants commented as follows:

*That someone would listen to how I feel. Both personally and with the breathing, you know? (...) The only time I felt like I was listened to was by the doctor from the Epital (virtual RCC service) that's really more than the other clowns (doctors) who don't bother to listen. They will just say that I should take more and more of this s***** medication. Well, it won't help to take more, when the medication is not working". [ID I8]*

Because of short consultations in general practice, the switch between doctors within GP centers, and the absence of COPD specialists, many experienced an unmet need for such coherence, as explained by the following quotes:

Then I came into something called a GP center, and the times I have now been to the doctor, I have now met 13 different doctors, so I don't get into close contact with any doctor to talk about this (their condition) [ID I11]

You only have 7 minutes with your doctor, right? So if you need to sit and go through your entire medical history each time, then those minutes will quickly pass [ID D3]

The desire for such care was emphasized by having experienced a virtual RCC service with continuous monitoring involving RCC staff, which includes HCPs and non-HCPs specialized in COPD. This provided an experience of feeling understood and, in some cases, being better medicated after consultations with the doctor. Those who had a more severe condition were more frequently contacted by the RCC staff, which along with being monitored provided a sense of security. This was emphasized by the following comments:

First of all, it really depends on the doctor you have. Their attitude towards COPD in general 'well, are you a smoker'? Well then, it's just the way it is, you have COPD, you just have to live with it. Turns out I also had asthma and pulmonary emphysema (...) meanwhile, at the Epital (virtual RCC service), they know exactly how it is. You don't have to explain and argument why you think you feel bad, cause they know [ID C12]

Then I will get a call every day and they will let me know if I should take some penicillin or prednisolone, which I have laying around as part of the provided acute medicine. So one is really followed closely. That's nice. It's also nice to have, so I don't have to go the doctors first, and then to the pharmacy (...) it makes one feel safe. [ID D3]

Correspondingly, those with a less severe condition had less contact with the RCC staff. However, some of these informants expressed a desire to have more contact, although this was expressed with hesitance:

They could call a little more often, you know? (...) I would have liked for him (doctor from the virtual RCC) to call and ask "how are you feeling?" and we could have a chat. But no, this is nonsense, overall, it's alright [ID D1]

The monitoring also appeared to affect medication adherence, as one described becoming more systematic and compliant after being monitored:

I stopped taking my medication because it didn't work after the first week, so it didn't really matter you know? Well, then I was enrolled in this (virtual RCC service), and I was forced to be more systematic. And nothing happened in the four first months. But then all of sudden, something started to happen. Eh, quite significantly actually I would say [ID D5]

Social Network

Having social support from HCPs as well as a social network does, for some, play an important role when dealing with a life-threatening disease. For many, the symptoms of the condition are accompanied by anxiety and new routines in daily life. The interviews indicate that this can be helped by relying on HCPs and peers, who can provide therapeutic and educational support.

While some rely on their social network for these needs (spouse, relatives, or friends), others intentionally choose to use secondary relations, such as HCPs and peers, if available. In this study, the informants experienced or expected to experience such support through their rehabilitation program and from the virtual RCC, as illustrated by the following comments:

I think I get some good inputs there (the rehabilitation program) (...) I feel like I can also feel an improvement. We do some exercises, have some lectures and then some learning afterwards. I am sure that when these 12 weeks are completed, it will have helped me on way or another, you know? [ID I10]

I have anxiety about not being able to breathe, or to get suffocated, to put it bluntly. It is very much associated with anxiety for me (...) I am very happy to attend this rehabilitation program because I am confident and hopeful that I will learn how to change my behavior, so I don't get so much anxiety, really. It's a bit disabling I think [ID I11]

Rehabilitation groups provide the setting to talk to individuals in a similar situation and can give a sense of "being in it together":

We exchange experiences and ask each other 'are you experiencing this too?' - because it is a safe environment (...) [ID C12]

Virtual services provide accessibility to well-known RCC staff who can provide support from a professional standpoint. In both cases, informants indicated that having these resources meant

opportunities to have conversations and support that could otherwise be difficult to have with social networks due to not wishing to burden or be of concern to their relatives.

>Well, my daughter has an understanding but (...) I think she is a bit afraid (...) I have good support in my daughter also (...) but it's better to have this network now (the virtual RCC service), they simply understand it better (...) I also have a huge network (in a setup similar to the rehabilitation program in format but not time-limited). I go down there and wine and cry, and laugh and sob if something is bothering me (...) it's nice to have this network too (rehabilitation program) where we are peers and have the same medical condition [ID I11].

Digital Context

For many who participated in the virtual RCC service, the usage of technology was an embedded practice that they did not address or were not conscious of in their everyday life. Besides, it was not until the equipment did not perform as expected that it became a nuisance or entered their daily life as a factor to be addressed. When establishing services such as a virtual service with digital equipment, there can be risks of introducing technologies that may be difficult for individuals to use. For example, for the virtual RCC service, some participants abandoned or failed to measure their lung capacity with spirometry twice daily due to breathlessness and the mouthpiece of the equipment not fitting. One of the informants said,

Sometimes when I puff the third time to get it stated... I buff, and then I cough and am about to die. I do two puffs and if it doesn't take it, then I won't bother. I just move on to the next [ID D4]

This can cause participants of the virtual RCC service to miss the potential benefits or perhaps even abandon the RCC service all together:

The spirometer and I simply didn't get along, so I ended up spraining a muscle in my chest. So that's when it stopped (the RCC service). [ID C12]

Lack of mental surplus, forgetfulness, tiredness, and having to bring equipment when being away from home for longer periods are also factors that can create noncompliance in providing spirometry data twice daily, as one of the informants said,

Sometimes I work, and I come home late, you know? So sometimes I've had to skip it because it's gotten so late in the evening. If you're in the city or something else or on vacation, where you have to bring it... I've had difficulty installing it in those cases [ID C15]

While this became a barrier to the RCC service for some of the informants, others expressed a determination to persevere and deal with the equipment until it worked for them. It appeared to be related to the level of skill:

When I had to change the batteries on this oxygen saturation device. Oh my god, that is advanced. It's not just something you do. You have to figure out how to take it apart. And when you finally take it apart, you can't re-assemble it. (...) good one is born with

a certain amount of stubbornness. I won't give up before it works [ID D3]

The sharing of personal data did not appear to be a worry among the participants, and the few that spoke of the subject stated that it did not have any significance, as they had trusted that no one would misuse their data or personal information. One informant said,

Why would I have anything against that? (Sharing personal data with the RCC service). I don't assume that they would... the only thing they could misuse is my social security number (...) I don't go around being worried about things like that [ID D6]

Self-management

Many of the informants have an interest in acquiring knowledge as well as developing skills and insight that help them manage their condition. Many wish to be less dependent, have fewer hospital visits, receive optimal treatment based on their condition, and have a sense of control and security.

The informants' statements indicate that factors promoting self-management include access to information, which is relevant and mediated in a tailored and pertinent manner. Many have smartphones, computers, and access to an abundance of information. Despite this access, the ability to utilize the information requires facilitation. Several participants noted that when HCPs and peers provided tailored information and guidance on how to use, for example, equipment, medication, and services in the health care sector, this would make one more likely to take advantage of the information and reflect on new behavior and choices. As one informant stated,

I have been made aware during this program (Rehabilitation), that I can actually use my inhalator in advance... this one that I can take when needed. I wasn't told that by the doctor who prescribed it (...) at the same time, I have just been summoned to the lung department, for another examination. (...) simply because I was encouraged by one of the others at the program (...) I would like to be sure that I am getting the right medicine, and I hope I can get a clarification on that [ID I10]

For some, tools enable monitoring and create an ability to follow the condition and support the ability to act. Having the resources available at home and before the need arises can give the individual the ability to take responsibility as well as use what is relevant to them. For example, participants of the RCC service had access to a box with medicine to be used for acute treatment, which was associated with rapid action upon exacerbations and initiation of treatment both with and without initial consulting with HCPs. This is perceived as something that creates less dependence and prevents visits to the hospital.

I was feeling worse and worse (believed to have pneumonia) (...) I have gotten to that point where I don't want to go to the doctor when I am feeling so bad. But then it was really nice to be able to start treatment myself – and it worked, clearly [ID C12]

Sometimes I have to take a round of it (acute medicine) and then I feel better – and that means I don't have to go to the hospital every time I am losing my breath, they can fix it just by giving me some of the medication I have laying around at home [ID D7]

Having the ability to monitor own condition through equipment and interpreting data can help create meaning between the current state and medication dynamics. By contrast, enabling the RCC staff to monitor an individual's current state might result in less engagement, because the individual can rely on being monitored and thereby be less alert. As an example, some align their concerns with the feedback they receive from their virtual service, where no contact upon sending data is perceived as an indication of a stable condition:

When I send the data, then there is also someone who, kind of like, watches over me [ID D4]

And then I can say if I don't get the call, then it's not so bad after all [ID D3]

There is a difference in how informants may perceive their ability and role in relation to services. One informant reported a coresponsibility based on insights into her condition, which made her actively involved, whereas in relation to the medical treatment of her condition by the RCC staff, she relied on the professionals. The confirmatory interviews made it more evident that the degree to which one wishes to be actively involved depends on personal preferences. While some preferred to deliver data, but did not pay additional attention to it, others took an interest in following along themselves.

Well-being

When participating in either of the services most informants experienced better physical, mental, and social health, which contributed to a positive change in well-being.

Informants suggested that exercise accomplished on a fixed weekly basis by a facilitator and together with peers creates motivation to be active. Those enrolled in the virtual RCC service were encouraged to acquire exercise equipment. Those who had more understanding of equipment and data monitoring, as well as users who are skilled and receptive to using technology, seemed to be more likely to own and use an at-home exercise bike:

The doctor (from the virtual RCC) said that it would be a good idea to buy an exercise bike, and he is completely right, so we have done that and we are using it [ID D3]

Even though virtual services can motivate to acquire exercise equipment, informants from the confirmatory interview emphasized that physical presence and having exercise as a group activity is a superior method for increasing activity level.

You can do the exercises at home, but several agree that they find it difficult to be motivated when you are sitting home by yourself. So it's kind of like motivation that you have to show up twice a week, you know? [ID I10]

The rehabilitation program is the most motivating by far [ID C12]

The social aspect of having a network of peers is also beneficial, and because many experience a decline in motivation, as well as social distance after the rehabilitation program ends, several reattended or wanted to reattend to maintain the achieved benefits.

I would like to re-attend. It's a shame it's only those 12 weeks. It makes you maintain... you know, it's a little easier when you have it planned to make sure you actually go (exercise and socialize) [ID 15]

The fact that the program is not a persistent offer might reduce the positive impact on well-being. This calls for a more sustainable service.

During the confirmatory interviews, when asked about whether the group-based activity could be carried out in a virtual format, the importance of the social aspect was highlighted, creating different opinions about the subject. While some appreciated the idea as this would exclude obstacles related to transportation, create relationships across distances, and make it easier to follow through during the COVID-19 pandemic, others argued that the social aspect cannot be replaced virtually and that the motivation for exercise declines in an at-home setting.

Well, there isn't a lot of socializing in that kind of a digital course [ID C13]

I have thought about it. On one hand, it would be optimal that you wouldn't have to go places now with the high amount of infected (from Covid-19) (...) on the other hand, it's nice to get that push to go out and be physically around other people (...) it's also really good for people who are lonely [ID C12]

Being monitored, having medicine for acute treatment available, and having close contact with well-known RCC staff can improve well-being by making the individual feel safe and secure. The professional network can benefit social interaction related to care and medical decisions in a different, but valuable way that sets them apart from that of peers. These components are, in this case, enabled by a virtual service. Those who have experienced both the rehabilitation program and the virtual RCC service describe the services as being very distinct:

It's completely different services one would say, right? And in reality, services to different stages of the disease. One should attend the rehabilitation program earlier before it was necessary to be bombed with medication. In the rehabilitation program, there is the good aspect of the social, one could say. That's not the case for the telemedicine (virtual RCC service). But with the telemedicine (...) you could be pretty sure to be monitored by a professional, and that's pretty safe and secure. [ID C12]

While the rehabilitation program supports physical activity, social interaction, and teaching coping mechanisms, the virtual RCC offers close contact with COPD specialists, the ability to follow their condition through monitoring, and acting on exacerbations through available medication.

Discussion

Principal Findings

For people living with COPD, contact with HCPs is a key aspect of care, both medically and emotionally. It is important to have close contact with HCPs and feel understood, properly medicated, and motivated, all of which can have a significant impact on their well-being. There is a desire to experience coherent care where HCPs are specialized in the disease, familiar, and in close contact. This can be supported by virtual services in which continuous monitoring, at-home medicine for acute treatment of exacerbations, and quick access to a HCP who knows the individual can promote self-management and provide a feeling of security. It can also provide the individual with a deeper understanding of their condition, improve medication adherence, and in some cases prevent hospitalizations.

Delivering information in a relevant and tailored manner is important for the receptiveness of the information. Many informants also suggest that having regular in-person meetings with a network of peers and professionals can promote knowledge about how to cope with the condition, which can motivate them to make health-related decisions. Motivation to exercise is also reinforced when performed as a collective activity with peers as this can create a sense of camaraderie and socialization among peers. Although encouragement by the RCC staff to invest and use at-home exercise equipment is effective in increasing activity levels for some, being physically active together with peers supervised by a professional is highlighted as the preferred way of performing and increasing physical activity.

When given the opportunity, some individuals prefer to take advantage of professional and peer networks for therapeutic social support. This is due to these networks having more insight and knowledge of people living with COPD and because some are worried about “burdening” their relatives and network.

The identified potential barriers to the benefits of the rehabilitation programs are related to the limited period in which the rehabilitation service was offered (5-12 weeks). Many experienced a decline in motivation to exercise and keep in contact with peers after the program has ended, and therefore expressed a wish to reattend a rehabilitation program to maintain benefits. Technology can facilitate monitoring and utilize reported data to support tailored treatment, but technology itself is of less significance compared with factors such as support and close contact with HCPs. It can even act as a barrier to optimal utilization of the service due to different levels of skills and preferences of the participants. The identified potential barriers to utilizing the benefits of the virtual RCC service are related to differences in levels of contact depending on disease severity and skills related to the practical use of equipment. Having a less severe state of COPD means having less contact, and thereby an experience of less social support by the RCC staff. Nevertheless, the wish for more contact was expressed with hesitance by those who did not often experience exacerbations, presumably because the participants overall felt gratitude toward the service and did not wish to appear

unappreciative. The potential of social support might not be fully utilized in the 2 services included in this study as a result of these barriers.

Another barrier is related to the use of digital equipment. Although the sharing of personal data did not appear to worry the individuals, having difficulty in using the equipment or lacking the mental surplus to use it regularly can cause individuals to abandon the equipment, the RCC service altogether, or not fully utilize the potential of use, thus missing the benefits. This creates a barrier that makes the individual's skills in technology a contributing factor to the success of engaging in a virtual service. Therefore, when considering digital solutions, it is important to consider the individual's skill, preferences, and experience, as well as enabling alternative options to technology-based monitoring to preserve close and collaborative contact with HCPs. Further exploration is needed to assess how to accommodate the identified barriers related to the use of technology.

Comparison With Prior Work

The findings suggest that close contact with HCPs and the use of a virtual service with digital equipment can make the individual feel more secure. It also has the potential to promote self-management as individuals can gain an understanding of their condition and treatment and obtain tools to actively engage in their treatment with solicited advice from HCPs. This is in line with the discoveries made by Nissen and Lindhardt [43] who in their Danish study found that patients with COPD who used a telehealth solution similar to that in this study felt more secure and achieved a higher understanding and competence in self-management in relation to their disease. According to a systematic review by Gorst et al [44], some of the benefits of receiving telehealth are improved self-care, increased access to health care, improved health knowledge, ease of use, peace of mind, convenience, effective health management, appreciation of telehealth nurses, and believing telehealth to be as good or better than in-person care.

In a previous study [21] exploring the effect of telemedicine on patient-reported outcomes for those with COPD, participants reported feeling less active in managing their health after inclusion. Our findings may explain this as our informants experienced that the access to the tools and support was easier, and that the feeling of safety related to being monitored by the RCC staff eases their burden, thereby feeling less active in managing their own health.

Although we and others have found several benefits of telehealth, the use of technology may still impose a barrier for some users. This aligns with the findings by Gorst et al [44] who reported that barriers to using telehealth and reasons for declining to receive the service were, among others, related to technical problems. According to Gorst et al [44], other barriers were related to a preference for in-person care. Interestingly, but also contradictorily, they found that reported facilitators for telehealth believed that telehealth is as good as or even better than in-person care. Either way, preferences related to personal contact appear to be a factor in one's attitude or experience toward receiving telehealth. The informants in our study did not express feeling compromised with regard to contact with

HCPs because of the service. Instead, the technology seems to support close and quick contact with HCPs. However, this is dependent on the condition of their COPD, where those with fewer exacerbations have less contact with RCC staff and expressed a desire to be checked upon more often. The importance of medical and social support from HCPs perhaps explains why the attention to technology is of less significance for our informants unless they encounter problems in the daily use of these technologies. It might be perceived as a tool more than an individualized care component.

Our findings that group-based physical activity motivates and increases activity levels and that a network of peers provides knowledge and socialization correlate with findings from other studies [13,45,46]. These studies found that individuals living with COPD benefited on a social and psychological level from participating in group-based exercise interventions with coaching. They concluded that camaraderie and motivation are created when exercising with others with a similar condition and that depression and anxiety related to breathlessness decrease upon attending group activities. These studies also found that while many own exercise equipment at home, they do not use them due to a lack of motivation, and concluded, similar to this study, that participants wished to continue attending their programs to maintain benefits [45].

Interestingly, this subject was not discussed by participants of the virtual service, but could be explained by the service already being continuous, based on findings by Emme et al [47] who found that the benefits of telehealth depend on the availability and use of equipment. This means that the achieved coping in disease handling could not be sustained after cessation of the daily monitoring including virtual ward rounds. This points to a general tendency to wish for more sustainable services, which is in contrast to the GOLD recommendations for the duration of rehabilitation programs (ie, 6-8 weeks) [2].

A previous study [13] addressing cancer survivors and physical activity found a connection between the level of technology readiness and physical activity preferences. People scoring low in technology readiness generally tend to prefer a social or coaching approach, whereas those who score high in technology readiness generally prefer individual physical activity (eg, fitness centers and apps). There is a correlation between socioeconomic status and technology readiness, with lower socioeconomic status being associated with lower technology readiness and a preference for performing physical activity in a social context [13,48]. Our data support these findings as it seemed that those who were more engaged with their digital equipment were more likely to own and use an at-home exercise bike compared with those less engaged with their digital equipment. Yet, the general tendency was that for those who had experienced both services, there was a preference for group-based physical activity with coaching, which is similar to the findings in cancer survivors, where those with lower socioeconomic status preferred group-based activity. It also aligns with the GOLD recommendations that supervision in exercise interventions is important for its effectiveness in individuals living with COPD [2].

As the virtual service and the rehabilitation program are described as 2 distinct types of services with different benefits, we suggest that a combination of the 2, based on the individuals' preferences and skills, can improve future care for patients living with COPD. Both literature and our study suggest that a lasting offer of these services is the most beneficial as motivation, physical activity achieved, and other lifestyle changes decline after the service ends.

Whether physical activity with a network of peers could also be successfully carried out in a virtual format is yet to be fully discovered. The informants in this study had different preferences for virtual training with peers, which calls for a more systematic investigation of this area in the future. Future research should also be carried out to assess how to accommodate barriers related to technology.

Limitations

By recruiting from the TEMOCAP study, there might have been a narrow availability of informants with different backgrounds. There is a chance that those who accepted the invitation to the TEMOCAP study are more open to new ways in which health care can be provided. This could result in our informants having fewer reservations toward the use of digital technologies in treatment compared with the general population. This could explain why none of our informants reported having reservations toward the use of technology in their treatment in general, except when experiencing technical difficulties. Males were more likely to accept participation in the study compared with females, which should be considered when interpreting the study results. This ratio is different from that of the COPD population and may add to a positive opinion around technology use and a lack of other perspectives that may have been introduced if more females had participated. We had attempted to mitigate this by inviting an equal number of females and males for the second round of interviews. Further, it may have been difficult to interpret nonspoken signals (eg, body language such as gestures and restlessness) as the interviews were conducted virtually due to COVID-19. The use of a screen may also reduce the possibility to establish a relationship with the informants, and thereby a risk of them not disclosing more sensitive matters.

The limited knowledge about how the informants feel about the external use of their data, and whether this could be a barrier for some, could be due to a lack of focus on this topic in our interview guide. The topic was only briefly mentioned by a couple of informants, which only indicates their experience.

Strengths

To have a better understanding of our findings and strengthen the information power, data from the interviews were triangulated with a second round of interviews by adding the informants' perspective of the combined experience of the services mentioned. With our narrow focus of interest, which according to Malterud et al [49] increases the likelihood of information power, the results might not be representative on a wider scale, but seem to be representative for a population recruited in this way.

As author KP had a possible conflicts of interest, he did not participate in the interview process or analysis, but participated

only in the planning and discussion processes. TK and EHJ are external to Epital Health and the context of virtual services, but prior to the study had obtained knowledge about telemedicine services and people living with chronic conditions in a Danish setting.

Conclusions

The findings call for a future design to address medical as well as mental care, individual preferences, the potential of peers

and facilitators, and different levels of skills to overcome potential barriers of technology. Taking preferences and skills into account, this study points to a combination of the identified valued elements from virtual and in-person services as a foundation for the future care of individuals with COPD to provide lasting medical and social support across allied HCPs and peers. Lasting offers of these services are recommended to maintain motivation and achieved lifestyle changes.

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Data Availability

Our institution follows the FAIR (Findability, Accessibility, Interoperability, and Reusability) principles. We therefore in principle always want to make our data accessible but as this study addresses interview data from a small population, we do not find it possible to make these data available without disclosing recognizable health and personal data. The data set is therefore not available. Please contact us if you need any specific information.

Conflicts of Interest

KP is a co-owner of the Epital Health Ltd. Other authors have no conflicts of interest to declare.

Multimedia Appendix 1

Interview guide: first interview.

[[PDF File \(Adobe PDF File\), 43 KB - rehab_v10i1e43237_app1.pdf](#)]

Multimedia Appendix 2

Interview guide: confirmatory interview.

[[PDF File \(Adobe PDF File\), 132 KB - rehab_v10i1e43237_app2.pdf](#)]

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Abbreviations

- BDI:** The Beck Depression Inventory
- COPD:** chronic obstructive pulmonary disease
- COREQ:** Consolidated Criteria for Reporting Qualitative Research
- ECM:** Epital Care Model
- GOLD:** Global Initiative for Chronic Obstructive Lung Disease
- GP:** general practitioner

HCP: health care professional

HeiQ: Health Education Impact Questionnaire

RCC: response and coordination center

READHY: Readiness and Enablement Index for Health Technology

WHO: World Health Organization

WHODAS II: World Health Organization Disability Assessment Schedule 2.0

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Original Paper

Examining Usability, Acceptability, and Adoption of a Self-Directed, Technology-Based Intervention for Upper Limb Rehabilitation After Stroke: Cohort Study

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Abstract

Background: Upper limb (UL) recovery after stroke is strongly dependent upon rehabilitation dose. Rehabilitation technologies present pragmatic solutions to dose enhancement, complementing therapeutic activity within conventional rehabilitation, connecting clinicians with patients remotely, and empowering patients to drive their own recovery. To date, rehabilitation technologies have been poorly adopted. Understanding the barriers to adoption may shape strategies to enhance technology use and therefore increase rehabilitation dose, thus optimizing recovery potential.

Objective: We examined the usability, acceptability, and adoption of a self-directed, exercise-gaming technology within a heterogeneous stroke survivor cohort and investigated how stroke survivor characteristics, technology usability, and attitudes toward technology influenced adoption.

Methods: A feasibility study of a novel exercise-gaming technology for self-directed UL rehabilitation in early subacute stroke survivors (N=30) was conducted in an inpatient, acute hospital setting. Demographic and clinical characteristics were recorded; participants' performance in using the system (usability) was assessed using a 4-point performance rating scale (adapted from the Barthel index), and adherence with the system was electronically logged throughout the trial. The technology acceptance model was used to formulate a survey examining the acceptability of the system. Spearman rank correlations were used to examine associations between participant characteristics, user performance (usability), end-point technology acceptance, and intervention adherence (adoption).

Results: The technology was usable for 87% (n=26) of participants, and the overall technology acceptance rating was 68% (95% CI 56%-79%). Participants trained with the device for a median of 26 (IQR 16-31) minutes daily over an enrollment period of 8 (IQR 5-14) days. Technology adoption positively correlated with user performance (usability) ($\rho=0.55$; 95% CI 0.23-0.75; $P=.007$) and acceptability as well as domains of perceived usefulness ($\rho=0.42$; 95% CI 0.09-0.68; $P=.03$) and perceived ease of use ($\rho=0.46$; 95% CI 0.10-0.74; $P=.02$). Technology acceptance decreased with increased global stroke severity ($\rho=-0.56$; 95% CI -0.79 to -0.22 ; $P=.007$).

Conclusions: This technology was usable and acceptable for the majority of the cohort, who achieved an intervention dose with technology-facilitated, self-directed UL training that exceeded conventional care norms. Technology usability and acceptability were determinants of adoption and appear to be mediated by stroke severity. The results demonstrate the importance of selecting

technologies for stroke survivors on the basis of individual needs and abilities, as well as optimizing the accessibility of technologies for the target user group. Facilitating changes in stroke survivors' beliefs and attitudes toward rehabilitation technologies may enhance adoption. Further work is needed to understand how technology can be optimized to benefit those with more severe stroke.

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KEYWORDS

stroke rehabilitation; interactive gaming; rehabilitation technology; technology usability; technology acceptability; self-management; usability; acceptability; stroke; rehabilitation; adoption; engagement; acceptance; limb; mobility; mobile phone

Introduction

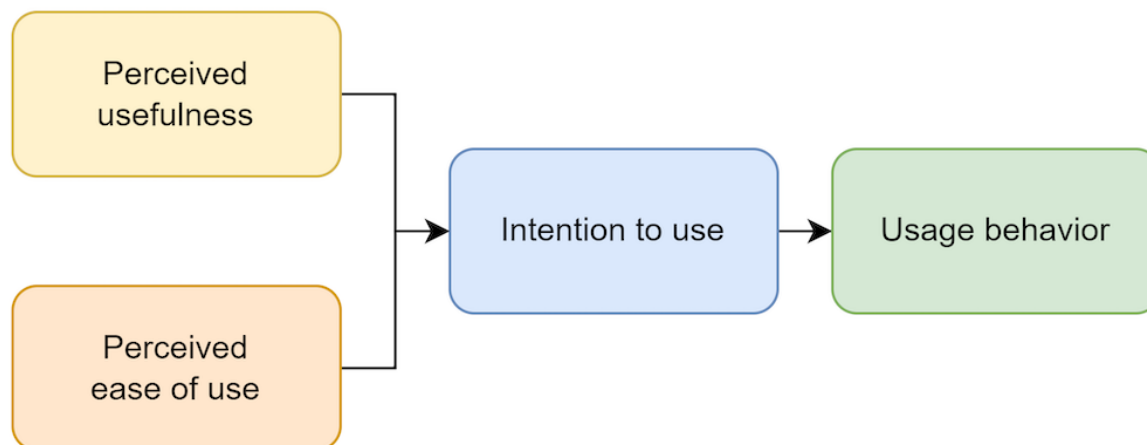
Stroke rehabilitation outcomes are strongly influenced by dose, or amount, of rehabilitation [1-5]. Rehabilitation dose in conventional clinical practice is insufficient for meaningful improvements in upper limb (UL) outcomes [6]. Increasing dose presents organizational and individual challenges [7,8]; digital technologies may offer a solution to this [9-13]. Technologies have the potential to complement therapeutic activity within conventional rehabilitation, connect clinicians with patients remotely, and empower patients to drive their own recovery, reducing the burden on rehabilitation services, overcoming regional resource disparities, and increasing access to rehabilitation [14].

Rehabilitation technologies often encompass behavior change concepts, which serve to optimize user engagement (goals and planning, feedback and monitoring, repetition and substitution, comparison of outcomes, reward and threat) [15], as well as features and components that enhance conditions for motor relearning [16]. These features include enriched environments, multisensorial stimulation, opportunities for massed practice that is variable, task-specific, and goal-oriented, real-time and longitudinal performance feedback, results feedback, increasing difficulty, and adjusting to each user's unique and changing needs or abilities. In this work, we focus on self-directed rehabilitation technologies that enable users to complete >50% of training independently [17], allowing for formal or informal support for intervention components such as obtaining and setting up equipment and charging electrical devices. These interventions are of particular interest in the current health care context, due to the potential resource efficiency; bolstering the ability of stroke survivors to engage in rehabilitation activities with minimal professional support and thus presenting a pragmatic solution to dose enhancement and facilitating increased access to rehabilitation across the stroke recovery pathway.

While rehabilitation technology research has become increasingly prevalent in line with technological innovations in

this field [18], clinical adoption remains poor [19,20]. Perceived barriers and facilitators to the adoption of stroke rehabilitation technologies have been proposed [20-31], influencing technology design in terms of accessibility, reliability, adaptability, and clinical utility [23,27,29,32-38]. Previous research focuses on design features of the devices, whereas the influence of stroke survivor characteristics, the usability of technologies, and users' attitudes and beliefs about rehabilitation technologies are poorly understood [39], limiting clinical interpretation and generalizability [40]. Moreover, most previous studies of technology adoption are based on research environments with high levels of support and supervision rather than on unsupervised, natural environments, where stroke survivors spend the majority of their time [41-44].

Technology usability (or user performance) refers to a measure of how well a specific user, in a specific context, can use technology to achieve a defined goal effectively and efficiently [45]. Usability is a key theme presented in qualitative literature examining the perceptions of stroke survivors and clinicians and their experiences of rehabilitation technologies [26,46]. Usability is also central in the design of rehabilitation technologies; however, usability outcomes are rarely reported in clinical trials [45]. Technology acceptance refers to the user's willingness to use technology for its intended use. It is widely considered as a preadoption stage and also has value in predicting adoption [47]. Like usability, technology acceptability is thought to be associated with specific stroke survivor characteristics including age, sex, previous experience with technology, available support, and time since stroke [48]. The technology acceptance model (TAM) [49] proposes that acceptability is determined by 2 main factors: perceived ease of use and perceived usefulness [49]. Perceived ease of use refers to the degree to which a person believes that the use of a system will be effortless, while perceived usefulness refers to the degree to which a person believes that the use of a system will be advantageous to them [49]. The easier the use of a system is perceived to be, the higher the probability that a person experiences the system as useful and subsequently is willing to use it [49] (Figure 1).

Figure 1. Technology acceptance model [49].

The TAM has been frequently adapted to understand the acceptance of health care technologies among clinicians [50-55]. Perceived ease of use and perceived usefulness have been strongly associated with the adoption of telemedicine platforms in a stroke context [56]. Different factors are reported as important in predicting technology acceptance among different professional stakeholders [56], for example, in telemedicine trials, perceived ease of use was found to be more important to nonnurses (radiologists, physicians, and allied health care professionals) and perceived usefulness was more important to nurses. Perceived usefulness of telemedicine services is a major factor explaining adoption by clinicians [57]. Only a small number of studies [58,59] have applied the TAM to examine stroke survivors' acceptance of UL rehabilitation technology (interactive gaming and mobile rehabilitation apps); however, these studies do not evaluate real-world adoption or consider stroke survivor characteristics. This study evaluates how real-world adoption, in the absence of close professional support, relates to acceptance, usability, and participant characteristics.

Methods

Ethics Approval

The study was approved by the UK National Research Ethics Service (78462). All participants gave informed written consent prior to recruitment.

Study Design

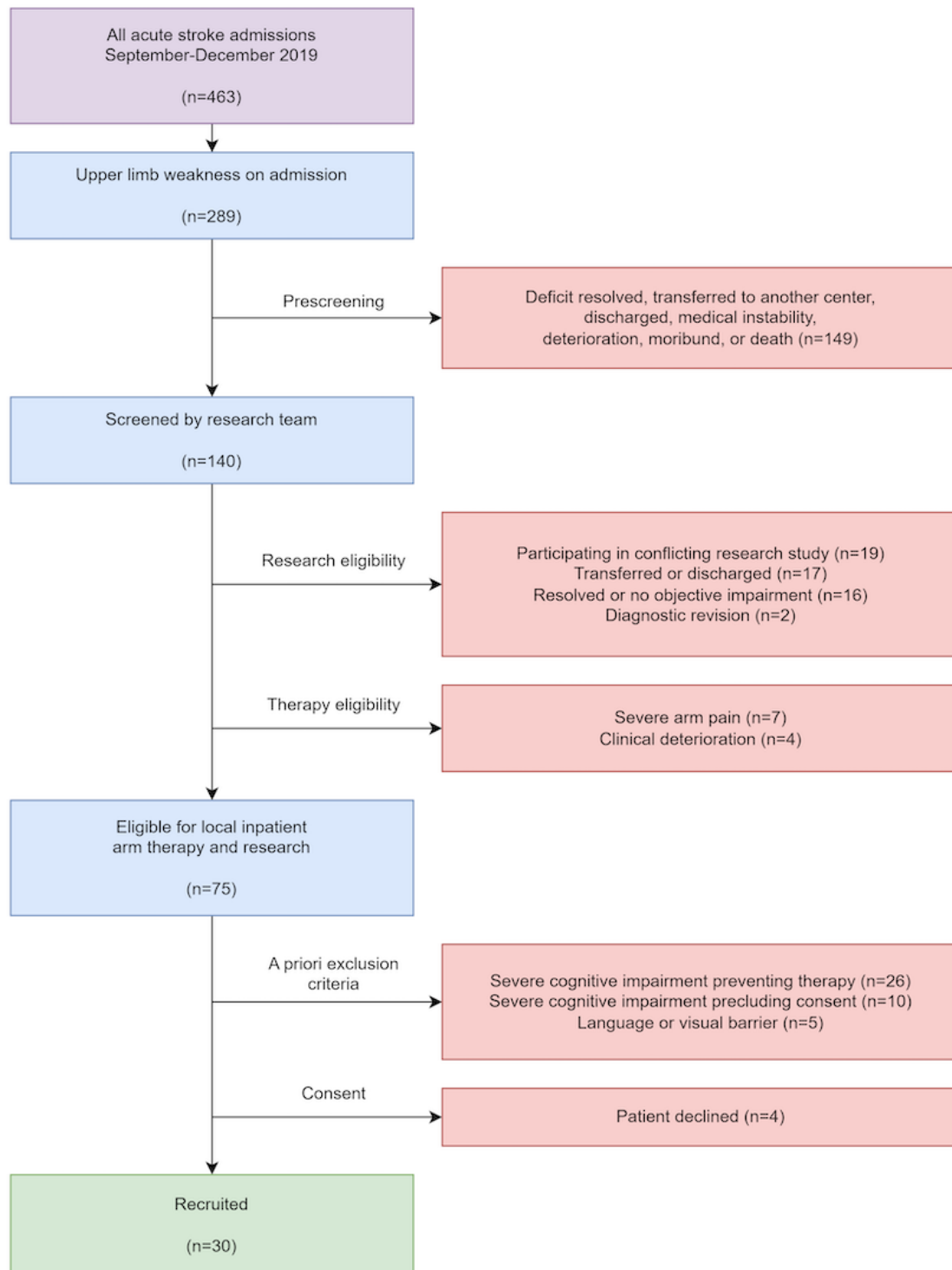
This paper reports the results of a questionnaire survey of stroke survivors enrolled in a prospective, nonrandomized feasibility study of an adapted UL rehabilitation system for self-directed rehabilitation.

Aim

The aim of the study is to explore the usability, acceptability, and adoption of a low-cost, self-directed, exercise-gaming technology while examining the impact of relevant user demographics and clinical variables in a heterogeneous stroke survivor cohort (see [Multimedia Appendix 1](#) for a diagrammatic representation of this working theory or hypothesis in the form of a logic model). Research feasibility results are discussed in a separate publication [60].

Patient Population

Participants were a convenience sample of inpatient, early subacute stroke survivors (n=30) in hyperacute or acute stroke units at a single center, presenting with new UL weakness (of any severity) and able to provide informed consent. Those with uncompensated visual deficits, unremitting UL pain, or significant language or communication difficulties were excluded. Patients were screened and referred by the treating clinical team at a central London stroke center (turnover ~1500 stroke cases per annum) between September and December 2019 ([Figure 2](#)).

Figure 2. Recruitment flow diagram.

Intervention

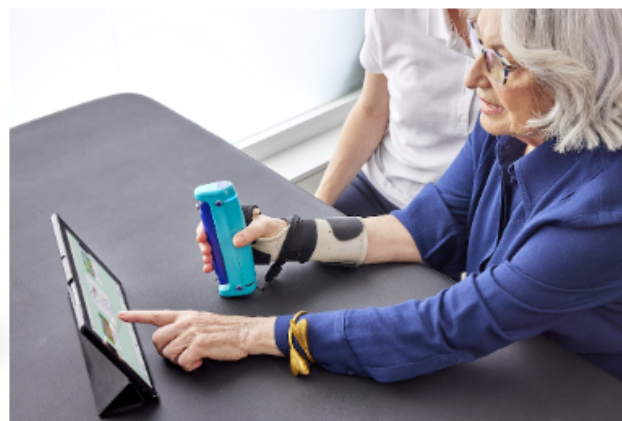
An interactive exercise-gaming system (nonimmersive virtual reality) [17,61] aimed at improving UL motor recovery after stroke by promoting self-directed, repetitive UL activity was used. The technology comprised a flexible, handheld device that sensed grip force as well as tracking finger, wrist, and arm movements [62] (Figure 3). The device housed an inbuilt motor enabling haptic feedback and wireless communication with a computer tablet on which there were a suite of UL exercise games (GripAble app). Once participants selected an activity,

the app provided instructions to guide the user. Participants were trained to use the system by an occupational therapist in a single session, issued with a standardized user manual and used the system for the remainder of their in-hospital admission. The occupational therapist rated each user's performance in engaging with the intervention (usability) using a 4-point rating scale based on the Barthel index (BI). This enabled us to understand intervention usability and also to recommend "conditions of use" for participants (independent, modified independence, assistance, or unable). The occupational therapist also used clinical judgment to advise participants on facilitating

conditions to enhance intervention performance (such as pillow support of the UL, timetabling practice, or hands-on assistance from a relative, friend, or informal caregiver) where appropriate. Participants were encouraged to use the system “as much as possible” as an adjunct to conventional therapy with all intervention advice provided using a standardized script. Participants were not prompted or supervised in use of the

device during the intervention period, although they could receive assistance from relatives, friends, or informal caregivers. Participants were reviewed weekly by the research team to screen for technical issues with the intervention or identify additional user support needs. Adverse events were monitored by the treating clinical teams or self-reported by participants.

Figure 3. GripAble device and patient using device. The image demonstrates the patient performing single-player grasp and release activity. Images copyright of GripAble.co, reused with permission.



Measures

Participant Characteristics

The following demographic and clinical features were recorded on study entry: age, sex, prior technology exposure (prior use of and familiarity with a smartphone, tablet, laptop, or computer, as self-reported by participants), Edinburgh Handedness Scale, time (in days) since stroke at enrollment, stroke type (ischemic or hemorrhagic), stroke severity (National Institute of Health Stroke Scale), UL impairment severity (Fugl Meyer-Upper Extremity Assessment), cognition (Montreal Cognitive Assessment), premorbid functional status (modified Rankin Scale), poststroke functional independence status (BI), mood (Hospital Anxiety and Depression Scale), fatigue (Fatigue Severity Scale), and pain (Faces Pain Rating Scale).

User Performance (Usability)

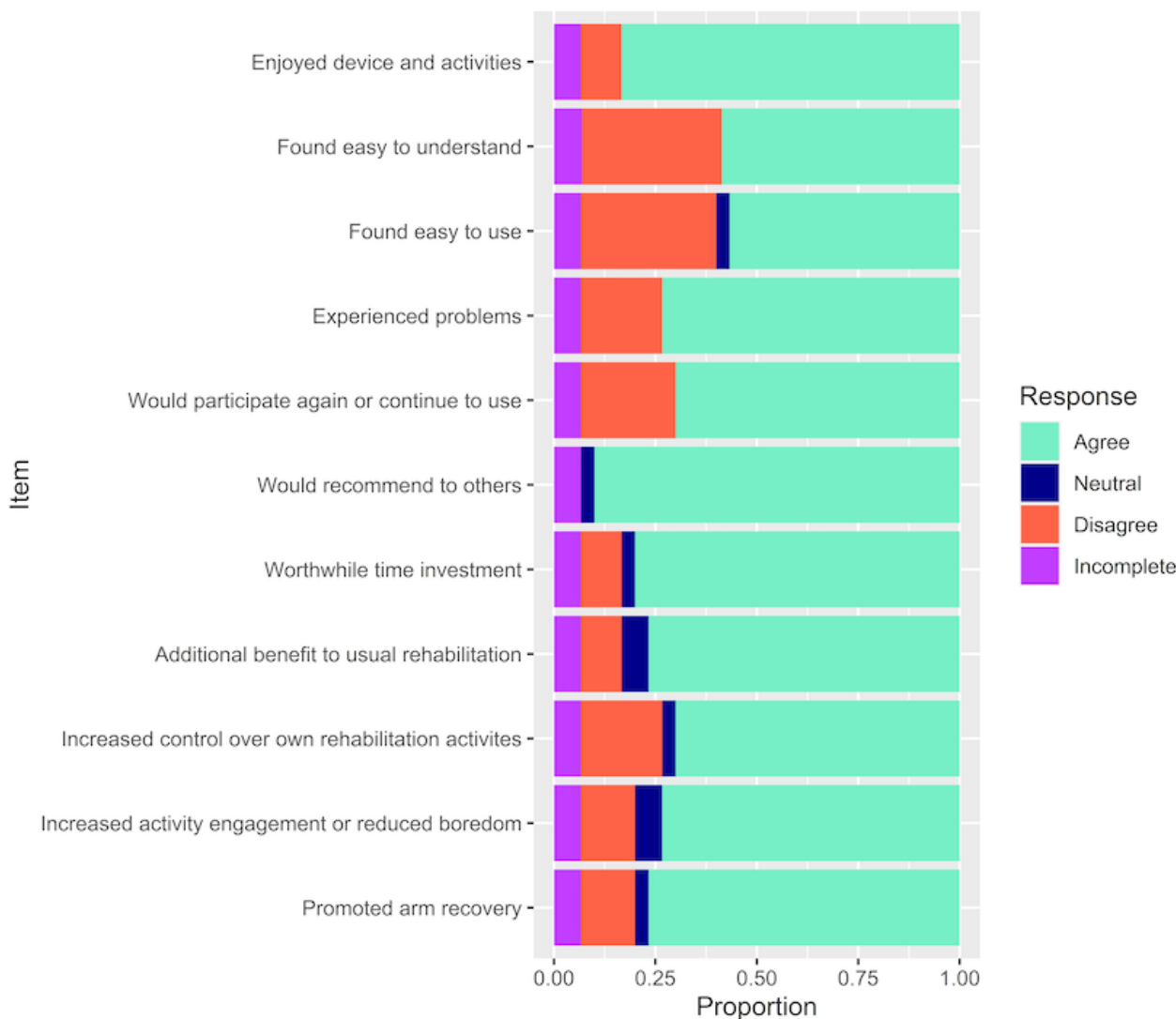
User performance (usability) was rated by the occupational therapist at participant enrollment or intervention setup. A 4-point scale was defined using the BI performance classification; users were scored as 4, independent; 3, requiring support for setup only (modified independence), 2, requiring supervision and support (assistance), or 1, unable to use meaningfully (unable). User performance ratings were made based on the following device functionalities: physical set up, turning on, accessing the activity platform, selecting and

executing exercise software, executing the physical exercise requirements, and device charging. Final ratings were based on the lowest rating allocated for any domain of device functionality. In the context of this work, other more commonly used scales, such as the system usability scale, did not align with the features and mechanisms of this technology, the context in which it was used, and the data required to inform the intervention. Devising a custom scale enabled us to identify key functionalities associated with effective use of the device. Adopting the taxonomy of the BI enabled clear categorization of the user performance and indicated associated user support needs while also facilitating communication of user performance and needs in a language accessible to clinicians, service users, and family members or informal caregivers.

Technology Acceptability

An 11-item survey based on the TAM was adapted from available measures [51] (see Figure 4 for survey items) and administered at the study end point. Items measured included perceived usefulness (n=5 items), intentions to use (n=2 items), and perceived ease of use (n=4 items). Participants indicated their level of agreement with each item on a 3-point Likert scale (“disagree,” “neutral,” and “agree”). Participants’ comments or supporting statements in the context of their technology acceptance ratings were recorded and used as a contextual aid; no formal qualitative analysis was undertaken.

Figure 4. Technology acceptance survey responses.



Technology Adoption

Adherence, defined as the active time (minutes) on a task each day (repetitive UL training or interactive gaming), was used as a surrogate measure for technology adoption [63]. Adherence was measured by (1) self-reported session times and (2) digital time-on-task recorded by the device. These measures were strongly correlated (intraclass correlation coefficient for absolute agreement $r=0.87$; $P<.001$). Self-reported times were 14.5% (IQR -0.06% to 20.9%) greater than electronic logs, since the former includes preparatory and rest periods and corresponds more closely to “time scheduled for therapy” as conventionally reported in rehabilitation studies [63,64].

Data Analysis

Data analysis was performed with R (version 4.0.2; R Foundation for Statistical Computing) and RStudio (version 1.3.1093; Posit, PBC). Baseline clinical and demographic variables and questionnaire responses were organized into a single data matrix. Questionnaire responses were coded numerically (-1=“disagree,” 0=“neutral,” and 1=“agree”). Missing data were imputed using k-nearest neighbor imputation (k=3) [65]; imputation was performed with the caret library. Scores summarizing overall technology acceptance, perceived usefulness, intent to use, and ease of use were defined as per the formulae defined in Table 1, whereby questionnaire responses are coded numerically (-1=“disagree,” 0=“neutral,” and 1=“agree”) and combined as per the corresponding formula to generate scores.

Table 1. Scores summarizing overall technology acceptance, perceived usefulness, intent to use, and ease of use.

Score	Formula	Score range
Overall technology acceptance	“Promoted arm recovery” + “increased activity engagement or reduced boredom” + “increased control over own rehabilitation activities” + “additional benefit to usual rehabilitation” + “worthwhile time investment” + “would recommend to others” + “would participate again or continue to use” – “experienced problems” + “found easy to use” + “found easy to understand” + “enjoyed device and activities”	–11 to 11
Perceived usefulness	“Promoted arm recovery” + “increased activity engagement or reduced boredom” + “increased control over own rehabilitation activities” + “additional benefit to usual rehabilitation” + “worthwhile time investment”	–5 to 5
Intent to use	“Would recommend to others” + “would participate again or continue to use”	–2 to 2
Ease of use	“Found easy to use” + “found easy to understand” + “enjoyed device and activities” – “experienced problems”	–4 to 4

To assess clinical determinants of technology acceptance, bivariate correlations were measured between baseline participant characteristics (age, prior technology exposure, stroke severity, cognition, and UL impairment severity) and clinical outcomes (overall technology acceptance rating and intervention adherence). These variables were selected based on clinical reasoning and existing literature in the field indicating precedent [48]. Associations between integer variables were evaluated using 2-sided Spearman correlation tests. Bivariate associations between binary and integer variables were measured using the 2-sided Wilcoxon rank sum test. *P* values were

adjusted for multiple hypothesis testing using the Holm method [66].

Results

Sample Characteristics

In total, 30 participants were recruited over 3 months, with 29 completing the intervention. One participant was withdrawn by the research team due to medical complications unrelated to research participation. The median enrollment duration was 8 (IQR 5-14) days. Sample characteristics and data collected are summarized in [Table 2](#).

Table 2. Participant characteristics (n=30).

Variable	Value	Complete, n
Age (years), mean (SD)	70.3 (11.9)	30
Sex, n		30
Female	16	
Male	14	
Stroke subtype, n		30
Hemorrhagic	8	
Ischemic	22	
NIHSS, ^a mean score (SD)	8 (4.4)	30
Time since stroke (days), mean (SD)	11.1 (8.1)	30
MOCA, ^b mean score (SD)	19.9 (5.5)	24
BI, ^c mean value (SD)	47.1 (19.4)	29
FM-UE, ^d mean score (SD)	33.1 (16)	28
FSS, ^e mean score (SD)	5 (1.3)	29
FPRS, ^f mean score (SD)	1.5 (2.6)	29
HADS,^g mean score (SD)		26
Depression	6.7 (4.1)	
Anxiety	5.6 (3.8)	
Prior technology exposure, n		30
No	13	
Yes	17	
Reported daily activity (minutes), mean (SD)	26 (12.1)	20
Usability, mean score (SD)	1.6 (1)	29

^aNIHSS: National Institute of Health Stroke Scale.

^bMOCA: Montreal Cognitive Assessment.

^cBI: Barthel index.

^dFM-UE: Fugl Meyer-Upper Extremity Assessment.

^eFSS: Fatigue Severity Scale.

^fFPRS: Faces Pain Rating Scale.

^gHADS: Hospital Anxiety and Depression Scale.

User Performance (Usability)

The technology was usable for 26 of 30 participants (87%). The remaining 4 participants (13%) were unable to use the device with their affected UL due to the severity of motor impairment (absence of voluntary finger extension or 0/5 on the Oxford Rating Scale [Medical Research Council Manual Muscle Testing Scale]). Motor weakness was monitored throughout enrollment for these 4 participants and remained unchanged. User performance varied; 7 participants were fully independent with all aspects of the technology use (device retrieval, setup, and self-directed training), 9 participants achieved modified independence (required only physical setup to use the system often due to restricted mobility), and 8 participants required assistance (supervision or support) to complete training sessions due to combined physical and cognitive impairments.

Acceptability

The overall technology acceptance rating was 68% (95% CI 56%-79%). TAM subcategories were also explored independently. In total, 58% of respondents perceived that the device was easy to use (4 items), 86% reported an intent to use (2 items), and 77% perceived that the device was useful (5 items). Individual item responses are summarized in [Figure 4](#).

Adoption or Adherence

Participants (n=20) engaged with the device for a median of 26 (SD 12.1) minutes of training daily ([Table 2](#)), increasing the conventional UL training dose (25 minutes) by 2-fold [[60](#)].

Interactions or Associations Between Variables

National Institute of Health Stroke Scale (global stroke severity) correlated positively with overall technology acceptance rating ($\rho=-0.56$; 95% CI -0.79 to -0.22 ; $P=.007$). No statistically

significant correlations were observed between technology acceptance and participants' age, prior technology exposure, Montreal Cognitive Assessment score, or Fugl Meyer-Upper Extremity Assessment score. [Table 3](#) shows a full summary of participant variables and technology acceptance.

Lastly, associations of technology adoption with technology usability and technology acceptance variables were examined. Technology adoption (intervention adherence) correlated

positively with user performance (usability: $\rho=0.55$; 95% CI 0.23-0.75; $P=.007$) and perceived ease of use ($\rho=0.46$; 95% CI 0.10-0.74; $P=.02$) as well as perceived usefulness ($\rho=0.42$; 95% CI 0.09-0.68; $P=.03$). No significant correlation was observed between participants' self-reported intent to use the technology and intervention adherence during the trial period. [Table 4](#) shows a full summary of correlations among intervention adherence, technology usability, and acceptability variables.

Table 3. Correlations between participant variables and technology acceptance.

Method	Predictor	Outcome	Result, ρ (95% CI)	Adjusted P value
Spearman	Age	Acceptance	0.04 (-0.40 to 0.44)	.85
Wilcoxon rank sum	Prior technology exposure	Acceptance	0.00 (-1.00 to 3.00)	.73
Spearman	NIHSS ^b	Acceptance	-0.56 (-0.79 to -0.22)	.007
Spearman	MOCA ^c	Acceptance	0.20 (-0.14 to 0.52)	.50
Spearman	FM-UE ^d	Acceptance	0.39 (0.00 to 0.66)	.08

^aLocation difference.

^bFM-UE: Fugl Meyer-Upper Extremity Assessment.

^cMOCA: Montreal Cognitive Assessment.

^dFM-UE: Fugl Meyer-Upper Extremity Assessment.

Table 4. Correlations among intervention adherence, technology usability, and acceptability variables.

Method	Predictor	Outcome	Result ρ (95% CI)	Adjusted P value
Spearman	Usability	Intervention adherence	0.55 (0.23 to 0.75)	.007
Spearman	Perceived usefulness	Intervention adherence	0.42 (0.09 to 0.68)	.03
Spearman	Intent to use	Intervention adherence	0.25 (-0.09 to 0.54)	.18
Spearman	Ease of use	Intervention adherence	0.46 (0.10 to 0.74)	.02

Discussion

Principal Findings

This self-directed, technology-facilitated intervention was broadly usable and acceptable within this study cohort. Stroke severity correlated negatively with technology acceptance; those participants with the most severe stroke reported lower acceptability ratings across all domains. Participants achieved an average UL training dose of 26 minutes daily as an adjunct to conventional face-to-face UL rehabilitation. This adjunctive experimental training dose exceeded the conventional care dose typically observed in subacute stroke rehabilitation settings [64]. Technology adoption positively correlated with technology usability, perceived ease of use, and perceived usefulness, indicating that the usability of technology, as well as the effort associated with using the technology, influenced actual use. Furthermore, our findings suggest that perceived usefulness of technology, in this case the extent to which participants associated the technology with UL rehabilitation and recovery, influenced adoption. A strength of this study is the broad sampling of participants recruited in the acute or subacute stroke recovery phase, including older adults, those with cognitive impairment, and those with moderate to severe stroke, representing cohorts frequently excluded from stroke

rehabilitation research [67]. Less than half of the participants ($n=13$, 43%) had previously owned or used a smartphone.

Although the technology was usable for the majority of participants, many required facilitating conditions to optimize their participation, highlighting the importance of assessing and addressing individual user needs. Clinical adoption of rehabilitation technologies may be improved by enhancing usability and acceptability. This may be achieved through design optimization, education, and user support, targeting the domains of usability, perceived ease of use, and perceived usefulness. In this study, a positive association was observed between perceived usefulness of technology and its adoption, presenting a promising avenue to improve engagement. A robust clinical evidence base may enhance perceived usefulness of rehabilitation technologies among stakeholders. Thus far, systematic reviews and meta-analyses have found evidence in the domain of technology-facilitated UL interventions after stroke to be insufficient or of low quality, leaving limited scope for interpreting the efficacy of such interventions [17,48,68,69] and thus restricting the extent to which clinical guidelines or individual clinicians may advocate for adoption.

This study examined a stroke rehabilitation intervention focusing on interactive gaming and nonimmersive virtual reality with a target function to achieve repetitive, task-specific UL training

to promote UL motor recovery. We observed that participants with the most severe UL impairment showed a trend toward lower technology acceptance ratings. In this sense, patient characteristics can be linked with specific technology characteristics (the mechanism and target function, that is, repetitive UL training for UL recovery). Rehabilitation technology is often discussed with ambiguity; there is a lack of consensus on the taxonomy, classification, and categorization of technology. This may lead to barriers in interpreting the efficacy and applications of technology among target users. Individual technologies comprising unique mechanisms and target functions are likely to benefit from individual evaluation, incorporating the relevant user cohort to identify important interactions between user characteristics and outcomes in usability, acceptability, and adoption as well as clinical efficacy. Thorough reporting of technology subtypes and participant subgroups may advance clinical translation. The use of a framework for describing and categorizing rehabilitation technologies, and indeed digital health technologies more broadly, would likely enhance reporting standards.

Limitations

Although this study population was heterogeneous in terms of age, sex, and clinical characteristics, it represented a single institution; future work will incorporate a multicenter design. Imputation may have biased associations where data missingness patterns were nonrandom, although multivariate imputation was used to minimize this bias. The power of our analysis was limited by the sample size—consequently, some real effects may have failed to generate statistically significant associations. The sample size was kept intentionally small to allow for feasibility testing in this instance, and while this addressed the current aims, a larger sample size will be recruited in a planned subsequent trial (ClinicalTrials.gov NCT04475692). As an observational study, findings are subject to the limitation that observed correlations do not necessarily imply causal relationships.

In the TAM survey, neutral responses were limited to questions that required a hypothetical comparison to an experience without rehabilitation technology (ie, conventional rehabilitation). The cognitive demands of such theoretical comparisons likely exceed those of questions interrogating the participants' own experience. All respondents to the nonhypothetical questions "enjoyed device and activities," "found easy to understand," "experienced problems," and "would participate again or continue to use" chose to agree or disagree rather than remain neutral. This observation may guide future survey development to improve participant engagement and response reliability. A further limitation of the TAM survey used here is that questions were largely unidirectional; inverting questions may have reduced the risk of positive response bias.

Future Work

Findings suggest that technology acceptance and subsequently adoption negatively correlate with stroke severity in this instance. Identifying interventions for severe stroke is a key

clinical, academic, and patient priority [70], a focus for future work may be on adapting technology or intervention design to enhance acceptability and adoption for those with the most severe poststroke impairments.

Technology adoption is a complex and dynamic process. We implemented a postintervention TAM survey only; administering both pre- and postintervention surveys may support our understanding of the mechanisms of technology adoption as well as mediating conditions. Several authors report significant changes in technology acceptance among users over time or in line with specific facilitating conditions (eg, social support, peer support, increased availability and frequency of training, system upgrades) [23]. Furthermore, perseverance with technology-facilitated interventions is anticipated to change over the intervention timespan [48]; understanding factors that influence the long-term adoption of rehabilitation technologies for stroke survivors will form an important aspect of future research (ClinicalTrials.gov NCT04475692).

Closed questionnaires and quantitative data collection allowed us to examine specific and tangible aspects of technology usability, acceptability, and adoption along with clinical and demographic variables; richer themes and context may be derived from a mixed methods exploration, encompassing the broader spectrum of participants' experiences and feelings.

Finally, the adoption of health technology hinges upon multiple stakeholders and may in a large part be determined by technology usability and acceptability among clinicians [19]; this is echoed in Health Education England's recent development of a digital competency framework for National Health Service staff [71]. In the context of this self-directed intervention, we focused on user experience from the perspective of the patient; further work may explore acceptance among broader stakeholders, including clinicians and caregivers, who play a pivotal role in supporting self-management in this setting.

Conclusions

In an age of digitalized health care, technology usability and acceptability represent increasingly important determinants of health outcomes [9,72,73]. We explored the adoption of a low-cost (<£1000; US \$1283) rehabilitation technology used in a self-directed context within a heterogeneous cohort of stroke survivors. To our knowledge, this is the first study to concurrently examine technology usability, acceptability, and adoption in this context and evaluate the influence of stroke survivor characteristics. The technology was usable and acceptable to the majority of participants and greatly supplemented conventional rehabilitation provisions. We have presented a robust analysis identifying associations between stroke survivor characteristics, technology usability, acceptability, and adoption. Our findings provide insights that will inform intervention planning and implementation, emphasize the need for specificity when reporting digital health interventions, and reiterate the importance of a holistic and person-centered approach to optimize the translation of technologies into clinical practice.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

PB was part of the scientific group involved in the early development and testing of the technology used in this trial (GripAble).

Multimedia Appendix 1

Stroke upper limb rehabilitation technology adoption logic model.

[[DOCX File, 38 KB - rehab_v10i1e45993_app1.docx](#)]

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Abbreviations

BI: Barthel index

TAM: technology acceptance model

UL: upper limb

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Review

Models and Approaches for Comprehension of Dysarthric Speech Using Natural Language Processing: Systematic Review

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Abstract

Background: Speech intelligibility and speech comprehension for dysarthric speech has attracted much attention recently. Dysarthria is characterized by irregularities in the speed, strength, pitch, breath control, range, steadiness, and accuracy of muscle movements required for articulatory aspects of speech production.

Objective: This study examined the contributions made by other studies involved in dysarthric speech comprehension. We focused on the modes of meaning extraction used in generalizing speaker-listener underpinnings in light of semantic ontology extraction as a desired technique, applied method types, speech representations used, and databases sourced from.

Methods: This study involved a systematic literature review using 7 electronic databases: Cochrane Database of Systematic Reviews, Web of Science Core Collection, Scopus, PubMed, ACM, IEEE Xplore, and Google Scholar. The main eligibility criterion was the extraction of meaning from dysarthric speech using natural language processing or understanding approaches to improve on dysarthric speech comprehension. In total, out of 834 search results, 30 studies that matched the eligibility requirements were acquired following screening by 2 independent reviewers, with a lack of consensus being resolved through joint discussion or consultation with a third party. In order to evaluate the studies' methodological quality, the risk of bias assessment was based on the Cochrane risk-of-bias tool version 2 (RoB2) with 23 of the studies (77%) registering low risk of bias and 7 studies (33%) raising some concern over the risk of bias. The overall quality assessment of the study was done using TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis).

Results: Following a review of 30 primary studies, this study revealed that the reviewed studies focused on natural language understanding or clinical approaches, with an increase in proposed solutions from 2020 onwards. Most studies relied on speaker-dependent speech features, while others used speech patterns, semantic knowledge, or hybrid approaches. The prevalent use of vector representation aligned with natural language understanding models, while Mel-frequency cepstral coefficient representation and no representation approaches were applied in neural networks. Hybrid representation studies aimed to reconstruct dysarthric speech or improve comprehension. Comprehensive databases, like TORGO and UA-Speech, were commonly used in combination with other curated databases, while primary data was preferred for specific or unique research objectives.

Conclusions: We found significant gaps in dysarthric speech comprehension characterized by the lack of inclusion of important listener or speech-independent features in the speech representations, mode of extraction, and data sources used. Further research is therefore proposed regarding the formulation of models that accommodate listener and speech-independent features through semantic ontologies that will be useful in the inclusion of key features of listener and speech-independent features for meaning extraction of dysarthric speech.

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KEYWORDS

dysarthria; speech comprehension; speech contextualization; meaning extraction; ontology extraction; familiarity; topic knowledge

Introduction

The comprehension of dysarthric speech in usual discourse goes beyond basic recognition of the words uttered by the speaker. Effective comprehension acknowledges the legacy communication structure of speaker-channel-listener, with a focus on the intended message. As such, it is important to figure out the intended message of the dysarthric speaker, particularly after the recognition of the words uttered. The nature of dysarthric speech makes the comprehension task graver following the adaptive means taken up by such speakers, which may only be understood better by listeners who are familiar with their manner of expression and choice of vocabulary [1,2]. Having knowledge of the topic of discussion during discourse may be helpful in understanding what the patient with dysarthria is saying; however, it has been shown that even the patterns of intertopic switching by these speakers are outside of the usual discourse norms. As such, the primary task of listener-targeted remediation in offsetting the intelligibility burden associated with dysarthria from the speaker is left with the listener [3,4].

Speech contextualization is the most direct approach taken toward comprehending speech. Linguistically, context refers to a part of the real world where certain events or conversations occur, and it is frequently mistaken with another meaning, namely, knowledge about the same thing [5]. To discern context, there must be some common information between the speaker and the listener, at least to an acceptable degree. The concepts of comprehensibility and intelligibility may be distinguished by the fact that comprehensibility incorporates signal-independent information, such as syntax, semantics, and physical context. This distinction implies that the ability of a listener to retrieve the semantic code of spoken speech is dependent on both the acoustic-phonetic information and all relevant signal-independent information [6]. This dependence influences the main assumption of this study that events occurring within and without the speech itself are crucial for deciphering the intended meaning of the words spoken, thereby informing the context of the situation.

With the recent growing interest in the explicit modelling of events in structural conceptual models, ontology extraction has become one of the formidable trends and tools of use for explicitly representing events in structural models [7]. Ontologies are mainly perceived as a knowledge graph able to formally model different aspects of our real world [8]. A common issue with these ontologies is that, being manually crafted and maintained by domain experts, they tend to evolve relatively slow and become quickly outdated. To keep up with the pace of the constant evolution of the research landscape, some institutions are crowd-sourcing their classification scheme [9]. More efficient techniques, such as the use of self-learning vector machines, have been proposed to counter these shortcomings [10].

Speech comprehension as implemented in neural machine translation and automated speech recognition models are mostly ineffective as attributed by their universal assumptions that tend to factor out the listener or intended listener while trying to locate context from isolated sentences or in some cases

interrelated sentences from the same speaker [11,12]. The close standing techniques, such as semantic projection, assume similarity in vocabulary level between the speaker and listener with little emphasis put on levels of familiarity or topic sentence as the bridge between the message source and the intended recipient [1,2].

The fundamental structure for these solutions, which is word vector mapping, bears few pointers that could aid word embedding in informing meaning when plugged into any sort of machine translator, whether affective or attention-based [5,13]. These challenges are more elaborate in dysarthric speech where speech listeners are more likely to create linguistic generative models for new talkers based on their understanding of the distribution of auditory cues associated with each linguistic category [14].

Therefore, this study reviewed models and methodologies that are used in comprehending meaning from audio dysarthric speech by means of speech-event representations, otherwise known as situational projections. Following the fact that familiarization formed the core paradigm of the reviewed works as a technique that affords listeners an opportunity to retune their stored linguistic representations [15,16], the following key research question arose: following the unique characteristics of each speaker, how do the reviewed models generalize over new dysarthric speech given the specificity of the speaker? This study discusses the approaches used in generalizing speaker-listener underpinnings in relation to familiarization in light of ontology extraction as a technique of interest.

Methods

Goal and Review Questions

Goal of the Study

The goal of this study was to systematically map (classify), review, and synthesize studies that focus on the use of natural language processing and natural language understanding (NLU) in extracting meaning from dysarthric speech. Moreover, this study aimed to detect recent trends and directions of the field to identify opportunities for future research from both researchers' and practitioners' perspectives. Guided by the established guidelines for conducting systematic literature review studies [17] and the established procedure for reporting the findings of the review [18,19], the selection and review process was developed and reported. Based on the above goal, review questions (RQs) were raised and grouped under 1 of 2 categories.

Category 1 RQs

The following RQs were general to all systematic literature review studies:

1. RQ 1.1. Mapping of studies by contribution types: what are the contributions presented in the studies? The motivation for this RQ is that the contribution identified in the respective studies largely influences the nature of the proposed solution regarding whether they are approaches, methods, or tools for contextualizing or comprehending dysarthric speech.

2. RQ 1.2. Mapping of studies by research method types: how many studies presented empirical or theoretical frameworks? Following the multidisciplinary nature of this study, it was likely that the manner of comprehending dysarthric speech would vary, hence this RQ.

Category 2 RQs

The following RQs were specific to the topic (contextualizing dysarthric speech):

1. RQ 2.1. The mode of meaning extraction used: what modes of meaning extraction were used in the models and approaches of the reviewed studies? The main rationale for this RQ was to investigate how different studies tended to include or exclude the listener decoding process from the meaning extraction process as influenced by both their inputs and output.
2. RQ 2.2. The nature of word representations used: what is the nature and ability of the word representation used in the meaning extraction from dysarthric speech? Due to the ability of different word representations used within the reviewed studies, such as word vectors, context vectors, and ontology web vectors, it was necessary to ask this question.

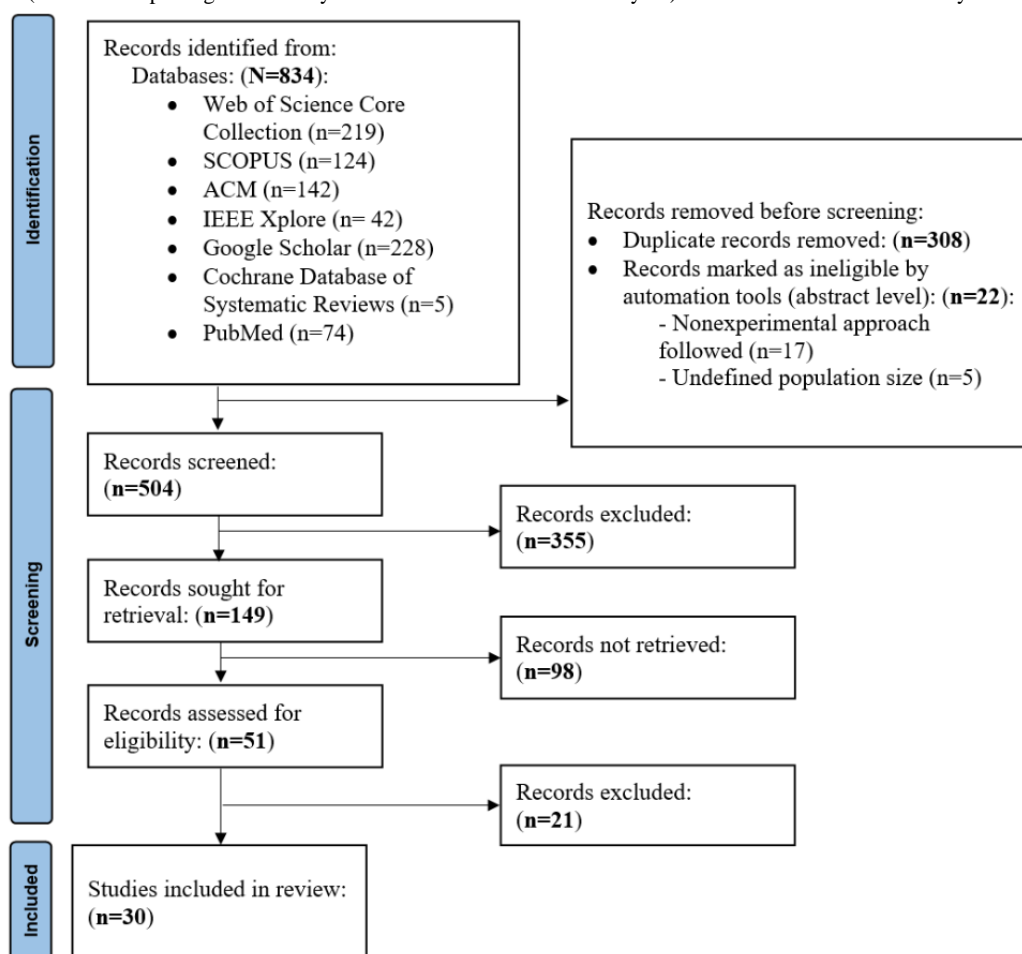
3. RQ 2.3. Data sources: what data sources were used to train the meaning extraction models? This RQ was formulated for the purpose of assessing the richness of the solution offered by the reviewed studies.

Search Strategy

This systematic review was reported in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [18,19]. A comprehensive literature search was conducted on 7 databases from inception to 2023 to identify relevant articles. The databases searched included the Cochrane Database of Systematic Reviews, Web of Science Core Collection, Scopus, PubMed, ACM, IEEE Xplore, and Google Scholar for studies reporting meaning extraction tools, approaches, and methods for dysarthric speech.

The selection of articles is presented in Figure 1. Further, we defined search strings for each database searched, in accordance with the PICO (Problem, Intervention, Comparison, and Outcome) structure [20] (Multimedia Appendix 1). The keywords for the PICO structure were guided by the general question “can listener-based natural language processing models and approaches improve the comprehension of dysarthric speech?”

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart for the selection of systematic review literature.



The following sentences further describe the PICO structure followed:

1. Problem: studies related to dysarthria or dysarthric speech and variations (“dysarthria” OR “dysarthric” OR “dysarthrias” OR “dysarthrics”).

2. Intervention: studies related to natural language processing approaches or techniques used for speech comprehension and their synonyms or abbreviations (“natural language processing” OR “NLP” OR “natural language understanding” OR “NLU” OR “automated speech recognition” OR “intelligibility” OR “listener*” OR “listen” OR “technique” OR “approach”).
3. Comparison: given the significant difference in our objectives and goals from those of past research on the topic, there were no comparable studies to use as a baseline.
4. Output: comprehension tasks and synonyms arising from the use of natural language processing approaches (“comprehension” OR “meaning” OR “contextualization*” OR “context*” OR “comprehension*” OR “comprehend” OR “understand”).

Using “AND” and “OR” operators to link these ideas, we came up with the following general search phrase: (“Dysarthria” OR “Dysarthric” OR “Dysarthrias” OR “Dysarthrics”) AND (“natural language processing” OR “NLP” OR “natural language understanding” OR “NLU” OR “automated speech recognition” OR “intelligibility” OR “listener*” OR “listen” OR “technique” OR “approach”) AND (“comprehension” OR “meaning” OR “context” OR “contextualization” OR “comprehend” OR “understand”). Slight variations depending on the databases searched are documented in [Multimedia Appendix 2](#).

Inclusion and Exclusion Criteria

Out of 834 search results, a total of 30 studies were included for review. Studies that were included must have fulfilled the following criteria: (1) studies that focused on meaning extraction and not just on intelligibility, (2) studies that focused on dysarthric speech, and (3) studies that clearly defined approaches, tools, or methods for dysarthric speech comprehension.

Studies that were excluded included the following: (1) literature investigating other speech disorders, such as aphasia; (2) studies which conducted other speech tasks, such as measuring the severity of dysarthria, classification of dysarthric type, and assessment of the speaker’s dysarthric level; (3) literature that did not apply natural language processing interventions, such as speech therapy rehabilitation or clinical approaches; (4) literature that focused on dysarthric speech features or characteristics, leaving out dysarthric speech patterns; and (5) studies that solely focused on dysarthric speech intelligibility and not its comprehensibility.

CADIMA systematic review software [21] was used for screening automation. A 2-stage screening process was used. To reduce bias, 2 reviewers screened all titles and abstracts. The first step assessing relevance to the inclusion criteria was performed by the 2 researchers independently, and the papers passed to the next step if at least 1 reviewer decided so. In the events where consensus at the title and abstract level screening could not be achieved between the 2 reviewers an adjudication sourced from a third person on a consultation basis was sought.

During the second stage, 2 independent reviewers performed a full-text blind review, with consensus obtained after deliberation between reviewers, when required. The consensus meetings

were held to resolve disagreements and uncertainty. Finally, the objectivity of the criteria was assessed, either prereview on a test set by measuring agreement or postreview.

Data Synthesis and Analysis

As per the RQs, 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) mode of meaning extraction used in each study, (5) nature of word representation used in light of their abilities to effectively extract meaning from dysarthric speech, (6) speech patterns considered, and (7) data sources used in the studies. Tables and graphs were developed to summarize the information points.

Quality Assessment

Quality assessment was conducted by 2 independent reviewers on 2 levels. First, the overall assessment of the quality of studies was chosen to be reviewed, and second, the risk of bias (ROB) was assessed. After completing the independent assessments, areas of discrepancies in each of the reviewers’ evaluations were identified. A constructive discussion of the identified discrepancies ensued for purposes of highlighting the reasons for the differing assessments. Active reference to the study protocol used [22] formed the main basis for a consensus to be achieved during these discussions.

The goal of the quality assessment was to determine the significance of each chosen document. We described the evaluation largely to reflect the validity of the chosen studies, even if the quality rating had no bearing on the choice of the primary investigations. The study’s compliance with the TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) [22] standard served as a gauge of its quality. Each article was given 1 or 0 points depending on how closely the TRIPOD checklist was followed or not. Additionally, every paper that was reviewed scored higher than 50%. For more information on the outcomes of the TRIPOD assessment standards, see [Multimedia Appendix 3](#).

Given that the participants of the studies reviewed patients with dysarthria, the Cochrane RoB2 tool was used to assess the ROB. Results of the domain-specific and overall ROB assessment ratings of the set of 30 studies are shown in [Figure 2](#). The individual ROB ratings of all studies are included in [Multimedia Appendix 4](#). The ROB was assessed using 5 domains, including randomization process bias, deviation from intended outcome bias, missing outcome data bias, measure of outcome bias, and selection of reported results bias.

In the randomization process bias domain, 20 (67%) studies were rated as low ROB, 6 (20%) as causing some concern, and 4 (13%) as bearing no information needed. These ratings indicated that little bias occurs when a trial’s results are affected by human choices or other factors not related to the treatment being tested. In the deviation from intended outcome bias domain, 21 (70%) studies were rated as low ROB due to a majority of the studies being specific in their outcome either as actual solutions or empirical solutions, weak or strong as they may be ([Figure 3](#)). Furthermore, 8 (27%) studies were rated as

causing some concern and only 1 (3%) study as bearing high ROB. This may be attributed to the primary goal of this review where the studies selected were focused on achieving

comprehensibility, yet a majority tended to skew more toward intelligibility.

Figure 2. Summary of the risk of bias assessment.

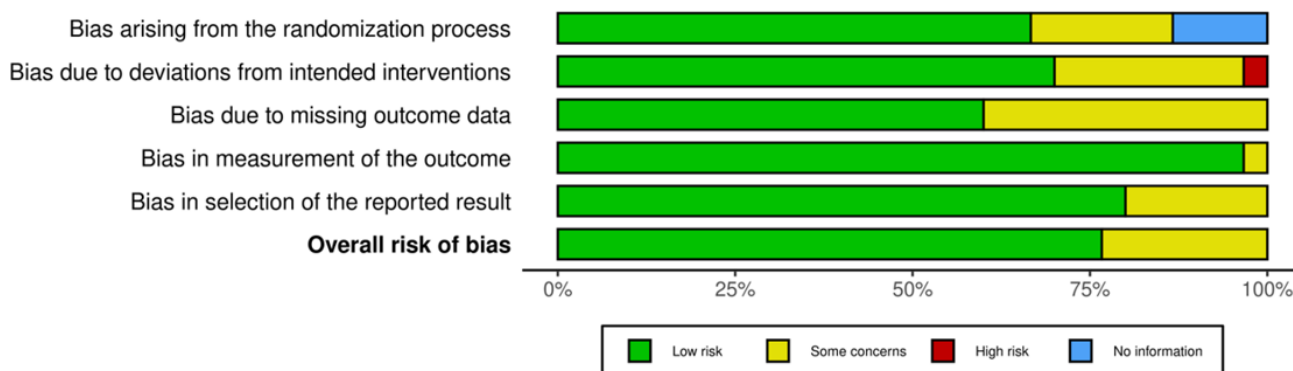
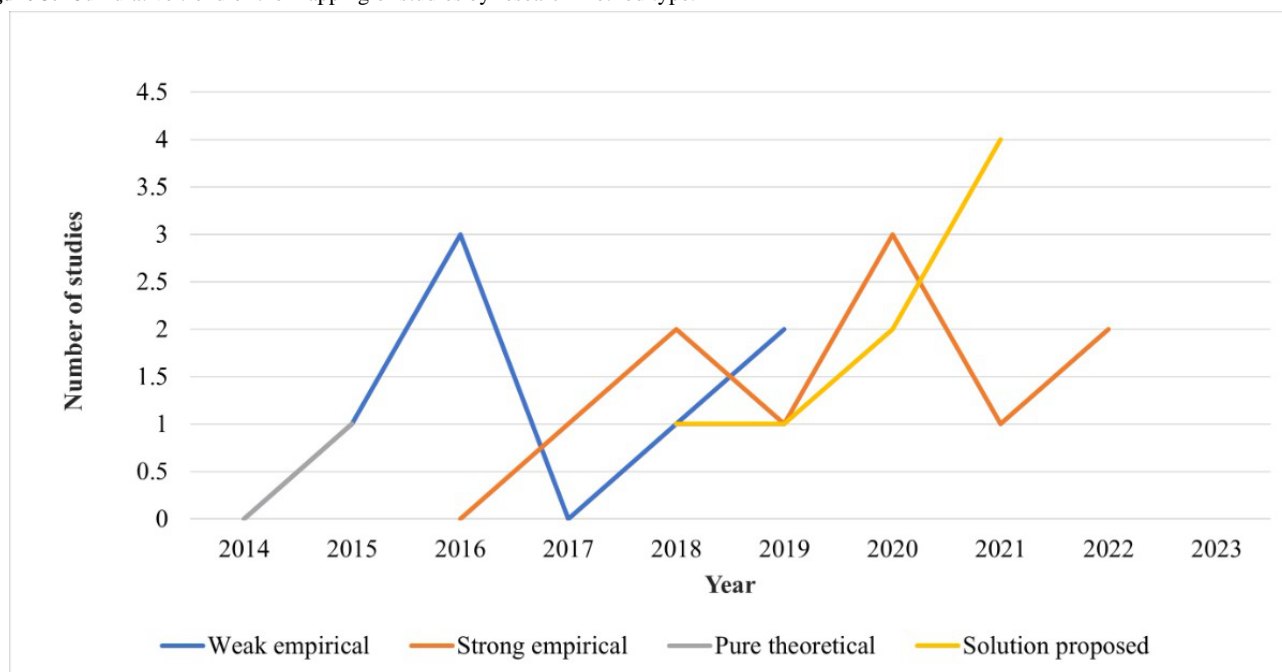


Figure 3. Cumulative trend of the mapping of studies by research method type.



The missing outcome data bias domain comprised the lowest proportion (n=18; 60%) of low ROB ratings among all 5 domains in our investigation and the highest proportion (n=12; 40%) of somewhat concerning ROB ratings. This may have been posed by a majority of studies not reporting the clear state or data type of the data churned out of their proposed solution for use in dysarthric speech comprehension. The measure of outcome bias domain comprised the highest proportion (n=29; 97%) of low ROB ratings among all 5 domains in our investigation. Only 1 (3%) study somehow concerns ROB. The main reasons for the high ROB were strong internal and external validation used in a majority of the studies as a means of quantifying the effectiveness of the proposed solutions therein.

In the selection of reported results bias, 24 (80%) studies had low ROB with 6 (20%) of the studies causing some concern over the ROB. Overall, only 23 (77%) studies received a low ROB rating, whereas 7 (33%) studies were judged to have a somewhat concerning ROB. Of these 7 studies, 1 [23] received a high ROB rating on deviation from intended outcome as

intelligibility rose as its core objective instead of comprehensibility.

Results

This section is structured according to the classification of studies and technical issues regarding the contextualization of dysarthric speech.

Classification of Studies

First, the studies were classified according to their contribution. We discovered 4 apparent contributions from the studies: (1) hybrid (a combination of clinical and NLU approaches), which formed approximate 17% (n=5) of the pool; (2) NLU techniques, which formed 43% (n=13) of the pool; (3) theoretical approaches, which formed 10% (n=3) of the pool; and (4) clinical therapy approached, which formed 30% (n=9) of the pool. Generic acoustic tools and theoretical tools were grouped

into 1 category following the fact that the acoustic concepts applied in both studies were similar.

The studies were mapped by research method type. The identified research methods from the studies were weak empirical studies, strong empirical studies, pure theoretical studies, and studies bearing proposed solutions that intended to derive meaning from dysarthric speech. As illustrated in the cumulative trend diagram in [Figure 3](#), earlier studies (2015-2019) attracted a majority of weak empirical studies on dysarthric speech comprehension, with strong empirical studies having their onset from 2016 onwards. The distribution of pure theoretical studies was sparse through the years, while studies proposing actual solutions for meaning extraction from dysarthric speech appeared mainly from 2018 onwards.

Technical Issues Specific to the Topic (Contextualizing Dysarthric Speech)

Mode of Meaning Extraction Used

It was important to establish the mode of meaning extraction from dysarthric speech to aid in showing how different studies acknowledged the role of the listener in remediating dysarthric speech. The mode of meaning included the specific speech inputs into the proposed models. Studies that solely used speech features [[15,24-35](#)] were heavily speaker-dependent on their approach and tended to lean more toward intelligibility of the dysarthric speaker than their comprehensibility.

Studies that emphasized speech patterns [[23,27,36-42](#)] were interested in the formation of words spoken, omissions in their patterns, and inclusion of interesting vocabulary during discourse. These studies were much aligned toward word representation and drawing meaning out of the same by leveraging other speech-independent features, such as the speakers' emotions. Closely tied to studies that relied on speech pattern were studies that used semantic knowledge [[43,44](#)] that mostly worked by combining language rules, background knowledge, and semantic change patterns so as to understand semantic similarity-based relevance between questions and corresponding answer sentences.

Finally, studies that had a hybrid approach [[23,45-51](#)] combined speech features, speech patterns, and semantic knowledge so as to go beyond the mere task of intelligibility and pose questions on possible comprehensibility of the speech being studied. These studies incorporated the use of familiarization and topic knowledge techniques.

Nature of Speech Representations Used

Investigating the nature of the word representation was instrumental in establishing the robustness of the approaches, tools, or solutions proposed in the studies reviewed. Whereas some representations, such as Fourier transformation and Mel-frequency cepstral coefficients (MFCC), are popular in speech processing, their abilities to handle dimensions of semantic knowledge are questionable [[5,13](#)]. It is worth noting that for most studies that used MFCC [[28,29,31,35,36,47](#)], variations of artificial neural networks were used in all except one [[26](#)], in which a stochastic model was applied.

This uniformity was unlike the case in studies that used no representation at all [[24,25,27,30,32,37,44,46](#)] in which a mix of models ranging from hybrid (neural models and clinical approaches) to support vectors were used. The tasks of this category mostly involved assessment of intelligibility in domain specific cases of dysarthria, such as Parkinson disease, or any other noise, with comprehensibility being a secondary or aiding factor.

The studies that used vector encoding [[15,38-43,50,51](#)] used NLU-based models, such long short-term memory neural networks or combinations of gated recurrent unit and convolutional neural networks to achieve the tasks of dialogue assessment in dysarthric speech, language understanding, and semantic pattern tracking.

Finally, studies that used a hybrid approach [[23,33,34,45,48,49](#)] combined MFCC with variations of vector encoding. These studies were characterized by variations of models, such as adversarial networks, support vector machines, gated recurrent unit and convolutional neural networks, and hidden Markov models. The tasks in each of these studies also varied and were very heavily geared toward reconstruction of dysarthria through assessment of the semantics presented.

Databases Used

The choice of the database used was assessed to ascertain the depth of the approach, tool, or solution proposed in the reviewed studies. This was important in informing this study of the flexibility of data used in achieving dysarthric speech comprehensibility. Extensive and well-documented databases, such as the TORGO database and the UA-Speech database, contain data sets that have the potential to yield the in-depth speech patterns necessary for speech comprehension. Studies that used these 2 databases [[26,31](#)] (n=2; 6% of the studies) or a hybrid of any other databases (n=11; 37% of the studies) [[28,33,37-41,47-49,51](#)] focused more on the application of the data in their proposed models, with little effort going into curation and preprocessing of the data.

However, a majority of the reviewed studies (n=17; 57% of the studies) involved audio data that were primarily sourced. These studies [[15,23-25,27,29,30,32,34-36,42-46,50](#)] foremost curated the data and augmented their input data representations to accommodate features that ordinary speech representations would not have accommodated in their natural form. Further models for speech processing were developed and these representations were used to train the models.

Discussion

Summary of Findings

The ultimate purpose of this study was to gain an in-depth understanding of the current state of research in remote sensing for the comprehension of dysarthric speech, to give suggestions about future lines of research, and to find new possibilities and application areas. This can be achieved by an analysis and discussion of the results presented in the previous section.

The mapping of contributions made by the reviewed studies indicated that mostly NLU or clinical approaches were used.

This was evidenced in the findings of reviewed method types where the number of actual proposed solutions only began to rise in 2020, having been preceded by empirical studies that perhaps meant to justify the suitability of the clinical approaches used.

The mapping of studies by method types also indicated an increase in theoretical research from 2020 onwards, which bore the theoretical framework necessary for justifying the new actual proposed solutions for extracting meaning from dysarthric speech. Studies preceding 2018 were mostly characterized by weak empirical or pure theoretical studies.

It is worth noting that a majority of the studies heavily relied on speaker-dependent speech features, thereby leaning more toward intelligibility with little focus on the semantics of the speech input. Studies that solely used speech features were biased toward performing dysarthric speech intelligibility tasks as opposed to comprehensibility. This was contrary to studies that used speech patterns, semantic knowledge, or a hybrid of the two, which aimed at applying rules, background knowledge, and familiarity features in order to comprehend dysarthric speech.

The use of vector representation was a prominent speech representation used in a majority of the studies; this was in tandem with the findings of the contributions made by the reviewed studies, given that most natural language processing models or approaches preferred to use vectors and no representation approach solutions. Whereas vector-based representations were largely applied in NLU models, MFCC representations as well as studies that applied no representation were mostly applied in variations of artificial neural networks or a mix thereof. The studies that applied hybrid representation were unique in the sense that they delved more toward reconstructing dysarthric speech or assessing approaches for reconstructing dysarthric speech so as to achieve better meaning.

Comprehensive databases, such as TORGO and UA-Speech, were rarely used in solitude; their combination with other curated databases resulted in a slightly higher number of hybrid data sources compared to TORGO or UA-Speech independently. The majority of studies, however, used primary data curated for specific tasks intended for the objective.

Implications

With NLU studies gaining traction from 2020 onwards, and a number of NLU approaches being hybridized with clinical approaches, there is an inference that dysarthria is indeed deemed a major medical condition warranting a similar approach [52-54]. This is pegged heavily on the need of such approaches to be dependent on human intervention, which has been the norm over the past few years of dysarthric speech research.

This posits that the proposition of a speech comprehensibility solution for dysarthric speech may, both in the present and future, rely on clinical findings to inform the models being proposed. While this dependence on clinical approaches may possibly be seen as being problematic to potential stand-alone NLU approaches, it may be appraised as a potential strength for informing the overall generalizability of the approaches, particularly with regard to providing speaker-specific meaning

extraction [12,55]. Where generalizability is high, the human intensive effort that would have been put in becomes rigorous. As such, there arises a need for models that are both speech-dependent and speech-independent to allow for a variation of features necessary for achieving comprehension [2].

There has been limited breakthrough in the study of speech comprehension models with the onset of actual proposed solutions from 2020 onwards, as the findings indicate that a merely theoretical approach was followed, meaning that the output of these studies are theoretical frameworks as opposed to actual solutions. This perhaps may be tied to either a lack of sufficient data needed as primary inputs to the proposed frameworks or a narrow technical gap presented by the same [26,56]. This can be reflected by the vast use of primary data by most of the reviewed studies as opposed to existing databases, perhaps out of a lack of sufficient data within the existing dysarthria speech databases.

The slim gap problem faced by existing theoretical frameworks involves the significant assumption made that intelligibility is similar to comprehensibility [57]. This is reflected by much reliance on speech features as opposed to speech patterns that would require more data points to draw meaning. This assumption has resulted in the formulation of representations that are not sufficient to perform a speech contextualizing task, which goes beyond a simple translation of the words spoken [5,13]. It is suggested that intelligibility be treated as an objectively different task from comprehensibility, which in this study is deemed as the message derived from speech given both speech-dependent and speech-independent factors.

Additionally, the limitation in the gap for the presently existing theoretical frameworks may first be attributed to a biased definition of redefining familiarity, which alludes to a heavy connotation in communication theory. There is need to redefine familiarity as a projection of word feature vectors into the d-dimensional semantic word space with consideration of a set of classes that constitute several situational markers, such as topic events and emotional events [7,58]. This shall be useful to natural language models that seek to incorporate such vectors as inputs necessary for inferring context of speech and thereby comprehending speech.

Limitations

This study is limited to only a review of 30 studies by virtue of the scope of the study that sought to review methods and approaches used to comprehend dysarthric speech using techniques of natural language processing. The strict definition of comprehension left out a number of studies whose task solely focused on intelligibility as a task. Additionally, the study was limited to the previously discussed research questions and as such did not address other prominent techniques, such as the use of additional techniques (eg, computer vision) while attempting to comprehend dysarthric speech. This followed the fact that the comprehension of speech could be limited to a few speech-related events for the purposes of meaning extraction, as much as additional nonspeech features would enrich the discussed methods and approaches.

Conclusion

By reviewing the relevant studies, this systematic review mapped and reviewed the body of knowledge on studies that attempted to extract meaning from the inputs and generic nature of dysarthric speech. In total, 30 papers were systematically reviewed and synthesized in accordance with the formulated RQs. Following this summary, this paper provides an index of the vast body of knowledge in this area. An important finding ensuing from this study was that actual meaning extraction was minimal, with a majority of the studies leaning toward speech

intelligibility solely. This general finding is important as it informs communication scholars and dysarthria clinical experts of the crucial need to include the listener as a party during meaning extraction experiments. This finding is also important for NLU experts who need to formulate representations that are robust enough to incorporate listener factors, such as familiarity, topic knowledge, and nonspeech events, that may bear pointers toward the meaning of dysarthric speech. Therefore, this study presents to the science community the need for further research with regard to the formulation of semantic ontologies that will be useful in NLU for meaning extraction.

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Authors' Contributions

BA contributed to the conceptualization of the systematic review; the introduction, methodology, results, discussion, and conclusion sections; as well as the writing of the original draft and its validation. BS contributed to reviewing and editing the manuscript, supervision, and study validation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PICO (Problem, Intervention, Comparison, Outcome) framework of the research questions.

[[DOCX File , 14 KB - rehab_v10i1e44489_app1.docx](#)]

Multimedia Appendix 2

Databases and search terms used in the literature search.

[[DOCX File , 16 KB - rehab_v10i1e44489_app2.docx](#)]

Multimedia Appendix 3

TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) checklist and results for quality assessment of the prediction models.

[[DOCX File , 195 KB - rehab_v10i1e44489_app3.docx](#)]

Multimedia Appendix 4

Cochrane risk of bias. Assessment of the risk of bias for each study.

[[DOCX File , 231 KB - rehab_v10i1e44489_app4.docx](#)]

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Abbreviations

MFCC: Mel-frequency cepstral coefficient

NLU: natural language understanding

PICO: Problem, Intervention, Comparison, and Outcome

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

ROB: risk of bias

RQ: review question

TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Original Paper

Rehabilitation Supported by Immersive Virtual Reality for Adults With Communication Disorders: Semistructured Interviews and Usability Survey Study

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Abstract

Background: Individuals who have acquired communication disorders often struggle to transfer the skills they learn during therapy sessions to real-life situations. Immersive virtual reality (VR) technology has the potential to create realistic communication environments that can be used both in clinical settings and for practice at home by individuals with communication disorders.

Objective: This research aims to enhance our understanding of the acceptance, usefulness, and usability of a VR application (SIM:Kitchen), designed for communication rehabilitation. Additionally, this research aims to identify the perceived barriers and benefits of using VR technology from the perspective of individuals with acquired communication disorders.

Methods: Semistructured interviews and usability surveys were conducted with 10 individuals with acquired neurogenic communication disorders aged 46-81 (mean 58, SD 9.57) years after trialing an immersive VR application. The audio-recorded interviews were transcribed and analyzed to identify themes.

Results: The quantitative data regarding the usability of the system associated with participants' immersion experience in the VR application were promising. Findings from semistructured interviews are discussed across five key thematic areas including (1) participant's attitude toward VR, (2) perceived usefulness of the VR system, (3) perceived ease of use of the VR system, (4) their willingness to continue using VR, and (5) the factors they perceived as challenges or facilitators to adopting this VR technology.

Conclusions: Overall, participants in this study found the VR experience to be enjoyable and were impressed by the realism of the VR application designed for communication rehabilitation. This study highlighted personally relevant, immersive VR interventions with different levels of task difficulty that could enhance technology uptake in the context of communication rehabilitation. However, it is essential that VR hand controller technology is refined to be more naturalistic in movement and able to accommodate user capabilities.

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KEYWORDS

communication disorders; speech and language therapy; rehabilitation; virtual reality; human-computer interaction; technology acceptance; acceptance; communication; therapy; usefulness; usability; survey; barrier; mobile phone

Introduction

Advancements in the capabilities and affordability of virtual reality (VR) technologies have contributed to the growing interest in the application of VR within health contexts [1-4]. In particular, the application of VR has the potential to facilitate clinical assessment and rehabilitation [5,6]. VR technology facilitates interaction with computer-generated, realistic images, sounds, and other sensations that simulate real-world environments. User interactions with VR systems may be “nonimmersive” involving a desktop, smartphone, or tablet screen displaying a digital world that can be explored, “semi-immersive” where partial immersion in the digital environment is made possible using projection screens (eg, driving or flight simulator), or “immersive” where the sense of physical presence or “being there” within the digital environment is facilitated through the use of head-mounted displays (eg, HTC Vive or Meta Quest) [7].

Studies suggest that individuals with conditions such as Parkinson disease, brain injury, acute and chronic pain, mild cognitive impairment, and posttraumatic stress disorder can benefit from the use of VR to improve physical skills [8-12], reduce pain [13-15], improve attention [16], and reduce anxiety [17-20]. In the discipline of speech-language pathology (SLP), research into the use of VR for the rehabilitation of communication disorders acquired during adulthood due to acquired brain injury (including traumatic brain injury), stroke, anoxia, brain infection, and diseases such as Parkinson disease and multiple sclerosis is emerging [21-23]. A small number of studies have shown positive effects on the functional (ie, real-life) communication skills of patients who had stroke associated with the delivery of communication rehabilitation via nonimmersive VR platforms such as digital worlds displayed on desktop computers [24]. A recent study using semi-immersive VR environments (eg, railway station, hotel, restaurant, supermarket, amusement park, and cinema) to deliver intensive treatment to individuals with poststroke communication impairment showed participants gained significant improvements in language-specific skills (eg, repetition and oral language comprehension), communication skills, and psychosocial well-being [4]. Interestingly, compared with a control group who received conventional treatment only (ie, individual communication therapy conducted in person), participants in this study who were exposed to the semi-immersive VR treatment made gains in a wider range of communication and language skill areas [4]. To the best of our knowledge, there have not been any studies investigating the use of immersive VR in the management of acquired communication disorders, although the potential usefulness of immersive VR has been recognized [22,25]. Immersive VR exposure therapy has been applied successfully to the treatment of neurologically intact individuals with public speaking anxiety [26]. Immersive VR has also been associated with reduced anxiety and improved confidence in public speaking environments for individuals who stutter [27-29].

The potential for immersive VR to create sufficiently realistic communication environments that could be accessed easily within the clinic and home practice setting is attractive for SLPs

working with individuals with communication impairment [22,30,31]. In traditional clinic settings, it is challenging for SLPs to assist patients in transferring skills learned within the clinic into authentic, real-world communication environments [32]. Roleplay is often used as a bridge between clinic and real-world communication contexts. Given the complexity of communication and the influence of different environmental aspects (eg, noise and busyness) and personal factors (eg, emotions, motivation, fatigue, education, and culture) on communication success, it is useful for SLPs to work with patients on communication skills within a range of personally relevant environments. This often involves going out to a café, the hospital pharmacy, or some other relatively convenient setting where patients can practice interacting with others, applying their communication skills, and improving their confidence. However, these opportunities can be limited for clinicians constrained by time, workload, and service delivery protocols. Furthermore, these locations of convenience may not provide the personally relevant, contextualized, communication practice that is so critical to achieving optimal treatment outcomes [33]. VR can deliver a variety of realistic and immersive environments [23]. Moreover, VR environments may be manipulated by the clinician to increase or decrease complexity according to skill level, provide feedback on performance (visual, auditory, and haptic), and enable high repetition intensity to promote learning and improved participation in activities of daily living.

This research aimed to enhance our understanding of the acceptance, usefulness, and usability of an immersive VR application, SIM:Kitchen [31] designed for use in communication rehabilitation. Additionally, this study aimed to determine the perceived barriers and benefits to engagement with VR technology among people with neurogenic communication disorders. Identification of the determinants of VR acceptance by individuals with neurogenic communication disorders is an essential step prior to further development and refinement of the VR application for effective clinical uptake. This information will help not only to predict future adoption but also to develop appropriate solutions to address the potential barriers and challenges to the use of this VR technology.

Methods

Participants

Participants were recruited using a convenience sampling strategy from the general community in South East Queensland, Australia, via patient support groups, social media (ie, Facebook and Twitter), and snowball sampling methods. The University of Queensland’s media channels were also used to increase the exposure of the study. The study advertisements included a brief description of the study and a participant information sheet and explained the voluntary nature of participation in the research. Interested individuals were instructed to contact the research team by phone or email to assess their eligibility.

Eligibility to participate in the study required individuals to meet the following criteria determined by the expert judgment of a qualified speech pathologist on the research team (DA) to ensure their ability to communicate about their VR experience:

(1) diagnosed with a neurogenic communication disorder (eg, aphasia, dysarthria, apraxia of speech, and cognitive-communication impairment) due to acquired brain injury (eg, stroke and traumatic brain injury), (2) the age of 18 years or older, (3) sufficient English language skills to understand and answer interview questions, (4) adequate cognition skills to support communication assessed via a brief cognition or memory screening test (moderate to mild cognitive impairment—score of 13 or above out of 30; Montreal Cognitive

Assessment [34]), and (5) adequate mobility and balance to walk or maneuver their wheelchair with minimal assistance. A total of 10 individuals aged between 46 and 81 (mean 58, SD 9.57) years participated in this study with no dropouts. Most participants (n=7) were well-educated having completed at least undergraduate degree level study. Further details of participants' demographic, diagnosis, and experience with technology are outlined in Table 1.

Table 1. Characteristics of individual participants' demographics.

Participants	Age (years), gender	Highest education	Employment status	MoCA ^a	Diagnosis (year)	Communication disorder	Experience with technology ^b
P1	56, Female	Undergraduate	Not employed	21	Encephalitis (2016)	Mild dysarthria	4
P2	46, Male	High school	Not employed	16	Traumatic brain injury (2017)	Mild dysarthria, auditory memory difficulties	3
P3	48, Male	High school	Not employed	15	Stroke (2017)	Mild dysarthria, Mild to moderate auditory memory difficulties	2
P4	61, Male	Did not complete high school	Not employed	16	Hydrocephalus (1985)	Moderate dysarthria, mild to moderate cognitive-communication disorder, auditory memory difficulties	2
P5	69, Female	Postgraduate	Not employed	22	Stroke (2019)	Mild aphasia	4
P6	81, Male	Undergraduate	Retired	15	Stroke (2017)	Moderate aphasia (comprehension better than expression), auditory memory difficulties	4
P7	57, Male	Postgraduate	Full-time	21	Stroke (2021)	Mild aphasia, mild dyslexia (acquired), slight apraxia of speech	3
P8	50, Male	Undergraduate	Not employed	15	Stroke (2010)	Mild to moderate aphasia, auditory memory difficulties	2
P9	54, Female	Undergraduate	Not employed	20	Functional neurological disorder (2016)	Mild anomia	3
P10	60, Male	Postgraduate	Not employed	13	Stroke (2012)	Moderate aphasia (comprehension better than expression), auditory memory difficulties	3

^aMoCA: Montreal Cognitive Assessment.

^bExperience with technology scale (1=inexperienced to 5=experienced).

Ethical Considerations

This study was conducted according to the ethical guidelines of the University of Queensland and the National Statement on Ethical Conduct in Human Research (approval 2019001282). Prior to inclusion in the research, all participants were fully briefed, both orally and through the written participant information sheet, and written informed consent was obtained. All the data collected in this study were deidentified to ensure the privacy and confidentiality of participants' data. After the completion of the study, participants received a US \$77 gift voucher as a token of appreciation for their participation.

VR Platform, Hardware, and Description

The immersive VR application evaluated in this research was designed and developed following the principles of the human-centered design approach to ensure it meets the needs of end users [35]. The iterative design process involved a series of interviews with SLP as an initial step to enhance safety prior to the involvement of patients [31].

The VR application consisted of a simulated VR kitchen environment (SIM:Kitchen) developed using Unity Technologies game engine (version 2020.2.3), and ran on a Meta Quest 2 headset and hand controllers in Room scale mode in either

seated or standing position. User interactions were implemented using HurricaneVR’s physics interaction toolkit (Cloudwalkin Games). The simulated VR kitchen enables two types of user interactions. These are (1) the SLP communicating with the participants via an adult avatar to perform a series of tasks in the SIM:Kitchen environment (eg, participant has to describe the room or objects or sounds around them, have a conversation with an adult within the room, introduce themselves to a child within the room, and have a conversation with the child, request

something to drink, and make a sandwich). The SLP can also enable lip-syncing of the adult and child characters via an Android app that wirelessly connects to and controls the SIM:Kitchen application and (2) the participants can remain seated and safely interact with objects in the VR kitchen using the hand controllers while wearing a Meta Quest headset where they can hear and respond to communications and instructions delivered by the SLP. Figures 1 and 2 show the study setting and screenshots of the VR application.

Figure 1. Speech pathologists can manipulate the interactions in the virtual reality scenario via a tablet or mobile phone (left) and patients wear a Quest headset and use 2 hand controllers to interact with objects (right).

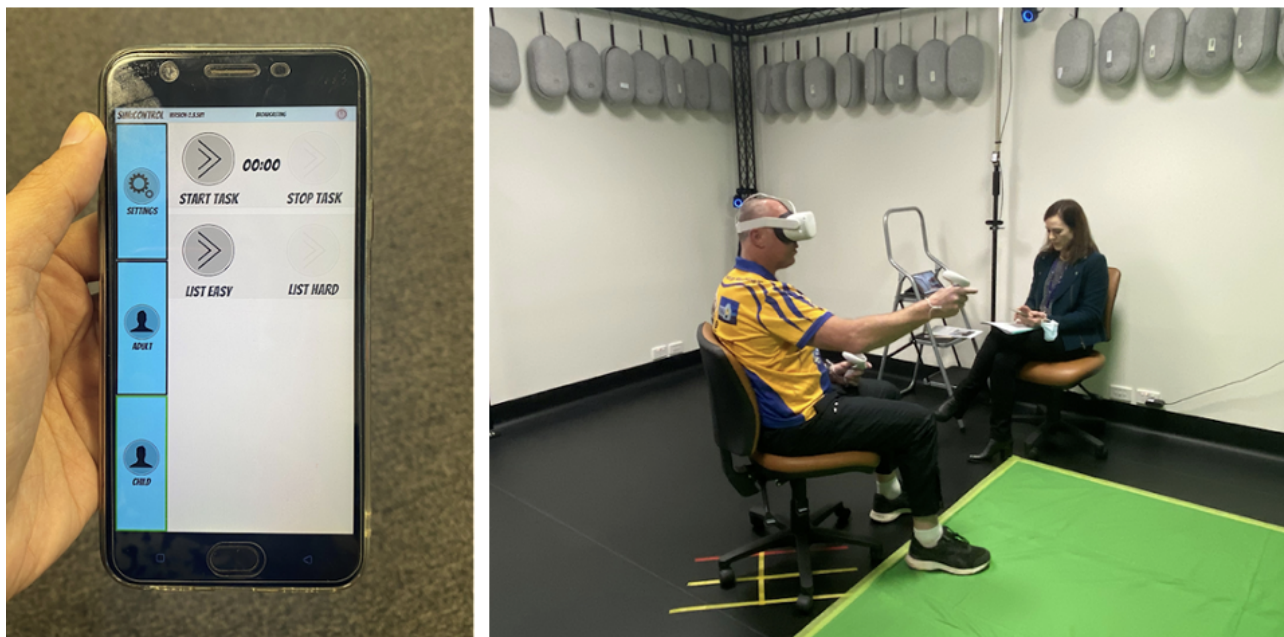


Figure 2. A kitchen and adult avatar in a home (left) and objects in the fridge that could be interacted with (right).



Data Collection Procedures and Measures

Participants attended a 90-minute session at RECOVER Injury Research Centre, The University of Queensland. Upon arrival,

participants completed a brief questionnaire regarding demographics and level of experience with using technology. Thereafter, a researcher (AV) provided detailed information about the functionality of the VR headset and hand controllers.

Participants were given approximately 10 minutes to familiarize themselves with the VR equipment to ensure they felt comfortable using the hand controllers and interacting with digital objects within the simulated VR kitchen environment. Participants remained seated in a chair throughout the introductory task to minimize the risk of disorientation or fall due to the immersive nature of the VR application.

Next, several communication tasks were completed within the simulated kitchen environment, of approximately 20 minutes' duration. An experienced speech pathologist on the research team (DA) instructed participants to perform a series of tasks and interactions with other avatars present in the SIM:Kitchen environment. All participants completed a similar list of tasks that included describing the room or objects or sounds around them, having a conversation with an adult avatar within the room, introducing themselves to a child avatar within the room, having a conversation with the child, and making the child a sandwich. Participants were given short breaks (approximately 5 min) between each task to ensure their comfort and check for any symptoms of motion sickness while wearing the VR headset.

Following the VR trial, participants completed a series of questionnaires and participated in a short interview conducted by a member of the research team (DA). Three questionnaires were completed by each participant (duration approximately 10 min) with the assistance of the same researcher (DA) to ensure comprehension of the content and answer questions as required. Questionnaires included the following:

1. System Usability Scale (SUS) [36,37], which included 10 items (5-point Likert scale, "strongly disagree" to "strongly agree") generating composite scores ranging from 0 to 100 to evaluate the usability of the VR system.
2. Subjective mental workload (NASA Task Load Index, NASA-TLX) [38], which is designed to gauge the workload and effort participants put into the tasks including mental demand, physical demand, temporal demand, performance, effort, and frustration while engaging in the VR experience. NASA-TLX included 6 items. Each item is scored on a 0-100 scale with scores across all 6 items summed and then averaged.
3. Simulator Sickness Questionnaire (SSQ) [39], which included 16 items (4-point Likert scale, "not at all" to "severe") to ascertain comfort levels and identify any adverse impacts of the VR experience. Final scores were calculated as per instructions provided by Kennedy et al [39].

Finally, a semistructured interview (approximately 30 min) was conducted to explore participants' views about their experience of the SIM:Kitchen to determine perceived usability and acceptance of VR technology in general and identify benefits and barriers to potential use within speech pathology sessions. The interviewer (DA) did not have a prior relationship with the participants. An interview guide was developed by AV and reviewed by other members of the research team (DA and DT). The interview guide ([Multimedia Appendix 1](#)) was developed following the theoretical framework of the technology acceptance model (TAM) [40,41] due to its demonstrated ability to capture the concepts of perceived usefulness, usability, ease

of use, and intention to use as measures of user acceptance. The TAM has been validated in a range of studies of user acceptance in public health [42]. Moreover, replication studies have suggested that the TAM is a valid and robust model [43,44]. In this research, quantitative surveys were used to assess the usability of the system. Subsequently, semistructured interviews were conducted to provide deeper insights into the quantitative findings. This approach aimed to enhance the comprehensibility of the results and to gain insights into the factors that hinder, or aid communication rehabilitation facilitated by an immersive VR application.

Data Analysis

The data from questionnaires (ie, demographic and postquestionnaires) were analyzed descriptively using Excel (Microsoft Corp; AV). The audio-recorded interviews were transcribed (AV and DA) and imported into NVivo (version 11; QSR International). To reduce the participant's time commitment, transcripts were not returned to the participant for comment. However, participants were encouraged to contact the research team if they wished to share any additional information after the interview. A qualitative content analysis was conducted by 2 researchers (AV and DA) with experience in qualitative data analysis to identify patterns across responses and their relation to research questions [45]. Initially, data were categorized based on the principles of the TAM. Themes that did not fit within this framework were considered during the coding process. This review and refinement process led to the development of the final themes and subthemes. Two other researchers (CB and NB) also reviewed the themes and subthemes to validate the themes and enhance the trustworthiness of the coding. Discrepancies were discussed and guided the thematic development, resulting in coherent themes reflecting a comprehensive and precise set of meanings for participant comments. The Research Team and Reflexivity Statement are included in [Multimedia Appendix 2](#). The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was used to guide the qualitative reporting [46].

Results

Quantitative (System Usability, Workload, and Motion Sickness)

The average System Usability Scale score of the SIM:Kitchen application was 60.75 out of 100 suggesting an average usability [37] from the perspective of participants. Additionally, the average scores of NASA-TLX workload across mental (mean 39, SD 34.7), physical (mean 34.50, SD 30.9), temporal (mean 12.5, SD 15.3), performance (mean 39.50, SD 23.9), effort (mean 41, SD 33.2), frustration (mean 26.25, SD 23.5), and total workload (mean 33.3) show low levels of workload associated with using the SIM:Kitchen application. Finally, the average Simulator Sickness Questionnaire scores for nausea, oculomotor, and disorientation and total score were 14.79, 18.27, 17.82, and 18.1, respectively, suggesting low motion sickness symptoms after trialing the VR system [47].

Qualitative (Semistructured Interview)

Overview

The content of the semistructured interviews conducted for this study can be organized into five key thematic areas including (1) attitude toward VR and SIM:Kitchen, (2) perceived

usefulness of VR system, (3) perceived ease of use of VR system, (4) intention to use VR, and (5) perceived adoption barriers and enablers. These key themes with underlying subthemes or categories are presented in narrative form and summarized in [Textbox 1](#).

Textbox 1. Summary of themes and subthemes.

<p>Attitude to virtual reality (VR) and SIM:Kitchen</p> <ul style="list-style-type: none"> • Enjoyable and engaging • Without real-world distractions • Representative of real life <p>Perceived usefulness of VR system</p> <ul style="list-style-type: none"> • Potential benefits of VR in communication rehabilitation • Potential benefits from provision of performance feedback • Potential benefits from design of personalized, goal-based tasks with variable levels of difficulty • Potential benefits from design for use with groups or remotely • Potential benefits of alternative VR scenes or scenarios <p>Perceived ease of use of VR system</p> <ul style="list-style-type: none"> • Physicality and interaction with VR equipment • Experience of immersive VR environment <p>Intention and motivation to use VR</p> <ul style="list-style-type: none"> • Provision of instruction or support • Feedback on performance • Demonstrated benefits <p>Perceived adoption barriers or enablers</p> <ul style="list-style-type: none"> • Personal factors • User-friendliness • Accessibility to the range of clients or communication needs • Demonstrated benefit

Attitude Toward VR and SIM:Kitchen

Overall, participants in this study were positive about their experience of the immersive SIM:Kitchen environment and the possibility of using VR for communication rehabilitation. Participants commented that the SIM:Kitchen environment was “wonderful” (P6) and “a great idea” (P2 and P7) that “could be really beneficial for (communication) practice” (P5). In addition, participants felt that the experience of being in the SIM:Kitchen environment was “engaging” (eg, P9), “not boring” (eg, P2), and rather “enjoyable” (eg, P3). One participant stated they were “blown away” by the simplicity, realism, and ease of use of the VR system (P9). Another commented that having a window you could see out of in the SIM:Kitchen environment was a nice feature, especially for people prone to claustrophobia (P7). It was apparent to some participants that VR could transport you into a scenario that could be enacted rather than “reading stuff off a sheet of paper” (P5), as may be the case in

traditional communication rehabilitation activities. One participant observed that for her the SIM:Kitchen environment created a “clean space” without real-world distractions where “you can leave your pre-existing anxieties about ... speech behind” [P7]. Having the visual cues from the SIM:Kitchen environment available to support communication was considered helpful and representative of real-life communication situations (eg, P2 and P10). However, for some, VR was still considered to be limiting and a “barrier to reality” compared with practicing communication within real-life situations (P4 and P7).

Perceived Usefulness of VR System

Benefits of VR in Communication Rehabilitation

A number of participants expressed uncertainty about how VR could be used to assist in the rehabilitation of communication following acquired brain injury (P3, P4, and P9). One participant in the study initially expressed strong negativity regarding the usefulness of VR for communication rehabilitation stating that

“people would like the idea of VR” but that dealing with the frustration of using VR combined with the existing frustration of having aphasia and trying to communicate “... they’re going to feel like a total failure” [P4]. However, as the interview progressed and ideas were explored, this participant’s stance about the usefulness of VR for communication rehabilitation shifted as she suggested VR may be useful for building communication skills with people who enjoy gaming, especially 20- to 25-year-olds who may already have gaming skills and feel comfortable with VR.

The majority of participants were positive about the potential usefulness of VR for communication therapy “Having practice speaking in a safe environment would be very helpful” [P2], “... you put yourself in the (VR) scenario (to practice communication). I think this (VR) would be much more engaging. A lot of people would really enjoy that a lot more ...” [P5]. The concept that VR might remove the fear of failure and help develop communication confidence was discussed by participants in the interview (eg, P1, P2, P4, and P7). It was also suggested that VR could be particularly useful in the early stages following a stroke, where a 3D VR environment could provide realistic visual cues to assist in improving word-finding skills (P4, P5, and P10). One participant (P5) generated numerous ideas about how VR could be useful for communication rehabilitation:

... at the very beginning in rehab, when I couldn’t speak very well and coming up with certain words ... of things (that flashed up on an iPad) and you had three seconds to name what the thing was ... you could do the same thing in the grocery store (VR environment) ... things could be going by and you have to say ‘broccoli, cucumber, onion’ ... I think it would really help

and

... when I was just leaving rehab they wanted me to read more details, longer things and do something like prepare a recipe. So that’s something I think (you could do) in the (VR) kitchen ... Break up these two eggs and have your mixing bowl and just start doing something like that and see if the person can follow through all the things like that (steps) and prepare something.

Design Features to Maximize Usefulness

Design features suggested for future development of VR communication rehabilitation systems included personalizing goal-based tasks with different levels of difficulty (eg, P2). In addition, the capacity of the VR system to offer performance ratings and feedback options was identified as an essential feature to assist with communication rehabilitation: “I always like to know if I’ve done something to improve” [P2]. The potential for VR to be used with groups of individuals undertaking communication rehabilitation was also considered, especially in relation to remote connection and conversation with others that could bring enjoyment and build confidence (eg, P1, P2, and P9). Participants commented that there would be definite benefits in creating VR environments, where multiple

users could log in from different locations to participate in the conversation (eg, P9).

Benefits of Alternative Scenes or Scenarios or Tasks

When asked to consider other environments that would be useful to simulate using VR to assist with communication rehabilitation, 1 participant answered: “Any environment would be good ... as long as there was somebody you could talk to” [P1]. Other participants liked the idea of a supermarket: “... where you have your list of things and an empty basket and then have to go and look up and down the aisle to find items to put in the basket” [P5], where opportunities for practicing simple small talk could be created (eg, while standing in the queue at the deli or checkout; P2). Another participant suggested he would be more inclined to communicate within a VR café scenario or men’s shed environment than a kitchen (P9). Additional environments mentioned as potentially useful for VR communication rehabilitation were a doctor’s surgery, a shopping center, communication with neighbors when taking the dog for a walk, and a pharmacy (eg, P1, P2, P9, and P10).

Perceived Ease of Use of the VR System

Physicality and Interaction With Hardware

Moving things with the hand controllers was frustrating, not realistic, and somewhat problematic for many participants (eg, P1, P2, P3, P4, and P6). One participant (P6) felt that for him, activating a different button on the hand controllers might have assisted him to use them more successfully. Others felt that with additional time and practice, the use of hand controllers might become easier and less problematic for some people but may still be problematic for individuals with weakness or paralysis of their upper limbs (P2). One participant felt that the operation of the VR equipment was too complicated for individuals already struggling to focus on their communication (P4).

General mobility and movement within the VR environment felt restricted for some participants (eg, P10) due to the safety requirement of the study for participants to remain seated rather than stand up and move around to explore the simulated kitchen environment. Others felt comfortable and safe seated on a swivel chair during their immersion in the VR environment (eg, P7). For a small number of participants, vision through the headset was blurry at times, requiring adjustment (P2 and P10). The VR headset itself was not considered to be bothersome or uncomfortable for most participants. However, it was acknowledged that for some people the headset may be considered heavy or uncomfortable on the face (P3 and P4).

Experience of the Immersive VR Environment

The immersive VR environment was considered “not real but ... life like” [P7]. All participants in the study felt comfortable within the SIM:Kitchen environment. Only 1 or 2 participants mentioned feeling slightly disorientated at the outset or end of the immersive VR experience (eg, P5 and P8). It was supposed that some individuals may require more time than others to acclimatize to immersion in VR environments (P8). The Meta Quest equipment used in this study did not allow for sound delivery through the headset, which diminished the sense of immersion and engagement for some participants (eg, P5).

Intention and Motivation to Use VR

Participants indicated that they would be motivated to use VR if training to use the VR system was provided and if performance feedback in the VR environment could be achieved (eg, P1, P2, P3, and P9). “I think if you have direction and feedback, and it was showing you were improving (that would motivate me to use the VR system)” [P2]. For most participants, the intention to use VR for communication rehabilitation was very much outcome-dependent based on the demonstrated benefits of VR to assist with communication improvement. “If someone could show me that it would be useful ... I will jump straight into it” [P9]. Some suggested that they would also be open to using VR for home practice (eg, P3 and P6) or as a “check-in tool” or reminder to implement speech strategies (P2). However, the assistance and supervision by a speech pathologist to manage the implementation of immersive VR for communication rehabilitation were considered essential for some (eg, P2).

Perceived Adoption Barriers and Enablers

Personal Factors

A number of factors were considered to have potential impacts on the adoption and continued use of VR for communication rehabilitation. For instance, a tendency to become claustrophobic could impact the use of VR:

People who are claustrophobic probably wouldn't like it. It doesn't sort of worry me 'cause I can resign myself to the fact that I'm going to use it so I do it. But people... they mightn't like that (VR) because they mightn't like that (headset) on their face. [P1]

In addition, it was suggested that immersion in the 3D VR environment and learning to use the hand controllers could take some people more time than others, which could affect the successful adoption of VR (P2 and P8). Moreover, individuals who feel dizzy or otherwise uncomfortable within the immersive VR environment may be reluctant to pursue VR as a means to improve their communication (P2). Personal drive to improve was also mentioned as a factor that could influence the adoption of VR for communication rehabilitation among individuals with acquired communication disorders (P1 and P4).

Physical ability, level of cognitive and communication impairment, as well as the level of confidence in communicating in the real world were raised as additional factors that could impact on the adoption of immersive VR for the rehabilitation of individuals with acquired communication disorders (eg, P2, P4, and P7). In relation to communication confidence, individuals who already felt confident to practice their communication in real-world situations did not think that they would use VR (P4 and P7).

User-Friendliness

Technical difficulties and the need for assistance to operate the VR system were identified as factors that could limit the adoption of VR for communication rehabilitation. “When technology doesn't work you get frustrated and give up” [P2]. Frustration with the inconsistency of operation of the hand controllers to interact with items in the SIM:Kitchen

environment was identified as a factor that may negatively impact upon adoption and continued use (eg, P3)

While headset comfort was not highlighted as a specific issue for participants in this study, it was acknowledged that VR headset comfort could impact upon adoption and continued use of VR for some people (eg, P1, P3, and P8). Clarity of vision through the headset was raised as a minor issue for several participants and a factor that could discourage the use of VR (eg, P1, P2, and P10).

Accessibility and Demonstrated Benefit

Participants in this study considered that the successful adoption of VR among individuals with communication disorders would rely foremost on demonstrated benefits (eg, P1 and P9). Moreover, participants felt that motivation for continued use of VR would occur if feedback while using the device showed improvement in communication outcomes for individuals (eg, P2 and P3).

The availability of VR equipment at an easily accessible facility or within the user's home was noted as a potential enabler to the adoption of VR for communication rehabilitation. Conversely, increased travel time to access VR equipment for communication rehabilitation was considered a potential deterrent to use and a barrier to adoption (eg, P1). Physical and communication abilities were also considered factors that could variably influence individuals' access to and willingness to adopt VR for communication rehabilitation. “There's a wide range of disability (in terms of) limb function ... that's part of it (to consider)” [P5].

Discussion

Principal Findings

This study compliments and extends upon our earlier mixed methods study exploring the views of speech-language pathologists about the potential usefulness of immersive VR for communication rehabilitation [31]. A mixed methods approach was used to explore the perspectives of individuals with neurogenic communication disorder as to the perceived acceptance, usefulness, and usability of immersive VR within the context of communication rehabilitation. Quantitative measures of system usability, mental workload, and motion sickness associated with participants' immersion experience in SIM:Kitchen were promising. Despite being a research prototype, the SIM:Kitchen VR application was considered to have average usability according to participants in this study. In addition, participants were not overly mentally taxed when using SIM:Kitchen and experienced low levels of motion sickness symptoms, if any, while using the VR system.

Key findings from the semistructured interviews conducted with participants in this study are discussed later with particular attention to the potential usefulness as well as identified barriers and enablers to the future adoption of VR for communication rehabilitation. Of the 10 participants in this study, all participants were selected based on their ability to communicate sufficiently well to offer their opinions about the immersive VR experience. While age, level of education, cognitive ability, level of communication impairment, and degree of prior exposure to or

experience with technology may have affected participants' generation of ideas about the potential use of VR for communication rehabilitation, general optimism toward VR was clear from responses. Overall, participants found the VR experience to be enjoyable and were impressed by the simplicity and realism of the SIM:Kitchen environment. Similar positive attitudes are reflected in other studies that have used VR environments with health care students, workers, and patients [31,48,49].

It is well known that a positive perception of the usefulness of a particular technology to address a specific need is critical to the successful adoption of that technology [40,50]. Some participants in this study proposed specific communication rehabilitation tasks that could be carried out via VR to enhance therapy engagement and outcomes, suggesting an openness to VR as a therapy tool. In addition, participants put forward ideas for alternative VR scenes or scenarios (eg, café, doctor's surgery, and pharmacy) that could provide useful contexts for functional communication therapy tasks. Personally relevant interventions grounded in ecologically valid, real-life contexts are essential to maximize communication rehabilitation outcomes [33]. However, exposure to a wide range of personally relevant communication environments during traditional clinic-based rehabilitation is often difficult to achieve.

The potential of VR to create valid contexts for communication skills practice and the development of communication confidence has long been recognized [51]. Participants in this study could envisage the use of immersive VR in creating realistic representations of real-life communication environments. Moreover, it was considered that these simulated VR environments could hold additional value through the provision of less complex, less distracting, and "safer," less threatening, contexts within which to practice communication skills and gain confidence. This feature of VR to reduce or build up complexity may be important given the often-reduced ability following brain injury to inhibit environmental distractions (eg, background noise and visual distractors) and encourage attention on specific elements [52]. Confidence to communicate was a key challenge acknowledged by all participants in this study. The safe and supportive environment offered by immersive VR could help to facilitate the development of communication confidence.

A recent study reporting on the outcomes of conversational therapy for individuals with aphasia delivered through semi-immersive VR scenarios representative of everyday life (eg, supermarket, restaurant, amusement park, railway station, and post office) showed benefits for communication functioning including oral comprehension, repetition, and written language, as well as psychological aspects such as self-esteem and mood state [4]. Other studies delivering intervention via VR platforms have also shown improved communication outcomes for this group measured by formal functional communication assessment and participants' reports of maintained communicative confidence up to 1-year posttreatment [24,53,54]. Furthermore, positive effects on the generalization of functional communication skills from the digital environment to the real world have been demonstrated [21]. For participants in this study, these improvements in communication were considered

essential and firmly linked to motivation and intention to use immersive VR applications designed for communication rehabilitation.

Enjoyment was another factor participants touched upon as motivation for the use of immersive VR applications in communication rehabilitation. Studies using digital gaming therapies have reported therapeutic enjoyment to be positively correlated with clinical improvements [53,55,56].

Balancing the level of difficulty of tasks (including task instructions) and an individual's abilities may also be important in optimizing enjoyment and motivation to use VR [57]. It is conceivable that the inclusion of gamified VR tasks within communication rehabilitation programs that increase therapeutic engagement and enjoyment could foster enhanced outcomes. Moreover, manipulation of task complexity, measurement of performance, and feedback on performance (proposed determinants of adoption of VR for participants in this study) could also be incorporated into gamified VR communication practice tasks. Expert feedback on performance is essential for improving skills during speech pathology sessions. The question of whether similar benefits could be achieved with feedback delivered via immersive VR applications is an interesting one since the feedback has many different modalities (eg, qualitative or quantitative, specific or global, and implicit or explicit) and targets (eg, speech articulation clarity or loudness and overall communication success) and should be delivered with varying timing and frequency depending on individual ability, progress, and the goals of treatment [58]. Ideally, future design and development of immersive VR technology for use in communication rehabilitation should address the user-friendly and well-timed delivery of these distinct types of feedback. Addressing such complexities well may impact significantly upon the successful adoption of the technology within the health rehabilitation setting [59].

While the perceived usefulness of technology is highly important, successful adoption of technology is also intrinsically linked to ease of use and available support [40,60]. Mastering the use of the hand controllers was possibly the most difficult aspect of the immersive SIM:Kitchen experience for participants in our study. For many, the distraction and frustration created by difficulty using the hand controllers diminished realism and sense of immersion and detracted from the communication tasks within the VR experience. There are many occasions where communication and physical actions are carried out together (dual tasking, eg, having a conversation with another person while preparing a sandwich). In addition, hand gestures may be used by some individuals to facilitate and augment their communication. Therefore, for the purposes of communication rehabilitation, it is essential that VR hand controller technology is refined to be more naturalistic in movement and able to accommodate individual capabilities (eg, weakness, lack of dexterity, and precision of movement). Future steps in the SIM:Kitchen project will encompass enhancing the functionality of VR hand controllers through an iterative development process, which will be coupled with extensive testing involving patients. Additionally, we will explore the potential integration of hand gestures to facilitate a more naturalistic interaction, aiming to further enhance the SIM:Kitchen usability.

Participants also felt that the sense of realism and immersion within the VR environment would have been enhanced by delivering high-quality speech through the headset. Enhancing the gestures (especially lip movement during speech), facial expressions, and responsiveness of the characters could also improve the realism, immersion, and authenticity of communication interactions within the VR environment. Congruent cues such as these, delivered across multiple senses (ie, auditory, visual, olfactory, and tactile) are known to enhance immersion and sense of presence within VR environments [61]. Moreover, the inclusion of these cues, especially high-quality audio, may be important for optimizing memory and learning within the context of rehabilitation using immersive VR [62].

Ease of access to the VR system was highlighted as an important determinant of intention to use the device for communication rehabilitation. For participants in this study, direction from a clinician, and continuing support from the SLP about how to use the VR system and engage within the SIM-Kitchen environment to complete the directed tasks, was important. Similar views were held by participants in a recent study of aphasia intervention delivered via a computer-based digital environment, where the relationship with the person who delivered the intervention was highly valued [53]. However, from the clinician's perspective, the opportunity for client users to access and use VR asynchronously, without direct clinician supervision, is attractive [31,60]. Access to home-based rehabilitation options is convenient and could enable increased practice intensity for enhanced recovery of function [63]. With practice, client users could develop the skill and confidence to use VR systems and applications more independently at home or with the assistance of a friend, relative, or support worker rather than relying solely on the clinician. As VR technology develops and becomes simpler and safer to use, it is easy to imagine greater use of this technology in the future for home-based rehabilitation.

Study Limitations and Recommendations for Future Research

Despite every attempt to recruit a representative and larger sample, the number of participants was small in this study (N=10). However, the results mirror those of other recent studies suggesting that carefully designed immersive VR may be a beneficial inclusion in communication assessment and rehabilitation [31,64]. There was a relatively high median age range (mean 58, SD 9.57 years) of participants in our study that may have limited the breadth of information gathered. The notion that younger individuals may have more experience with immersive VR technology and a greater potential for acceptance

of the technology for rehabilitation should be examined. Only 2 participants (P9 and P10) in our study reported some minimal experience with the use of immersive VR. Future studies should include larger and more representative participant groups, incorporating a wider range of ages and demographics, encompassing individuals with varying levels of technological familiarity, diverse communication and neurological impairments, and differing countries of origin and cultures.

While the participant group for this study was relatively well-educated and did not include individuals with more severe cognitive and communication impairments, this was considered reasonable given the current lack of knowledge about the safety and suitability of immersive VR for individuals with acquired brain injuries.

The recent impacts of COVID-19 worldwide have expanded the development and adoption of technology including telehealth, digital care, artificial intelligence, and robotics [65]. Moreover, a return to pre-COVID-19 levels of engagement with technology seems unlikely. The time is ripe to take advantage of heightened awareness and openness to technology to explore opportunities and challenges associated with the use of immersive VR for communication rehabilitation. Future efforts to design immersive VR for communication rehabilitation should consider personalized VR intervention with different levels of interactivity and realism, taking into account individual abilities and level of physical or cognitive or communication impairment. Safety aspects should be prioritized while enabling adjustment of complexity of tasks, provision of feedback on performance, and achievement of outcomes that are at least equivalent to those obtained through traditional communication therapy approaches. The potential use of hands as opposed to the VR controllers and remote options for the use of VR technology via telehealth for communication rehabilitation should also be explored.

Conclusions

The results of this usability study were positive toward the use of immersive VR for communication assessment and rehabilitation and highlighted the importance of an iterative, co-design process involving end users in designing and developing this technology to maximize engagement and benefits. Additionally, this study revealed personally relevant, immersive VR interventions with different levels of task difficulty are required in the context of communication rehabilitation. However, VR hand controller technology needs to be optimized for more naturalistic movement and accommodation of differences in physical capabilities (eg, hand weakness and mobility impairment).

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Data Availability

The data collected from the participants in this research are not publicly available in order to comply with the ethics approval of the study.

Conflicts of Interest

SK has a financial interest in the tested VR application; therefore, he was not involved in the data collection and analysis of the data.

Multimedia Appendix 1

Interview guide.

[DOCX File, 15 KB - [rehab_v10i1e46959_app1.docx](#)]

Multimedia Appendix 2

Research Team and Reflexivity Statement.

[DOCX File, 16 KB - [rehab_v10i1e46959_app2.docx](#)]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

NASA-TLX: NASA Task Load Index

SLP: speech-language pathology

SSQ: Simulator Sickness Questionnaire

SUS: System Usability Scale

TAM: technology acceptance model

VR: virtual reality

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Original Paper

Use of Virtual Reality in Interdisciplinary Multimodal Pain Treatment With Insights From Health Care Professionals and Patients: Action Research Study

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Abstract

Background: Chronic pain is a widespread global health problem. Interdisciplinary multimodal pain treatment (IMPT) is a treatment option for people with chronic pain. Virtual reality (VR) could be used to broaden IMPT programs. However, despite the advantages of VR, it is rarely used in daily clinical practice.

Objective: This research aimed to explore how, when, and with whom VR can be used meaningfully during IMPT, either as an addition or substitution as a component of IMPT.

Methods: This research used an action research design to help health care professionals and patients learn how, when, and with whom they can use VR. Data were collected through reflection sessions with health care professionals and semistructured interviews with patients in 2 specialized centers that provide IMPT for chronic pain. Two researchers performed direct content analyses.

Results: In total, 4 physiotherapists, 1 occupational therapist, 3 psychologists, and 22 patients participated in this research. Three iteration cycles, including 9 reflection sessions and 8 semistructured interviews, were performed. Both health care professionals and patients considered VR to be useful in therapy as an addition but not a substitution. VR was used as a diagnostic and intervention tool with all patients at the rehabilitation center or home. VR was used to gain insight into patients' pain beliefs, cognitions, and irrational cognitions about additional damage and physical abilities. Considering VR as an intervention tool, the health care professionals had 3 goals: balancing relaxation and competition, grading activities, and exposure in vivo.

Conclusions: VR could be a valuable addition to IMPT for both patients with chronic pain and health care professionals. More research should be performed to assess the additional effects of VR on patients' participation in daily life.

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KEYWORDS

virtual reality; interdisciplinary multimodal pain treatment; chronic pain; pain; rehabilitation; digital health; physiotherapy; occupational therapy; physical therapy

Introduction

Chronic pain is a widespread global health problem. Pain is considered chronic when it persists beyond the expected healing period [1]. At present, 1 in 5 European adults experience chronic pain, of which about a third experience severe pain [2]. Chronic pain can have a significant influence on an individual's life. It may impair their ability to participate in daily life, interfere with their ability to work, and affect relationships and self-esteem [1]. Research shows chronic pain is one of the most prominent causes of lifetime-experienced disability during daily life, even more so than cardiovascular diseases, diabetes mellitus, or cancer [3]. Consequently, chronic pain has estimated direct and indirect health care costs of €20 million (US \$21.24 million) annually in the Netherlands, higher than those of several chronic diseases [4,5].

Interdisciplinary multimodal pain treatment (IMPT) is an option for people experiencing chronic pain. This program does not necessarily aim to reduce pain; instead, it aims to optimize daily life functioning and participation by addressing biomedical, psychological, and social factors contributing to chronic pain and its associated disabilities [6]. The interdisciplinary team responsible for this treatment spans the biopsychosocial spectrum, consisting of a physiatrist, physical therapist, psychologist, and often an occupational therapist. Patients with chronic pain who undergo an IMPT program show considerable improvement in physical and psychological well-being [6]. Nowadays, IMPT primarily involves a combination of physical and psychosocial treatment methods, including emotional awareness and expression therapy, pain neuroscience education, acceptance and commitment therapy (ACT), graded activity, exposure in vivo, and experiential learning through physical training [7]. These treatment modules are provided in gyms or consulting rooms using the physical attributes (eg, balls and dumbbells) and training devices (eg, treadmills) available at the treatment facilities. This limits the performance of specific activities (eg, playing tennis and gardening). Furthermore, some modules, such as exposure in vivo and physical training, require patients to practice at home to establish sufficient training intensity and generalization to daily life. However, the necessary attributes are rarely available in a home environment. Virtual reality (VR) could help to broaden the scope and application of physical and psychosocial treatment modules.

VR allows a user to view and interact with a simulated 3D world. For example, when playing tennis, a user sees a tennis court and a ball coming toward them. To hit the ball, the user

has to perform a physical movement. VR could be a meaningful addition to physical treatments by creating situations that are impossible to provide in available training facilities, adding variety, enhancing generalization, and providing insight for both health care professionals and patients into patient behavior (eg, being avoidant). Furthermore, VR often makes physical activity more enjoyable and can be applied in the patient's home or work environment. Several articles and systematic reviews have been conducted on clinical VR studies, showing that VR reduces experienced acute and chronic pain and kinesiphobia and enhances patient satisfaction and general health status [8-13].

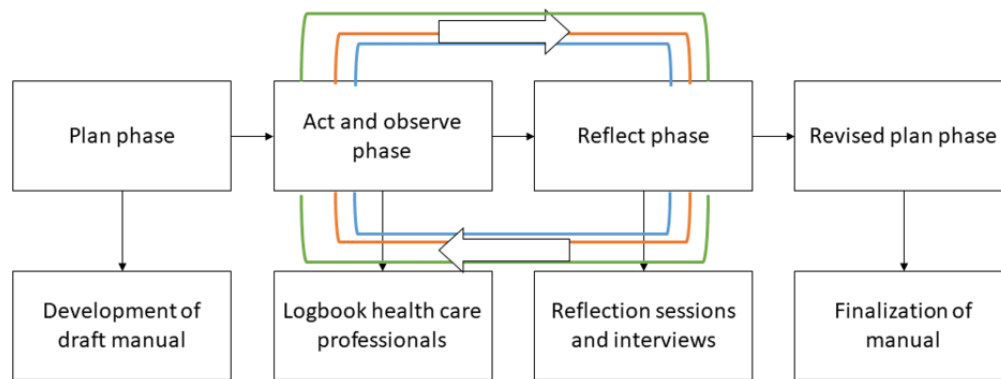
However, despite its advantages, VR is rarely implemented as a component of IMPT. This aligns with the trends of other eHealth apps. Several reports on the use of eHealth methods describe the transition from the pilot phase to implementation, highlighting that upscaling to daily clinical practice remains a bottleneck [14,15]. Barriers to and facilitators in implementing eHealth into daily clinical practice include the complexity of the eHealth tool, health care professionals' and patients' digital health literacy, and the perceived benefits [16-19]. Therefore, before implementing a new tool as part of IMPT, exploring when, how, and for whom it can benefit the clinical care process is vital. It is crucial to determine in which phase of the clinical care process a tool can be used (ie, diagnostic, therapeutic, or aftercare); which patients have the physical capacity, emotional well-being, and (digital) literacy skills to use it; and whether VR also can be used in a patient's home. Therefore, to facilitate optimal implementation, this research aims to explore how, when, and with whom VR can be used meaningfully during IMPT. It uses an action research design to address the following research questions: (1) how do health care professionals and patients use VR as an addition or substitution in IMPT? (2) What are health care professionals' and patients' experiences of using VR as an addition or substitution in IMPT?

Methods

Overview

This research used an action research design. Health care professionals and patients at 2 rehabilitation centers providing IMPT had the opportunity to experience, reflect, and learn how, when, and with whom they could use VR in the program. The action research design consisted of 4 phases: plan phase, act and observe phase, reflect phase, and revised plan phase. [Figure 1](#) presents a schematic overview of this design.

Figure 1. Schematic overview of the design, including data collection. Blue indicates the first round (n=7 health care professionals and n=7 patients), red indicates the second round (n=7 health care professionals and n=6 patients), and green indicates the third round (n=7 health care professionals and n=8 patients).



The research team developed a draft manual in the plan phase. The content of the draft manual was based on an earlier developed manual on how to use activity trackers in patients with chronic pain [20]. The content consisted of an introduction to VR, an introduction to the setting and context of the rehabilitation center, the possibilities of VR, and the use of VR in therapy.

In the act and observe phase, health care professionals used VR in daily clinical practice. The act and observe phase lasted for at least 4 to 6 weeks, during which part of the data collection occurred.

The remainder of the data collection was completed during the reflect phase. Health care professionals further developed the draft manual to suit their specific contexts and needs based on their and their patients' experiences. The act and observe phase and reflect phase were iterative cycles and were planned to be repeated until there was no need for the manual to be further developed. The manual was finalized in the revised plan phase.

Ethical Considerations

This study was approved by the local ethics board Medical Ethical Committee METC Zuyderland (METCZ20220030).

Setting and Context


This study was performed in 2 specialized rehabilitation centers that provide IMPT for patients with chronic musculoskeletal pain: the Centre for Integral Rehabilitation (CIR, locations Eindhoven and Velp) and the Adelante Healthcare group (Adelante, location Hoensbroek). Two locations of CIR participated and 1 location of Adelante participated. In both centers, an interdisciplinary team consisting of a physiotherapist or occupational therapist, a psychologist, and a psychiatrist provided therapy. Both centers provided pain neuroscience education, ACT, graded activity, exposure in vivo, and experiential learning through physical training [7]. CIR also provided emotional awareness and expression therapy. VR was used in all the above-described therapies.

VR

The Oculus Meta Quest 2 VR was used with 2 handheld controllers during this study. The VR software technology SyncVR (Syncv VR Medical [21]) was also used. SyncVR provides various games that can be played with 1 or 2 hands while standing, sitting, or lying down (Figures 2 and 3).

Figure 2. Examples of games for the lower body from SyncVR Fit. Copyright 2022. SyncVR Medical Holding BV [21].

LOWER BODY




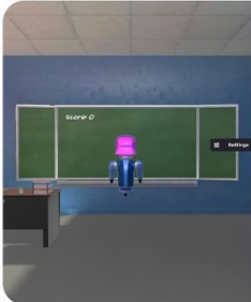







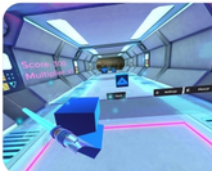

	<p>Skiing</p> <p>Tunnels approach with different heights and speed. Dodge the tunnels by squatting. Reach out to the blue hands on the left or righthand side and give a "high five" to gain points.</p>	<ul style="list-style-type: none"> • Legs • Arm • Hip/Knee flexion • Shoulder • Elbow
	<p>Please be seated</p> <p>Stand up from your school desk, while the teacher is writing on the board. Sit down on your chair when she turns around. Hold the squatting position until the teacher turns around again.</p>	<ul style="list-style-type: none"> • Hip/Knee flexion • Weight shifting
	<p>Ring Dive</p> <p>Perform squats while holding both your hands forward to pop the rings.</p>	<ul style="list-style-type: none"> • Legs • Thighs • Knee • Lower limb

Figure 3. Examples of games for the upper body from SyncVR Fit. Copyright 2022. SyncVR Medical Holding BV [21].

UPPER BODY		
	<p>Tennis</p> <p>The balls are shot randomly to the player, and they change speed and position a little. Get points by hitting the ball over the net.</p>	<ul style="list-style-type: none"> • Hands • Shoulders • Wrist • Hand/eye coordination
	<p>Boxing</p> <p>Hit the obstacles coming at you while matching the colors!</p>	<ul style="list-style-type: none"> • Cognitive • Hands • Hand/eye coordination
	<p>Sorting</p> <p>Put the items from the conveyor belt in the correct bins!</p>	<ul style="list-style-type: none"> • Hands • Shoulders • Cognitive
	<p>Fireflies</p> <p>Touch the fireflies before they fly away. Note: From difficulty level "Medium" and up, you have to touch them with a specific hand!</p>	<ul style="list-style-type: none"> • Hands • Shoulders
	<p>Archery</p> <p>Shoot the balloons using the bow and arrow.</p>	<ul style="list-style-type: none"> • Upper body • Focus
	<p>Saber Slash</p> <p>Slice the approaching cubes with the correct saber color and right direction!</p>	<ul style="list-style-type: none"> • Hands • Focus • Shoulders • Cognitive
	<p>Witchcraft</p> <p>Brew potions in the cauldron by throwing the right ingredients in the cauldron and stirring afterward.</p>	<ul style="list-style-type: none"> • Arms • Hands • Shoulder • Cognitive

Participants

Both health care professionals and patients were recruited through the rehabilitation centers. The manager of each rehabilitation center selected the health care professionals using convenience sampling. Health care professionals were included if they were motivated to use VR and could participate for the duration of the study. The health care professionals participated in all phases of the study.

Patients were eligible for inclusion if they received therapy from a participating health care professional and were eligible for blended therapy (ie, use of VR at the rehabilitation center or at home) according to the checklist for blended physiotherapy [22]. The checklist for blended physiotherapy assesses whether patients are eligible for blended therapy. The checklist consists of 8 items such as motivation, safety, equipment, digital skills, health literacy, self-management, time, and financial factors. Patients were selected via convenience sampling. Patients were

included if they had a therapy goal that could be (at least partly) achieved using VR. Patients were excluded if they had delirium, dementia, open head or facial wounds, epilepsy, or severe hearing or vision problems. The exclusion criteria were formulated to guarantee the participants' safety. After being provided with information about the research, patients had the opportunity to consider participation for at least 1 week. Patients participated in 1 cycle of the act and observe and the reflect phases. New patients were included if a new act and observe phase was started. The aim was to include 2 new patients in each act and observe phase for each participating health care professional.

Data Collection

Data were collected between April and December 2022 using a multimethod approach consisting of reflection sessions with the health care professionals, semistructured focus groups and individual interviews with the patients, and a logbook kept by the health care professionals. Demographic characteristics of the health care professionals and patients were also collected. These included data on the health care professionals' profession, gender, years of working experience, and years of experience with VR. Data on the patients' gender, age, diagnosis (categorized according to the International Classification of Diseases-11 [23]), treatment, and weeks of treatment were collected. Furthermore, additional parameters of the participating patients were measured to obtain additional insight into whether specific patient characteristics were important to consider when assessing the feasibility of VR. These included mood (using the Hospital Anxiety and Depression Scale (HADS) [24]), fear of movement (using a shortened version of the Photograph Series of Daily Activities (PHODA) [25]), aerobic capacity (using the 6-minute walk test (6MWT) [26]), reading ability (using the Single Item Literacy Screener (SILS) [27]), and digital skills (using the Quicksan Digital Skills assessment [28]). The HADS subscales range from 0 to 21, with a higher score representing a greater likelihood of anxiety or depression. PHODA ranges from 0 to 100, with a higher score representing a greater likelihood of fearing movement. In the 6MWT, walked distance is calculated as a percentage of the average physical capacity of a population of matched age, gender, and body weight. SILS ranges from 1 to 5, with a higher score representing lower reading abilities. Quicksan ranges from 1 to 3, with a higher score representing better digital skills. These questionnaires and tests were used to assess whether certain patient characteristics are important in determining how, when, and with whom VR can be used during IMPT.

Reflection Sessions With the Health Care Professionals

After each act and observe phase, a reflection session was held with the participating health care professionals of each center. These were held separately due to practical limitations (ie, different work schedules). These reflection sessions aimed to encourage participants to elaborate on how VR was used and to share experiences of its feasibility and use in daily clinical practice. The research team supported these reflection sessions by leading them and ensuring that the draft manual and clinical reasoning process were discussed. The research team improved

the draft manual by adapting it to the health care professionals' experiences. These group sessions took place either at the rehabilitation center or digitally via Microsoft Teams (Microsoft Corp). They lasted 45 to 60 minutes and were audio-recorded.

Semistructured Focus Group and Individual Interviews With the Patients

After each act and observe phase, a semistructured or focus group interview was conducted with the participating patients. The interviews were conducted in person at a convenient location for the patients or digitally via Microsoft Teams. The research team led them. The topic list and interview guide were based on a previously developed framework [20]. This framework was initially developed to assess the feasibility of activity trackers but was adapted to the VR context ("VR" replaced the term "activity tracker"; [Multimedia Appendix 1](#)). The interviews lasted 30 to 60 minutes and were audio-recorded. The research team used the information gathered during the interviews and focus groups to improve the draft manual.

Health Care Professionals' Logbooks

During each act and observe phase, the participating health care professionals had the option to collect their observations in a logbook. Questions in the logbook were "What was the goal of VR treatment with this patient," "Was this patient eligible for VR treatment," "What worked well," and "What am I going to change during the next treatment?"

Data Analyses

To analyze the data, the research team transcribed verbatim the audio recordings of the reflection sessions with the health care professionals, the semistructured focus group, and the individual interviews with the patients. They used directed content analyses to analyze all the data. NVivo (version 12; QSR International) was used during the analysis process. The researchers used deductive coding based on the applied framework ([Multimedia Appendix 1](#)). When a text fragment was relevant but did not match an existing code, an "other" code was created using inductive coding. Two researchers (DU and EC) coded the first transcript and every fifth transcript thereafter. A third researcher (RS) was consulted if the researchers did not reach a consensus. Descriptive statistics of the health care professionals and patients were presented as medians (range). The scores of the measurement tools (HADS, PHODA, 6MWT, SILS, and Quicksan) were calculated and interpreted according to their guidelines.

Results

Overview

The research team performed 3 iteration cycles, including 9 reflection sessions and 8 semistructured focus group interviews.

Health Care Professional and Patient Characteristics

The research included 4 physiotherapists, 1 occupational therapist, and 2 psychologists ([Table 1](#)). In addition, 22 patients ([Table 2](#)) participated in the study.

Table 1. Characteristics of the health care professionals (n=7).

Characteristics	Values
Gender (male), n (%)	3 (43)
Age (years), median (IQR)	34 (31-43)
Occupation, n (%)	
Physiotherapist	4 (57)
Occupational therapist	1 (15)
Psychologist	2 (28)
Working experience (years), median (IQR)	10 (3-22)
Experience with VR ^a , months, median (IQR)	0 (0-0)
Number of patients with whom VR was used, median (IQR)	2 (1-3)

^aVR: virtual reality.

Table 2. Characteristics of the patients (n=22).

Characteristics	Values
Gender (male), n (%)	10.0 (45)
Age (years), median (IQR)	48.0 (32.0-56.0)
Diagnoses, n (%)	
Primary pain	2 (9)
Cancer pain	0 (0)
Postsurgical and posttraumatic pain	5 (22)
Neuropathic pain	3 (13)
Headache and orofacial pain	0 (0)
Visceral pain	0 (0)
Musculoskeletal pain	11 (48)
Other	2 (9)
Number of weeks in therapy before starting VR ^a treatment, median (IQR)	6.0 (6.0-10.0)
HADS ^b anxiety score, median (IQR)	8.8 (5.3-11.8)
HADS depression score, median (IQR)	9.0 (6.3-12.0)
PHODA ^c score, median (IQR)	26.5 (20.6-42.9)
6MWT ^d score, median (IQR)	67% (60.0-74.5)
SILS ^e score, median (IQR)	1 (1.0-1.0)
Quickscan Digital Skills score, median (IQR)	2 (3.0-3.0)

^aVR: virtual reality.

^bHADS: Hospital Anxiety and Depression Scale.

^cPHODA: Photograph Series of Daily Activities.

^d6MWT: 6-minute walk test.

^eSILS: Single-Item Literacy Screener.

Of the 22 patients involved in the study, 10 were willing to participate in an interview. The coding framework was based on a previous framework [20] developed to assess the feasibility of activity trackers. The framework was adapted to the VR context by replacing the term “activity tracker” with “VR” (Multimedia Appendix 1). The categories were instructions, characteristics of the VR device, correct functioning, skills and

beliefs, goal of the VR device, and use of the VR device. No categories were added based on the inductive analyses. No third researcher was needed during the analyses to resolve any disagreements. The experiences of the health care professional and the patient clearly varied depending on how the VR device was used. For example, a good experience with a device was closely linked to receiving adequate instructions on using it.

Due to this strong link between the “use” of VR and the “experience” of VR, these aspects were described together.

Instruction

During the reflection session, all health care professionals indicated that they started their sessions by explaining to the patient how the VR device worked (ie, using the controllers). However, the health care professionals set up the VR device before the treatment session because they felt that setting it up with the patient was too time-consuming. Health care professionals expressed that they required good insight into how the device worked to guide the patient. Therefore, they had to play the games themselves. Health care professionals expressed that having a guide with screenshots of the games would have been helpful. Throughout the study, the health care professionals felt increasingly confident in providing instructions as they gained more experience with the VR device. The patients generally indicated that the health care professionals’ technical explanations of VR software and devices were sufficient. However, patients who lacked technical skills or had no previous experience with other game consoles felt that the instructions were too limited:

If you are younger, you might have experience with game consoles, but if you are a little bit older, it would be helpful to provide some more technical information. [Patient]

It is important to explain VR very well; they handed me the consoles while I was already wearing VR [glasses]. I would prefer a moment to look at the consoles to see what they are and how and which buttons I have to use. When you are already wearing VR [glasses], you can’t see them [consoles] anymore. [Patient]

The health care professionals’ explanations of the goal of VR varied. During the first session using VR, the health care professionals did not explain the goal of using VR. They also did not inform the patient whether they could stop the game or choose another one. Health care professionals chose to obtain information about pain beliefs, fear avoidance beliefs, and irrational cognitions to assess the patient’s physical abilities. The health care professionals feared that if they explained the purpose of VR, the patients would become more vigilant and act differently. During the follow-up (intervention) session using VR, the health care professionals did explain the goal because the patients were already aware of VR:

Okay, and why didn’t you share those instructions? [Interviewer]

Well, I didn’t want that he felt I had certain expectations since he is really sensitive to that, especially if he doesn’t meet those expectations. [Health care professional]

Patients expressed that they did not need explanations of the goal of using VR. They were not bothered by the fact that their health care professionals initially did not explain the goal of using VR. The patients claimed that if they knew the goal, they would not have achieved the results they had:

They [healthcare professionals] instructed me as little as possible about the goal of VR. Since I would likely focus too much on that goal, I think it was very smart of them [healthcare professionals]. [Patient]

Characteristics of VR

Both health care professionals and patients claimed that the VR devices were easy to install and use. They liked the games’ interfaces. However, when health care professionals were asked about their wishes, they said they would prefer some games to be more related to the reality of daily life. For example, they could involve putting dishes in (high) cabinets. This could help patients with the transfer from VR to the real world. Furthermore, all games were in the patients’ primary language (Dutch), except 1, which was in English. For some patients, this dissuaded them from wanting to play the English game. “There was one English game, which wasn’t an option for my patient since she couldn’t understand English” [Health care professional].

The health care professionals and patients reported that they felt everybody, apart from those already excluded from the study, could use VR. They also added an additional exclusion criterion, severe balance issues, to protect the safety of patients. The health care professionals stated that the characteristics of participants (which were available through validated questionnaires used to measure anxiety, depression, fear of movement, physical capacity, reading ability, and digital skills) did not influence whether they introduced the VR device. Patients with limited digital skills required more instruction before using the VR device. Nevertheless, these patients then used the device effectively. However, health care professionals considered the patient’s digital skills and reading ability before providing a VR device to use at home.

Health care professionals mentioned that VR would be suitable for other patient populations, such as those with heart disease or spinal cord injuries. Two patients expressed that they lacked sufficient hand strength to push the console buttons. Patients reported that the VR hardware was comfortable to wear. Two patients experienced dizziness or nausea after using the VR device; this was addressed by using VR for a shorter period in the next session:

I experienced that I could use VR for a maximum of 15 minutes before I got nauseous. [Patient]

Some patients indicated that they would like more feedback from the VR device. Many would like some encouragement and motivation from the device. Other patients wanted to receive feedback when they were “overactive.” These findings suggest that VR software should be able to adapt its feedback to the goals and beliefs of each patient.

Correct Functioning

Health care professionals and patients reported almost no technical problems with the VR devices. Any problems that occurred were managed and mitigated.

Skills and Beliefs

Health care professionals believed they were sufficiently skilled to use VR without support in their daily practice. The patients

indicated that after receiving instructions from the health care professionals, they could use the VR device independently. Both health care professionals and patients believed that VR could add value to daily clinical practice:

I notice the enthusiasm of the patients when they use VR; they are so enthusiastic. They really want to talk about their experience. [Health care professional]

Goal of VR

Throughout this study, the health care professionals discovered they could use VR as both a diagnostic and an intervention tool. As a diagnostic tool, health care professionals used VR to gain insight into their patients' pain beliefs, fear avoidance beliefs, and irrational cognitions about potential additional damage and physical abilities. This was always central to the first session using VR. The health care professionals identified 3 goals for using VR as an intervention tool: exposure, graded activity, and balancing pacing and competition. During the final act and observe phase, patients were allowed to use VR at home as an intervention tool with the same goals described above:

I want them [the patients] to experience movements which they think can't perform; by working with VR, they experience they perform that movement. [Health care professional]

Use of VR

In both centers, health care professionals and patients indicated that VR could be used only in individual sessions. In the participating rehabilitation centers, therapy trajectories start with group sessions. Therefore, the point when VR is introduced may differ for each patient. However, in this study, all patients started using VR after roughly 6 weeks (of a 10-week therapy trajectory). The health care professionals indicated that VR theoretically could have been used sooner. However, they all felt they needed time to develop relationships with patients, especially those with anxiety or kinesiophobia.

Patients, however, were divided; on the one hand, some of them felt VR could be used. The patients' opinions were divided. On the one hand, some of them felt that VR could be used sooner. On the other hand, some patients expressed that they needed time to feel comfortable with their health care professional and the process and would not wish to use VR sooner. Both health care professionals and patients indicated that VR did not interfere with their relationship:

I was really focusing on my emotions and could really experience them during VR. If we would have used VR sooner in the trajectory, I think it would have missed its purpose since I didn't know how and what to feel during that time. [Patient]

Generally, therapy sessions lasted between 45 and 60 minutes. VR was used for 15 to 30 minutes during these sessions. Both health care professionals and patients thought this was sufficient. The remaining part of the session was mostly spent discussing the patient's experience using VR. The discussion primarily focused on the patient's experience rather than the results of the game. Furthermore, the health care professional and patient discussed the lessons learned from the experience:

We discussed what he [the patient] was thinking, if he crossed boundaries, and if he discovered new things. [Health care professional]

Health care professionals found that some patients would not believe they performed certain activities during VR (eg, squatting or raising an arm). Throughout this study, health care professionals came up with a solution to this; they filmed patients using VR and showed them these recordings. This was a valuable feedback tool. When patients used VR at home, health care professionals experienced some difficulties discussing VR sessions. There was no feedback tool, so health care professionals had to lead the conversation solely based on the patients' experiences.

The health care professionals claimed that observing a patient using a VR device provided helpful information for their diagnostic and therapeutic processes. Furthermore, they expressed that patients were tasked with performing challenging movements by playing a fun game. Patients also indicated that using VR made physical activity fun and distracted them from their pain and disabilities. Furthermore, they were more focused and less distracted by external stimuli (eg, other patients or noise) when using VR. Regular physical exercises are often perceived as boring and mandatory, a problem that VR could partly solve. Both health care professionals and patients perceived VR as an addition to IMPT rather than a substitution for it:

I had to prevent the footballs from going into the goal, and I was thinking about my back, but I didn't feel my back at all. I was just playing! [Patient]

The games and VR are some kind of trigger to move and behave differently than they are used to in real life. [Health care professional]

According to patients, using VR at home meant that they could use and practice with VR whenever they wanted. Furthermore, they could share their experiences and goals with their family members:

Surprisingly, they [his children] had the same feeling as I did. They didn't like to lose a game; for me, this was a reassurance that I am not the only one who feels like this. [Patient]

Discussion

This study aimed to explore how, when, and with whom VR can be used meaningfully during IMPT. The research questions were (1) how do health care professionals and patients use VR as an addition or substitution in IMPT? (2) What are health care professionals' and patients' experiences of using VR as an addition or substitution in IMPT?

In this study, health care professionals used VR as a diagnostic and therapeutic tool. As a diagnostic tool, VR provided new information for health care professionals, including insight into patients' pain beliefs, fear avoidance beliefs, and irrational cognitions about additional damage and physical abilities. When using VR, patients were not aware of the underlying goal of the exercise; therefore, health care professionals felt they could observe more natural behaviors (eg, persistent or avoidant

behavior). When considering VR as a therapeutic tool, health care professionals had several goals such as creating a balance between relaxation and competition, graded activity, and exposure in vivo. VR provided the health care professionals more treatment options. Both health care professionals and patients had positive experiences using VR in daily clinical practice. VR provided health care professionals with additional information for their diagnostic and therapeutic processes. Patients expressed that VR made physical activity fun again, distracted them from their pain and disabilities, and helped them focus more on their own experiences.

Several systematic reviews highlight that VR can improve pain intensity, kinesiophobia, mobility, functional capacity, neuropsychological outcomes, quality of life, and physical sensations [11-13,29-31]. Other systematic reviews outline that VR is not effective for people with chronic pain but is effective for those with acute pain [10,30,32]. However, reducing pain is not the primary goal of IMPT. According to Baker et al [29], the most common VR mechanism is distraction and embodiment; distraction is more relevant in treating acute pain and embodiment in treating chronic pain. Patients mentioned both mechanisms and indicated that VR-elicited distraction could be used during ACT treatments and with patients with pain-related fear. However, the immersion and inherent distraction of the VR environment may prevent health care professionals from testing expectancies or the conscious experience of disconfirming the feared consequences of performing a particular activity or movement [33]. The experienced intensity of pain can be influenced by the activity a patient performs. A fun activity (eg, VR) could provide more distraction than a “boring” activity with the same physical intensity. Patients also mentioned that they wanted feedback when they were “overusing.” However, research has shown that people with chronic pain often incorrectly perceive overuse [34].

This study has some limitations. First, there may have been a selection bias for both health care professionals and patients. The participating health care professionals were likely already open and enthusiastic about the use of VR and eHealth. Therefore, the health care professionals may have been open to experimenting with VR and were not afraid to use it. Only 1 health care professional already had experience using VR. Studies show that if health care professionals have previous positive experience with eHealth, they experience more advantages of other eHealth technologies [35,36]. Health care professionals with previous negative experiences may have refused to participate in this study, which could have resulted in a more positively oriented group of health care providers. However, early adaptors can inspire and guide their colleagues when implementing an innovation. The participating health care professionals may represent such early adaptors in daily practice. Second, the same selection bias may have been present in the patients because the health care professionals were free to choose which patients were included in this study. Therefore, health care professionals may have selected patients open to eHealth or VR. The researchers did not assess the criteria the health care professionals used to select their patients. The results show that all patients had sufficient digital skills, although the

clinimetric properties of the questionnaire are unknown. Health care professionals’ experiences suggest that other characteristics, such as patients’ anxiety, depression, fear of movement, and physical capacity, did not influence the instruction and use of VR or its feasibility. Third, only 10 of the 22 patients were willing to participate in an interview. Therefore, the whole scope of patients’ experiences may not have been included. Patients’ reasons for not participating in an interview included the required time investment, illness, or failure to attend the interview.

This study is made more robust by its use of iterative cycles. Iterative cycles gave health care professionals time to reflect on their clinical reasoning and use of VR in their daily clinical practice. By experimenting with VR, therapists could learn how, when, and with whom VR could be used. In addition, by discussing their experiences, they could learn from and inspire each other. Furthermore, the patients’ experiences were anonymously shared with the health care professionals. Credibility and transferability were checked to ensure the reliability of this study. Credibility was ensured by using data triangulation (multiple data sources), researcher triangulation, and method triangulation (multiple data collection methods). Transferability was ensured by providing a comprehensive description of the study population and process.

All patients reported that their technical skills were sufficient to use this VR device. Future researchers could conduct a study in which more patients have no or limited digital skills and limited reading ability. However, patients may not need digital skills to use VR during therapy sessions in a rehabilitation center. In this study, health care professionals set up the VR device for their patients. Therefore, the patients only needed to learn how to play the game. If VR is used at home or as a substitution for regular care, patients may need some digital skills to use the VR device by themselves.

This research exemplifies how to use VR in daily clinical practice with patients with chronic pain undergoing an IMPT program. Further research could focus on whether using VR in daily clinical practice positively affects patients’ participation in daily life. Furthermore, future research could focus on the further development of VR devices. A greater variety of games could be developed, especially those involving the lower extremities, activities based on daily life, and relaxation exercises. Furthermore, devices could give the patient and health care professionals direct feedback. By adding these features, VR devices could be used as a substitution for an IMPT program instead of merely an addition.

In conclusion, both health care professionals and patients with chronic pain had positive experiences with VR during IMPT. VR was used as an addition to IMPT for patients with chronic pain and as a diagnostic tool providing insight into pain beliefs, fear-avoidance beliefs, and irrational cognitions about additional damage and physical abilities. As a therapeutic tool, VR was used to create a balance between relaxation and competition, graded activity, and provide exposure in vivo at the rehabilitation center or at home. VR is not yet a substitution for care. Further research should be performed to establish the

effects of VR on patients' participation in daily life and how VR could be used as a substitution for other treatments.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Topic list based on a previously developed framework [20].

[DOCX File, 14 KB - [rehab_v10i1e47541_app1.docx](#)]

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Abbreviations

- 6MWT:** 6-minute walk test
- ACT:** acceptance and commitment therapy
- CIR:** Centre for Integral Rehabilitation
- IMPT:** interdisciplinary multimodal pain treatment

HADS: Hospital Anxiety and Depression Scale

PHODA: Photograph Series of Daily Activities

SILS: Single Item Literacy Screener

VR: virtual reality

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Original Paper

Smartphone Global Positioning System–Based System to Assess Mobility in Health Research: Development, Accuracy, and Usability Study

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Abstract

Background: As global positioning system (GPS) measurement is getting more precise and affordable, health researchers can now objectively measure mobility using GPS sensors. Available systems, however, often lack data security and means of adaptation and often rely on a permanent internet connection.

Objective: To overcome these issues, we aimed to develop and test an easy-to-use, easy-to-adapt, and offline working app using smartphone sensors (GPS and accelerometry) for the quantification of mobility parameters.

Methods: An Android app, a server backend, and a specialized analysis pipeline have been developed (development substudy). Parameters of mobility by the study team members were extracted from the recorded GPS data using existing and newly developed algorithms. Test measurements were performed with participants to complete accuracy and reliability tests (accuracy substudy). Usability was examined by interviewing community-dwelling older adults after 1 week of device use, followed by an iterative app design process (usability substudy).

Results: The study protocol and the software toolchain worked reliably and accurately, even under suboptimal conditions, such as narrow streets and rural areas. The developed algorithms had high accuracy (97.4% correctness, F_1 -score=0.975) in distinguishing dwelling periods from moving intervals. The accuracy of the stop/trip classification is fundamental to second-order analyses such as the time out of home, as they rely on a precise discrimination between the 2 classes. The usability of the app and the study protocol was piloted with older adults, which showed low barriers and easy implementation into daily routines.

Conclusions: Based on accuracy analyses and users' experience with the proposed system for GPS assessments, the developed algorithm showed great potential for app-based estimation of mobility in diverse health research contexts, including mobility patterns of community-dwelling older adults living in rural areas.

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KEYWORDS

geographic information system; rehabilitation; prevention medicine; geoinformatics; out-of-home mobility

Introduction

From a functional perspective, mobility can be defined as the “ability to move oneself independently from one point to another” [1]. In the last years, broad conceptions of mobility that integrate individual mobility behavior (eg, mobility patterns) with environmental factors (eg, built environment or transportation modes) have gained importance [2,3]. Despite this development, in health sciences, most studies still assess mobility using self-report questionnaires that come along with self-reporting biases such as overestimating the time spent being active [2,4,5]. To allow for a more objective measurement of mobility, personal factors and environmental differences were integrated with data collected via a global positioning system (GPS) and data from geographic information systems (GISs) [6]. Especially, as the use of global navigation satellite systems such as GPS has become more reliable and less costly, the number of related studies has increased substantially. Among the various studies performed in this regard, researchers have examined the relationship between real-life mobility (eg, assessed through GPS) and health outcomes such as depressive symptoms [7,8], cognitive functioning [9,10], and general health status [11,12]. GPS/GIS-based mobility patterns further have the potential to inform about health behaviors such as physical activity outside the home and routines in mobility behavior (eg, time of the day first moved or revisited locations). Moreover, frameworks to guide the analysis under spatial and temporal aspects or attributes of movement (eg, active transport by foot or passive motorized transport) have been developed over time and include GPS-derived outcomes of life or activity space [13,14].

There are several devices with underlying server infrastructure and data analysis pipelines capable of GPS tracking, including GPS watches, smartphones, and trackers such as the frequently used Qstarz device (ie, BT-Q100XT; QStarz International Co, Ltd) [15].

However, several aspects, such as accuracy, data security, and offline use, must be considered when working with GPS devices. For instance, data by Lee et al [16] showed that although accuracy ranged widely across studies and devices, overall these devices can be considered good. To adequately assess environmental interaction and human mobility behavior (eg, attributes of location and revisited locations), precisely identifying visited locations and trips between these locations is crucial [17].

For data security, most devices use preexisting software, where server locations remain with the software provider, and scientists may not be able to adequately adapt or change the output [15]. In addition, not every GPS assessment device supports offline use, which may be required to offer solutions applicable in combination with high data-protection standards or assessment of GPS data in rural areas without an internet connection.

The usability of GPS sensors, including those implemented in mobile devices, has been shown to be high in diverse groups of participants, including schoolchildren [18], commuting working adults [19], or community-dwelling older adults. Nonetheless, technical and usability obstacles have been

reported and must be evaluated in different areas and populations, including in health promotion, disease prevention, therapeutic, and rehabilitation settings and research.

The aim of this study is to demonstrate a multicomponent system for conducting GPS-based studies, including an easy-to-use, low-cost, and easy-to-adapt smartphone app, over longer sampling intervals without a permanent internet connection and respective analysis pipeline.

Methods

Overview

This study was conducted in the context of the MOBILE study (Mobility in Old Age by Integrating Health Care and Personal Network Resources in Older Adults Living in Rural Areas) funded by the German Federal Ministry of Education and Research (grant number 01GY1803), an interventional study focusing on promoting out-of-home mobility including GPS-based mobility outcomes. The development of the technical components in measuring GPS-based outcomes is described in this paper.

While developing the GPS for the study’s purpose, we describe 3 consecutive steps: (1) outline each component of the system (development substudy); (2) report an integration study evaluating the system’s capabilities to derive accurate variables about users’ activity behavior (accuracy substudy); and finally, (3) examine the user experience in a sample of community-dwelling older adults and describe an iterative app design process to further optimize the usability for this specific group of users (usability substudy).

Development of the App and Analysis Pipeline

In the first step of developing the GPS we created the system architecture, which consists of an Android (Google Inc/Alphabet Inc) smartphone app, a remote server, and an analysis pipeline. All components are described in more detail in the following sections.

This architecture allows for much flexibility as it does not require particular hardware or privacy policies concerning server hosting. The server is hosted at Technical University Berlin, which ensures data security and GDPR (General Data Protection Regulation) conformity of the European Union.

The GPS.Rec2.0 Mobile App

The mobile app (GPS.Rec2.0) can be deployed on most phones running Android versions 6.0 or above. We deliberately supported this rather dated operating system version, because it allows us to support a wide bandwidth of different devices. The app offers a simple interface to configure recording parameters such as sample frequency and GPS accuracy. It can be configured to automatically start in the background after a reboot, which is particularly useful for intervention scenarios in which participants need to charge the devices. Other than this, the users are not expected to interact with the app in any way. The app stores several millions of records on the internal memory of the device. As soon as an internet connection is established (eg, in the laboratory, after an intervention), it transfers all the records to a configured server destination. This

way, researchers access the recorded data retrospectively and ensure privacy matters simultaneously (ie, no live tracking possible). This design also allows us to have minimum interaction so participants are not distracted in their everyday lives. Our study protocol foresees participants to plug the phone into a charger at home and take the phone with them whenever they leave the house. Other than that, no interaction with the phone is necessary. In addition, this setup allows us to use comparably inexpensive smartphone hardware. We performed our tests on ZTE's Blade A5 (2019), a basic, entry-level smartphone costing around €50 (US \$54). When deciding on a hardware platform, we tested several devices offering at least 16-GB memory space, 1-GB RAM, and 1000 mAh battery capacity. The latter is probably the most critical specification as it allows the system to run and continuously record data even when participants forget to charge it for 1 night. Further, reducing the GPS query frequency helps to reduce battery consumption. We set a 10-second interval for acquiring position data.

In addition to recording GPS position data, the app records physical motion using the 3-axis accelerometer. The physical motion data are added to the analysis pipeline and further improve data quality as they help to distinguish between motion and stillness. The sampling frequency was set to 1 Hz, which was found to be suitable for our purpose. The smartphone app

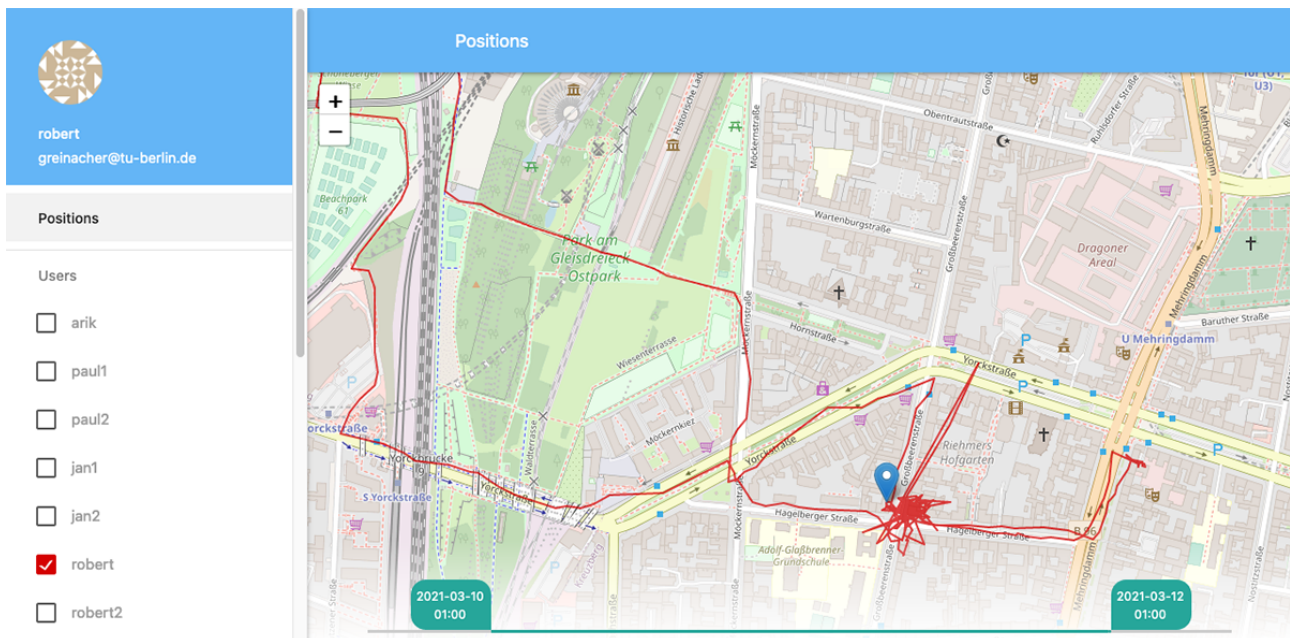
is free software under the GNU General Public License version 3.0.

Server Backend

The backend server is a dockerized Ruby on Rails app offering 2 main components. First, it acts as a backend for the smartphone and provides a REST API (representational state transfer application programming interface) to retrieve recorded data from the study smartphones once they are back in our laboratories. This communication is SSL (secure sockets layer) encrypted using Let's Encrypt certificates (Internet Security Research Group). As we provide the software in a dockerized format, researchers can deploy this backend quickly on their servers and need not rely on any third-party service. This way, we ensure compliance with local privacy policies.

The second component of the server app is a user interface for visualizing the raw records obtained from different users participating in the study (Figure 1). Here, users and time intervals can be filtered, visualized, and directly downloaded as a CSV (comma-separated values) file for further processing and analysis. This tool is particularly useful for visual feedback if data are received and if the selected time interval contains the expected information. Although this interface is potentially reachable from the internet, users need to authenticate themselves using the same credentials (username and password) needed to log-in to the mobile app. The server backend is free software under the GNU General Public License version 3.0.

Figure 1. Screenshot of the server components user interface. It provides a straightforward assessment of the raw records given by a user ID and a time interval.



Analysis Pipeline

The data analysis is provided as Python3 (The Python Software Foundation) libraries. Although fully featured GIS tools such as ArcGIS Pro (Esri) or QGIS (QGIS Development Team) exist, we decided to create a new analysis pipeline for faster batch processing up to several hundred study data sets. This streamlines the process and provides better accuracy, as we will demonstrate in the "Results" section.

The analysis is based on the Stop & Go Classifier, which identifies stop and trip intervals within the data set. As most mobility variables are based on this first distinction rather than raw GPS point clouds, this is the fundamental first step. For example, variables such as the number of "revisited places," "time out of home," or the "time spent in transit" can be directly constructed after an initial stop/trip interval detection. However, other metrics, such as the "perimeter of the convex hull," are

constructed based on individual GPS points instead of only a list of identified important locations.

Figure 2 visualizes the data flow through the analysis pipeline. First, the data are recorded on a mobile device and stored locally. Later, when securely connected to the internet, the mobile app copies the recorded data to our private cloud, the server app. The server securely stores all samples (GPS and accelerometer data) from all users over the entire study period. If necessary, this provides a central access point for analyses, even for multiple analysts. The third phase is data analysis. We first consult the study protocol to carve out the study period for each user precisely. This is a necessary technicality because we shipped the configured study smartphones to the participants via postal service for this study. As a result, the supplied phones often also recorded the shipping routes. Therefore, our participants were instructed to start using the phone 1 day after receiving it through the postal mail. Thus, for the analysis, it was necessary to trim the start and end dates of the recorded data according to the actual study dates. Using the correct study dates, we accessed the web server and downloaded only records in the interval of interest. The downloaded data contained raw

GPS and accelerometer samples and several status information of the recording device (eg, battery status and time stamps). In the preprocessing phase, basic filters are applied, such as removing duplicates and converting the accelerometer records into a motion score that describes the physical motion the recording device underwent at any given moment [20]. Lastly, the data are fed into the Stop & Go Classifier described earlier to identify trips and stops before the final set of features is extracted from all data available.

The analysis pipeline is designed in such a way that it reads a given CSV containing GPS and (optionally) accelerometry data, processes these, and outputs several result tables. These contain a list of all the important locations in a data set (ie, the stop intervals) and a detailed analysis of all variables of interest per day.

Table 1 provides a list of potential variables that may interest health researchers using the presented mobility analysis software framework. The list distinguishes variables based on all GPS samples and integrated variables built up using the stop/trip detection metrics.

Figure 2. Flowchart of the data acquisition, storage, and processing steps. The analysis phase consists of several subtasks to determine the correct study interval, preprocess the raw GPS (and accelerometer) records, run the stop/trip classification, and combine its results into a feature vector of the variables of interest. GPS: global positioning system.

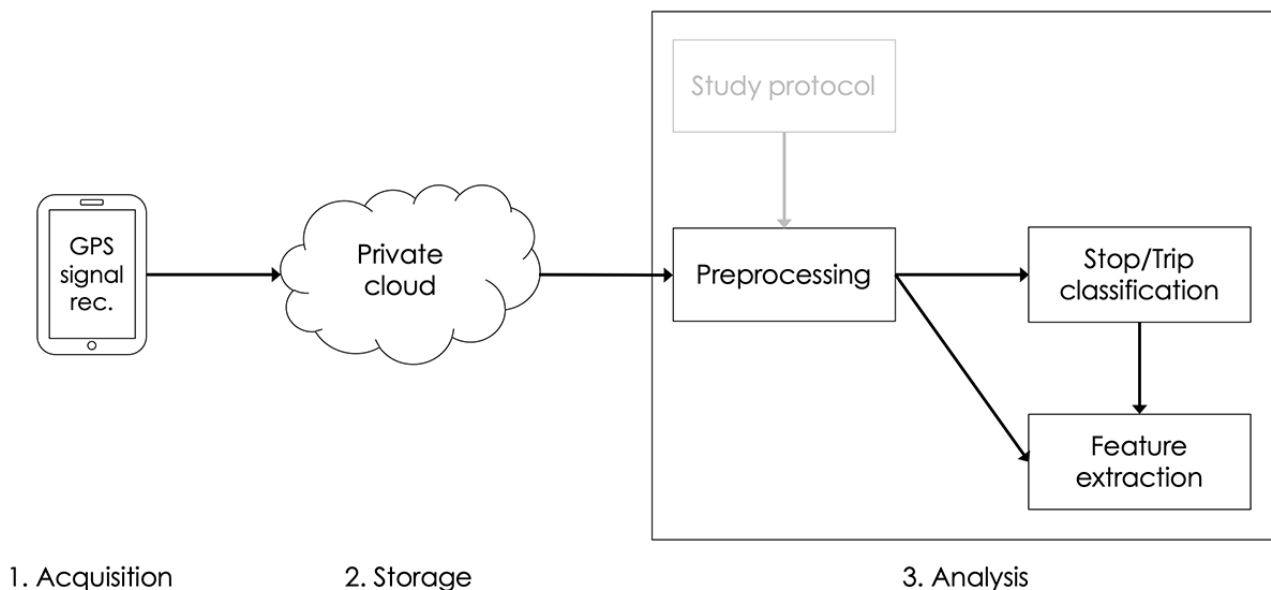
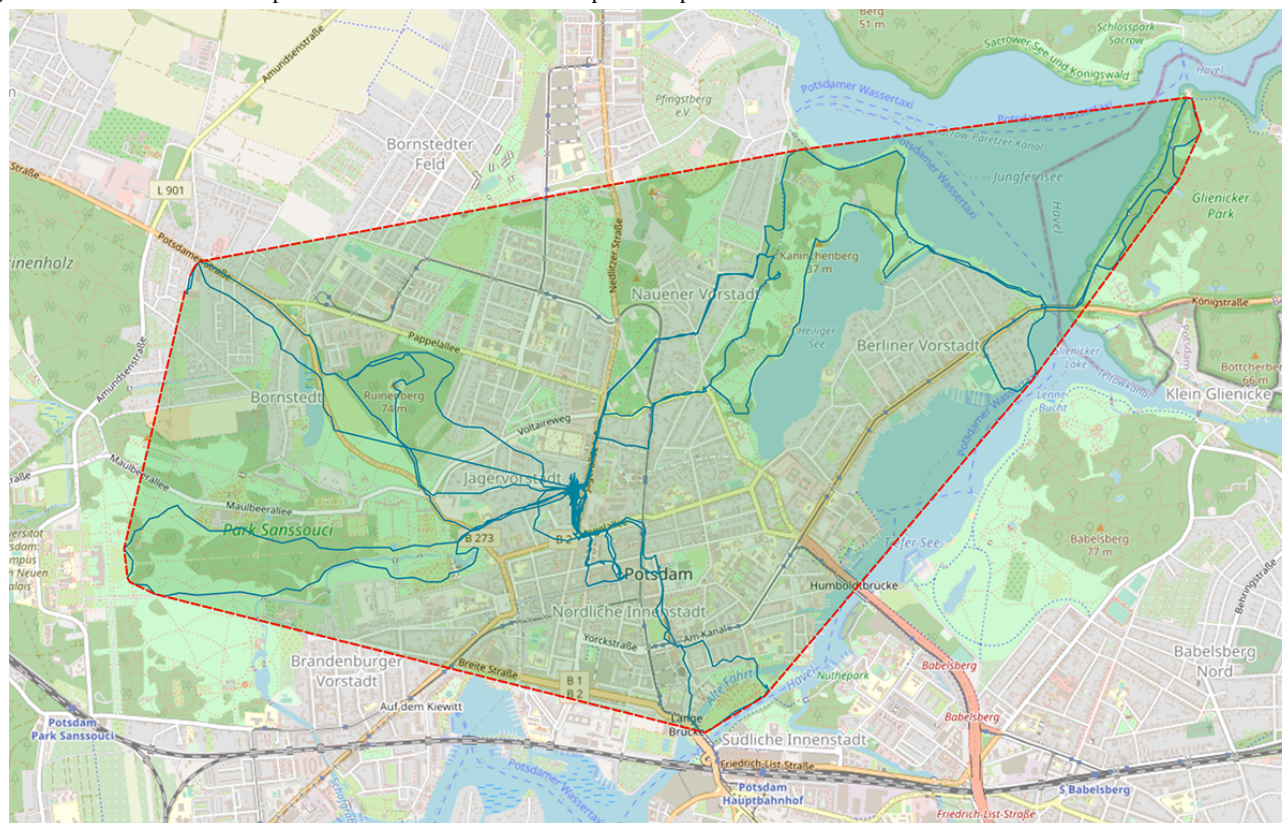


Table 1. A list of all measures observed and calculated from the raw GPS^a and acceleration data collected during the trial.

Source and variable	Description
Based on all samples	
Trip	Period of movement
Stop	>5 minutes at the same place (within a radius of 100 m)
Maximum distance from home (daily)	Maximum radius from home per day
Average distance from home (daily)	Average distance from home per day
Area standard ellipse (daily)	The minimum span ellipse that can fit all of the positions of the data set that is computed using a minimum covariance estimator [9,13,21]
Area convex hull (including perimeter, surface, compactness)	Life-space measure [13,22]; see Figure 3
Daily revisited life space %	Percentage of the daily convex hull that has overlap with any convex hulls of the other included study days
Average revisited life space %	Average percentage overlap of the daily convex hull with the convex hulls of the other included study days
Daily path area	Daily path area (DPA) is created by buffering each individual's GPS trip with a 200-m buffer zone, then dissolving all buffered trips into 1 polygon and removing bodies of water [16,23]
Based on stop/trip intervals	
Home	Home address, special case of stop
Number of locations (daily)	Stop counts per day
Number of revisited locations (daily)	Stop counts per day
Number of unique locations (daily)	Unique stop counts per day
Daily duration (daily)	Time out of home
Time on foot/bike	Total trip time done by foot/bike [13,24]
Time in vehicle	Total trip time done by car/public transport [13,24]
Average time at home (daily)	Average time spent at home [9]
Time of the day first move	Time of the day of first trip
Time most moved	Time of the day of most trips in the categories morning/noon/evening
Revisited paths %	Percentage of identical trips among all trips
Entropy in location	Entropy is a measure for time distribution over different stop locations. A higher entropy either indicates a more regular time distribution with a higher number of locations or a higher number of locations [7].

^aGPS: global positioning system.

Figure 3. Hull curve around the position records of the whole example time span.

Accuracy Evaluation Using a GPS Diary

To evaluate the validity of our analysis scripts, we conducted a field test dedicated to collecting GPS and acceleration data under realistic conditions and combined these data with a diary study. While the devices ran as we used them in the field (parameters described in the “The *GPS.Rec2.0* Mobile App” section), the diary contains changes of place, reference positions, and the beginning and ending of each stay. This way, we can compare the recorded data and their analysis with the ground truth of the testers involved. To obtain the most accurate reference data, we created a diary app (iOS app, run on iPhone XR) to log whenever a test person enters or leaves a position. This way, we can ensure precise tracking and digitally obtain time stamps and position data. For accuracy analysis, we focused on comparing exact timings of location changes, position deviations, durations of movement, and durations of dwell.

The diary contained 3 pieces of information per record: the beginning and end time of a stop, coordinates of the location (ie, longitude and latitude), and a reverse lookup address for easier identification of the samples. Position and time stamp are the only information we need to validate the automatic stop/trip detection of the GPS records.

Having stop intervals in the diary as ground truth, we labeled each GPS record from the mobile app as either “stop” or “trip.” Simultaneously, we ran the analysis pipeline to classify the raw, unlabeled GPS data set. This allowed us to obtain 2 sets of labels based on the diary and algorithmic analyses, which we can use to quantify the goodness of the classification.

Usability in a Sample of Community-Dwelling Older Adults

As the *GPS.Rec2.0* app is being used in the MOBILE study with older adults (age ≥ 75), handling of the smartphone and app was tested in a usability study with a convenience sample of 9 participants (6 women and 3 men that were between 71 and 83 years of age and lived in a rural area of Brandenburg, Germany). The sample size was oriented on similar studies such as that by Brusilovskiy et al [25], who used GPS technologies for community health engagement, or Price et al [26], who performed a validation study for different GPS devices. The usability study was conducted between July and September 2020 after the first wave of COVID-19 infections in Germany. During this time, restrictions on social contact were still high as no vaccination was available yet, and therefore all components of the usability study were accomplished without personal contact. Participants received the smartphone with an installed preversion of the *GPS.Rec2.0* app, study information, consent paper, and a postservice usability questionnaire (Multimedia Appendix 1).

In addition, they were contacted via telephone and informed about how to turn on the phone, ensure that the app was running, and sufficiently charge the battery by charging the smartphone overnight, as well as requested to take the smartphone with them on every trip outside for 7 consecutive days. For additional usability, smartphones were prepared with stickers indicating the needed functions (eg, where to charge the smartphone or how to turn it on). After the testing phase, participants sent back the phone, consent paper, and questionnaires. Further, they were interviewed about their experiences within a structured phone call. Data have been analyzed descriptively as well as with

content analysis. The content analysis categorizes interview content to examine patterns in communication in a noninvasive manner [27].

Ethical Approval

Ethical approval was obtained by the Charité Ethics Commission embedded in the broader MOBILE study with the case number EA1_052_20 on May 14, 2020. In the ethics statement the implementation of a pilot study, including GPS device testing, interviews, and questionnaires, was explicitly listed.

Results

Development of the App and Analysis Pipeline

All components were developed iteratively and tested regularly. Apart from feature tests, testing the integration between smartphones, backend, and analysis was most important during the development process. Over the entire development period, we implemented regular field tests to identify design or implementation issues early on. The final app can record large numbers of position samples over a long period, even without a stable connection to the synchronize destination/backend. The backend can synchronize multiple clients simultaneously and cope with intermittent uploads (eg, disrupted internet connection during the upload process). As a fallback strategy, the mobile app can export GPX (GPS Exchange Format) files of the recorded data. This covers severe problems with the syncing process without losing any data.

In addition, the mobile phone’s battery life lasted at least two days and presented itself as suitable for the study.

We developed the analysis pipeline simultaneously, allowing us to iterate fast and reproduce design decisions of the backend on the analysis pipeline (eg, functions to fetch data via APIs). Furthermore, this allowed us to test outcomes and quantify recording and analysis accuracies as soon as possible in the development process.

Accuracy Evaluation Using a GPS Diary

Over 4 months between October 2021 and May 2022, we recorded 692 stops using the GPS diary app (5.5 stops/day). During the same period, the *GPS.Rec2.0* app recorded 122,808 GPS samples (969.7/day; 1 every 89.1 seconds). This data set is publicly available. To compare the diary records with the results of our analysis pipeline, we used 2 approaches to quantify the system’s accuracy. Based on true positives (sample programmatically identified as a stop, which is a stop according to the diary), true negatives (sample identified as a trip and was recorded on a trip), false positives (identified as a stop but was a trip), and false negative (identified as a trip but was a stop), we analyzed balanced accuracy values (0.965) and F_1 -scores (0.975). Besides that, the system can correctly label 97.40% (119,614/122,808) of all samples.

While examining at the sample level is important to compare classification performance with other classifiers, it seems suitable to further examine analysis performance based on actual stop intervals—as these are the measure of interest at this stage. Furthermore, this allows the evaluation of systematic errors more easily than simple sample-by-sample comparisons. Hence, we aggregated the algorithmically obtained labels per sample to form intervals of stops and trips. Out of the 692 stops known to the diary, the system detected 667 stops; 97.3% (649/667) of these detected stops were identified correctly (corresponding to a similar time interval within the diary). The system, however, failed to identify 26 stops and 33 trips. Compared with the ground truth diary recordings, 19 diary stops were fragmented: a fragmented stop is detected as a set of several individual stops instead of 1 stop capturing the entire duration. This is an important metric, as many subsequent mobility assessment analyses buildup on these raw detected stops (eg, the average number of significant locations per day per person is computed using the total number of stops). Table 2 lists all relevant classification results of our accuracy substudy.

Table 2. Classification performance of our Stop & Go algorithm that was used to distinguish dwelling intervals (stops) from transit intervals (trips).^a

Performance	Stop & Go classification including motion score	Stop & Go classification without motion score
Correct, n/N (%)	119,614/122,808 (97.40)	118,865/122,808 (96.79)
Balanced accuracy	0.965	0.966
F_1 -score	0.975	0.966
Stop counts (system/dairy), n	667/692	708/692
Missed stops, n	26	26
Fragmented stops, n	19	43
Trip counts (system/dairy), n	667/691	708/691
Missed trips, n	33	28
Runtime (seconds)	33.12	49.31

^aOur algorithm can include accelerometer data to further refine results (ie, “motion score”); however, most conventional stop/trip classifiers do not offer such a feature. For better comparability with other systems, we reported results for both with and without accelerometer data.

Usability in a Sample of Community-Dwelling Older Adults

Results of the questionnaire are reported in [Table 3](#) and indicate that the smartphone was easy to integrate into the everyday life of the older adults interviewed. Participants reported little worries about data security or damage to the cell phone (8/9,

89%, fully agreed), followed by worries about battery level, damage, takeaway, and comprehensibility (6/9, 67%, fully agreed in all cases). In the qualitative interviews, participants described the need for a small belt bag to always carry the smartphone around, especially during summer activities such as gardening, shopping, or riding a bicycle.

Table 3. Questionnaire results of the usability substudy (n=9).

Variables	Disagree, n (%)	Rather disagree, n (%)	Somewhat agree, n (%)	Fully agree, n (%)
Joy: I enjoyed the 7 days of testing.	N/A ^a	N/A	5 (56)	4 (44)
Integration: The use of the GPS ^b device is easy to integrate into my everyday life.	N/A	1 (11)	3 (33)	5 (56)
Time and activity: While using the GPS device, I need more time for my daily activities outside the home.	4 (44)	1 (11)	3 (33)	1 (11)
Battery level: The battery level lasts long enough for everyday use.	N/A	1 (11)	2 (22)	6 (67)
Damage: I am afraid of damaging the GPS device.	6 (67)	2 (22)	1 (11)	N/A
Privacy: I think that my personal data collected with the GPS device are properly protected.	N/A	1 (11)	2 (22)	6 (67)
Takeaway: I always remember to take the GPS device with me when I leave the house.	N/A	1 (11)	2 (22)	6 (67)
Comprehensibility: The external labeling of the GPS device is easy to understand.	N/A	N/A	3 (33)	6 (67)
Charging: The GPS device is easy to charge.	N/A	1 (11)	N/A	8 (89)
Help: When problems occur with the GPS device, I know whom to contact for problem solving.	N/A	1 (11)	N/A	8 (89)
Usefulness: The data collected by the GPS device are useful for (health) science.	N/A	N/A	4 (44)	5 (56)
Time: Filling out the questionnaires took too much time.	5 (56)	1 (11)	2 (22)	1 (11)

^aN/A: not applicable (ie, no participant responded in the category).

^bGPS: global positioning system.

Discussion

Principal Findings

This study aimed to develop a smartphone-GPS-based system for mobility analyses in health research and to test this system for accuracy and usability. Based on the experience of expert and user stakeholders with the proposed system for assessing GPS, it shows great potential for app-based estimation of mobility in community-dwelling older people.

The main findings of this study are that the developed GPS-based system works well for mobility analyses as the app functions without technical difficulties and performed well even under suboptimal conditions. Furthermore, the algorithm achieves high accuracy and its usability was piloted with older adults, which demonstrated low barriers and easy implementation. The system includes the following: the *GPS.Rec2.0* app, a backend for centralized data storage, and an associated analysis pipeline for the automatized transformation of raw GPS data into predefined variables. The app showed good accuracy in the accuracy substudy with staff members and good usability in successive tests in the usability substudy,

which involved a sample of community-dwelling older adults living in a rural area.

The comparison between the system with and without the accelerometer data in [Table 2](#) shows the most dominant advantage in the fragmented stops metric. As the recording device's physical motion helps reduce the number of fragmented stops by more than half (43 vs 19), the number of identified stops is crucial for many mobility and daily activity indicators. Hence, reducing fragmented stops is an important objective, as fragmented stops artificially inflate the number of stops. Our system, the signal processing Stop & Go algorithm, helps to interpret GPS data more accurately. This component can be used independently from our other components, as it is released as a stand-alone open-source library [20].

Comparison With Prior Work

In terms of accuracy, our study showed good-to-very good stop/trip identification results, which are comparable with other studies investigating the accuracy in other systems (see Spang et al [28] for a comparison of algorithms). One key element of any mobility analysis system is the algorithm for classifying trips and stops, which is the foundation for further mobility analyses. In terms of performance, our system showed higher

accuracy, F_1 -score, more true stops and trips, and fewer false stops and trips than similar systems (MovingPandas and scikit-mobility). Although our system outperformed the reference systems in most areas, the number of missed trips was detected better using MovingPandas. Concerning the usability of the system, most participants indicated that the system is easy to implement in everyday life, which is in line with findings from other GPS usability studies in diverse urban adults [19] showing high levels of GPS acceptability and usability as well as low levels of wear-related concerns. Likewise, a study on patients with cardiac issues from urban and rural areas found low barriers and high ease of use; however, especially in rural areas, the periodic signal interruption was reported [29]. Thus, our approach provides a feasible tool not only in urban but also in rural areas and for older adults who are often excluded from GPS studies.

Strengths and Limitations

This study has several strengths, including the mixed methods stepwise approach across substudies and the innovative system pipeline. However, some limitations need to be considered when interpreting these findings. First, although we developed an open-source system ready to use, performing a new study would require considerable resources and technical know-how. We tried to mitigate this by providing detailed descriptions about the source codes' repository websites. This should make it easier to adapt the tools we developed to new research projects and swiftly test ideas. Second, we presented high levels of accuracy. Nonetheless, misclassifications occurred, and thus, in the future further algorithms are necessary to improve the classification performance even further. We are actively developing the classification module of the described system as a separate open-source contribution. As such, we are working on parameter tuning tools to provide easy and flexible setups, even for sensors or sampling rates different from what we used. This should further improve the reliability of the described toolchain. Third, we tested the usability in community-dwelling older adults; thus, although the system is quite generic and can likely be applied to a variety of settings and populations, we cannot rule out any usability issues in other populations. Future studies should test the system's usability in other health contexts and cohorts, including urban areas or outpatient rehabilitation setting and the labor force or students.

Two main advantages lie within our system. First, the app was constructed for offline use, which has several positive attributes (ie, longer battery life, high data protection, no live-tracking

possible), and thus has benefits over commercial GPS apps that include mobile data. The second advantage is that the open source development of the app includes the hosting of data on university servers rather than relying on existing commercial systems (eg, Qstarz or Garmin Forerunner; compare [15] with potential limitations to data protection). It ensures maximum data and privacy security and lets scientists alter the system architecture if necessary.

Although this proposed system was developed for the use case in health research with older adults, we assume that our systems also work well in different study populations such as schoolchildren or people with impairments. Furthermore, we believe our system is suitable for various study designs, such as observational or interventional studies.

Code Availability

The *GPS.Rec2.0* app [30] is available as free software under a GNU General Public License version 3.0. The backend component [31] for storing, visualizing, and accessing recorded position and accelerometer samples of the *GPS.Rec2.0* app is also available.

The classification component of the analysis pipeline is available as an independent component, the Stop & Go Classifier. It is free software under a BSD 3-Clause license.

The test data set [32], used to evaluate the classification data set, was recorded using the described *GPS.Rec2.0* app. The data set contains GPS and acceleration records as well as stop/trip annotations. It is publicly available at the Open Science Framework under a CC-BY Attribution 4.0 International license.

Future Directions and Conclusions

In future GPS-based health studies, the system and its algorithms should be evaluated in a clinical study and analyzed with respect to clinical, subjective, and behavioral measures. We explicitly see potential for use in interventional studies, as it is a great tool to evaluate interventions that, for instance, focus on promoting out-of-home mobility, fostering new routines, changing mobility habits, or following patients after cardiac rehabilitation. As an individualized/tailored approach is used often (compare [33,34]), we believe it is possible to develop our system even further and add live feedback options for the user. Overall, GPS-based measurements can add great value to various study designs and populations and should be considered and examined more often in health research.

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Authors' Contributions

RPS developed and designed the *GPS.Rec2.0* app, the analysis pipeline, and the diary app. RPS shaped the first draft and provided the tables and figures. SAM conducted the interviews and the analysis. CH, SAM, MB, JNVA, and PG made substantial suggestions to qualify the draft further. All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire assessing usability of the GPS device. GPS: global positioning system.

[[DOCX File , 152 KB - rehab_v10i1e42258_app1.docx](#)]

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Abbreviations

CSV: comma-separated values

DPA: daily path area

GDPR: General Data Protection Regulation

GIS: geographic information system

GPS: global positioning system

GPX: GPS Exchange Format

MOBILE: Mobility in old age by integrating health care and personal network resources in older adults living in rural areas (research project name)

REST API: representational state transfer application programming interface

SSL: secure sockets layer

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Original Paper

Clitoral Therapy Device for Alleviating Sexual Dysfunction After Female Genital Mutilation: Randomized Controlled Trial

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Abstract

Background: Female genital mutilation is considered a crime but is still practiced today in Africa and the Middle East, despite all the laws that make this procedure illegal due to the long-term physical and psychological harm it causes to women. Millions of girls and women living today have undergone genital mutilation, which involves removing the external female genitalia either partially or totally, based on the belief that it restricts feminine sexuality, thereby “saving” a girl for marriage. For girls and women, the surgery offers no health advantages. Girls’ right to control critical decisions regarding their sexual and reproductive health is violated because genital mutilation is frequently done against their will and frequently without their consent, leading to lifelong psychic trauma in addition to sexual dysfunction and lack of satisfaction due to distortion of the genitalia that threatens marital stability.

Objective: To determine the effect of a clitoral therapy device on improving sexual domains in women suffering from sexual dysfunction after female genital mutilation.

Methods: This study examined 80 married women aged from 20 to 45 years who were referred from the gynecology outpatient clinic of the Faculty of Medicine, Suez University, for sexual dysfunction resulting from female genital mutilation. The women were divided into 2 equal groups: the study group received a clitoral therapy device and traditional psychosexual education and were closely followed for 3 months, while the control group received only traditional psychosexual education for 3 months. The Arabic version of the Female Sexual Function Index (FSFI) questionnaire was used to assess sexual outcomes pre- and posttreatment in the 2 groups.

Results: Our findings revealed a significant increase in the 6 domains of the FSFI pretreatment in both groups compared to posttreatment ($P > .001$), except the orgasm domain in the control group, which showed only a nonsignificant increase ($P = .16$).

Conclusions: Clitoral therapy devices may be an effective, safe, noninvasive rehabilitation method for sexual dysfunction following female genital mutilation.

Trial Registration: ClinicalTrials.gov NCT05039775; <https://clinicaltrials.gov/ct2/show/NCT05039775>

KEYWORDS

female genital mutilation; FGM; clitoral therapy device; CTD; Eros device; sex therapy; Female Sexual Function Index; FSFI; Middle East; psychological; sexual; women; sexual dysfunction

Introduction

The Eros Clitoral Therapy Device (CTD; UroMetrics, Inc) represents a nonpharmacological technique to promote clitoris engorgement causing sensory nerve ending stimulation. This could be advantageous for a wide population of women suffering from dysfunction in their sexual relations, such as the ability to reach orgasm to nearly full satisfaction. It is a compact, handheld medical gadget with a vacuum-type vibrator manufactured of soft plastic with an appropriate cap size to cover the clitoris; it resembles a computer mouse [1]. It enhances blood flow to the clitoris by gently sucking the clitoris and the surrounding region. Blood is drawn into the clitoris by this suction, resulting in clitoral and later vaginal vascular engorgement, which increases vaginal lubrication and, as a result, stimulates sensory nerve endings. This enhances the female reaction by boosting blood flow to the clitoris and external genitalia, which facilitates reaching orgasm as vaginal lubrication is improved after using the device [1,2].

The anatomical basis for this orgasm-promoting platform is ultimately provided by vascular congestion of the genitalia, which leads to the physiological expression of the orgasmic experience. Before and during the application of the CTD, physiological examinations of clitoral and vaginal blood flow reveal a significant increase in blood velocity in these areas [2,3].

This clitoral engorgement contributes to female sexual arousal and satisfaction. It causes sensory and vasomotor nerve endings to fire, which helps with genital feeling and triggers somatic and autonomic reactions that promote arousal (ie, enlargement of the genitalia and lubrication) and thus orgasm, in addition to contributing to an early female sexual response, thereby boosting libido in women who have low desire due to decreased vaginal lubrication. This can be achieved during the use of Eros-CTD, as the woman can regulate the level and time of vacuum, which can be kept either constant or rapidly modulated according to her choice [3,4].

The Eros-CTD has been certified by the US Food and Drug Administration (FDA) for promoting female sexual function by improving orgasm quality (ie, the regularity of orgasm by direct clitoral stimulation) [3,5,6].

Without direct clitoral stimulation in intercourse, around one-third of all women reach orgasm, as most women report that they use clitoral and vaginal stimulation with their partners to experience orgasm during vaginal penetration; when underlying parts of the clitoris are stimulated, women are better able to raise their sexual excitement [7,8].

Regarding female sexual arousal disorder, small nonblinded investigations have demonstrated that using the Eros-CTD device increases blood flow to the pelvis, vagina, and clitoral

region, which may dramatically enhance arousal, orgasm, and general satisfaction; for patients who prefer to avoid using pharmaceuticals or hormonal therapy, this procedure offers a successful, safe option [9].

In individuals with female sexual dysfunction who are free of cancer, the CTD has demonstrated great promise; among 32 participants who were included in a previous study, 20 had female sexual dysfunction and 12 did not. The patients with female sexual dysfunction reported more genital sensation, vaginal lubrication, orgasm ability, and sexual satisfaction after using the CTD for 3 months. All investigated domains showed gains in people without female sexual dysfunction, as well [10].

Individuals who have female sexual dysfunction and may benefit from Eros-CTD include victims of female genital mutilation (FGM). Most Middle Eastern women and women living in various regions of Africa refer to FGM or cutting as “sunna” or “pharaonic circumcision.” This surgical procedure has a profound impact on the lives of women and girls, as it hinders their psychological and physical health through anatomical alteration and chronic urogenital infection, resulting in loss of libido, arousability, and orgasm; therefore, it is currently considered a serious topic and has turned into a major global political issue [11]. FGM is classified into 4 types according to the World Health Organization (WHO): removing the prepuce with or without some or all of the clitoris is type I; removing the clitoris and partially or totally cutting the labia minora is type II; partial or total cutting of the external genitalia and decreasing the diameter of the vaginal opening is type III; clitoral or labial stretching or incision, cauterization of the clitoris and surrounding tissue by burning, tightening the tissues that surround the vaginal orifice, vaginal cutting, and introducing destructive materials such as herbs inside the vagina to cause bleeding to tighten the vaginal opening are examples of FGM type IV [12].

Despite the Egyptian High Court’s 1997 ban on the surgery, Egypt has the highest percentage of women who have undergone FGM in the world [13]. Nevertheless, Egyptian women believe they are entitled to sexual pleasure to the point that their husbands are unable to satisfy their wives sexually, which is highly dangerous to men in Egyptian culture [14]. FGM victims have unique medical, gynecological, obstetric, and psychological issues that physicians and medical staff are typically unable to handle, which is aggravated by the procedure’s illegality. The most common issue is sexual-function impairment, which can be caused by psychological trauma, scar tissue development, or partial nerve injury [15].

Disrupted sexual function with all types of FGM includes decreased vaginal secretion during intercourse, discomfort, decreased sexual satisfaction and desire, orgasm latency, and anorgasmia. Scarring, pain, and unpleasant memories linked to FGM can all contribute to these issues. Sexual dysfunction in

men was also documented in a previous study conducted among women in Sudan, where type III FGM is the most common, due to male bodily discomfort when engaging in sexual activity, sex causing pain in the spouse, and marital conflict [16].

Many interventions based on psychotherapy, assistive technologies such as clitoral therapy devices and mechanical vibrators, and exercises for therapeutic purposes have been successfully used in the management of female sexual dysfunction with no known negative consequences [17].

Mechanical vibrators are intended to elicit clitoral engorgement for treating orgasm and arousal issues. Primary and secondary anorgasmia have been successfully treated with mechanical vibrators, particularly when they are paired with psychological counselling; clitoral vacuum engorgement devices like Eros-CTD engage the clitoris using a gentle vacuum and work even when there are damaged blood vessels [18].

Patients using the InterStim Therapy Device, which causes stimulation of sacral nerves S2 to S4 to manage urinary incontinence, have reported enhancement of sexual arousal and orgasm after its application; this inspired its use for sexual arousal and orgasm disorder in women [19].

Other management protocols have been used to address sexual dysfunction in women, such as cognitive behavioral therapy and “simmering,” which involves reading sexual or educational literature, watching romantic and exotic media, keeping a journal about fantasies and sex, and focusing attention on sex. Another protocol is sensate focus: this additional therapy entails the couple committing to weekly sessions of love play, which involves guidelines for graduating from nongenital touch and excitement to genital play and intercourse. Pelvic floor rehabilitation is used to treat pain during sexual intercourse, as it may improve genital blood flow [20].

Also, topical medicines for managing dyspareunia have been applied to the vulvar or vaginal area, including topical lidocaine, which can be administered on a regular basis or used as postcoital analgesic. In addition, the off-label intravaginal use of topical diazepam has been reported to decrease pain during sexual intercourse [21].

Psychosexual support has been used to treat female sexual dysfunction symptoms by lowering anxiety levels and improving sexual skills through a variety of techniques, such as good communication, listening skills, emotion and perception expression, and conflict resolution [22]. Psychosexual support and sex education have already been identified as being successful for managing sexual dysfunction in both men and

women. Short-term psychotherapy principles are followed in treatment, with specialists and patients working on specific concerns in an individual, couple, or group setting. Reinforcement, interpretation, challenge, cognitive reframing, and home practice are among the basic psychotherapy strategies traditionally used in sex therapy protocols [23]. Therefore, this study was designed to determine the effectiveness of Eros-CTD for treatment of female sexual dysfunction symptoms that result from FGM as a complement to traditional psychosexual education.

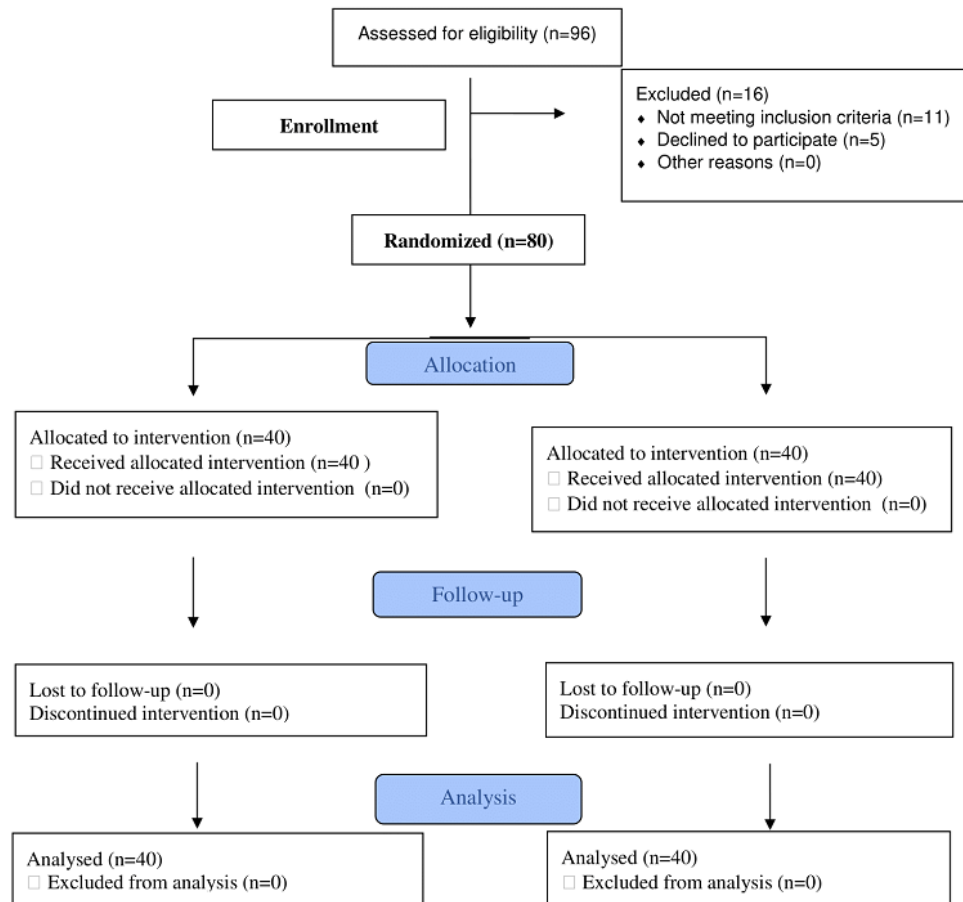
Methods

Subjects

This study included 80 married women aged from 20 to 45 years who were suffering from sexual dysfunction in more than one sexual domain (arousal disorder, orgasm disorder, or both). All participants were diagnosed with sexual dysfunction resulting from a history of type 1 FGM (clitoridectomy) [24]. The participants had sexual desire, were comfortable with the ideas of self-stimulation and psychosexual support, and were medically stable. All included participants were referred from the gynecology clinic of the Faculty of Medicine, Suez University, to the outpatient clinic of the Faculty of Physical Therapy, Badr University, located in Cairo, to receive clitoral therapy intervention and psychosexual education sessions between September 2021 and December 2021. Each participant underwent a detailed medical history assessment and an examination of the pelvis. Participants were excluded if they had metastases, bladder or bowel disorder, or major complications of any disease; a history of female sexual disease or sexual assault; or were using antidepressant medications.

Design

This was a double-blinded randomized controlled trial that used a validated, reliable questionnaire. Subjects were randomly divided into 2 equal groups in a prospective outcome registry. The design of this study is shown as a flow chart in Figure 1. A randomized computer-generated table of letters was constructed prior to the commencement of data collection by a researcher who was not involved in recruiting or managing patients. The study groups were then assigned at random using individual, sequentially lettered index cards. The index cards were folded and stuffed into opaque envelopes that were then sealed. Unaware of the baseline assessment results, a different researcher then opened these envelopes and began therapy based on the group's task. Each participant was given either the letter A or B in the sealed envelope.

Figure 1. Flowchart of study design.

Ethical Considerations

The study was approved by the Ethical Review Committee of the Faculty of Physical Therapy, Cairo University (P.T. REC/012/003189). This study was conducted according to the ethical guidelines of the 1964 Declaration of Helsinki and 1975 Declaration of Tokyo. It was carried out in a transparent manner, presented according to the CONSORT (Consolidated Standards of Reporting Trials) criteria, and registered at ClinicalTrials.gov (NCT05039775). After inclusion, all patients provided informed consent in the Arabic language before participation.

The privacy and confidentiality of the participants were achieved by keeping their signed informed consent forms in a locked file inside a locked locker. Participants' personal data that were recorded on computer were kept in a secured file with a strong password that was not shared. The subjects received compensation in the form of the Eros-CTD itself and transportation to the outpatient clinic of the Faculty of Physical Therapy on buses provided by Badr University.

Treatment

The Female Sexual Function Index (FSFI) questionnaire was used to assess all participants before and after therapy. The FSFI was created to assess sexual function in women who have engaged in sexual activity in the preceding 4 weeks. Validation research for the FSFI revealed that it had a sensitivity and specificity cutoff score of 26.55 to identify women with

dysfunction in sexual activity. It has been shown to be effective in both healthy and chronically ill women [25].

The FSFI has been translated into over 20 languages, becoming the gold standard in assessing female sexual dysfunction (FSD) and an essential instrument in FSD clinical studies. The Arabic version of the FSFI is a locally approved, validated, and reliable tool for assessing FSD in the Egyptian community. Desire, arousal, lubrication, orgasm, pleasure, and pain are the 6 dimensions of FSD quantified by this 19-item, multidimensional, self-reported scale [26,27].

All participants filled out the Arabic FSFI in an examination room before starting treatment. A physiotherapist checked the questionnaires to make sure that all questions were filled in (to avoid overlooking questions). The participants were then asked to fill out the questionnaire again after 3 consecutive months of regular treatment [28].

Both groups in this study received traditional psychosexual education at the outpatient clinic of the Faculty of Physical Therapy, Badr University, under supervision of a psychiatry consultant. Psychoeducation included educating the patients and their partners on the stages of sexual arousal before orgasm and giving them tips and techniques to be applied at home based on the work of Masters and Johnson; this protocol, which depends on masturbation, is still the most common way of treating sexual problems and the most effective treatment to date for lifelong lack of orgasm in women. Patients were encouraged to gradually follow certain steps: first, to stroke the

full body outside the genital areas; second, to learn how to change between active and passive positions and massage the body and genital areas using hand stimulation; and third, the woman inserted the penis into the vagina and the couple experimented with different sex positions. The participants applied these steps and returned weekly with their feedback to the therapist [10,22,28].

In addition, participants in the study group used the Eros-CTD and were closely followed for 3 months. A female physiotherapist gave direction on the use of Eros-CTD therapy after enrollment. The mechanism of regulating and tuning the vacuum to the participants' personal comfort level was explained to them before they were invited to try using the device for 5 to 10 minutes in the examination partition. The female physiotherapist returned to the partition after this quick practice session to answer any queries and undertake a quick external genital assessment. Participants were instructed to apply the equipment alone or with a partner in the privacy of their own house. Participants modified the vacuum intensity after applying the equipment to the clitoris for a duration based on their comfort and arousal throughout the first 3 home sessions. They repeated the vacuum application 4 times weekly for 3 consecutive months for a total of 5 to 15 minutes of continuous application or 30 minutes of intermittent application. Each participant was asked to record any changes in sexual experience, such as labial engorgement, orgasm, and lubrication, during the first 3 sessions. Participants were contacted by phone

to discuss their progress and any positive or negative changes [2].

Statistical Analysis

The sample size was calculated based on pilot study conducted with 16 subjects. We estimated that a minimum proper sample size of 40 subjects in each group was necessary to reject the null hypothesis with 80% power at the $\alpha=.05$ level with an effect size of 0.68 using a 2-tailed Student *t* test for independent samples. Calculation of sample size was performed with G Power (version 3.0.11; Vanderbilt University). A comparison of subject characteristics between the groups was performed using an unpaired 2-tailed *t* test. All domains of the Arabic FSFI, including desire, arousal, lubrication, orgasm, satisfaction, and pain, were compared between groups with the Mann-Whitney *U* test; within-group pre- and posttreatment comparisons were made with the Wilcoxon signed rank test. The significance level was set at $P<.05$ for all statistical tests. SPSS (version 26; IBM Corp) was used for statistical analysis in this study.

Results

Demographics

The Levene test for equality of variance was performed and showed that data were normally distributed. Table 1 shows participant characteristics for both groups. There were nonsignificant differences between the groups in mean age, weight, height, and BMI ($P>.05$).

Table 1. Participant characteristics.

	Study group, mean (SD)	Control group, mean (SD)	Mean difference	<i>t</i> (df)	<i>P</i> value
Age (years)	33.07 (7.21)	32.92 (7.27)	0.40	0.24 (78)	.81
Weight (kg)	61.34 (5.40)	59.72 (4.36)	1.62	1.47 (78)	.14
Height (cm)	162.93 (5.35)	163.70 (4.54)	-0.63	-0.56 (78)	.57
BMI (kg/m ²)	22.78 (1.17)	22.44 (1.04)	0.33	1.36 (78)	.18

Effect of Treatment on All Domains of the Arabic FSFI

Within-Group Comparisons

There was a significant increase in all 6 domains of the Arabic FSFI from pre- to posttreatment in both groups ($P>.001$), except in the orgasm domain in the control group, which showed a nonsignificant increase compared with pretreatment ($P=.16$), as presented in Table 2.

Between-Group Comparisons

There were nonsignificant pretreatment differences between groups ($P>.05$). A posttreatment comparison of the study and control groups indicated a significant rise in all domains of the Arabic FSFI in the study group compared with the control group ($P<.05$), as presented in Table 2.

Table 2. Within-group and between-group comparison of the Arabic version of the Female Sexual Function Index domains.

	Study group	Control group	<i>U</i>	<i>P</i> value
Desire domain				
Pretreatment score, median (IQR)	1.2 (1.2-2.4)	1.8 (1.2-2.4)	-0.445	.66
Posttreatment score, median (IQR)	4.8 (3.6-4.8)	1.2 (1.2-2.4)	-7.645	<.001
<i>Z</i>	-5.430	-2.236		
<i>P</i> value	<.001	.03		
Arousal domain				
Pretreatment score, median (IQR)	0 (0-1.2)	1.2 (0-1.2)	-1.279	.20
Posttreatment score, median (IQR)	3.6 (2.4-3.6)	0 (0-1.2)	-7.281	<.001
<i>Z</i>	-5.455	-2.449		
<i>P</i> value	<.001	.01		
Lubrication domain				
Pretreatment score, median (IQR)	1.2 (0-1.2)	1.2 (0-1.2)	-0.224	.82
Posttreatment score, median (IQR)	4.8 (3.6-4.8)	0 (0-1.2)	-7.902	<.001
<i>Z</i>	-5.670	-2.236		
<i>P</i> value	<.001	.03		
Orgasm domain				
Pretreatment score, median (IQR)	0 (0-0)	0 (0-0)	0.0	>.99
Posttreatment score, median (IQR)	1.2 (1.2-3.6)	0 (0-0)	-7.806	<.001
<i>Z</i>	-5.431	-1.414		
<i>P</i> value	<.001	.16		
Satisfaction domain				
Pretreatment score, median (IQR)	0 (0-1.2)	0.6 (0-1.2)	-0.668	.51
Posttreatment score, median (IQR)	3.6 (2.4-3.6)	0 (0-1.2)	-7.458	<.001
<i>Z</i>	-5.601	-2.00		
<i>P</i> value	<.001	.046		
Pain domain				
Pretreatment score, median (IQR)	0 (0-1.2)	1.2 (0-1.2)	-0.315	.75
Posttreatment score, median (IQR)	3.6 (2.4-3.6)	0 (0-1.2)	-7.749	<.001
<i>Z</i>	-5.586	-2.236		
<i>P</i> value	<.001	.03		

Discussion

Principal Findings

The purpose of this study was to determine the effectiveness of the Eros-CTD as a supplement to traditional psychosexual education on female sexual dysfunction resulting from FGM among married women in Egypt. Our findings illustrated that when compared to traditional sex therapy alone, this electrical modality may have a substantial effect on all sexual-function elements. There was a significant rise in the 6 domains of the Arabic FSFI from pre- to posttreatment ($P > .001$), except the orgasm domain in the control group, which showed a nonsignificant increase compared to pretreatment ($P = .16$).

Comparison to Prior Work

The study population was selected with reference to a prior study, conducted in 2003, of 7 patients with sexual arousal disorder who had normal hormone levels at the time of the study. The 7 respondents were able to use the equipment with ease and noted minor to modest pleasure and being able to reach orgasm at home with no negative side effects. That study revealed that using the Eros-CTD induced a significant increase in the diameter of the clitoral and corpus spongiosum and increases in the peak systolic and end-diastolic velocity values in the clitoral and corpus spongiosum; all factors improved in the orgasm domain, in agreement with the results of our study [29].

In another previous study, conducted by Schroder et al [2], patients with sexual dysfunction induced by radiation therapy used the Eros-CTD 4 times weekly for 3 consecutive months for the purpose of self-stimulation and passion foreplay for 15 to 30 minutes intermittently. Improved vaginal mucosal coloration, hydration, and elasticity were found during gynecologic exams after 3 months of treatment, showing enhancement in all aspects assessed by the sexual function assessment instruments; this also supports the results of our study [30,31].

To ensure the safety of the therapy, we chose the Eros-CTD manufactured by Uro-Metric, because it is approved by the FDA and is intended to promote excitement by gently suctioning blood flow to the clitoris. Two earlier short-term trials found that CTDs help women with sexual arousal disorder and decreased lubrication, and hence may reduce dyspareunia linked with diminished desire, corroborating the findings of this study [6,32-34].

Another study, conducted among 57 women with spinal cord injuries resulting in altered sexual response and decreased sexual arousal, examined the effect of vibratory stimulation on arousal as measured by the pulse amplitude of the vagina. Forty-six women with spinal cord injury and 11 nondisabled women in a control group were included. In both groups, stimulation of the clitoris by vibration resulted in higher pulse amplitude of the vagina as compared to manual clitoral stimulation, which corresponds to the findings of this study [35].

Among studies of different types of disorders, a previous study conducted among women with diabetes and arousal or orgasm disorders concluded that they could benefit from the FDA-approved Eros-CTD, as it increased genital blood circulation and improved the sensitivity of the genitalia; these results also confirm our study's findings [36].

Women with hypoactive sexual desire disorder can use nonpharmacological modalities like sex psychotherapy, vaginal dilators, and, if they have arousal or orgasm disorder, Eros-CTD equipment, according to the recommendations of the Association of Reproductive Health Professionals, which supports the idea of using these modalities with FGM patients [37].

Previous studies have shown that sex therapy, in comparison with other forms of psychosexual support therapy, appears to be more effective and faster for treating various problems related to sexual function and life and had a positive impact. However, some of the past literature does not show that sex therapy is effective for all sexual disorders observed in therapeutic settings; this corresponds to the outcomes of our study to some extent, as the control group who only received sex therapy showed improvement in all sexual domains except orgasm [22].

A previous study conducted among women with multiple sclerosis who had sexual dysfunction due to neural defects, decreased self-confidence, and depression revealed that these patients were sensitive to clitoral vibration, suggesting clitoral vibrators can be used for diagnosing sexual dysfunction in women with multiple sclerosis; this may be due to the vibratory sensation being mediated by large diameter nerve fibers that connect from the periphery to the center through the dorsal columns, which serve as the natural mediators of sexually induced sensations. This supports and explains the results of this study and the effectiveness of the Eros-CTD in improving sexual domains in women with sexual dysfunction due to FGM [38].

Another study conducted among 19 women who used clitoral vibration for the first time in their lives (once weekly for 1 month) found changes in the pattern of orgasm, supporting the idea that the Eros device can improve orgasm, which agrees with the results of this study [39].

Strengths

This study had many strengths. First was the availability of a valid and reliable Arabic questionnaire to assess the outcomes of the study. Second was the availability of a validated and reliable portable Eros device that is FDA approved. Third, the data were easily analyzed, as they were precise. Fourth, the selection process was well designed, and we selected subjects from different reproductive ages so that we could obtain a representative sample of the population, which made our findings generalizable.

Limitations

The first limitation of this study was the restricted sample size and sample availability; although FGM is a very common procedure among Arabic women, these women often do not have enough courage to face the resulting sexual problems and discuss them with the appropriate specialists. This is because of old Eastern traditions and customs that place blame on married women who discuss or complain about any sexual problems in their relationship with their husband. Second, there was uncertainty among our participants on how to correctly practice psychosexual education during intimate relations.

Conclusions

The results obtained in this study lead us to conclude that CTDs may be a safe, effective, reasonably priced modality that can be used to enhance sexual domains in women who suffer from sexual dysfunction in one or more sexual domains as a result of FGM.

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Data Availability

The data sets generated during and/or analyzed during the current study are not publicly available to ensure the privacy of our patients, but are available from the corresponding author on reasonable request.

Authors' Contributions

HRS and RHA conceptualized and designed the study; YAA assessed and referred all participants and analyzed the data; HRS, MHEE, and MAG prepared the manuscript; RAE and WOAE-K wrote sections of, revised, and edited the manuscript; and RMK and HRS applied the intervention methods. All authors approved the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT checklist.

[\[PDF File \(Adobe PDF File\), 125 KB - rehab_v10i1e43403_app1.pdf\]](#)

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Abbreviations

- CTD:** clitoral therapy device
- FDA:** Food and Drug Administration
- FGM:** female genital mutilation
- FSFI:** Female Sexual Function Index
- WHO:** World Health Organization

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Original Paper

Prediction of Physical Activity Patterns in Older Patients Rehabilitating After Hip Fracture Surgery: Exploratory Study

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Abstract

Background: Building up physical activity is a highly important aspect in an older patient's rehabilitation process after hip fracture surgery. The patterns of physical activity during rehabilitation are associated with the duration of rehabilitation stay. Predicting physical activity patterns early in the rehabilitation phase can provide patients and health care professionals an early indication of the duration of rehabilitation stay as well as insight into the degree of patients' recovery for timely adaptive interventions.

Objective: This study aims to explore the early prediction of physical activity patterns in older patients rehabilitating after hip fracture surgery at a skilled nursing home.

Methods: The physical activity of patients aged ≥ 70 years with surgically treated hip fracture was continuously monitored using an accelerometer during rehabilitation at a skilled nursing home. Physical activity patterns were described in our previous study, and the 2 most common patterns were used in this study for pattern prediction: the upward linear pattern ($n=15$) and the S-shape pattern ($n=23$). Features from the intensity of physical activity were calculated for time windows with different window sizes of the first 5, 6, 7, and 8 days to assess the early rehabilitation moment in which the patterns could be predicted most accurately. Those features were statistical features, amplitude features, and morphological features. Furthermore, the Barthel Index, Fracture Mobility Score, Functional Ambulation Categories, and the Montreal Cognitive Assessment score were used as clinical features. With the correlation-based feature selection method, relevant features were selected that were highly correlated with the physical activity patterns and uncorrelated with other features. Multiple classifiers were used: decision trees, discriminant analysis, logistic regression, support vector machines, nearest neighbors, and ensemble classifiers. The performance of the prediction models was assessed by calculating precision, recall, and F_1 -score (accuracy measure) for each individual physical activity pattern. Furthermore, the overall performance of the prediction model was calculated by calculating the F_1 -score for all physical activity patterns together.

Results: The amplitude feature describing the overall intensity of physical activity on the first day of rehabilitation and the morphological features describing the shape of the patterns were selected as relevant features for all time windows. Relevant features extracted from the first 7 days with a cosine k-nearest neighbor model reached the highest overall prediction performance (micro F_1 -score=1) and a 100% correct classification of the 2 most common physical activity patterns.

Conclusions: Continuous monitoring of the physical activity of older patients in the first week of hip fracture rehabilitation results in an early physical activity pattern prediction. In the future, continuous physical activity monitoring can offer the possibility

to predict the duration of rehabilitation stay, assess the recovery progress during hip fracture rehabilitation, and benefit health care organizations, health care professionals, and patients themselves.

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KEYWORDS

continuous ambulatory monitoring; physical activity; pattern prediction; older patients; hip fracture rehabilitation; wearable sensing

Introduction

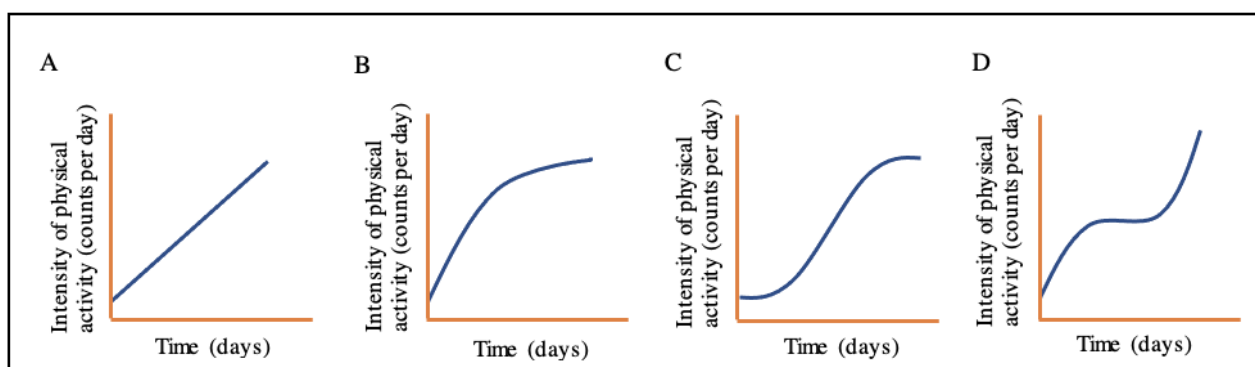
Physical activity is an important aspect in an older patient's rehabilitation process after hip fracture surgery. Being physically active during rehabilitation results in faster improvement of mobility, faster independency in activities of daily living, and higher confidence in walking earlier in rehabilitation [1-5]. Continuous monitoring of physical activity during hip fracture rehabilitation can be used to assess how older patients progress in their physical activity over time [6,7]. Insights into an older patient's physical activity progress is considered highly relevant, since this information can be used for a more proactive treatment policy, and it can provide personalized feedback on a patient's physical activity level and recovery progress [8,9].

Recently, we described the patterns and evolution of overall physical activity over time in older patients rehabilitating after hip fracture surgery [9]. Patterns were described for a sample of 66 older patients, and physical activity was continuously monitored during rehabilitation at a skilled nursing home by using a MOX wearable device, which was attached to the patients' thigh. The results revealed different physical activity patterns when older patients were rehabilitating after hip fracture surgery. The most common pattern was the S-shape pattern (23/66, 35%), in which patients showed a slow increase in physical activity at the start of rehabilitation, followed by a

steep increase and reaching a plateau at the end of rehabilitation. The other patterns found were the upward linear pattern (15/66, 23%), the hill-shape pattern (6/66, 9%), and the cubic curve pattern (6/66, 9%) (Figure 1) [9].

Knowing the expected physical activity pattern at an early stage of the rehabilitation phase could be clinically useful for multiple reasons. First, it could possibly contribute to an early indication of the duration of rehabilitation stay since our previous findings [9] showed a significant difference between the physical activity patterns and the duration of rehabilitation stay. Patients with the upward linear pattern had the shortest duration of rehabilitation stay (16 days) and patients with the cubic curve pattern the longest (42 days). Second, knowing the expected physical activity pattern at an early stage in the rehabilitation phase could provide health care professionals the ability to give patient-specific feedback and to assess a patient's progress. Last, for patients, it could provide information about what to expect during rehabilitation. The next step to further investigate the patterns of overall physical activity over time is by exploring whether those patterns can be predicted early in the rehabilitation phase. There is no previous study that has predicted the recovery patterns of continuously monitored physical activity. Therefore, this study is an explorative study aiming to determine whether the recovery patterns of overall physical activity in older patients rehabilitating after hip fracture surgery at a skilled nursing home can be predicted at an early stage in the rehabilitation phase.

Figure 1. Patterns of overall physical activity in older patients rehabilitating at a skilled nursing home after hip fracture surgery [9]. (A) Upward linear pattern. (B) Hill-shape pattern. (C) S-shape pattern. (D) Cubic curve pattern.



Methods

Study Design and Participants

This explorative study was conducted from January 2019 until June 2021 and was part of the "Up&Go after a hip fracture" project, which is a longitudinal observational study of older patients after hip fracture surgery with the aim to optimize the rehabilitation for these patients. The patient data of our previous

study [9] about the patterns of overall physical activity were used for this study to explore whether the physical activity patterns can be predicted. A total of 66 older patients were enrolled in our previous study [9]. All patients were aged 70 years or older, surgically treated for a hip fracture at Ziekenhuisgroep Twente, and temporarily admitted to one of our collaborating skilled nursing homes (TriviumMeulenbeltZorg, Carintreggeland, or ZorgAccent) for

geriatric rehabilitation. Exclusion criteria were severe cognitive impairment (ie, diagnosed with dementia), total hip replacement, pathological or periprosthetic fracture, plaster allergy, terminal illness, and contact isolation. Patients were enrolled 1 day before discharge to one of the collaborating skilled nursing homes.

Ethics Approval

This study was approved by the Medical Research Ethics Committee Twente (K19-10) and by the institutional review board of Ziekenhuisgroep Twente (ZGT17-40), The Netherlands. The project was considered as not subject to the Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen). All patients gave written informed consent to participate. The privacy and confidentiality of our enrolled patients was achieved by storing the signed informed consent forms in a folder in a locked cabinet. Study data obtained from the enrolled patients were deidentified and stored at Castor electronic data capture or in a secure folder on the computer of Ziekenhuisgroep Twente.

Study Procedure

All enrolled patients were continuously monitored during their rehabilitation at the skilled nursing home by using a MOX wearable device (Maastricht Instruments BV). The MOX is a small waterproof device, which consists of a triaxial accelerometer with a sample frequency of 25 Hz to measure physical activity from the lower extremities. The MOX was attached to the upper thigh of a patient, was capable of storing 1.5 GB of data, and had a battery life of 7 days. Raw MOX accelerometer data, measured during daytime (7 AM to 10 PM), were first preprocessed. A moving average filter with a window size of 0.12 seconds was used to eliminate noise acceleration [10]. A fourth order Butterworth High Pass filter was used with a cutoff frequency of 1 Hz to eliminate gravity acceleration [10]. Then, the overall intensity of physical activity measured at the lower extremities was calculated from the raw data as a parameter of physical activity by calculating the signal magnitude area, which is defined as the area under the curve of the accelerometer signals.

The overall intensity of physical activity was calculated per day and plotted for each rehabilitation day and each individual patient. First, to assess the physical activity patterns, figures

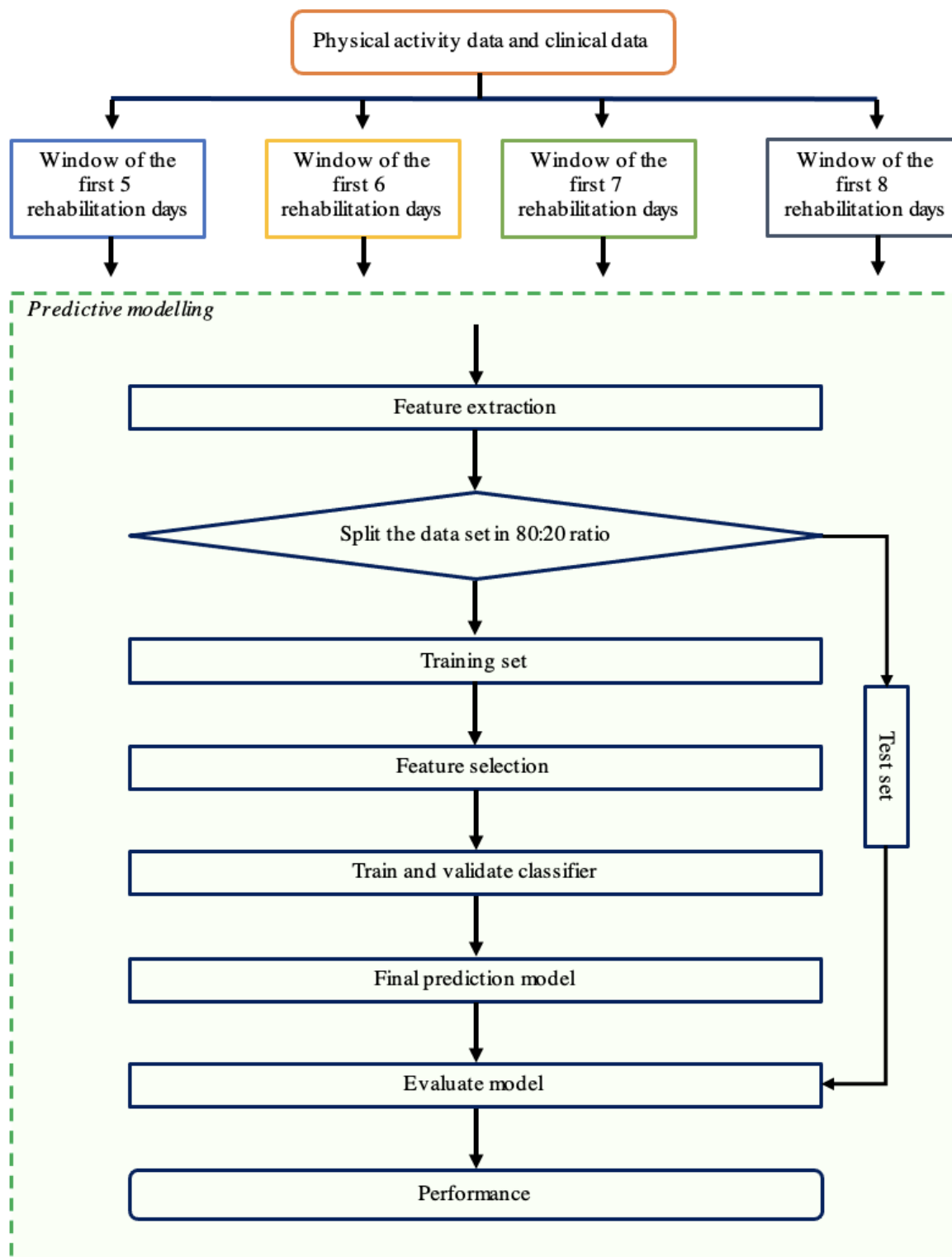
were smoothed using a Gaussian-weighted moving average filter. Second, the physical activity patterns were visually analyzed by 2 experts in the geriatric rehabilitation field, who identified 6 unique physical activity patterns. Last, 18 independent raters visually analyzed and classified the physical activity pattern of each enrolled patient into one of the predefined unique patterns. When there were 2 patterns frequently chosen by the raters for a patient and the difference in the number of votes was equal to or smaller than 2, a final decision of the pattern was made by 2 experts in the geriatric rehabilitation field. Based on the visual analysis, 4 common patterns of overall physical activity were found in our previous study [9] for the 66 enrolled patients; a total of 15 (23%) patients were classified with the upward linear pattern, 6 (9%) patients with the hill-shape pattern, 23 (35%) with the S-shape pattern, and 6 (9%) with the cubic curve pattern. The remaining 16 patients (24%) were classified as “Else.” More details about the classification of the physical activity patterns are described in our previous paper [9].

For further analysis, we decided to focus on the prediction of the physical activity patterns of patients classified with the upward linear pattern (n=15) or the S-shape pattern (n=23), leaving the data of 38 patients for data analysis. This decision was made due to the small sample size of the patients classified with the hill-shape pattern and cubic curve pattern (n=6 for both patterns) and the high heterogeneity of the physical activity patterns in the “Else” group.

Data Analysis

To predict the physical activity patterns, that is, the upward linear pattern or the S-shape pattern, we used the workflow diagram shown in Figure 2. First, features were extracted from the physical activity data and clinical data for 4 different time windows. These features were used as an input for the pattern prediction model. Second, patients were split into a training set and test set by using a ratio of 80:20, and relevant features necessary for the prediction model were selected. Third, the prediction model was trained and validated with the physical activity data of the patients within the training set, and lastly, the final prediction model was tested on the physical activity data of the patients within the test set.

Figure 2. Workflow diagram for pattern prediction.



Feature Extraction

Four types of features were extracted in this study: (1) statistical features, (2) amplitude features, (3) morphological features, and (4) clinical features. The statistical, amplitude, and morphological features were all extracted from the overall intensity of physical activity data. For the statistical features, the mean intensity, median intensity, SD, IQR, maximum intensity, minimum-maximum range, and root mean square

values were calculated. For the amplitude features, the overall intensity at day 1 and the mean amplitude deviation were calculated. For the morphological features, the slope, characteristics of the third-degree polynomial curve describing the shape of the pattern, mean first order difference, and mean second order difference were calculated. The characteristics of the third-degree polynomial curve were defined as coefficient a, coefficient b, and coefficient c, which were derived from the third-degree polynomial equation: $y = ax^3 + bx^2 + cx + d$. More

detailed information about the statistical, amplitude, and morphological features can be found in [Multimedia Appendix 1](#).

To aim for early pattern prediction, we did not calculate the statistical, amplitude, and morphological features by using the overall intensity of physical activity data of the entire rehabilitation period. Instead, they were calculated for 4 different time windows containing the overall intensity of physical activity data of the early rehabilitation phase. The 4 defined time windows were a window of the first 5 rehabilitation days, a window of the first 6 rehabilitation days, a window of the first 7 rehabilitation days, and a window of the first 8 rehabilitation days. Multiple time windows were chosen to assess at which moment in the postoperative rehabilitation phase the physical activity patterns could be predicted most accurately. A window of 5 days was chosen as smallest window, since patients need time to get used to rehabilitation. The maximum window length of 8 days was chosen to aim for pattern prediction early in the postoperative rehabilitation phase. Statistical, amplitude, and morphological features were calculated for each defined time window.

Clinical features were extracted based on the results of our previous study [9]. The Barthel Index (BI), Fracture Mobility Score (FMS), Functional Ambulation Categories (FAC), and the Montreal Cognitive Assessment (MoCA) score were included, since all the features showed a significant or close to significant association with the physical activity patterns [9]. The BI described the level of activities of daily living independency at admission to rehabilitation and ranged from 0 (completely dependent) to 20 (completely independent) [11]. The FMS and FAC both scored the level of mobility at admission to the rehabilitation center. The FMS scored mobility regarding the use of walking aids and ranged from 0 (fully mobile without aids) to 5 (no functional mobility) [12]. The FAC scored mobility regarding the walking ability and ranged from 0 (not able to walk) to 5 (independent walking) [13]. The MoCA assessed the presence of mild cognitive impairment and ranged from 0 to 30 [14]. A score of 26 was considered normal.

All features were normalized between 0 and 1 by using min-max normalization because some features have a wide range of values, which can dominate over the features with a small range of values. Thus, through normalization, features with a wide range of values will not overrule the features with a small range of values, as shown as follows: $x' = (x - \min(x)) / (\max(x) - \min(x))$, where x is the original feature and x' the normalized value of the feature.

Feature Selection

To evaluate the relevance of using each extracted feature and to prevent the prediction model from overfitting, the correlation-based feature selection (CFS) method [15,16] was used, which ranked all the features and selected a subset of relevant features based on the symmetrical uncertainty. A feature is defined as a relevant feature when it highly correlates with the physical activity patterns and is uncorrelated with the other features [15,16]. The symmetrical uncertainty is a normalized version of the information gain and ranges from 0 to 1, with 1 indicating a high correlation and 0 indicating no correlation

[16]. Relevant features were selected when the symmetrical uncertainty between the feature itself and the class was higher than the predefined threshold and the symmetrical uncertainties between the feature and other features. The predefined threshold used for this study was 0.9. This threshold was chosen to only select features that were highly correlated with the class. Since the window size of the predefined time windows affected the values of the calculated features, feature selection was performed for each defined time window, resulting in a feature subset for each time window.

Training Prediction Model

The prediction of physical activity patterns, that is, the upward linear pattern and the S-shape pattern was performed by predictive modeling by using machine learning techniques. All patients were divided into a training set and a test set by randomly selecting 80% (30/37) of the patients for training and 20% (7/37) for testing. Division of the patients was performed proportionally to the physical activity patterns, where both the training set and test set contained roughly the same distribution of patients with the upward linear pattern and the S-shape pattern as in the total patient group of patients. For each time window, the selected features were entered into the classification learner app of MATLAB R2017b (MathWorks, Natick) to train and build an eventual prediction model. The physical activity patterns were predicted using classifiers, namely, decision trees, discriminant analysis, logistic regression, support vector machines, nearest neighbors, and ensemble classifiers. The trained classifiers were validated by the 5-fold cross-validation method. For each window, the classifier with the highest accuracy in the validation phase was chosen as the final prediction model for the test set.

Testing Prediction Model

The final prediction model obtained for the different time windows was tested on the patients within the test set. The overall performance of the prediction models was evaluated by calculating the precision, recall, and F_1 -score for each pattern of overall physical activity (ie, the upward linear pattern and the S-shape pattern) in each model. Precision characterizes the proportion of the correctly classified patients within a physical activity pattern (true positive) to the total number of patients classified with that pattern (true positive + false positive) and was calculated as follows: $\text{precision} = \text{true positive} / (\text{true positive} + \text{false positive})$ [17-19]. Recall characterizes the proportion of correctly classified patients within a specific physical activity pattern (true positive) to the total number of patients that actually have that specific pattern (true positive + false negative) and was calculated as follows: $\text{recall} = \text{true positive} / (\text{true positive} + \text{false negative})$ [17-19]. F_1 -score is a machine learning metric and measures the accuracy of the prediction model by combining the precision and the recall scores and ranges from 0 to 1 [19,20]. F_1 -score was calculated as follows: $F_1\text{-score} = (2 * \text{true positive}) / (2 * \text{true positive} + \text{false positive} + \text{false negative})$. Since precision, recall, and F_1 -score were calculated for each individual physical activity pattern, an overall performance score was also calculated: the micro F_1 -score, which is the normal F_1 -score but then calculated

for all N different physical activity patterns [20]. The micro F_1 -score is calculated as follows: $\text{micro } F_1\text{-score} = (2 * \text{sum of the true positives for all patterns}) / (2 * \text{the sum of the true positives, true negatives, and false negatives for all patterns})$.

Results

Participant Data

A total of 38 out of 66 patients from our previous study [9] were included in this study. One patient was excluded from the analysis due to missing data in the first week of rehabilitation, leaving 37 patients for the analysis. Out of the 37 patients, 15 (41%) were classified with the upward linear pattern and 22 (59%) were classified with the S-shape pattern. The mean age of all the patients was 83.5 (SD 5.8) years, and 26 (70%) patients were females. A total of 36 (97%) patients lived at home before

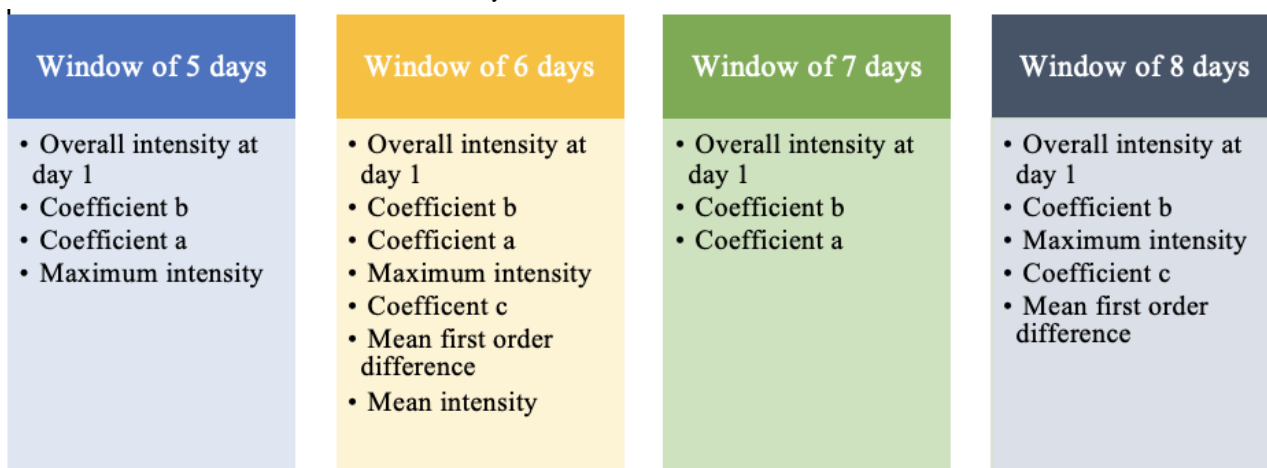
the hip fracture with or without help, and 1 (3%) patient lived in a residential home. The mean duration of the geriatric rehabilitation stay was 29 (SD 15) days.

Pattern Prediction

Features

Multiple features were selected by the CFS method for each time window (Figure 3). The overall intensity at day 1 and coefficient b were selected as relevant features for all time windows. Coefficient a was selected as a relevant feature in almost all time windows, except for the window of the first 8 days. The maximum intensity was selected as a relevant feature in almost all time windows, except for the window of the first 7 days. Coefficient c and the mean first order difference were only selected for the window of the first 6 days and the window of the first 8 days.

Figure 3. Feature subset for each time window selected by the CFS method.



Prediction Model

A total of 30 patients were assigned to the training set and 7 patients were assigned to the test set. Table 1 presents the performance of the prediction model for each defined time window, where pattern 1 is defined as the upward linear pattern of overall physical activity and pattern 2 as the S-shape pattern of overall physical activity. The best performing prediction model was the model based on the time window of the first 7

rehabilitation days. For this time window, the final model was a cosine k-nearest neighbor prediction model. The results of using this prediction model on the test set showed the following performance: precision of 100%, recall of 100%, and an F_1 -score of 1 for predicting both the upward linear pattern of overall physical activity as well as the S-shape pattern of overall physical activity. The prediction model had an overall micro F_1 -score of 1.

Table 1. Pattern prediction performance of each time window^a.

	Window of 5 days		Window of 6 days		Window of 7 days		Window of 8 days	
	Pattern 1	Pattern 2	Pattern 1	Pattern 2	Pattern 1	Pattern 2	Pattern 1	Pattern 2
Precision (%)	50	67	75	100	100	100	60	100
Recall (%)	67	50	100	75	100	100	100	50
F_1 -score	0.57	0.57	0.86	0.86	1	1	0.75	0.67
Final model	Cosine k-nearest neighbor		Linear support vector machine		Cosine k-nearest neighbor		Cosine k-nearest neighbor	

^aPattern 1 is defined as the upward linear pattern of overall physical activity. Pattern 2 is defined as the S-shape pattern of overall physical activity.

Discussion

To the best of our knowledge, this is the first study to explore the ability of predicting recovery patterns at an early

rehabilitation stage by using continuously monitored patterns of overall physical activity in older patients rehabilitating at a skilled nursing home after hip fracture surgery. The prediction of 2 different physical activity patterns was explored using the overall intensity of physical activity data in 4 different time

windows. This resulted in 4 prediction models with a varying overall prediction performance. Using the window with overall intensity of physical activity data of the first 7 days of rehabilitation resulted in a prediction model with the highest overall prediction performance (micro F_1 -score=1). This was followed by the window of the first 6 rehabilitation days (micro F_1 -score=0.86), the window of the first 8 rehabilitation days (micro F_1 -score=0.71), and lastly by the window of the first 5 rehabilitation days (micro F_1 -score=0.57). Early prediction of the physical activity patterns in older patients during rehabilitation at a skilled nursing home after hip fracture surgery seems promising based on those first results, since these results indicate that we can distinguish between the 2 most common patterns, which gives the confidence to continue this research, explore the prediction of the other physical activity patterns, and further validate the results in a large number of patients.

As the results show, the prediction model using overall intensity of physical activity data of the first 7 rehabilitation days correctly predicted the physical activity patterns of all the patients within the test set ($n=7$). This suggests that at least 1 week of continuous physical activity monitoring is necessary to obtain the most accurate prediction of the physical activity patterns for the total rehabilitation period of older patients. Using only physical activity data of the first 7 rehabilitation days enables early prediction of the eventual physical activity patterns, which is considered highly relevant and clinically useful for multiple reasons. First, early prediction of the physical activity patterns can possibly give an early indication of the duration of rehabilitation stay at a skilled nursing home after hip fracture surgery, since our previous study showed a significant association between the patterns of overall physical activity and the duration of rehabilitation stay [9]. Unlike some other countries, the Dutch health care system does not have prefixed times for rehabilitation stay at a skilled nursing home after hip fracture surgery; therefore, it will benefit health care organizations if early prediction of the physical activity patterns can enable an early indication of the duration of rehabilitation stay. An early indication of the length of rehabilitation stay will not only optimize a patient's discharge planning at the skilled nursing home but also give more insight into the availability of beds, which could optimize the patient flow between the hospital and the skilled nursing home. For health care organizations, this is beneficial since it can optimize capacity planning. For patients, a better transfer process from the hospital to the skilled nursing home could lower the duration of hospital stay, which results in a faster recovery process and a lower chance of in-hospital complications and mortality [21-24]. Second, early information about the expected pattern of overall physical activity can help patients manage their expectations of recovery. For patients, it is beneficial to know what to expect since it can prepare them for what is coming, manage their expectations, and help them set realistic goals. As shown by literature, patients need active involvement in their rehabilitation process to set realistic expectations and goals and to be more engaged during rehabilitation [25,26]. Therefore, it is recommended to share the expected pattern of physical activity with patients and to actively involve them in their recovery progress, even if continuous physical activity monitoring shows a sudden deterioration in

physical activity. Third, early information about the expected physical activity pattern can help health care professionals manage their expectations. This is beneficial for health care professionals since it enables them to continuously assess a patient's progress as a result of the 24/7 continuous monitoring of physical activity. When the expected pattern of a patient is known, but if the pattern is suddenly different from expected, this is considered as being offtrack of the expected pattern. For example, when a patient's physical activity level suddenly decreases when the expected physical activity pattern is an upward linear pattern, this may indicate sudden deterioration in the patient's health condition due to some complication and clinicians should get some alarm bells for timely intervention. Early detection of a sudden deterioration in physical activity could encourage health care professionals to figure out what is causing this situation and intervene to prevent and reverse further deterioration. All of this promotes a patient-tailored rehabilitation program based on the needs and progress of each individual patient, which is also shown by literature as an important aspect for the recovery process of patients [25]. Last, early information about the expected physical activity pattern can motivate health care professionals to optimize the recovery process of older patients by trying to shift patients to a more favorable physical activity pattern. Furthermore, early information can also motivate patients to be more physically active. To decrease the duration of rehabilitation, for example, we can aim to shift patients to an upward linear pattern, when possible, since patients with this pattern had the shortest duration of rehabilitation stay. However, before this can be reached, research is first needed to assess which physical activity pattern is the most optimal pattern for older patients during hip fracture rehabilitation. Moreover, the exact activity levels within each pattern need to be assessed, and it needs to be assessed whether it is feasible to shift patients from one pattern to another. Additionally, it is also recommended to perform more detailed research in the future about the association between the physical activity patterns and the duration of rehabilitation stay to assess whether there are some confounding factors by using population-based statistical analysis to enrich knowledge for daily practice.

The intensity of overall physical activity on the first rehabilitation day was shown to be an important feature in predicting the physical activity patterns for all time windows. The intensity indicates that the level of physical activity at admission to rehabilitation is highly important in a patient's subsequent physical activity pattern during rehabilitation. This result supports the importance of physical activity early in the postoperative rehabilitation phase and is in line with literature showing that higher physical activity levels result in a faster recovery in physical functioning [1,3,27]. This result can help health care professionals to understand the importance of early and frequent mobilization after hip fracture surgery. Furthermore, this finding suggests that health care professionals could focus even more on early mobilization during the in-hospital phase so that patients are discharged with higher physical activity levels to skilled nursing homes for rehabilitation.

Statistical, amplitude, and morphological features were extracted based on the intensity of physical activity data. Since this is the first study exploring the prediction of physical activity patterns, the statistical and amplitude features were chosen based on previous literature on machine learning algorithms for physical activity classification [28-31]. These features were common features and extracted from the time domain. Frequency domain features were not considered suitable for this study since the signals from the physical activity patterns were considered nonstationary. Additionally, morphological features were extracted from the overall intensity of physical activity data. The results of this study suggest that morphological features are also highly relevant in predicting the physical activity patterns for all time windows. Morphological features provided information about the shape of the patterns, which might explain their important role in this study, since the upward linear pattern and the S-shape pattern showed differences in their shape. The relevance of morphological features also stresses the importance of having continuously monitored physical activity data of older patients during hip fracture rehabilitation in contrast to using only the overall intensity of physical activity on the first day of rehabilitation. For future studies, it is recommended to keep focusing on the continuous monitoring of older patients with hip fracture and to focus on features related to the shape of the overall physical activity patterns.

In our previous study [9], patients with a higher BI score at admission to the rehabilitation center were more likely to be classified with the upward linear pattern of physical activity compared with patients with lower BI scores, which is in line with that reported in the literature [1,3,9,27]. However, clinimetric features such as the BI were not found in this study to be relevant for the prediction of the physical activity patterns. Pattern prediction was only predicted by features based on the continuously measured intensity of overall physical activity data, which is probably due to the higher range of those continuous physical activity features, since most clinimetric features were discrete variables. This result further supports the importance of continuously monitoring the physical activity of older patients during rehabilitation after hip fracture surgery.

Multiple classifiers were assessed in this study. The cosine k-nearest neighbor appeared to be the most accurate prediction model for all time windows, except for the window of the first 6 rehabilitation days. The principle underlying the k-nearest neighbor classifier is that it memorizes all training data, and based on those data, new unlabeled data can be classified. Features of new unlabeled data are compared against features in the complete training set, and the pattern of overall physical activity label of the k closest training data is used to determine the pattern of overall physical activity of the new unlabeled data [30,32,33]. However, there is no generally accepted classification method for predicting the physical activity patterns. The k-nearest neighbor is the first step to further explore the prediction of the physical activity patterns.

This study also had some limitations. The first limitation was the low number of enrolled patients, making this study an explorative study focusing on the prediction of only the 2 most common physical activity patterns. Although the results showed

a 100% correct classification of the 2 most common physical activity patterns by using physical activity data of the first 7 days, the results need to be interpreted cautiously due to the low number of enrolled patients, and we cannot draw any firm conclusions yet. Therefore, it is recommended to continue investigating the patterns of overall physical activity in older patients rehabilitating after hip fracture surgery. For future studies, more patients should be included so that we can build stronger conclusions, assess more accurately which time window for feature calculation is the most optimal, include the prediction of the other physical activity patterns found in our previous paper (ie, hill-shape pattern, cubic curve pattern, and the “Else” group), and increase the generalizability [9]. Furthermore, to support the health care professionals, it is recommended to develop machine learning techniques on the common physical activity patterns found in our previous study [9], which can be used in future studies for automatic pattern recognition. In this way, visual analysis will be redundant. Additionally, for future research, it is recommended to use a Bluetooth version of the MOX accelerometer and to further develop and validate physical activity detection algorithms and prediction models, which can be integrated into a digital platform. By connecting the Bluetooth MOX accelerometer with the digital platform, live physical activity data can be obtained from a patient, which can be directly analyzed within the digital platform. In this way, using the MOX device is more applicable in clinical practice. A second limitation of this study is that we did not use more advanced techniques for feature selection and prediction modeling due to the explorative nature of this study. Even though the CFS considered the collinearity between features, it is recommended for future research to include a wrapper feature selection method, which is generally more accurate and tends to perform better than filter-based methods [34,35]. To train and validate the classifiers, we used MATLAB’s classification learner app. Using this learner resulted in highly valuable insights in the potential classifiers for pattern prediction. However, a disadvantage of using the classification learner is that there is less control of the hyperparameter optimization. For future studies, it is recommended to implement the hyperparameter optimization to improve the classification performance when using a short window size for feature extraction.

The aim of this explorative study was to investigate whether the 2 most common patterns of overall physical activity in older patients rehabilitating after hip fracture surgery can be predicted at an early stage of rehabilitation in the skilled nursing home. This study shows that the upward linear pattern and the S-shape pattern could be 100% predicted at an early stage of rehabilitation (within the first 7 days). The overall intensity of physical activity on the first rehabilitation day and morphological features were relevant features to predict those 2 common physical activity patterns. The results of this study seem promising for early prediction and can offer the possibility of predicting the duration of rehabilitation stay, assess the recovery progress during hip fracture rehabilitation, and benefit health care organizations, health care professionals, and patients themselves. More research is needed to further confirm the conclusions based on this study.

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Data Availability

The data sets analyzed during this study are not publicly available since our patients did not give permission to share the data publicly. The data, however, are available from the corresponding author on reasonable request and with permission of the Up&Go after a hip fracture project. For data, please contact the corresponding author DvD (d.vdartel@zgt.nl).

Authors' Contributions

All authors contributed to the concept and design of this study and drafted the manuscript. DvD and YW contributed to data acquisition, data analysis, data interpretation, statistical analysis, and administrative, technical, or material support. All authors contributed to the critical revision of the manuscript for important intellectual content. YW, JHH, and MMRV-H supervised this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed explanation of the extracted features.

[[DOCX File, 21 KB - rehab_v10i1e45307_app1.docx](#)]

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Abbreviations

BI: Barthel Index

CFS: correlation-based feature selection

FAC: Functional Ambulation Categories

FMS: Fracture Mobility Score

MoCA: Montreal Cognitive Assessment

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Original Paper

Low-Cost Technology-Aided Programs for Supporting People With Motor, Visual, and Intellectual Disabilities in Functional Forms of Occupation and Communication: Proof-of-Concept Study

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Abstract

Background: People with motor, visual, and intellectual disabilities may have serious problems in independently accessing various forms of functional daily occupation and communication.

Objective: The study was aimed at developing and assessing new, low-cost technology-aided programs to help people with motor or visual-motor and intellectual disabilities independently engage in functional forms of occupation and communication with distant partners.

Methods: Two programs were set up using a smartphone interfaced with a 2-switch device and a tablet interfaced with 2 pressure sensors, respectively. Single-subject research designs were used to assess (1) the first program with 2 participants who were blind, had moderate hand control, and were interested in communicating with distant partners through voice messages; and (2) the second program with 2 participants who possessed functional vision, had no or poor hand control, and were interested in communicating with their partners through video calls. Both programs also supported 2 forms of occupational engagement, that is, choosing and accessing preferred leisure events consisting of songs and music videos, and listening to brief stories about relevant daily topics and answering questions related to those stories.

Results: During the baseline phase (when only a conventional smartphone or tablet was available), 2 participants managed sporadic access to leisure or leisure and communication events. The other 2 participants did not show any independent leisure or communication engagement. During the intervention (when the technology-aided programs were used), all participants managed to independently engage in multiple leisure and communication events throughout the sessions and to listen to stories and answer story-related questions.

Conclusions: The findings, which need to be interpreted with caution given the nature of the study and the small number of participants, seem to suggest that the new programs may be viable tools for helping people with motor or visual-motor and intellectual disabilities independently access leisure, communication, and other forms of functional engagement.

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KEYWORDS

technology; smartphone; tablet; motor impairment; visual impairment; intellectual disability; leisure; communication; stories

Introduction

Background

People with extensive motor disabilities or combinations of motor disabilities and blindness may have serious problems in independently accessing various forms of functional daily occupation [1-5]. The problems may be even more severe when people present with intellectual disability in addition to motor and visual impairments [6-12]. In the latter case, people may not be able to control leisure events such as music, videos, and comedy because of difficulties in reaching and managing common tools used for playing those events (eg, music devices, computers, and television) [6,10,13]. They may find it arduous or impossible to communicate with relevant partners not present in the immediate context because of difficulties in handling a telephone call or sending an SMS text or voice message or reading an incoming message [14-16]. Similarly, they may not succeed in engaging in common daily activities (eg, cooking and cleaning) [8,17,18] and may also find it challenging to participate in simple cultural and cognitive activities (eg, listening to brief stories and answering questions related to them) [19-22].

The possibility of setting up effective programs to help people with disabilities improve their situation and gain some level of independence is increasingly viewed as closely connected to the use of assistive technology solutions [3,23-27]. For example, a variety of such solutions have been developed to support programs aimed at helping (1) people with blindness manage Braille reading and orientation and mobility [23,24] and (2) people with pervasive motor disabilities manage leisure and communication via eye gazing [26,27]. Assistive technology solutions have also been developed to support people who present with sensory, motor, and intellectual disabilities (people who could hardly benefit from the technology solutions developed for individuals with blindness or individuals with pervasive motor impairment) [10,11,28-34].

Some of these last technology solutions were aimed at promoting leisure and communication with distant partners [35,36] or leisure, communication with distant partners, and functional activities [37]. For example, Lancioni et al [35] worked with 6 participants who presented with serious motor and sensory impairments and moderate intellectual disability. The technology used with 4 participants consisted of a tablet with the Android operating system, SIM (subscriber identity module) card, proximity sensor, multimedia player, internet connection, Google account, and the WhatsApp Messenger and MacroDroid apps. Every session started with the tablet sequentially illuminating and verbalizing the names of 2 pictures (choice areas) representing leisure and communication (SMS text messaging), respectively. The participants could select either picture (area) by approaching with their hand the proximity sensor of the tablet while that picture (area) was illuminated. Selection of an area led the tablet to present different alternatives within that area, such as different types of music and videos or

different communication partners. If the participants chose a leisure alternative, the tablet presented specific options that could be accessed. If the participants chose the communication alternative (a communication partner), the tablet presented various messages that could be sent to that partner. For 2 participants who could not use the aforementioned hand response due to their extensive motor impairment, a smartphone was available on their wheelchair's headrest. This allowed them to make their choices by turning their head toward the smartphone, thus activating the proximity sensor of the smartphone.

Lancioni et al [37] worked with 5 participants who presented with motor, visual, and intellectual disabilities. The technology included (1) a smartphone with the Android operating system, SIM card, internet connection, Google account, and MacroDroid app, and (2) 8 mini voice-recording devices. Each device contained a recorded verbal message that was uttered as the participant applied a simple hand pressure on the device. The message consisting of a request for a leisure event or a telephone call activated the smartphone's Google Assistant, which in turn led the smartphone to present a leisure event or start a call. Periods with leisure events and telephone calls were interspersed with daily activity periods. During the latter periods, smartphone's instructions for the activity steps were available.

The results of the aforementioned studies showed that the technology-aided programs were suited for leading the participants to independently manage leisure and communication and possibly combine them with daily activities. On the basis of these results, one can find new motivation to develop additional, upgraded programs that (1) would target leisure, communication, and other forms of useful engagement; (2) would be practical and easily accessible in terms of technology components and cost; and (3) would suit participants with limited motor abilities.

Objectives

This study was an effort to develop 2 new, low-cost technology-aided programs, namely, programs relying on technology components that are commercially available (off-the-shelf), easy to operate and maintain, and have costs of less than US \$1000 [38,39]. The first program involved a smartphone linked via Bluetooth to a 2-switch device and was assessed with 2 participants who were blind, had moderate hand control, and were interested in communicating with distant partners through voice messages. The second program involved a tablet linked via a Bluetooth interface to 2 pressure sensors and was assessed with 2 participants who possessed functional vision, had no or poor hand control, and were interested in communicating with their partners through video calls. In addition to leisure and communication, both programs sought to support a third (functional) type of occupation that would (1) be feasible for the participants' motor, sensory, and intellectual conditions and (2) replace the conventional daily activities (not suitable for these participants), which had been used in previous programs [37]. This third occupation consisted of listening to

brief stories dealing with relevant daily topics (eg, sport, geography, music, and food) and answering questions related to those stories.

Methods

Participants

The participants are here identified through the pseudonyms of Aubrey, Joseph, Collins, and Dylan. Aubrey and Joseph were the participants who used the first program while Collins and Dylan were the participants who used the second program. Table 1 summarizes their condition by reporting their chronological age, their visual and motor impairments, and their age equivalents for receptive and expressive communication as

measured via the second edition of the Vineland Adaptive Behavior Scales [40,41]. Their chronological age varied between 25 (Dylan) and 53 (Aubrey) years. Their Vineland age equivalents on receptive and expressive communication were between 5 years and 10 months and 7 years and 1 month, and between 4 years and 5 months and 6 years and 5 months, respectively. Their communication occurred verbally. Their utterances, however, were not clear and easy to understand for people not familiar with them. They were attending rehabilitation and care centers. The psychological records of those centers indicated that the intellectual disability levels of Joseph, Collins, and Dylan were rated to be in the moderate range, whereas that of Aubrey was reported to be in the mild to moderate range.

Table 1. Participants' pseudonyms, chronological age, visual and motor impairments, and Vineland age equivalents for receptive communication and expressive communication.

Participants (pseudonyms)	Chronological age (years)	Visual and motor impairments	Vineland age equivalents ^{a,b}	
			Receptive communication	Expressive communication
Aubrey	53	Blindness and spastic tetraparesis, with inability to ambulate	7; 1	6; 5
Joseph	46	Blindness and right arm and leg paresis, with ability to ambulate	6; 6	5; 9
Collins	31	Spastic tetraparesis, with lack of hand control and inability to ambulate	5; 10	4; 5
Dylan	25	Spastic tetraparesis, with reduced hand control and need of some support to ambulate	5; 10	4; 7

^aThe age equivalents are based on the Italian standardization of the Vineland scales [40].

^bThe Vineland age equivalents are reported in years (number before the semicolon) and months (number after the semicolon).

The participants were included in the study following a number of criteria. First, they enjoyed having access to leisure events, such as preferred songs, and exchanging voice messages or making video calls with preferred communication partners (eg, family and staff members) not present in their immediate context. Notwithstanding their interest, they were relying on the assistance of staff or caregivers for accessing both leisure and communication events. Second, they had expressed interest in listening to simple stories concerning topics such as sport, daily events, singers, and geography and to answer questions related to those stories. Third, they had also shown eagerness to use the technology systems set up for this study to support their independent access to leisure, communication, and stories and related questions. Their eagerness followed a preliminary familiarization with the systems. Fourth, staff (1) considered technology-aided programs critical to help the participants reach independence in basic areas of daily life, and (2) agreed with the areas targeted within the study, that is, leisure, communication with distant partners, and listening to simple stories and answering questions related to them, as well as with the systems arranged for the participants. Staff had been able to see the systems ahead of the study.

Ethical Approval and Informed Consent

All participants had gone through a preliminary familiarization step with the technology system available for them (ie, the smartphone and the Bluetooth switch device or the tablet combined with the Bluetooth interface and pressure sensors)

and had shown eagerness to use such a system to manage leisure, communication, and stories. Given their moderate or mild to moderate level of intellectual disability, the aforementioned eagerness was considered to be a clear sign of their willingness (consent) to be involved in the study. Even so, due to the fact that they were unable to read and sign a consent form, their legal representatives were involved in the consent process, that is, in reading and signing the consent form for the participants. 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, Italy (P020320221).

Setting, Research Assistants, Sessions, Leisure and Communication, and Stories

The participants' daily context (ie, areas of the rehabilitation and care centers they attended) served as the study setting. Three research assistants were employed for carrying out the study sessions of the 4 participants and for recording the data (discussed later). They were psychology graduates who had experience in implementing technology-aided intervention programs with people with different levels of disabilities and using data recording procedures.

The study included baseline and intervention sessions, which were carried out on an individual basis, once or twice a day, 3-6 days a week. During baseline sessions, the participants had a smartphone or a tablet (see below) and the research assistants invited them to use the device available to access leisure events (music) and communication (audio messages or video calls)

and respond to questions related to stories that the smartphone and tablet read. During the intervention sessions, the participants had the technology system set up to help them access leisure and communication and respond to story-related questions. Each session encompassed 4 leisure and communication periods and 3 stories (see below).

The stories (1) concerned a variety of familiar topics, such as sport, singers and other renowned people, animals, geography, and food recipes; (2) were chosen by the research assistants based on the participants' general abilities and interests; (3) lasted between 2 and 4 minutes based on the topic represented and participant's interest on such topic; and (4) were taken from YouTube or copied from websites.

Technology System I

This technology system was developed for the first program and used by Aubrey and Joseph who were blind, had moderate hand control, and were interested in communicating with their preferred, distant partners through voice messages more than through telephone calls. The technology involved a smartphone with the Android operating system combined with a Bluetooth Blue2 switch (a $16 \times 7 \times 2$ -cm device encompassing 2 adjacent pressure-sensitive buttons; AbleNet, Inc). The smartphone was equipped with a SIM card, internet connection, and Google account (Alphabet, Inc), and contained the WhatsApp Messenger (Facebook, Inc) and MacroDroid (Jamie Higgins) apps. The MacroDroid served to regulate the smartphone's functioning in accordance with the intervention conditions and to assist with data recording (see the "Measures and Data Recording" section). The smartphone was also provided with the telephone numbers of the participants' communication partners. The 2 buttons of the Bluetooth Blue2 switch were discriminated through a smooth and a hairy cover, respectively.

At the start of a session, the smartphone checked whether there were messages for the participants and eventually read those messages. Thereafter, it verbalized the following sentence: "You can listen to music by pressing the smooth button or can send a message by pressing the hairy button." If the participant pressed the smooth button, the smartphone verbalized at intervals of 2-4 seconds the names of 4 preferred singers (which could be different during the study). If the participant pressed the same (ie, smooth) button after a singer's name, the smartphone played a song by that singer. At least four songs (which could vary across sessions) were available for each singer. Songs were played for 1.5 minutes [37].

If the participant pressed the hairy button, the smartphone verbalized at intervals of 2-4 seconds the names of 5 preferred communication partners, which included family and staff members. If the participant pressed the same (ie, hairy) button following one of the names, the smartphone (1) got ready to send a voice message on WhatsApp to that name (partner) and (2) asked the participant to speak (verbalize) the message they wanted to send. Once the message had been spoken the participant had to press the same button to send the message and have confirmation that it was sent out. At the end of a song or message sequence, the smartphone automatically repeated the phrase indicating that it was possible to access music or send a message through the pressure buttons provided the time

elapsed from the start of that leisure and communication period had not exceeded 3 minutes.

If the time elapsed was more than 3 minutes, the smartphone invited the participant to listen to a brief story presented by the smartphone and then to answer questions related to the story. The stories concerned a variety of topics and lasted between 2 and 4 minutes (see the "Setting, Research Assistants, Sessions, Leisure and Communication, and Stories" section). At the end of a story, the smartphone presented 5 questions about it. For each question, the smartphone gave the participant 2 possible answers and indicated the pressure button to be activated in relation to each answer (questions and answers were programmed by the research assistants). For example, following a story over a particular football team, 1 of the questions could be "Was that player NAME playing as a goalkeeper or as a center-forward? You can press the smooth button for goalkeeper and the hairy button for center-forward." If the participant gave the wrong answer (ie, pressed the wrong button), the smartphone did not provide any feedback and paused. When the participant gave the correct answer (ie, pressed the correct button), the smartphone said "OK, Correct" and presented the next question. Once all the questions had been answered, the smartphone repeated the phrase indicating that it was possible to access music or send messages through the pressure buttons. The same process continued for the rest of the session, which included 4 leisure and communication periods interspersed with 3 stories each followed by the related questions. After completing the questions for the third story, the smartphone would read any message that had arrived during the session.

Technology System II

This technology system was developed for the second program and used by Collins and Dylan who possessed functional vision but had no or poor hand control, and were interested in communicating with their partners through video calls. The system involved a tablet with the Android operating system combined with a Bluetooth Encore Plus interface (Leonardo Ausili) linked to 2 pressure sensors. The sensors (ie, 2 Buddy Buttons with a diameter of 6.3 cm; Leonardo Ausili) were placed at the sides of the wheelchair's headrest (Collins) or on the desk before the participant, about 25 cm apart (Dylan). The tablet (like the smartphone) was equipped with a SIM card, internet connection, and Google account, and contained the WhatsApp Messenger and MacroDroid apps. The tablet was also provided with the telephone numbers of the communication partners and with their prerecorded answers to telephone calls (see below). This system worked as the first one with 4 exceptions. First, at the start of a session and through any of the leisure and communication periods, the tablet's verbalization was: "You can listen to music by pressing the red button" or "You can call somebody by pressing the green button." Second, music videos were used instead of songs. Third, video calls were used instead of voice messages. Fourth, the tablet played a prerecorded message of the communication partners if they did not answer a call.

Experimental Conditions

Design and General Procedures

For each pair of participants (ie, Aubrey and Joseph who used the first program, and Collins and Dylan who used the second program), the intervention was introduced according to a multiple probe across-participants design [40]. That is, the second participant of the pair was presented with a larger number of baseline sessions spread over a longer period as a way to control for the impact of variables such as maturation and history [42,43]. For the participants of the second pair, moreover, the baseline was repeated with a consequent break of the intervention period into 2 phases. In essence, each of these 2 participants experienced an ABAB sequence [43]. The baseline (A) phase(s) served to determine whether the participants could use a smartphone or a tablet to access leisure and communication events and to answer questions related to specific stories. The intervention (B) phase(s) focused on the use of the technology system available to the participants. To ensure procedural fidelity (ie, the research assistants' appropriate application of the baseline and intervention procedural conditions [44]), a study coordinator who had access to video recordings of the sessions provided the research assistants with regular feedback and possible guidance regarding their performance [37].

Baseline

During the baseline sessions, the participants sat in front of a desk where they found the smartphone (Aubrey and Joseph) or the tablet (Collins and Dylan), which were not using MacroDroid and thus functioned in the standard manner. At the start of a session with Aubrey and Joseph, the research assistant explained that they could access preferred songs or send a message to preferred communication partners by saying "Hey Google play singer's NAME or song's TITLE" or "Hey Google send a voice message on WhatsApp to partner's NAME" and then speaking the message. They could also answer the questions about stories that the smartphone would read to them by saying "Ok Google write a note" before giving any answer. Thereafter, the research assistant encouraged the participants to ask for a singer or a specific song. If the participants made an unsuccessful request or failed to make any request for 15-20 seconds, the research assistant provided help (ie, made a request for them to minimize any frustration). The song being played would be stopped after about 1.5 minutes in line with what occurred during the intervention (see the "Technology System I" section). Following the end of the song, the research assistant told the participants that they could send a message to a preferred partner. Again, to reduce participants' frustration, the research assistant provided help after an unsuccessful effort or failure to make an effort for 15-20 seconds. Help consisted of the research assistant uttering the phrase required to ready the Google Assistant about the WhatsApp message to be sent to a partner so the participants could speak out the message and send it to the partner.

Once the first leisure and communication period (ie, a period of about 3 minutes) was over, the research assistant activated the smartphone for the presentation of a story and of questions related to it. The participants were to listen to the story and then

answer the questions. If the participants failed to produce the phrase required for answering the first question (ie, "Ok Google write a note"), the research assistant would (1) produce it for them so that they could provide the answer, (2) block the smartphone's reading of the following questions (to reduce participants' frustration), and (3) encourage the participants to ask for a new singer or song and then send a new message (thus starting a new leisure and communication period). During this second leisure and communication period, conditions were as during the first. The session then continued with a new story and questions followed by a new leisure and communication period until 4 such periods and 3 stories had occurred.

The baseline conditions for Collins and Dylan matched those described for Aubrey and Joseph with 1 specific exception. That is, they had the opportunity to start telephone calls to preferred partners (rather than sending voice messages) by saying "Hey Google call partner's NAME." The decision to include audio calls rather than video calls (which would have been even more pleasing for both participants and indeed were used during the intervention) was due to the fact that the Google Assistant available in a standard smartphone or tablet does not allow one to start video calls.

Intervention

During the intervention sessions, the 2 pairs of participants used the 2 technology systems, which worked as described above (see the "Technology System I" and "Technology System II" sections). At the start of the sessions, the smartphone read to the participants of the first pair any message that had arrived and then informed them that they could listen to music or send messages using the smooth and hairy button, respectively. The tablet informed the participants of the second pair that they could activate music and video calls using the red and green buddies on the wheelchair's headrest (Collins) or on the desk (Dylan). A 3-minute time interval was allocated for this leisure and communication period as well as for any of the following 3 periods scheduled within every session. Any leisure event, message, or call started within the 3-minute interval was to be completed irrespective of whether it would extend the interval. At the end of the single leisure and communication periods, the smartphone or tablet read a story and then presented the 5 related questions that the participants had to answer. Following the last story and prior to the start of the last leisure and communication period, the smartphone read any incoming message(s) to the participants of the first pair. At the end of the sessions, the research assistant gave all participants feedback about their answers to the story-related questions, that is, pointed out how many questions they had answered correctly at first attempt.

The initial 4-6 sessions were used as practice sessions. In the beginning, the research assistant relied on verbal and physical guidance to help the participants use the technology system available to access leisure events, send voice messages or make video calls, and answer the story-related questions. Afterward, any form of research assistant's help was faded out and eventually the participants were to manage the use of the technology system independently. The regular intervention sessions that followed did not include research assistant's help

unless the participant requested for it. Such request was virtually absent.

Measures and Data Recording

A total of 5 measures were recorded. The first 3 included leisure events (songs and music videos) activated, voice messages sent or video calls made, and correct answers to the story-related questions produced at first attempt (with the first response given to the questions). All these 3 measures implied independence from any research assistant's help. The other 2 measures were session duration and voice messages received (read by the smartphone). This last measure was recorded only for the first pair of participants. During the intervention sessions, the smartphone and the tablet automatically recorded all the measures via MacroDroid (ie, made a log of all session events and the related times of occurrence for the research assistants to use). During the baseline sessions, the research assistants recorded the measures. Interrater agreement was checked in all baseline sessions with the involvement of a reliability observer in data recording. The percentage of interrater agreement (computed by dividing the number of baseline sessions in which the research assistant and the reliability observer reported the same number of songs or music videos, messages or calls, and correct answers to the story-related questions as well as duration times differing less than 2 minutes by the total number of baseline sessions, and multiplying by 100%) was 100% for all participants.

Data Analysis

The frequency of leisure events (ie, songs and music videos) accessed and voice messages sent or video calls made, and the percentage of story-related questions answered correctly at first attempt (with the first response given to the questions; see the "Technology System I" section) were presented in graphic form. The differences between the baseline and intervention data values on the single measures of every participant were analyzed through the percentage of non-overlapping data (PND) method [45]. This method verifies the size of the intervention effect by determining the percentage of intervention data points that are above the highest point of the baseline data.

Results

Technology System I

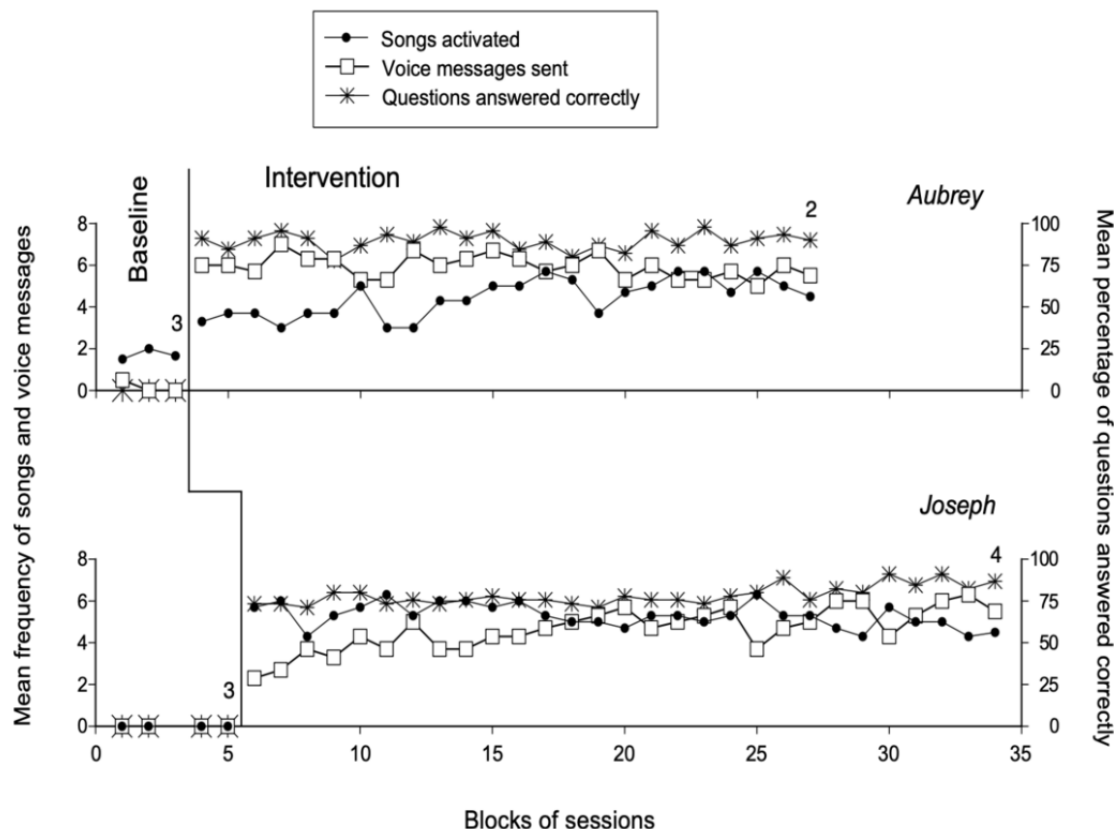
The 2 panels of [Figure 1](#) summarize the baseline and intervention data for the participants involved in the first

program who used Technology System I (ie, Aubrey and Joseph). The black circles and empty squares represent the mean frequency of songs activated and of voice messages sent per session, respectively, over blocks of 2 sessions during the baseline phase and blocks of 3 sessions during the intervention phase. The asterisks represent the mean percentage of story-related questions answered correctly at first attempt over the same blocks of sessions. The practice sessions used at the beginning of the intervention phase are not reported in the figures.

The baseline phase showed that Aubrey (who received 7 sessions over a period of 1 week) activated a mean of 1.7 songs per session, managed to send a total of 1 voice message, and did not answer any story-related question. Joseph (who had 9 sessions spread over a period of more than 2 weeks) failed to access any song, to send any message, and to answer any story-related question. The practice sessions at the beginning of the intervention led the participants to use the technology system, that is, a smartphone in combination with the Bluetooth Blue2 switch, successfully, and to become independent in activating songs, sending voice messages (and accessing incoming messages), and listening to stories and answering the story-related questions. During the 71 (Aubrey) and 88 (Joseph) intervention sessions occurring after the practice sessions, the participants' mean frequency of songs activated was 4.4 and 5.3 per session, respectively. Their mean frequency of voice messages sent per session was 5.9 and 4.7, respectively. Their mean percentage of correct responses to the story-related questions was 89 and 78, respectively. Their mean frequency of voice messages received was 2.4 and 1.7 per session, respectively. Their mean session duration was about 30 and 26 minutes, respectively.

Comparisons between intervention and baseline data carried out through the PND method on songs activated, voice messages sent out, and correct responses to story-related questions provided indices of 1.0 (ie, all intervention values exceeded the baseline's highest value) with an exception. The exception concerned the songs activated measure, on which Aubrey had an index of 0.97 (ie, an index that still expresses a strong intervention effect [45]).

Figure 1. The 2 panels summarize the baseline and intervention data for Aubrey and Joseph. The black circles and empty squares represent the mean frequency of songs activated and voice messages sent per session, respectively, over blocks of 2 sessions during the baseline and blocks of 3 sessions during the intervention. Blocks with different numbers of sessions (ie, at the end of the phases) are marked with a numeral indicating how many sessions are included. The asterisks represent the mean percentage of story-related questions answered correctly at first attempt over the same blocks of sessions.



Technology System II

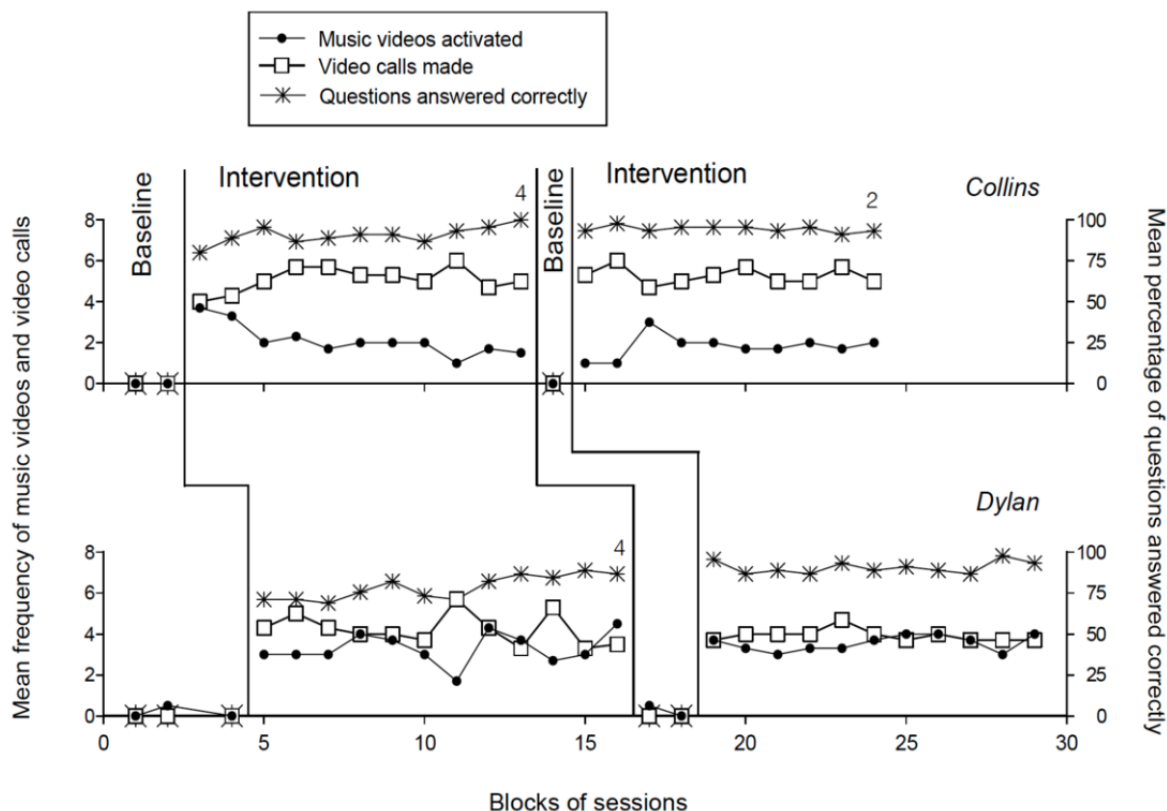
The 2 panels of Figure 2 summarize the baseline and intervention data for the participants involved in the second program who used Technology System II (ie, Collins and Dylan). The data are plotted as in Figure 1, but the black circles and empty squares represent music videos activated and telephone calls made, respectively.

The first baseline phase showed that Collins (who received 4 sessions within 1 week) did not manage any form of response. Dylan (who received 6 sessions spread over 2 weeks) activated 1 music video. The number of baseline sessions used for Collins was limited (in this baseline phase as well as in the second; see below) because of her clearly insufficient skills to use the tablet and her related frustration. During the 34 (Collins) and 37 (Dylan) sessions of the first intervention phase, the mean frequency of music videos activated per session was 2.1 and

3.3, respectively. Their mean frequency of video calls made per session was 5.1 and 4.2, respectively. This frequency also includes video calls without a response from the partner (ie, calls in which the tablet played a prerecorded message of the partner called). Their mean percentage of correct story-related responses was 91 and 79, respectively. Their mean session duration was about 26 and 28 minutes, respectively. The data of the second baseline phase (including 2 and 4 sessions, respectively) and the second intervention phase (including 29 and 33 sessions, respectively) were similar to those obtained during the first baseline and intervention phases.

Comparisons made between intervention and baseline data through the PND method on each of the measures provided indices of 1.0 with an exception. This concerned the songs activated measure, on which Collins had an index of 0.95 (ie, an index that still expresses a strong intervention effect [45]).

Figure 2. The 2 panels summarize the baseline and intervention data for Collins and Dylan. The data are plotted as in Figure 1.



Discussion

Principal Findings

The findings suggest that the new technology-aided programs were helpful for enabling the participants to independently activate preferred songs or music videos, send and receive voice messages or make video calls, and listen to brief stories and answer related questions. These findings, which need to be interpreted with caution given the nature of the study and the small number of participants, seem to extend the evidence of previous work focused on helping people with motor, sensory, and intellectual (cognitive) disabilities manage multiple forms of functional occupation [11,34,37,46]. Indeed, they seem to indicate that (1) various technology solutions might be profitably arranged to address different participants' needs; (2) programs might be set up to include a form of cognitive exercise (ie, listening to brief stories and responding to questions about the stories) for participants who would have serious difficulties engaging in practical occupational tasks; and (3) voice messages might be used to allow participants, who have basic speech skills but are not keen on telephone calls, to have a personalized (emotionally direct) form of communication with their preferred partners. In light of the above, a number of considerations would seem pertinent.

First, technology systems that are simple, based on commercially available devices, and able to support intervention programs for people with different needs might be viewed as fairly practical (suitable) for rehabilitation contexts [47,48]. In this study, 2 such technology systems were evaluated for allowing people with different characteristics to reach comparable goals. The smartphone combined with the Bluetooth Blue2 switch

appeared helpful for participants who were blind, but had a level of hand control that allowed them to use the pressure buttons of the Bluetooth Blue2 switch. The tablet interfaced with the buddy buttons seemed adequate for participants who possessed functional vision but had no or poor hand control, and therefore needed the buddy buttons' position to be adapted to their plausible response mode (ie, at the wheelchair's headrest or at different points of the desk).

Second, communication with distant partners may take different forms depending on the participants' skills and preferences and the technology solutions available in the program [35,46]. In this study, voice messages were used with the first pair of participants whose verbal skills were not sufficient to successfully activate the smartphone's Google Assistant, but were adequate to record and send voice messages comprehensible to the preferred communication partners. It was also thought that voice messages could represent a fairly personal and emotionally relevant form of communication for the sender and the receiver [49,50]. Video calls were used with the second pair of participants who had functional vision and were keen on this type of communication interaction.

Third, listening to smartphone or tablet presentations of brief stories and answering story-related questions represents a type of engagement that may be rather infrequent for participants with multiple disabilities [19-22]. Yet, such an engagement might be a meaningful alternative to other forms of occupation, such as practical daily activities, which are impossible or difficult to manage for participants with motor or visual and motor impairments. The same engagement might also be helpful to stimulate the participants' attention and memory and thus

might have a positive impact on their cognitive functioning [19,20].

Fourth, while these preliminary findings seem to be promising as to the impact of the programs, some clarification may be needed with regard to the programs' applicability and costs. Regarding applicability, it may be noted that both programs rely on the use of a small number of commercially available devices that are easily portable and probably acceptable within daily contexts [47,51-53]. The cost of the technology systems used for the programs is about or slightly more than US \$500. This includes about US \$200 or \$250 for the smartphone and about US \$250 for the Bluetooth Blue2 switch (Technology System I), and about US \$250 or \$300 for the tablet, \$150 for the Bluetooth Encore plus interface, and \$120 for the 2 buddy sensors (Technology System II). The cost of the MacroDroid app is practically insignificant.

Limitations

Three main limitations of the study can be underlined. The first limitation concerns the fact that only 2 participants were involved in each program. Based on this, the study as a whole can be viewed as preliminary, as a proof of concept, rather than as a definite demonstration of the ultimate value of the programs investigated [40,41,52]. Replication studies with new participants would be crucial to ascertain the strength and generality of the data obtained with the 2 programs and the feasibility of improving the programs [54-56]. The use of a multiple probe design without a withdrawal (second baseline) phase for the first pair of participants might technically be viewed as a methodological weakness [57]. In practice, however, the second baseline could hardly be considered a methodologically indispensable condition with those participants given their well-known and consolidated speech difficulties [37,58,59]. Indeed, one would not have expected the participants to improve their speech skills and become efficient in activating the smartphone's Google Assistant through their utterances. This point (ie, lack of speech improvement) was documented

with the second pair of participants for whom a second baseline phase was carried out after an intervention period.

A second limitation concerns the absence of any specific assessment of the participants' satisfaction with (enjoyment of) their program. While anecdotal reports suggest that the participants wanted to be involved in the program sessions and were happy to access their preferred music and contact their preferred communication partners, a direct evaluation of their satisfaction with the program would be highly desirable. Such evaluation could involve 2 main steps. One step could consist of asking them to make choices between program sessions and some other form of daily engagement considered to be pleasing for them [60]. Another step could be to compare their mood expressions (eg, indices of happiness) during the program sessions and during other daily engagement situations [34,61,62].

A third limitation concerns the fact that no social validation of the programs was carried out. While the staff initially interviewed had expressed support for the programs and the technology involved (see the "Participants" section), a more specific and wider validation process should be pursued. Such validation could be carried out by asking groups of staff personnel familiar with this population to watch short videos of participants using the programs and then rate the programs' friendliness, relevance, and applicability [63,64].

Conclusions

The findings, which need to be interpreted with caution given the nature of the study and the small number of participants, seem to suggest that the new programs may be suitable to help people with motor or visual-motor and intellectual disabilities independently access functional forms of occupation and communication. Notwithstanding the encouraging findings, general statements about the programs and their overall implications for daily contexts must await the outcome of new research directed at replicating and extending this study and overcoming its limitations.

Data Availability

Data are available on the Open Science Framework [65].

Conflicts of Interest

None declared.

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Abbreviations

PND: percentage of non-overlapping data

SIM: subscriber identity module

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Original Paper

The Usability of a Touchpad Active Video Game Controller for Individuals With Impaired Mobility: Observational Study

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Abstract

Background: Video games are a popular sedentary activity among people with impaired mobility; however, active video game hardware typically lacks accessibility and customization options for individuals with mobility impairments. A touchpad video game system can elicit moderate physical activity in healthy adults; however, it is unclear if this system is usable by adults with impaired mobility.

Objective: The purpose of this study was to assess the usability of a touchpad video game controller system adapted for adults with impaired mobility. Additional outcomes explored were enjoyment, perceived exertion, self-efficacy, participant feedback, and researcher observations of gameplay.

Methods: Participants played several video game titles for 20 minutes with a touchpad video game controller as they stood or sat in a chair or their wheelchair. Usability was assessed with the System Usability Scale (SUS) and the Health Information Technology Usability Evaluation Scale (Health-ITUES) surveys after gameplay. After each video game, participants reported enjoyment using a visual analog scale (0 to 100 mm) and a rating of perceived exertion using the OMNI 0 to 10 scale. Self-efficacy was measured before and after gameplay. Participants provided feedback at the end of their session.

Results: In total, 21 adults (6 females and 15 males) with a mean age of 48.8 (SD 13.8) years with various mobility impairments participated in this study. The touchpads received mean usability scores on the SUS 80.1 (SD 18.5) and Health-ITUES 4.23 (SD 0.67).

Conclusions: The SUS scores reported suggest the touchpad system is “usable”; however, the Health-ITUES scores were slightly below a suggested benchmark. Participants reported moderate to high enjoyment but perceived the exertion as “somewhat easy.” Self-efficacy was moderate to high and did not differ pre- to postgame play. The participants regarded the touchpads as novel, fun, and entertaining. The generalizability of our results is limited due to the heterogenous sample; however, our participants identified several areas of improvement for future iteration.

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KEYWORDS

active video games; exergames; usability; enjoyment; disability; mobility limitation; mobility impairment

Introduction

Habitual physical activity improves health and quality of life; however, half of the people with a disability in the United States are categorized as physically inactive [1-4]. While not every

person with a disability possesses a mobility impairment, individuals with impaired mobility encounter personal and environmental barriers that affect participation in physical activity (eg, lack of transportation, poor facility access, and inexperienced staff) [5-8]. While physical activity research typically focuses on traditional exercise, and sport programs

[1,2], home-based inclusive alternatives such as an arm ergometer may be viewed as tedious and boring [9]. Additional opportunities to engage in healthy physical activity are needed for individuals with mobility impairments. Technology, such as video games, can augment traditional exercise and may increase adherence to a healthy lifestyle [10].

While half of adults in the United States engage in sedentary video game play [11], active video games (AVGs) have been identified as a means to promote leisure time physical activity in adults and children [12-14]. AVGs typically integrate active trunk and limb movements to control onscreen video game actions (eg, Nintendo Wii and Xbox Kinect). Research indicates that increased energy expenditure is elicited in persons with impaired mobility during AVG play and may mitigate the effects of sedentary behavior [15-20]. Additionally, AVGs can circumvent barriers to physical activity such as transportation and facility access among individuals with impaired mobility [8]. However, most current AVGs are not typically inclusive of those who have difficulty standing, weakness in their lower extremities, poor motor control, or use an assistive device [21,22].

Given that AVGs can foster feelings of autonomy, competency, and relatedness, these games may fulfill basic psychological needs and augment the enjoyment derived from participation in physical activity [23,24]. Furthermore, AVGs have been shown to be an enjoyable opportunity to increase weekly physical activity minutes [19]. Additionally, enjoyment exhibits a stronger influence on positive exercise behavior compared to health or fitness motives [25]. Because people are more likely to participate in physical activity if they are certain they can do it [26], self-efficacy has been found to highly correlate with positive physical activity behavior [27]. Increased self-efficacy is related to increased AVG enjoyment [28,29], exercise adherence [30], exercise duration [31], and AVG approval [32].

The research and development team with the Rehabilitation Engineering Research Center on Interactive Exercise Technologies and Exercise Physiology for People with Disabilities previously showed that AVG play can be adapted for wheelchair users [33], be enjoyable, and elicit light to moderate physical activity [18]. A newly developed device called the GAIMplank was demonstrated to be usable and accessible among individuals with impaired mobility [13]. Another video game controller called the touchpad system (TPS) was originally designed as an easy to assemble low-fidelity proof of concept to elicit physical activity using sedentary video games. Research demonstrated that sedentary video games could be adapted to elicit moderate physical activity in healthy adults by using the TPS [34]. However, the TPS system has not been tested among adults with impaired mobility. The aim of this study was to assess usability of the TPS among individuals with impaired mobility and examine enjoyment, perceived exertion, task self-efficacy, and player feedback regarding use of the system.

Methods

TPS Development

The TPS is an internally developed AVG controller designed to add physical activity to sedentary video games. This prototype translates physical contact into video game commands. Because the TPS is recognized as a USB controller, this system can provide commands to any video game title that features controller support. The current proof-of-concept has been adapted for use by people with impaired mobility.

We constructed 6 touchpads using a particle board base, conductive aluminum tape, electrical wire, and duct tape. The touchpads were wired to a MAKEY-MAKEY circuit board (MAKEY-MAKEY LLC, Santa Cruz, CA) that was connected to the video game computer as a controller. All but 1 touchpad measured 20 cm × 20 cm, and the final touchpad was larger (61 cm × 31 cm). Each touchpad was placed on an adjustable stand that enabled varying height, distance, and orientation (vertical to horizontal). The smaller touchpads were placed in front or to the side of the player. The larger touchpad was placed behind the player.

To ensure safety, adjustable parallel bars were located on both sides of the player during gameplay. The participants played video games approximately 1.8 m away from a flat-screen television. Touchpads were placed so they did not block the player's view of the screen. All wires were secured away from the player to prevent any trip hazard during gameplay.

Design and Setting

This was a cross-sectional usability testing study. We assessed usability and embedded participant feedback to help explain our results. All written consent and data collection took place at the University of Alabama at Birmingham within the RERC RecTech Exercise Science and Technology Laboratory. Participants attended a single 60- to 90-minute session to test the usability of the system.

Ethics Approval

The procedures of this study were approved by the University of Alabama at Birmingham's institutional review board (IRB 300003265).

Participant Recruitment

We recruited participants from the local community of Birmingham, AL, using flyers and word of mouth. Sample size estimates were based on identifying common usability barriers for the system, and issues specific to the 3 modes of play (standing, chair sitting, and wheelchair sitting). According to Cazañas et al [35], a sample of 17 individuals would reasonably identify 80% of common problems in the system, and groups of 4 to 9 are sufficient to identify problems specific to the mode of play. In total, 21 participants were recruited to account for modest attrition.

Interested individuals were included if they were an adult 18 to 75 years of age, had a self-reported mobility impairment, and possessed the ability to exercise with their upper extremities. Individuals were excluded if they were unable to converse in

English, weighed greater than 181.4 kg (400 lbs), had significant visual impairment that prevented them from seeing a large flat-screen television, had cardiovascular disease within the previous 6 months, had severe pulmonary disease or renal failure, currently pregnant, ongoing exacerbation of a health condition, or any other condition that would interfere with testing procedures. Participants received a US \$50 gift card at the end of their visit.

Measures

Participant usability of the TPS was assessed using the System Usability Scale (SUS) and the Health-Information Technology Usability Evaluation Scale (Health-ITUES). The SUS is comprised of 10 statements, and participants rate their agreement of each statement with a 5-point Likert scale from “strongly disagree” to “strongly agree.” Across 206 usability tests and 2324 responses, the SUS was found to be a robust and reliable ($\alpha=.91$) tool to measure usability [36,37]. The SUS is robust to small sample sizes and applicable to many systems [36,38,39]. The SUS can produce a score from 0 to 100 and a score equal to or greater than 68 indicates above-average usability [37,39]. In addition to the single score, factor analyses suggest a 2-factor structure of learnability and usability [40]. The SUS scores were summed and converted from a 0 to 40 into a 0 to 100 scale, and a score of 68 was the threshold to indicate the TPS is “usable” [36].

Similar to the SUS, the Health-ITUES is made up of 20 statements that participants rate on a 5-point Likert scale from “strongly disagree” to “strongly agree” [41]. The subscales of the Health-ITUES demonstrate high internal consistency and reliability ($\alpha=.85-.92$) [42], and the construct validity of the Health-ITUES has been established [43]. Health-ITUES scores can typically be difficult to generalize; however, a cut-point score of 4.32 has been suggested as a cutoff to represent a system is “usable” [44]. Health-ITUES was scored by calculating a mean score for each subscale, and a total score by calculating the mean of the subscale scores.

Participants reported their enjoyment with a visual analog scale (VAS), which is a 10-cm scale with anchor phrases at each end [45]. The anchors for our enjoyment VAS were from “not enjoyable at all” to “most enjoyable.” Using an electronic tablet computer, participants touched the line on the spot that best represented their enjoyment. The length of the line is used as a measure of their enjoyment and is reported to be the closest 0.1 cm. Enjoyment VAS scores were converted from centimeters to millimeters and reported from 0 to 100.

Participants rated their perceived exertion using the OMNI 10-point ratings of perceived exertion (RPE) scale [46]. The scale was shown and explained before data collection. Participants could point to or say a number from 0 (extremely easy) to 10 (extremely hard). A researcher confirmed the RPE number with the participant before recording the response. A

score of 4-6 would be considered somewhat easy to somewhat hard.

Task self-efficacy was assessed using the video game play appraisal (Multimedia Appendix 1). This scale asks respondents to rate their certainty on 6 dimensions of video game play with the TPS from 0 (no certainty) to 10 (absolute certainty). The scale was created based on expert recommendations [26,47], and the video game play dimensions were chosen to represent the key steps in video game interaction [48]. Among a sample of 30 healthy adults, this scale exhibited high internal consistency ($\alpha=.95$), and good test-retest reliability with an ICC_{3,2} (intraclass correlation coefficient) 0.83 (95% CI 0.62-0.91) [34]. The participants’ understanding of the task itself is vital to the validity of a task self-efficacy scale [47]; therefore, prior to video game play, each participant watched an instructional video illustrating how the TPS is used while sitting in a fixed chair, standing, and seated in a wheelchair.

Participant Feedback and Researcher Observations

After the participant completed usability surveys, they provided open-ended feedback through surveys and semistructured interviews. The survey and interview questions were designed to explore the participant’s perspectives on accessibility, overall experience, and identify areas of improvement. The initial 8 participants were asked to answer open-ended questions on their own. To gain richer feedback from the responses, the remaining participants were interviewed by a member of the research staff using an interview guide (Multimedia Appendix 2). Interviews were audio recorded and later transcribed. The transcriptions were merged with responses to the open-ended questions where appropriate. Researchers documented written observations from gameplay sessions regarding modifications, adaptations, areas of improvement, and suggestions for future touchpad iteration.

Instruments

The TPS is an alternative video game controller that substitutes typical game controls with large movements. The system is designed to control a wide variety of video games available on PC and is easily adapted to users of varying abilities.

The TPS consists of 6 individual touchpads, circuit board, and laptop computer. Each touchpad is a square of particle board with a surface of conductive tape that was placed within a flexible stand that could be adjusted in any direction. All touchpads were wired into a small circuit board microcontroller (Makey-Makey LLC, Santa Cruz, CA) that converts electrical input into computer keys. Touchpads were connected to computer keys that corresponded with video game controls. The microcontroller functions as a video game controller and was connected to the PC via USB cable. The PC was used to run the 4 video game titles that participants played (Table 1). A 127-cm television flat screen was used to display the games 1.8 m in front of the participant.

Table 1. Description of video game titles and commands required for gameplay.

Game	Genre	Game description	Commands required
Flower	Flight; exploration	Player moves a floating flower petal around a peaceful meadow	Left, right, forward (up), backward (down)
PAC-MAN Championship Edition DX+	Arcade; action	Navigate a maze to collect points by eating pellets and avoid ghosts that chase the player	Left, right, forward (up), backward (down), bomb
Super Destronaut	Shooter	Player moves a spaceship left and right, shoots aliens, and dodges attacks	Left, right, shoot
Super Indie Karts	Racing	Player steers a go-kart around a track against computer opponents and uses power-ups	Steering left and right, activate special items

To use the TPS, the player sat in a chair (Figure 1), sat in their wheelchair (Figure 2), or stood (Figure 3) within a set of parallel bars that they could hold or lean onto for added stability. Once the player was situated, the touchpads were moved around them at a distance that was within reach but made the player lean and reach to make physical contact. The hand or forearm activated touchpads in the front and to the sides of the player were 20 cm × 20 cm in size and placed at trunk height to the players. A

larger 61 cm × 31 cm touchpad was created to go behind the player and was placed at scapula height for the seated player and hip height for standing players. To activate this larger touchpad, the participant wore a light harness with a conductive material either around their shoulders (seated) or hips (standing). The player leaned rearward to make contact and activate the larger touchpad.

Figure 1. Participant using the touchpad system sitting in a chair.

Figure 2. Participant using the touchpad system sitting in their wheelchair.

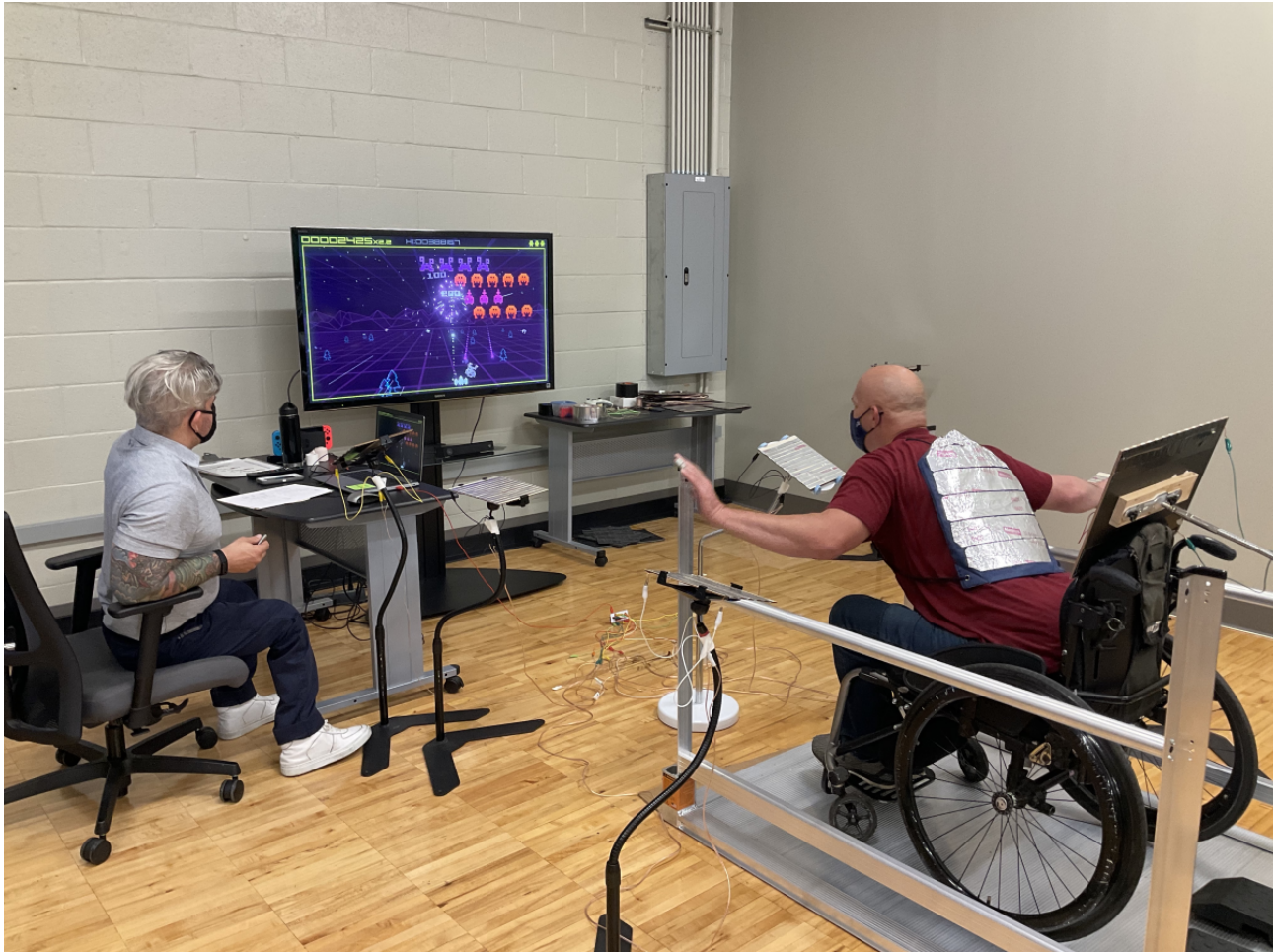
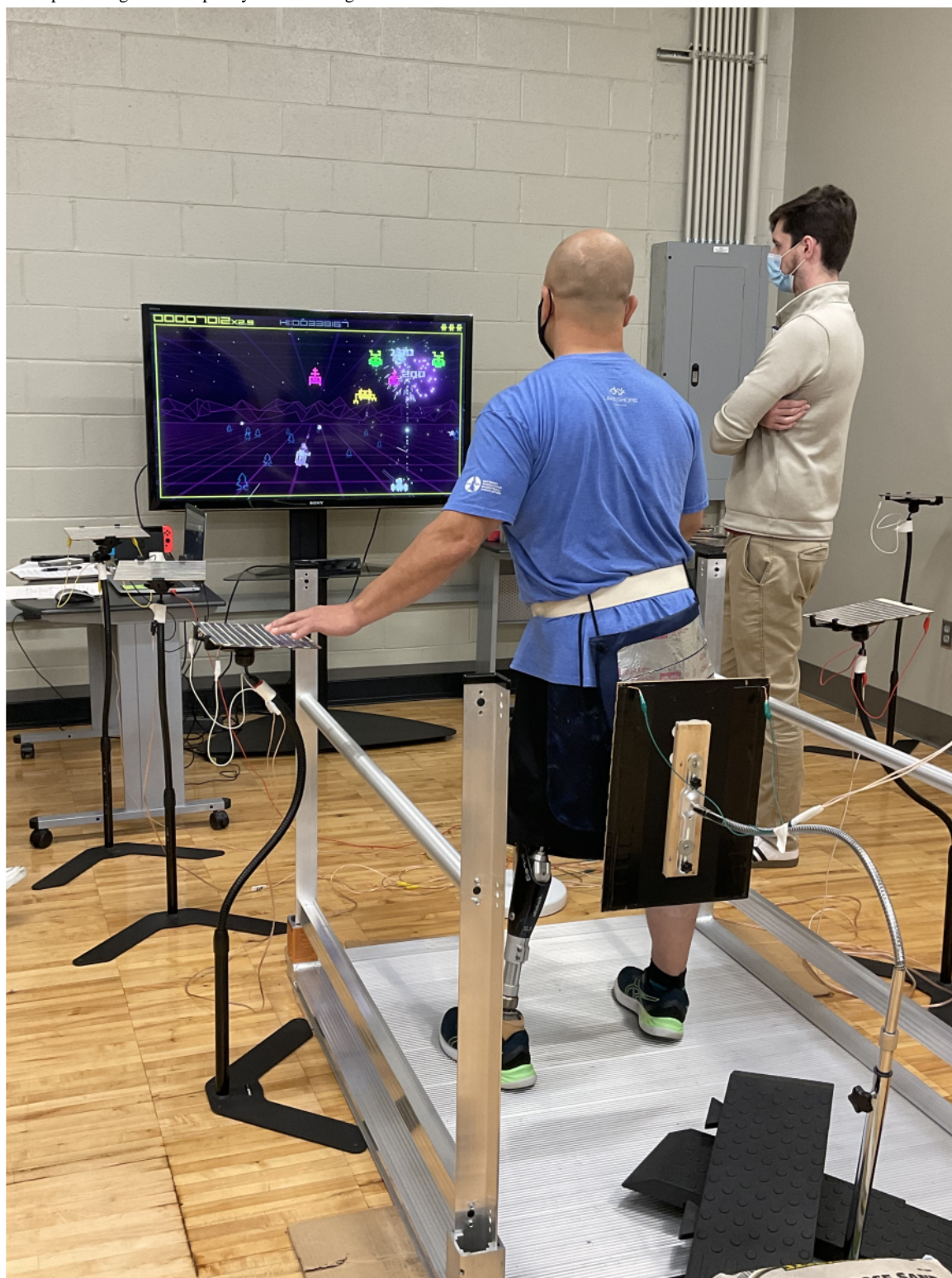


Figure 3. Participant using the touchpad system standing.



Procedures

Each person was screened for eligibility by phone before visiting the laboratory. The visit began with reviewing test procedures and then obtaining written informed consent from the participant. Participants answered a baseline questionnaire that asked about their demographics, prior video game experience, and physical activity habits. Next, the participant's heart rate

and blood pressure were measured to ensure the participant was safe to engage in physical activity.

Before the TPS was used, the participant was shown the play area and watched an instructional video that demonstrated both the seated and standing use of the system. After watching the video, the participant rated their self-efficacy before playing. The TPS session consisted of playing 4 different video game titles for 5 minutes each with 5 minutes of rest in between each video game title. The TPS session began with playing a relaxing

slow-moving game (Flower) to enable the participant to acclimate to the necessary movements. The sequence of the remaining 3 video game titles was randomized. Immediately at the end of playing each video game, participants were asked to provide an RPE and enjoyment score. At the end of the TPS session, the participant rated their self-efficacy and completed the SUS and Health-ITUES. The entire session was recorded with the participant's consent.

Data Analyses

Participants' characteristics are reported as mean (SD) and range. The interitem reliability of SUS, Health-ITUES, and self-efficacy scores was assessed using Cronbach α . A 2-way mixed effects ICC_{3,2} was used to assess test-retest reliability of self-efficacy scores. Because self-efficacy and baseline questionnaire responses were not normally distributed, nonparametric statistics were used. A Wilcoxon signed rank test was used to determine if self-efficacy differed from pre- to postgame play. Spearman ρ correlations were calculated to explore relationships among physical activity minutes, video game minutes, usability, enjoyment, perceived exertion, and self-efficacy. For consistency, nonnormally distributed data are reported as mean (SD). Interview responses and open-ended questions were reviewed by a member of the research team to extract common themes and feedback. Data were analyzed using SPSS (version 27; IBM Corp).

The audio recordings of the participant feedback and written researcher observations were transcribed and combined into the same database. Participant feedback and researcher observations were examined and organized by 2 members of the research team separately. The same 2 researchers classified these data

into 3 main categories: accessibility, overall experience, and areas of improvement.

Results

Participant Characteristics

Usability testing was completed by 21 participants 48.8 (13.8) years of age. Our sample consisted of 15 males and 6 females and reported their race as either Black (n=8), White (n=12), or Asian (n=1). Participants reported impaired mobility due to stroke (n=9), spinal cord injury (n=3), amputation (n=3), cerebral palsy (n=2), spina bifida (n=2), or other (n=2). The primary mode of mobility included walking without assistive device (n=7), cane (n=6), prosthetic leg (n=1), rollator walker (n=1), and manual wheelchair (n=6). Participants used the TPS to play either standing (n=8), seated in a 4-legged chair (n=7), or seated in their own manual wheelchair (n=6). All participants were able to complete data collection. Some participants required slight modifications to play such as altering the height of the touchpad, moving the touchpad closer to the player, and adjusting the tilt of the touchpad.

Measures

Participant responses to the baseline questionnaire can be found in Table 2. When asked to rate enjoyment of certain activities from 1 "strongly disagree" to 5 "strongly agree," participants reported high agreement with both leisure time physical activity 4.6 (0.6) and video games 4.1 (1.1). However, there was high variability in our sample with reported weekly physical activity of 375 (257) minutes and video game play of 398 (643) minutes. There were no sex differences found for any baseline or outcome measures. The participants preferred playing video games on either video game consoles or cell phones.

Table 2. Participant responses to baseline questionnaire questions.

Question	Mean (SD)
Enjoys leisure time physical activity, 1=strongly disagree, 5=strongly agree	4.6 (0.6)
Weekday leisure time physical activity minutes	259 (177)
Weekend leisure time physical activity minutes	116 (103)
Enjoys playing video games, 1=strongly disagree, 5=strongly agree	4.1 (1.1)
Weekday video game play minutes	264 (462)
Weekend video game play minutes	138 (219)

Usability and subscale scores are reported with summary group scores in Table 3. The SUS demonstrated good reliability ($\alpha=.89$). Participants reported above-average usability with an average SUS scores of 80.1 (SD 18.5). The Health-ITUES

demonstrated excellent reliability ($\alpha=.92$). However, the mean Health-ITUES score of 4.23 (SD 0.67) did not meet the suggested cutoff of 4.32.

Table 3. Self-report touchpad system usability scores.

Mode of play	SUS ^a : overall		SUS: usability subscale		SUS: learning subscale		Health-ITUES ^b	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
All players	80.1 (18.5)	25-100	80.4 (18.0)	28-100	79.2 (27.5)	13-100	4.23 (0.67)	2.22-5.00
Chair sitting	68.6 (26.0)	25-95	79.1 (18.2)	28-97	79.2 (28.6)	13-88	3.89 (0.91)	2.22-4.80
Standing	87.2 (10.0)	72.5-100	79.3 (18.4)	72-100	86.0 (19.1)	75-100	4.51 (0.45)	3.75-5.00
Wheelchair	84.2 (11.7)	65-100	76.8 (24.0)	66-97	84.6 (23.9)	63-100	4.25 (0.48)	3.70-4.75

^aSUS: System Usability Scale.

^bHealth-ITUES: Health Information Technology Usability Evaluation Scale.

Overall enjoyment and perceived exertion scores including scores by video game title can be found in Table 4. Across all video games, participants moderately enjoyed gameplay with an overall mean VAS score of 70 (SD 22) mm. Perceived exertion of the participants was approximately “somewhat easy” with a mean RPE of 4.3 (SD 2.0).

Table 4. Enjoyment and ratings of perceived exertion by game and mode of play.

Game	Enjoyment (0-100 mm)		Rating of perceived exertion (0-10)	
	Mean (SD)	Range	Mean (SD)	Range
All players, across games	70.2 (22.4)	12-94	4.3 (2.0)	0.8-7.8
Chair sitting	67.1 (34.5)	12-94	5.3 (1.8)	2.5-7.8
Standing	72.8 (16.1)	42-93	3.4 (2.4)	0.8-7.5
Wheelchair	70.4 (13.9)	50-88	4.2 (1.1)	3.0-5.8
Flower	62.4 (25.8)	4-97	2.7 (2.0)	0-6
Chair sitting	62.6 (37.1)	4-97	3.6 (2.0)	1-6
Standing	61.3 (11.6)	49-79	2.3 (2.0)	0-6
Wheelchair	63.8 (28.6)	11-90	2.3 (2.1)	0-6
PAC-MAN Championship Edition DX+	76.8 (29.2)	0-99	5.0 (2.4)	1-10
Chair sitting	70.1 (36.6)	0-99	6.1 (1.8)	3-9
Standing	74.0 (33.0)	0-97	4.0 (3.0)	1-10
Wheelchair	88.3 (6.3)	80-99	5.0 (1.5)	3-7
Super Destronaut	79.6 (21.9)	17-100	4.6 (2.6)	0-10
Chair sitting	74.4 (31.0)	17-99	6.4 (2.2)	4-10
Standing	85.1 (14.2)	64-100	5.0 (2.2)	0-6
Wheelchair	78.2 (19.7)	47-98	3.0 (1.9)	1-7
Super Indie Karts	62.0 (31.4)	0-97	4.8 (2.6)	0-9
Chair sitting	61.4 (40.3)	0-94	5.0 (3.3)	1-9
Standing	70.6 (26.3)	10-97	4.3 (2.7)	0-8
Wheelchair	51.2 (27.8)	0-83	5.2 (1.6)	4-8

Self-efficacy scores by dimension and mode of play are included in Table 5. The 6 dimensions of the self-efficacy scale exhibited excellent internal consistency for both the preplay ($\alpha=.95$) and postplay measures ($\alpha=.97$). Similarly, the self-efficacy scale

demonstrated good test-retest reliability with average measures ($ICC_{3,2}=0.88$, 95% CI 0.71-0.95; $P<.001$). Participants were highly certain in their abilities to use the TPS (mean 7.6, SD 2.2). Self-efficacy did not differ from pre- to postplay.

Table 5. Self-efficacy scores by dimension and mode of play.

Video game appraisal question	All		Chair sitting		Standing		Wheelchair	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Maintaining focus throughout a 5-minute session								
Mean (SD)	8.9 (2.0)	8.5 (2.4)	7.0 (2.6)	6.6 (2.8)	9.8 (0.7)	9.1 (1.8)	10.0 (0.0)	10.0 (0.0)
Range	3-10	1-10	3-10	1-10	8-10	5-10	10-10	10-10
Seeing and hearing all the game information								
Mean (SD)	8.5 (2.2)	8.5 (2.5)	7.0 (2.5)	6.9 (3.7)	9.4 (0.9)	9.4 (0.9)	9.0 (2.4)	9.3 (1.0)
Range	3-10	0-10	3-10	0-10	8-10	8-10	4-10	8-10
Reacting fast enough to choose a next action								
Mean (SD)	6.7 (2.2)	6.8 (2.6)	5.7 (2.9)	4.9 (2.9)	7.4 (1.9)	7.8 (1.9)	6.8 (1.7)	7.8 (1.9)
Range	0-10	0-10	0-9	0-8	5-10	5-10	4-9	6-10
Determining strategies to move during play								
Mean (SD)	7.2 (2.2)	7.1 (2.6)	5.6 (2.6)	5.1 (3.0)	8.1 (1.4)	8.5 (1.8)	7.8 (2.0)	7.7 (1.9)
Range	1-10	0-10	1-9	0-8	6-10	5-10	4-10	6-10
Coordinating body movements to carry out a strategy								
Mean (SD)	7.1 (2.2)	7.0 (2.5)	5.9 (3.0)	4.9 (2.9)	8.3 (1.2)	7.8 (1.8)	7.2 (1.2)	8.3 (1.4)
Range	0-10	0-10	0-9	0-8	7-10	5-10	6-9	7-10
Moving well enough to maintain successful play								
Mean (SD)	7.3 (2.5)	7.6 (2.8)	5.7 (3.1)	4.9 (3.1)	8.5 (1.2)	9.3 (1.2)	7.7 (2.1)	8.7 (1.4)
Range	0-10	1-10	0-9	1-8	7-10	7-10	5-10	7-10
Total								
Mean (SD)	7.6 (2.0)	7.6 (2.4)	6.1 (2.6)	5.5 (2.9)	8.6 (1.0)	8.6 (1.2)	8.1 (1.3)	8.6 (1.1)
Range	1-10	0-10	1-9	0-9	8-10	7-10	6-10	8-10

We found no relationships between weekly physical activity or video game play minutes and outcome variables. Both usability measures were moderately correlated with each other ($r_s=0.50$). Enjoyment and perceived exertion did not exhibit a relationship with other outcome variables. Self-efficacy after using the TPS was moderately correlated with Health-ITUES scores ($r_s=0.43$).

Participant Feedback and Researcher Observations

Overview

Feedback was collected from 21 participants. Additionally, researchers provided written observations during every gameplay session. The combined feedback and observations illustrated the accessibility of the TPS, the overall experience of gameplay, and areas of future improvement.

Accessibility of the System

The most frequent comment about accessibility reported by our participants was that the TPS was easy and simple to use. A few participants noted that they could not play typical sedentary video games due to a lack of hand dexterity, and the TPS enabled them to participate in video games.

They (touch pads) helped me play the games rocking back and forth. Hitting the back, moving in each direction. So better than me pressing a joystick up and down. [Man, 40 years, cerebral palsy]

Researchers observed and participants suggested aspects of the TPS that were barriers to accessibility such as the touchpads moving and drifting position during gameplay. Applying a sandbag weight to the touchpad stands reduced movement and drift. Because the TPS relies on skin contact to activate each touchpad, a few participants occasionally encountered difficulty activating a pad. Researchers were able to mitigate this barrier by applying a small amount of moisturizer to the participant's skin. Amputee participants occasionally encountered difficulty activating a touchpad with their prosthetic; however, they were able to after a researcher placed a small amount of conductive tape on the surface of the prosthetic. A couple of participants who used a manual wheelchair did not have brakes, and blocks were needed behind their wheels to keep their chair from drifting.

Right now, it is a neutral (touch) pad, being a visual person...colors would help me which ones go which way. [Woman, 32 years, amputee]

No difficulty activating the pads, but the stands swiveled and moved out of their way and needed repositioning. [Researcher's note]

Experience Using TPS for Video Game Play

Participants were asked to describe their overall experience playing video games with the TPS. Comments were mostly

positive about their play experience. The most common response was that their experience was enjoyable.

I think other people will enjoy it as much as I did, especially if you are in a wheelchair. [Woman, 21 years, hydrocephalus]

I think it's going to be good especially with people with lot lesser ability. [Woman, 48 years, spina bifida]

Participants described the experience as novel, intuitive, and responsive. Some participants also remarked that they were motivated to play again in the future. Two participants with hemiparesis liked that they could use their affected side during gameplay.

I like the touch pads because I was able to use my impaired limb during play. [Woman, 42 years, poststroke]

One participant noted that gameplay with the TPS was not as physically demanding as they anticipated it would be. Another participant expressed concern about the time necessary to become proficient using the TPS.

It was exciting, but had never done it before...I think it would take time to master. [Man, 58 years, spinal cord injury]

Future Iteration or Areas of Improvement

Participants provided many suggestions, and researchers observed several areas to improve the TPS for future use. Many of our participants suggested that they try sports games with the TPS. It was suggested by participants and researchers alike that the touchpads should be mounted in a way that prevents the pad from moving. Another suggestion is that we use color, letter, or other visual systems to quickly let players know which action was associated with each touchpad. It was noted that the TPS be revised so as not to require skin contact. Finally, it was suggested that the next iteration of the TPS feature a solution to address using a wheelchair without brakes.

Discussion

Principal Findings

We assessed the usability of the TPS and explored the enjoyment, perceived exertion, task self-efficacy, participant feedback, and researcher observations. In total, 21 individuals with impaired mobility played several video game titles (Table 1) while sitting in a chair, standing, or sitting in their own wheelchairs. A promising result was that every participant was able to use the TPS to play all video game titles for at least 5 minutes; however, numerous modifications were needed to foster the experience for many of the participants.

Consistent with other AVG controllers for people with impaired mobility, the participants found the TPS usable (Table 3) [13]. However, the Health-ITUES scores were slightly below the suggested benchmark [44]. Only the participants who used the TPS standing reported a minimum score above the usability threshold of 68. The participants who played sitting in a chair reported a mean score barely above the threshold. This suggests the TPS can be improved to be more usable to seated players.

Additionally, our overall Health-ITUES mean did not meet the suggested cutoff score of 4.32. Interestingly, our chair-sitting group reported the lower usability scores with higher variability than those who played sitting in their own wheelchairs, which is not consistent with the usability results of another AVG controller we were testing in our laboratory [13]. The chair we provided gameplay was consistent but every wheelchair player used their own device. Therefore, participants' own personalized devices likely provide a more comfortable gameplay environment, which may have affected their usability scores.

Similar to previous studies using AVGs among individuals with impaired mobility, participants moderately enjoyed using the TPS (Table 4) [20]. Similar to their peers without impaired mobility, participants had moderate to high self-efficacy using the TPS before and after gameplay [34,49]. Our lowest self-efficacy scores were reported by participants who played sitting in a chair, who also reported the lowest usability, enjoyment, and highest perceived exertion. It is possible that the participants sitting in a chair to use the TPS had a less positive overall experience than their peers who played standing or from their own wheelchair. The only 2 participants who reported below moderate enjoyment were individuals' poststroke who reported not playing video games (0 minutes per week). Both individuals also reported low self-efficacy postplay and low usability scores. While AVGs can enhance self-efficacy [29,32], lower enjoyment and lack of experience playing AVGs may reduce self-efficacy.

These data suggest that our participants perceived their exertion as somewhat easy to somewhat hard during video game play using the TPS (Table 4), which is consistent among individuals with neuromuscular conditions [50]. It is unclear why the 3 participants with the highest mean perceived exertion were men >50 years. To better understand the influence of the warmup game (Flower) on perceived exertion, we calculated an exercise RPE by removing all the warmup game RPE values. This did not alter exertion. Our observed perceived exertion scores are consistent with RPE observed from previous TPS testing [34]. Our RPE findings are also comparable to scores reported by adults with impaired mobility, playing video games using an adapted Nintendo Wii balance board and an adapted gaming mat from a sitting and standing position [18,20].

The participants regarded the touchpads as novel, fun, and entertaining but they did encounter some accessibility barriers. Modifications such as repositioning the touchpads, adding conductive tape to prosthetics, and providing moisturizer for dry skin were not anticipated because they were not encountered in previous testing of the TPS [34] or with a similar controller in our laboratory [13]. While successful efforts were made during the study to overcome accessibility barriers and enable players who had difficulty using the palm of their hand to contact the touchpads, the need to adjust the position of the touchpads multiple times in a single session may have detracted from the participant's experience. The subgroup that encountered the most frequent difficulty contacting the touchpads using their palm played sitting in a chair, which may account for the lower usability among this subgroup.

For future iterations, the stands used to mount the touchpads need to resist movement when a player exerts considerable force to activate. Due to the large body movements and quick reactions required to play video games using the TPS, the touchpads need to stay fixed in position during gameplay. Even though each touchpad was made large to mitigate the need for movement precision, touchpad movement during gameplay may cause the player to lose screen focus and thus introduce frustration. The TPS needs to remain robust to a varying degree of force from multiple directions to better accommodate individuals with impaired mobility. The TPS is currently being refined based on usability, participant feedback, and researcher observations. This system can be refined to work with adaptive video game equipment such as the Microsoft Adaptive Controller. Because the TPS is not limited to a single user, future research should examine the use of this system for multiple players simultaneously.

Limitations

First, the participants in this sample represented various mobility impairments; therefore, the number of players within each mode of play is few, which makes mode comparisons difficult. Second, our participants reported a wide range of weekly physical activity minutes (Table 2), limiting our ability to

generalize these results to sedentary individuals with impaired mobility, and it is possible that physically active individuals may find the TPS more usable. Third, video game selection was limited to specific titles we felt could be demonstrated and learned quickly. Therefore, we chose video game titles that required simple commands and may not be indicative of more complex games. Additionally, the featured video games may not have appeal to some participants. Finally, we did not standardize touchpad placement relative to the player due to varied levels of dexterity. We used a consistent touchpad layout, and modifying the touchpad layout may limit the generalizability of our results; however, we feel this decision engendered rich feedback regarding the accessibility of the TPS.

Conclusions

The TPS enabled people with impaired mobility to participate in AVG play. The TPS allows typical sedentary video games to be played by adults with impaired mobility while sitting, standing, and with their own mobility aids. Participants found the TPS to be usable, experienced moderate enjoyment, and achieved moderate intensity physical activity through gameplay. Key areas of improvement to the system were identified based on our measures, participant feedback, and observation.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Video game play appraisal.

[DOCX File, 22 KB - [rehab_v10i1e41993_app1.docx](#)]

Multimedia Appendix 2

Semistructured interview guide.

[DOCX File, 17 KB - [rehab_v10i1e41993_app2.docx](#)]

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Abbreviations

AVG: active video game

Health-ITUES: Health Information Technology Usability Evaluation Scale

ICC: intraclass correlation coefficient

RPE: ratings of perceived exertion

SUS: System Usability Scale

TPS: touchpad system

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Original Paper

A Digital Box and Block Test for Hand Dexterity Measurement: Instrument Validation Study

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Abstract

Background: The Box and Block Test (BBT) measures unilateral gross manual dexterity and is widely used in clinical settings with a wide range of populations, including older people and clients with neurological disorders.

Objective: In this study, we present a newly developed digitized version of the BBT, called the digital BBT (dBBT). The physical design is similar to the original BBT, but the dBBT contains digital electronics that automate the test procedure, timing, and score measurement. The aim of this study is to investigate the validity and reliability of the dBBT.

Methods: We performed measurements at 2 time points for 29 healthy participants. BBT and dBBT were used at the first measurement time point, and dBBT was used again at the second measurement time point. Concurrent validity was assessed using the correlation between BBT and dBBT, the paired *t* test, and the Bland-Altman analysis. Test-retest reliability and interrater reliability were examined using the interclass correlation coefficient (ICC) by repeated measures with the dBBT within an interval of 10 days.

Results: Our results showed moderate concurrent validity ($r=0.48$, $P=.008$), moderate test-retest reliability (ICC 0.72, $P<.001$), a standard error of measurement of 3.1 blocks, and the smallest detectable change at a 95% CI of 8.5 blocks. Interrater reliability was moderate with an ICC of 0.67 ($P=.02$). The Bland-Altman analysis showed sufficient accuracy of the dBBT in comparison with the conventional BBT.

Conclusions: The dBBT can contribute to objectifying the measurement of gross hand dexterity without losing its important characteristics and is simple to implement.

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KEYWORDS

assessment; Box and Block Test; BBT; concurrent validity; dexterity; digital Box and Block Test; dBBT; hand dexterity assessment; interrater reliability; test-retest reliability; validate; validity

Introduction

Dexterity is the ability of a person to use their fingers, hands, and arms to perform tasks such as activities of daily living [1]. Manual dexterity is an important indicator of upper limb motor function [2] and is frequently measured by researchers and clinicians to represent rehabilitative effectiveness [3]. One of the most commonly used assessments for gross manual dexterity

(International Classification of Functioning, Disability and Health domain mobility d4) is the Box and Block Test (BBT) [4,5]. The BBT is easy to understand, requires a short time to complete, and is suitable for individuals with limited hand function. In addition to gross dexterity, the BBT assesses other motor components, such as eye-hand coordination or crossing the partition wall [6]. Furthermore, a strong correlation has been found between the BBT and activities of daily living [7]. The

BBT consists of a box divided into 2 equal parts by a partition. The task requires transporting blocks from 1 box to another at a time. The result of this test is the number of transported blocks with 1 hand within 60 seconds. The BBT was validated with healthy people. The resulting scores are then compared with clinical norm data [8,9]. Benefits of the BBT include ease and speed of implementation.

Despite the seemingly simple determination of the final result (number of blocks in 60 seconds), the therapist must observe carefully during the execution of the test—in addition to timing with a stopwatch—to detect possible errors in the execution. Care must also be taken to ensure that the patient moves only 1 block at a time from 1 box to another. If several are transported at the same time, only 1 block is added to the result. When transporting the individual block, the participant must cross the partition of the BBT with their fingers at a time, and this must also be monitored. Thus, the errors detected by observation minimize the final result, which could affect the reliability and objectivity of the evaluation. By automating the timing and correct counting of the blocks, a possible variability of the evaluation should be minimized, which ensures comparable test results over time. The BBT assesses a change in hand function over time. The automation of the test sequence minimizes possible variances due to different testers.

Several further developments use different technologies in addition to the conventional BBT to increase the objectivity and reliability of the manual dexterity measurement. Using the traditional BBT, various technologies have been used to digitally capture hand movement during test execution, such as depth cameras [10], motion sensors [11], or infrared sensors [12]. Furthermore, there are several research works using virtual reality [13-16]. All these developments have in common that the easy handling of the conventional BBT is lost, as a considerable amount of equipment is required and therefore technical understanding from users. At the same time, data collection is automated and improved.

We have thus developed a digital version of the BBT—the digital Box and Block Test (dBBT)—that combines the advantages of automatic data collection with ease of use. The aim of this study was to validate the dBBT in comparison with the original BBT in healthy adults. In particular, this study aimed to evaluate: (1) the concurrent validity, (2) the test-retest reliability, and (3) the interrater reliability of the dBBT.

Methods

Overview

We follow the COSMIN (Consensus-Based Standards for the Selection of Health Status Measurement Instruments) standard, which is the consensus-based checklist for the preferred design characteristics and statistical methods of studies on measurement properties [17].

Study Design

This research follows a test-retest design with crossover. The participants were randomly matched into 2 groups. Data for BBT and dBBT were collected at 2 measurement time points, with crossover after the first measurement point. The total data collection period was 10 days.

A total of 2 testers (raters 1 and 2) conducted all data collection. Before the study, the 2 testers performed 2 pretests.

Conventional BBT

The BBT was developed by Jean Ayres and Patricia Buehler in 1957 and modified to the current version by Patricia Buehler and Elizabeth Fuchs in 1976. Normative data for children and adults were established in 1985 [8,9].

The BBT is a widely used outcome measure to quantify upper limb motor function, especially gross manual dexterity [6]. The BBT comprises a wooden box (53.7 cm×25.4 cm×8.5 cm) that is divided into 2 compartments (25.4 cm each) by a partition and 150 blocks (cubes with 2.5 cm side length) in 1 of the 2 boxes [9]. Participants have to move the blocks one by one from 1 compartment of a box to another in 60 seconds. The BBT is timed with a stopwatch, and after 60 seconds, the transported blocks (on average 75-90 for healthy persons) are to be counted by the test administrator. A 15-second trial period is permitted at the beginning of the test.

The dBBT

The digital version of the BBT, the dBBT, is quite similar to the BBT but uses digital measurements. We have developed the dBBT to further standardize the measurement with the BBT by using digital functions to automatically measure the time and the achieved scores. Figure 1 shows an overview of the dBBT. The dBBT consists of the control unit and the test box with a partition. The test box is in form and dimensions oriented to the specifications of Mathiowetz et al [9]. The dBBT and the blocks were created using a 3D printer. Load cells are installed in the bottom of the 2 boxes to record the number of blocks automatically. A microcontroller in the control unit processes the sensor signals, automatically measuring the test time, and controls the user inputs through the buttons and the output through the display.

On the control unit, the start button starts the timing, and the LEDs on the partition light up green until the test time is over; then they light up red. The dBBT automatically counts the valid blocks (if 2 blocks are transported at the same time, the system counts only 1 block for the valid result) and shows the achieved score (number of blocks in 60 seconds) on the display. Also, the 15-second trial period is provided by the dBBT.

The prototype of the dBBT enables the assessment according to the standardized specifications of Mathiowetz et al [9].

Figure 1. The components of the digital Box and Block Test board and control unit.



Participants and Recruitment

Participants were occupational therapy students at the University of Applied Sciences in Vienna (Austria). The sample size calculation for evaluating correlation was calculated with G*Power Version 3.1.9.7 (Heinrich-Heine-University Düsseldorf). The calculation with the factors correlation point biserial model, 2 tails, effect size 0.5 [18,19], α error .05, and power 0.85 [20] resulted in a sample size of 26. Participants were recruited in the fall of 2022 through a presentation of the study in collaboration with a faculty member in the program. The inclusion criteria were (1) individuals without a history of neuromuscular or orthopedic dysfunction that would significantly affect dexterity and (2) 18 years or older. Handedness was identified by asking the participant which hand was used for writing. In total, 32 people participated in this study.

Data Analysis

We used SPSS Statistics (version 28.0; IBM Corp) for data analysis. Descriptive statistics were used to describe the study population. The normality of the data was evaluated using the Shapiro-Wilk test. Concurrent validity was determined by the Pearson correlation coefficient (r) for the relationship between the conventional BBT and the dBBT at measurement point 1. The correlation was classified as follows: no or very low, $r=0-0.25$; low, $r=0.26-0.40$; moderate, $r=0.41-0.69$; high, $r=0.70-0.89$; and very high, $r=0.90-1.0$ [20]. The level of statistical significance was set at $P \leq .05$.

The agreement between the BBT and dBBT was examined using the Bland-Altman analysis to check for systematic bias and estimate the limit of agreement (LOA) [20,21]. In the Bland-Altman scatter plot, the x-axis represents the mean of these measurements, and the y-axis shows the difference

between the 2 paired measurements. The fixed bias was statistically evaluated using the 95% CI of the mean differences between the BBT and dBBT values. A fixed bias is present when 0 is not within the range of the CI. After ensuring that the differences are normally distributed, SD can be used for defining the LOA mean (SD 1.96) [22]. LOAs show how much the scores can vary in stable patients. A change in scores within LOAs or smaller indicates a measurement error; outside the LOAs, it can be assumed that these are statistically significant changes [20].

For assessing interrater and test-retest reliability, intraclass correlation coefficients (ICC) were used. To estimate the correlation, the following classification of correlation was used [23]: less than 0.5 poor, between 0.5-0.75 moderate, between 0.75-0.9 good, and greater than 0.9 excellent. Measurement error was determined by estimating the standard error of measurement (SEM) using the formula $\frac{SD}{\sqrt{ICC}}$, where SD is the standard deviation of the means from all probands [20] of the test-retest scores and ICC from the test-retest reliability. Smallest detectable change (SDC) was calculated, based on the test-retest parameter SEM, as follows: $1.96 \times SEM$ [20]. The SDC represents an absolute measure of reliability (measurement error) and is used to assist in interpreting results and determining whether a change between repeated tests is a random variation or a true change in performance [24].

Data Exclusion

In the data set, outliers became apparent after data collection during the initial data analysis. These outliers showed up in differences in the measurement repetitions. Values with more than 20% (above the 90th percentile) difference between 2 measurements cannot be assigned to any natural variance in healthy persons. As the participants were all individuals with unrestricted hand function, a true outlier can be ruled out. A

possible reason is seen as an error in the test execution or data collection. Therefore, 3 corresponding data sets from a total of 32 participants were excluded from further analysis. The sample size of the assessed data was thus 29.

Experimental Procedure

The study design includes 2 measurement time points. The test procedures took place in a room specially prepared for this purpose at the University of Applied Sciences Campus Vienna. The setting and test instructions for the BBT and the dBBT corresponded to the standard set by Mathiowetz et al [9]. The test instructions were translated into German by the author. One measurement of the writing hand of each participant was performed. Participants sat on a chair in front of a table. The test box was centrally located in front of them. The box with the blocks was on the side of the hand to be tested. The instructions for the test were read out by the tester according to the standardized instructions, including a short demonstration. The participants performed a 15-second trial period before the recorded test. For the start, the participants have to position their hands on the left and right sides of the box; then the start signal is given, and the timing starts [9]. The tests were timed at the BBT with a stopwatch and at the dBBT with the implemented time measurement at the push of a button. If the participant transports several blocks at the same time, only one is counted. If a block has fallen from the table, the participant should not be distracted by it and continue with the task. If the block was already transported over the partition before it fell down, it will be counted in the result [9].

Data collection took place at 2 measurement times, with 10 days in between. This period was chosen to be small enough so that no change in hand function occurs, but at the same time large enough to minimize influences from practice or memory [18,25]. A total of 29 participants were randomized into both groups, resulting in 14 participants in group 1 and 15 in group 2. At the first measurement, group 1 was tested from tester 1 with the

dBBT, and then on the same day using the conventional BBT. Group 2 was tested by tester 2 in reverse order (first the conventional BBT, and then the dBBT).

At the second measurement point, 10 days after the first measurement, a total of 15 participants took part. Both groups were tested using the dBBT. Here, both groups changed the tester: group 1 was thus tested by tester 2 and group 2 by tester 1.

This study design was chosen to allow assessing both test-retest reliability and interrater reliability as well as the validity of the dBBT compared with the BBT.

Ethics Approval

The study protocol was in accordance with the Declaration of Helsinki and was approved by the ethics committee (EK Nr 97/2022) of the University of Applied Sciences Campus Vienna. This study has been registered on the Open Science Framework [26].

Results

Participant Characteristics

The characteristics of the healthy participants who participated in this study are summarized in Table 1. The mean age of the participants was 23.5 (SD 5.2) years. The majority of the participants (n=28) were female and right-handed.

The second measurement point was completed by 15 probands. Table 2 shows the means, SDs, maximum and minimum scores, and the number of valid values of the 3 measurements with the BBT, dBBT1 (both at the first measurement time point), and dBBT2 (at the second measurement time point). The BBT shows on average a few higher scores than the dBBT1 and dBBT2. The average score ranges (blocks in 60 seconds) are 81.83 for the BBT, 76.86 for the dBBT1, and 80.71 for the dBBT2.

Table 1. Participant characteristics (N=29).

Characteristics	Value
Sex (female), n (%)	28 (97)
Age (years), mean (SD)	23.5 (5.2)
Tested hand, n (%)	
Right	28 (97)
Left	1 (4)

Table 2. Average performance of healthy persons taking the Box and Block Test (BBT) and the digital BBT (dBBT) (blocks in 60 seconds).

	Score, mean (SD)	Score, range	Valid values
BBT ^a	81.83 (6.35)	69-93	29
dBBT1 ^b	76.86 (4.98)	68-86	29
dBBT2 ^c	80.71 (7.75)	63-92	15

^aScores of original BBT at time point 1.

^bScores of dBBT at time point 1.

^cScores of dBBT at time point 2.

Concurrent Validity

A Pearson correlation analysis was performed to determine if there was a correlation between the variables BBT and dBBT1 and between BBT and dBBT2.

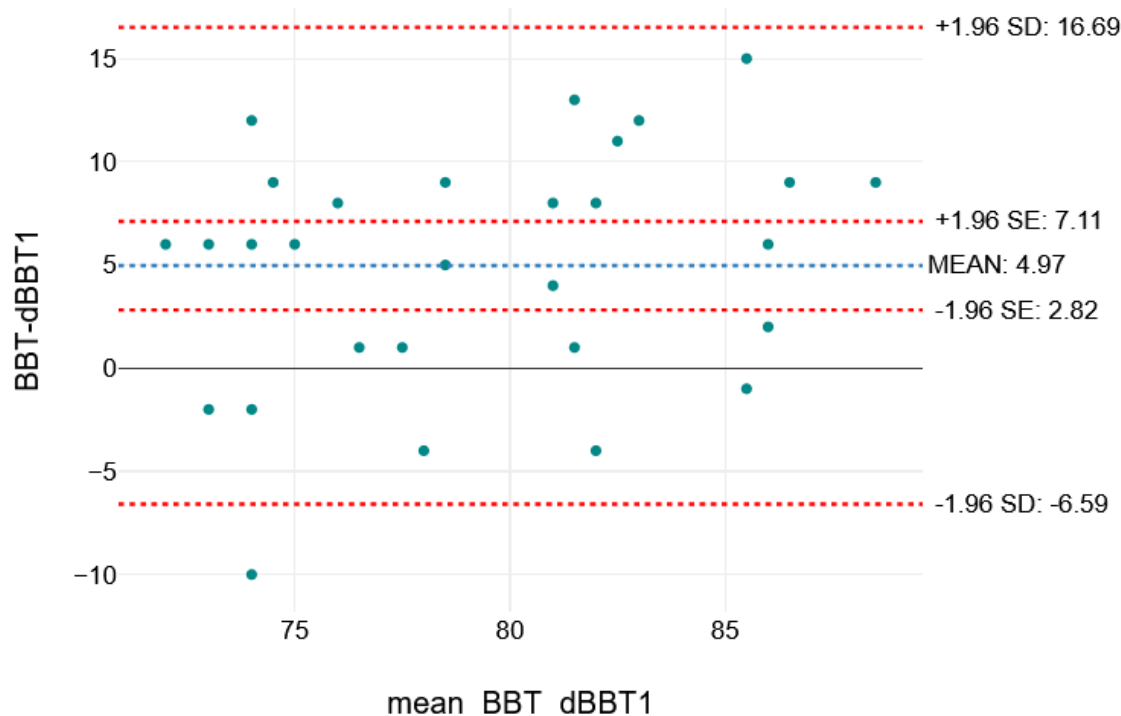
Our examination of BBT and dBBT1 ($n=29$) showed that BBT had higher scores (mean 81.83, SD 6.35) than dBBT1 (mean 76.86, SD 4.98) and dBBT2 (mean 80.71, SD 7.75). There was a moderate correlation of $r=0.48$ between the variables BBT and dBBT1. The result of the Pearson correlation analysis showed that there was a significant relationship between BBT and dBBT1 ($r_{29}=0.48$, $P=.008$).

A dependent samples t test showed that the difference between the scores of BBT and dBBT1 was statistically significant ($t_{28}=-4.96$, $P<.001$; 95% CI -7.21 to -2.72).

The Bland-Altman plot to evaluate the agreement between BBT and dBBT1 is shown in Figure 2. The fixed bias was statistically evaluated using the 95% CI (SE 1.96) of the mean differences between the BBT and dBBT values. For BBT and dBBT1, the mean difference was 4.97 (7.11-2.82), and a fixed bias was present.

All obtained values of BBT and dBBT1 (except one) were in the range of the LOAs (16.69 to -6.59), which indicates a sufficient agreement between the 2 measurement methods.

Figure 2. Bland-Altman plot for agreement between the scores of the Box and Block Test (BBT) and the digital BBT (dBBT1).



Test-Retest Reliability

For the calculation, the scores of the dBBT (blocks in 60 seconds) were compared at the 2 measurement points within a 10-day interval. From the whole sample of 29 healthy participants, 15 completed the second measurement. A total of 14 participants did not attend the second measurement point without giving a reason. The test-retest reliability for these 15 participants was determined by calculating the ICC (3, k) based on the 2-way mixed model (k fixed raters are defined), absolute agreement (agreement between 2 raters is of interest), and average measure [20,27]. The ICC is moderate, with an ICC of 0.72 (-0.23 to 0.93 ; $P<.001$). Because the ICC is only an expected value of the true ICC, it is appropriate to assess the degree of reliability on the basis of the 95% CI of the ICC value and not the ICC value itself [23]. The value 0 is included in the CI 95% range, indicating that the correlation is not statistically significant.

An SEM of 3.1 blocks was identified, which represented 3.88% of the mean score observed in the test-retest session.

The SDC was 8.5 blocks (10.77%); 95% of the tested population had a random variation of less than 8.5 blocks on repeated testing, and a value above would indicate a true change beyond an expected measurement error. An SDC% $<10\%$ is considered to indicate an excellent random measurement error [3]. The SDC% (10.77%) of the dBBT indicates that the dBBT is capable of supporting clinicians in assessing the significance of outcomes and interpreting treatment efficacy.

Interrater Reliability

Interrater reliability was assessed with ICC (2, k), based on the 2-way mixed and consistency model [20,27]. For this purpose, the results of tester 1 and tester 2 were compared for the 15 participants who completed the dBBT at both measurement points. The calculated interrater reliability was moderate, with an ICC of 0.67 (0.02-0.89; $P=.23$) and was statistically significant. The result was close to the limit of high interrater reliability, which is 0.7 [18].

Discussion

General

The aim of this study was to evaluate the concurrent validity, the test-retest reliability, and the interrater reliability of the newly developed dBBT.

Previous studies have presented various further developments of BBT assessments, such as the conventional BBT extended with additional technologies [10-13,28]. Other works have also investigated the BBT using virtual reality [14-16,29]. Compared with these BBT implementations, our new dBBT is unique because no additional technical equipment is required. It is a stand-alone solution, like the conventional BBT, and therefore does not require any additional skills from the test administrator or proband. At the same time, it offers digital functions that support the execution of the measurement (collection of time and result).

Concurrent Validity of the dBBT

On the whole, participants moved fewer blocks with the dBBT1 (mean 76.86, SD 4.98) and the dBBT2 (mean 80.71, SD 7.75) than in the original BBT (mean 81.83, SD 6.35).

The comparison of the new dBBT with the original BBT found a moderate correlation between the BBT and dBBT ($r_{29}=0.48$, $P=.008$). These results are comparable to Everard et al [4], who reported a correlation of $r=0.58$ ($P<.01$) for healthy people who completed hand dexterity measurement with the BBT and a virtual reality version of the BBT.

The scores of dBBT1 were significantly lower than the scores of BBT measurements ($t_{28}=-4.96$, $P<.001$; 95% CI -7.21 to -2.72).

The Bland-Altman plot showed that the dBBT1 achieved, on average, 4.97 fewer blocks than the measurement with the BBT. As the value 0 is not in the 95% CI of the mean (7.11-2.82), a fixed bias is assumed. All but one of the values collected fell within the LOAs (16.69 to -6.59), indicating that the dBBT has sufficient accuracy to provide an accurate measure of hand dexterity.

Test-Retest Reliability of the dBBT

The test-retest reliability, ICC (3,k), of the 2 dBBT sessions ($n=15$) was moderate, with an ICC of 0.72 (-0.23 to 0.93; $P<.001$), in healthy adults. A comparable study by Everard et al [4] reported ICC values of 0.7 to 0.9.

The SEM calculated for the dBBT was 3 blocks. SDC, useful for interpretation of real changes in hand dexterity, was 8.5 blocks (10.77%) for dBBT.

The ICC value indicates what proportion of the total variance over a range of values is due to heterogeneity among study participants [30]. In this study, only healthy participants of mainly similar age were tested. A lack of variance among the participants may result in a lower ICC value [20].

Interrater Reliability of the dBBT

The examination of interrater reliability showed a moderate ICC of 0.67 (0.02-0.89; $P=.23$). In contrast, in the study by

Mathiowetz et al [9], a high interrater reliability ($r=0.85-0.99$) was reported. However, this study is not directly comparable because the calculations were made using the Pearson correlation coefficient, which is no longer considered contemporary [17,20]. Platz et al [31] also showed high interrater reliability with an ICC >0.9 .

It should be noted in this interrater reliability result that the sample has low variances, which may lead to a low ICC value [20].

Clinical Implications

The BBT is suitable for use in clinical settings. It measures the dexterity performance of the hand. The BBT is particularly recommended for progress measurements of patients with neurological disorders [32]. The BBT is mainly used to assess therapy effects, that is, a measurement is taken at the beginning of a defined period and a repetition at the end. The assessment of a possible therapy effect is solely based on the comparison of these 2 measurements. Therefore, the fact that the dBBT measures on average 5 blocks less than the original does not affect its suitability as a measurement tool. It does not affect the ability of the dBBT to assess a possible therapeutic effect.

The dBBT shows moderate results in test-retest and interrater reliability. The dBBT enables compliance with the standardized measurement protocol, according to Mathiowetz et al [9]. It automatically measures the test time, counts the transported blocks, and shows the achieved result on a display. These functions help to increase objectivity. The material (plastic) is well suited for clinical use, compared with the original, which is made of wood. The shape of the dBBT is similar to the BBT, so it is just as easy for clinicians to transport and use.

In the next step, the practicability of the dBBT will be investigated in qualitative studies in order to be able to make statements about its clinical utility. After that, studies are planned with populations that typically use the BBT, with people after stroke and people with multiple sclerosis. These steps, which follow this study, will make it possible to make statements about the generalizability of the results.

Limitations

The study was conducted with healthy individuals without hand dexterity limitations. Therefore, the results need to be confirmed in future studies in patients with hand dexterity impairments.

In this study, the results of hand dexterity measurements from 2 measurement time points were collected and compared. From the authors' point of view, the fact that the majority of the participants were female had no influence on the present results.

The sample size was calculated to be sufficient for group comparisons according to our power analysis. However, at the second measurement time point, only 15 people participated, which could affect the strength of the calculations for test-retest reliability and interrater reliability.

The homogeneity of the participant group could also have an influence on the results.

Conclusions

This study showed that the newly developed dBBT is a valid, reliable, and usable tool to assess manual dexterity among

healthy participants. The dBBT provides automatic timing and counting to help further objectify the results of hand dexterity measurement.

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Data Availability

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

Conflicts of Interest

None declared.

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Abbreviations

BBT: Box and Block Test

COSMIN: Consensus-Based Standards for the Selection of Health Status Measurement Instruments

dBBT: digital BBT

ICC: intraclass correlation coefficient

LOA: limit of agreement

SDC: Smallest Detectable Change

SEM: standard error of measurement

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Review

Use of Assistive Technology for Persons with Psychosocial Disability: Systematic Review

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Abstract

Background: Assistive technology (AT) refers to assistive products (AP) and associated systems and services that are relevant for function, independence, well-being, and quality of life for individuals with disabilities. There is a high unmet need for AT for persons with disabilities and this is worse for persons with cognitive and mental or psychosocial disabilities (PDs). Further, information and knowledge on AT for PDs is limited.

Objective: The aim of this review was to explore the pattern of AT use among persons with PDs and its associated socioeconomic and health benefits.

Methods: The review was reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), and we conducted systematic searches in the 4 databases: PubMed, Embase.com, APA PsycInfo (Ebsco), and Web of Science (Core Collection) with the following index terms: "Assistive Technology," "Self-Help Devices," "Quality of Life," "Activities of Daily Living," "Mental Disorders." We included only AT individuals with PDs can independently use without reliance on a provider. Identified papers were exported to EndNote (Clarivate) and we undertook a narrative synthesis of the included studies.

Results: In total, 5 studies were included in the review which reported use of different AT for schizophrenia, bipolar disorder, depression and anxiety disorders. The APs described in the included studies are Palm tungsten T3 handheld computer, MOBUS, personal digital assistant, automated pill cap, weighted chain blankets, and smartphone function. All the AT products identified in the studies were found to be easily usable by individuals with PDs. The APs reported in the included studies have broad impact and influence on social function, productivity, and treatment or management. The studies were heterogeneous and were all conducted in high-income countries.

Conclusions: Our study contributes to and strengthens existing evidence on the relevance of AT for PDs and its potential to support socioeconomic participation and health. Although AT has the potential to improve function and participation for individuals with PDs; this review highlights that research on the subject is limited. Further research and health policy changes are needed to improve research and AT service provision for individuals with PDs especially in low-income settings.

Trial Registration: PROSPERO CRD42022343735; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=343735

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KEYWORDS

assistive technology; assistive products; psychosocial disability; inclusion; participation; rehabilitation; psychosocial; health policy; socioeconomic; well-being

Introduction

Assistive technology (AT) is a generic term used to refer to assistive products (AP) and associated systems and services that are relevant for maintaining or improving an individual's functioning, independence, well-being, and quality of life [1,2]. The 2022 global report on AT suggests that AT is relevant for inclusion and its use extends beyond persons with disabilities to include populations of persons with chronic conditions and also persons without disabilities [1]. Globally, about 2.5 billion are in need of AT, and this is expected to increase to over 3.5 billion people by 2050 [1].

This high unmet need for AT cuts across all types of disabilities but is often worse for AP related to mental and cognitive disabilities. The predominant examples of AT use and provision are often for physical disabilities, such as walking devices or hearing aids. However, individuals with psychosocial disabilities (PDs) need AT and would benefit from AT [1]. PDs are those disabilities that may arise on account of mental health conditions, and which hinder those individuals from leading independent and functional lives [3,4]. Functional capacity, which refers to the ability to perform tasks and activities necessary or desirable in life is an essential component of independent living and diagnostic criteria for mental health and neuropsychological disorders [5]. The World Health Organization estimates that a quarter of the world's population will have some form of mental health condition in their lifetime [6]. In the United States alone, nearly 1 in 5 adults live with a mental illness (57.8 million in 2021) which substantially interferes with or limits their daily life activities [7]. The 2022 global report on AT enumerates the benefits on APs for mental health to include "person-centeredness, convenience, ease of accessibility and different modes of accessibility, increased coverage and availability of services, cost effectiveness" [1,8].

Therefore, the usage of AT for individuals with PDs is critical. Ringland et al [9] highlights the need to understand mental illness as a PD and the importance of provision of AT to improve function. AT may support activities such as scheduling assistance, task management, calming and comforting, mindfulness, and distraction [8,10,11]. AT products that support mental function include items such as watches, electronic calendars, custom-made PDA (personal digital assistant), weighted or ball blankets, cell phones (using special mobile apps). Emphasizing patient independence, AT provides tools for self-management of mood and behavior tracking, monitoring of sleep and diet, symptom tracking, self-awareness of breathing rate, and self-measurement of pulse [8]. For example, in patients with schizophrenia, AT can provide blocking or managing auditory hallucinations with music or audio files, medication management, tools for connecting with community, monitoring of symptoms, and identification of coping strategies [12,13]. A report by the Nordic Center for Welfare and Social issues suggests that AT for persons with mental health problems have economic benefits such as increased ability for employment,

reduced need for care, and reduced use of health services [8]. The report underscores the importance of AT for PDs and describes the usefulness of AT such as a visual countdown timer for improved concentration for persons with manic depression; PDA in control over tasks for individuals with schizophrenia and ball blanket for relief of anxiety [8].

Despite the known improvements AT can provide for persons with PDs, the research on use of AT for mental health is limited [1,14]. The United Nations Convention on Rights of persons with disabilities recommends equitable use and provision of AT for persons with disabilities [15]. Research on use and provision of AT for individuals with PDs is relevant for socioeconomic, independence and well-being of affected individuals. The aim of this review is to respond to this need by exploring the use of AT for persons with PDs and associated socioeconomic and health benefits. In this study, we focused specifically on what AT individuals with PDs can use independently which are not provider dependent. Studies endorse the importance of user centered AT and its relevance in promoting use of AT and their independence.

Methods

Study Design

This review is reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [16]. The protocol for the review was registered in a PROSPERO (prospective register for systematic reviews) [17].

Search Strategy

To identify the relevant publications, we conducted systematic searches in the bibliographic databases PubMed, Embase.com, APA PsycInfo (Ebsco) and Web of Science (Core Collection) from inception up to December 20, 2022, in collaboration with a medical information specialist. The following terms were used (including synonyms and closely related words) as index terms or free-text words: "Assistive Technology," "Self-Help Devices," "Quality of Life," "Activities of Daily Living," and "Mental Disorders."

The references of the identified papers were searched for relevant publications. Only studies in the English language were accepted. Duplicate papers were excluded by a medical information specialist using EndNote (version 20.0.1; Clarivate), following the Amsterdam Efficient Deduplication-method [18] and the Bramer-method [19]. The full search strategies for all databases can be found in [Multimedia Appendix 1](#).

Data Collection

This review includes studies on the use of AT for mental health problems. Specifically, populations diagnosed with anxiety, depression, bipolar disorders, and schizophrenia, in adults older than 18 years. For the purpose of this review, our focus was on PDs; hence, studies on cognitive disabilities and intellectual disabilities were excluded [20,21]. Although AP includes

software, mobile-health, eHealth programs, and other internet-based services which rely on provider-led platforms, in this review we sought to include only hardware-based AP that may be independently used by the individual [1].

All relevant papers relating to the usage of AT for PDs until December 2022 were captured. Identified papers were exported to EndNote. The literature search generated a total of 6223 references: 1878 in PubMed, 2844 in Embase.com, 570 in APA PsycInfo, and 931 in Web of Science. After removing duplicates of references that were selected from more than 1 database,

4098 references remained. Further, 2 reviewers CFM and IDE independently screened all potentially relevant titles and abstracts for eligibility. If necessary, the full-text paper was checked for the predefined eligibility criteria (Textbox 1). Differences in judgement were resolved through a consensus procedure. Studies were included if they met the following criteria. After screening, 23 papers were selected for full-text screening; out of which five were selected for the final review. The flowchart of the search and selection process is presented in Figure 1.

Textbox 1. Eligibility criteria for study selection.

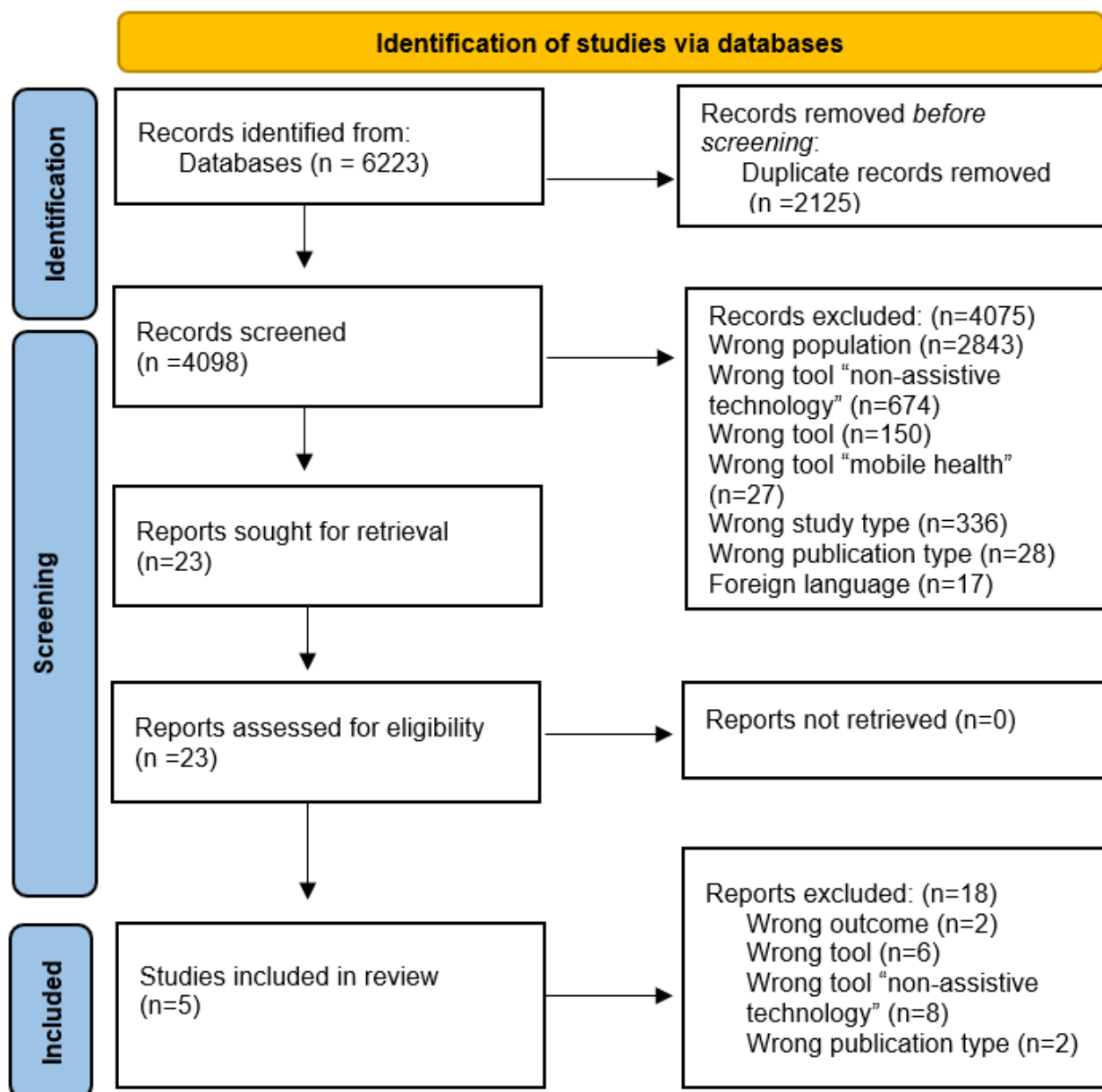
Inclusion criteria

- Studies on the utilization of assistive technology for persons older than 18 years who have been diagnosed with or are suspected of having a psychosocial disability
- Assistive technology or assistive products hardware that are under the control of the user
- Studies regarding disability associated with anxiety, depression, bipolar disorders, and schizophrenia
- Outcomes on function, treatment, and socioeconomic participation
- English language

Exclusion criteria

- Studies focusing on the use of assistive technology by individuals under the age of 18 years or not written in English will be excluded
- Assistive technology software
- Studies regarding autism and cognitive disabilities such as dementia or intellectual disabilities
- Other outcomes unrelated to outcome of interest
- Non-English language studies

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of the study selection process.



Data Synthesis

To synthesize the collected evidence, an extraction table was created. The following items were included: the authors, the aims, study design, country, PD population (ie, age, type of PD, setting, and outcome), APs and pattern of use, analysis, outcome (socioeconomic participation and health), and quality assessment. Quality assessment was conducted by CFM and reviewed together with IDE using the Mixed Methods Critical Appraisal Tool [22]. The Mixed Methods Critical Appraisal Tool is a systematic appraisal tool where 2 independent reviewers score the quality of the included studies [22]. The extraction was conducted by CFM and reviewed together with IDE. A summary of the data extraction is presented in Multimedia Appendix 2. Due to the limited and heterogeneous nature of the studies included in the review, a narrative synthesis was undertaken to highlight the use of AT for PDs.

Results

Study Characteristics

The characteristics of the 5 studies [23-27] included in the analysis are presented in Multimedia Appendices 2 and 3. The studies were heterogenous in their objective, country of origin, study design, AT type, and study population and were published between 2008 and 2021. In total, 2 studies were undertaken in the United States [23,25], and the other 3 were each in France, Sweden, and Italy [24,26,27]. Four of the studies were quantitative with three using experimental and randomized control trial design [24,26,27], one adopting a prospective design [25] while 1 study was a single patient case study report [23]. Of these 5 studies, two focused on AP for schizophrenia [23,24], one was specific for bipolar disorder [25], one was for a mixed group of depression, anxiety, and bipolar disorder patients [26], and one was for a combined group of schizophrenia and

depression patients [27]. The quality of the included studies ranged from moderate to strong. Further, 3 studies were of moderate quality [23,24,27] while 2 were of strong quality [25,26]. In the next sections, we will describe APs reported in included studies and their *pattern of use* for individuals with PDs and the outcomes reported in the studies that supports their *socioeconomic participation or health*.

APs and Pattern of Use

The analysis found 2 broad categories of AP; 3 studies focused on devices in the form of digital devices [23,24,27] and 2 studies reported devices with atypical digital element [25,26]. All digital devices could be used independently by the patient, although some needed preprogramming from the study researchers.

In total, 2 studies used versions of PDAs [23,24]. The Palm digital computer was used in the Kimhy and Corcoran [23] study as a means of complementary treatment with provider led cognitive behavioral therapy. The Palm computer was employed for the case report for a patient with schizophrenia [23]. The device prompted the user to input information regarding changes in thoughts, mood, behavior, and social contexts throughout the day [23]. The utility of a PDA device was also seen in the Sablier et al [24] study with schizophrenia patients, through the MOBUS device. The MOBUS device prompted the user to record symptoms of their condition when conducting activities of daily living (ADL) [24]. The device allowed the user to track their symptoms of “distress,” “tiredness,” and “voices,” along with a scale of the level of which they were experiencing the symptom [24].

The usage of a smartphone as a form of AP was tested in the study by Resta et al [27]. While the default for smartphone usage as a means of AT is to rely on specialty developed apps, this study highlighted the utility of the phone itself. The study used Samsung galaxy phones equipped with alarms which were set up to provide verbal reminders at the time an activity was due and then provided verbal instructions for the single activity steps [27].

In total, 2 studies focused on atypical digital devices, one testing the effectiveness of a pill cap monitor [25] and another treating insomnia with a weighted blanket [26]. The study regarding the pill cap monitor recorded instances of the bottle opening and stored it in memory chip, tracking patients’ presumed dosing episodes [25]. This small chip kept track of the number of openings per day for an 8-day period, data which could be viewed by providers [25]. For the user, the pill cap served as an external marker for keeping track of time of last dosing. For instance, 1 user was meant to take a medication every 8 hours and the monitor kept them informed of the time since last opening and presumed first daily dosage [25].

The weighted chain blanket was to be used nightly for combatting difficulties in falling asleep, problems staying asleep, and the subsequent daytime symptoms connected to sleeping issues in individuals with major depressive disorder, bipolar disorder, and generalized anxiety disorder [26]. The physical weight of the chain blanket was determined to have a calming sensory effect through deep pressure stimulation [26].

Outcomes and Related Socioeconomic Benefits

The studies analyzed reported influences of the different AP on the individuals’ daily functioning and socioeconomic benefits. These outcomes may be broadly classified into social function, productivity, and treatment or management.

Social Function

The APs impact on participants’ social settings and day-to-day activities was a prominent outcome observed in multiple studies. These studies consistently revealed notable improvements in social capabilities and overall functionality resulting from the use of these devices. For instance, the study conducted by Kimhy and Corcoran [23] emphasized how participants experienced enhanced recognition of dysfunctional thoughts with the aid of the PDA tool. Moreover, the PDA device served as a valuable confidence-building tool, enabling users to express themselves more productively and clearly [23]. Similarly, in the Sablier et al [24] study, the utilization of the PDA device was associated with increased ambition to engage in new activities and greater willingness to socialize. Notably, the use of weighted blankets to combat insomnia yielded an additional positive outcome by reducing daytime fatigue, which facilitated behavioral activation—an important factor for individuals with depression [26].

Productivity

One study’s findings described the use of the AT for improving participants’ ability to complete coursework tasks [23]. Further, the AT aided in an increased interest in activities with a greater sense of competency toward them [23]. The Resta et al [27] study using the smartphone functions, reported a significant increase in the number of activity steps correctly performed when supported by the devices’ prompting.

The secondary impacts of the utilization of the weighted blankets were reported as increased rates of activity, and patients were able to sustain daily activity for longer [26]. This was attributed to increased sleep maintenance, and decreased reports of resting periods needed during daytime activities, as well as reduced symptoms of fatigue [26].

Treatment or Management

A key outcome for 3 of the studies analyzed was the improvement in independent treatment management [23,25,26]. In the study by Ekholm et al [26] the targeting of insomnia led to an antidepressive effect on the participants. In this study, depressive and anxiety symptoms decreased significantly for participants allocated the weighted blanket which was attributed to the cyclical correlation between insomnia and depression [26].

Reduction in symptoms of anxiety, guilt, and depression was also reported in the patient in the study by Kimhy and Corcoran [23]. The utilization of the PDA device allowed the user to develop feelings of hopefulness and ambition toward their future [23]. Further, the utility of the pill-cap monitors in the Sajatovic et al [25] study showed clear improvement in adherence to medication and treatment.

Discussion

Summary of Findings

This review highlights the use of a variety of AT for PDs including schizophrenia, bipolar disorder, depression, and anxiety disorders. However, it also reveals a dearth of empirical studies on AT that individuals with PDs can use independently. This finding has several implications and may be subject to several interpretations. First, the selected 5 studies indicated relevance of AT for increased productivity (eg, in school work), increased motivation to try new activities and social function, improved medication adherence, improved sleep, and ADLs. These benefits demonstrate the need to prioritize AT for use by individuals with PDs. It also aligns with the report of the Nordic Center for Welfare and Social on AT use for mental health and the benefits for social function [8].

On the other hand, the limited nature of studies on the subject may imply an overarching lack of awareness of the benefits AT can have on the lives of those with these specific PDs. The lack of understanding about mental illness and its recognition as a disability is not new. This may explain the study by Ringland et al [9] that attempts to make a case for understanding mental ill-health as a PD and the importance of AT in this regard. The critical need to prioritize AT for mental health underscores its coverage in the 2022 AT report and call to prioritize coverage of AT based on peoples' needs [1]. Second, few identified studies may imply that the AT needs of individuals with PDs are not met especially in low- and middle-income countries. This evidence is based on the fact that all the studies included in this review are from high-income countries. Despite the limited number of studies recorded in this review, the included relevant literature provides important findings on AT types for PD and their critical user impact.

This review reiterates the relevance of different AT types for schizophrenia, bipolar disorder, depression, and anxiety disorder [23-27]. These findings are corroborated by previous studies which have reported AT use in different mental health problems [8,10,11,17,28]. The different first groups of AT reported in this review were digital in nature in the form of PDA [23,24] and the smartphone [27]. The rise in use of digital mental health apps and recognition of their importance has been previously reported [13]. The majority of these phone apps are outside the control of the individual or provider-controlled [13,29]. In this study, we have focused on AT within the control of the users. The potential for use of an AT in combination with machine learning to predict panic attacks has also been reported [30]. The second group of APs found in our review were not typically digital. The pill cap monitor and the weighted chain blankets reported in 2 different studies were reported as useful for individuals with different forms of PDs [25,26].

Our review underscores the relevance of different AP for improved social function, productivity, and treatment for individuals with PDs. While the PDA in the study by Kimhy and Corcoran [23] helped in the recognition of dysfunctional thoughts, the one by Sablier et al [24] increased the interest to try new activities. These reported outcomes are essential for improved function and participation for individuals with PDs

and ought to be available for those who need them similarly, the weighted blanket was reported to increase daytime activity levels and reduce daytime symptoms of fatigue, anxiety, and depression [26]. The potential of PDs to reduce energy levels and reduction in social participation has been previously reported [5]. The reported roles of the AP to help with these functions imply opportunities to improve the functional capacity of affected individuals and ADL.

Similarly, this review noted the impact of the AP on productivity. The PDA in the case report was reported to increase the ability to complete tasks [23] while the smartphone in Resta et al [27] increased the number of activity steps correctly performed. Further, the weighted blankets were reported which were reported to increase activities and may help boost an individual's productivity [26]. These findings have implications for use in individuals with low energy on account of PDs and may be adapted for use to help improve ADL.

Further, three of the studies included in the review reported improvement in the independent treatment management [23,25,26] for individuals with PDs. The implication of these findings is that the PDA may be used to improve the feeling of hopelessness [23] which is a cardinal feature in depression [5]. The pill cap's usefulness in improving treatment adherence may be adapted for individuals with other PDs having difficulties adhering to their medications [25]. The findings in these studies indicate that with adequate support, individuals with PDs can lead independent and productive lives which may improve their overall health outcomes [3]. The evidence suggests that the APs may offer reduced need for caregiver assistance and health care services. The potential of the weighted blankets to reduce depressive and anxiety symptoms in participants allocated the weighted blanket implies opportunities to use them for individuals who indicated a need for them.

This review highlights the lack of available options for individuals who may not have access to AP. Only about 10% of individuals in need of AT have access to them [13]. Of note, this estimate refers more to individuals with physical disabilities than those with PDs. This is true in low- and middle-income countries which is not represented in the countries included in the study. It is also pertinent to point out that electronic or digital APs may not be suitable or accessible for all patients, particularly the elderly or those with comorbidities such as learning disabilities or impaired. It is essential that interventions and policy actions on use and provision for APs for PDs conceives options to include and cater for the needs of such individuals.

This review has some limitations. First, our eligibility criteria meant that we only included AT products that were under the control of the user. We opted for this as it would have otherwise included several digital mental health, smartphone, and app-based tools which are sometimes provider-dependent and outside the control of the user. Through the study screening process, the reliance on smartphone apps as the "go-to" tool for individuals with PDs was prominent. APs that users can use independently are easier to use. Further, ethical and safety concerns of provider-controlled digital and AT products for

mental health have been previously reported [13,29]. Furthermore, the inclusion of only English studies limited the scope of the review.

Conclusions

This review revealed reported use of different AT for PDs including schizophrenia, bipolar disorder, depression, and anxiety disorders, that showed benefits in increasing productivity (eg, in school work), motivation to try new activities and social function, improving medication adherence, sleep, and ADLs.

Yet, we noted that these studies were limited in number and scope, and there were no studies from a low-and-middle country. This review indicated a pressing need for more empirical research focusing on the utilization, user experience, and evaluation of ATs tailored to individuals with PDs, especially from low-and-middle income countries. Such studies are essential for informing evidence-based policies and practices, ultimately leading to improved functioning, enhanced participation, and the promotion of inclusive environments for individuals living with PDs.

Acknowledgments

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Data Availability

The data used in this study are available from the corresponding author upon reasonable request.

Authors' Contributions

IDE conceptualized the systematic review with contributions from SSB, JP and NJ. IDE wrote the initial draft with contributions from CFM. RV completed the search strategy with contributions from IDE and SSR. CFM completed the study screening and extraction with the support of IDE. IDE, CFM, SSR, R V, SSB, JP and NJ reviewed the initial draft and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy for databases.

[DOCX File, 22 KB - [rehab_v10i1e49750_app1.docx](#)]

Multimedia Appendix 2

Study characteristics, objectives, and assistive product use and outcomes.

[DOCX File, 16 KB - [rehab_v10i1e49750_app2.docx](#)]

Multimedia Appendix 3

Assistive technology for psychosocial disability.

[DOCX File, 2757 KB - [rehab_v10i1e49750_app3.docx](#)]

Multimedia Appendix 4

PRISMA Checklist.

[PDF File (Adobe PDF File), 66 KB - [rehab_v10i1e49750_app4.pdf](#)]

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Abbreviations

ADL: activity of daily living

AP: assistive product

AT: assistive technology

PD: psychosocial disability

PDA: personal digital assistant

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: prospective register for systematic reviews

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Original Paper

Older Adults' Engagement and Mood During Robot-Assisted Group Activities in Nursing Homes: Development and Observational Pilot Study

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Abstract

Background: Promoting the well-being of older adults in an aging society requires new solutions. One resource might be the use of social robots for group activities that promote physical and cognitive stimulation. Engaging in a robot-assisted group activity may help in the slowdown of physical and cognitive decline in older adults. Currently, our knowledge is limited on whether older adults engage in group activities with humanlike social robots and whether they experience a positive affect while doing so. Both are necessary preconditions to achieve the intended effects of a group activity.

Objective: Our pilot study has 2 aims. First, we aimed to develop and pilot an observational coding scheme for robot-assisted group activities because self-report data on engagement and mood of nursing home residents are often difficult to obtain, and the existing observation instruments do have limitations. Second, we aimed to investigate older adults' engagement and mood during robot-assisted group activities in 4 different nursing care homes in the German-speaking part of Switzerland.

Methods: We developed an observation system, inspired by existing tools, for a structured observation of engagement and mood of older adults during a robot-assisted group activity. In this study, 85 older adult residents from 4 different care homes in Switzerland participated in 5 robot-assisted group activity sessions, and they were observed using our developed system. The data were collected in the form of video clips that were assessed by 2 raters regarding engagement (direction of gaze, posture as well as body expression, and activity) and mood (positive and negative affects). Both variables were rated on a 5-point rating scale.

Results: Our pilot study findings show that the engagement and mood of older adults can be assessed reliably by using the proposed observational coding scheme. Most participants actively engaged in robot-assisted group activities (mean 4.19, SD 0.47; median 4.0). The variables used to measure engagement were direction of gaze (mean 4.65, SD 0.49; median 5.0), posture and body expression (mean 4.03, SD 0.71; median 4.0), and activity (mean 3.90, SD 0.65; median 4.0). Further, we observed mainly positive affects in this group. Almost no negative affect was observed (mean 1.13, SD 0.20; median 1.0), while the positive affect (mean 3.22, SD 0.55; median 3.2) was high.

Conclusions: The developed observational coding system can be used and further developed in future studies on robot-assisted group activities in the nursing home context and potentially in other settings. Additionally, our pilot study indicates that cognitive and physical stimulation of older adults can be promoted by social robots in a group setting. This finding encourages future technological development and improvement of social robots and points to the potential of observational research to systematically evaluate such developments.

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KEYWORDS

human-robot interaction; social robot; nursing home; observational research; group activity; observational; pilot study; robot; engagement; mood; well-being; cognitive; elderly; social robot; nursing; aging

Introduction

Background

Given the global phenomenon of aging populations, strategies to reduce the risk of physical and cognitive decline and the associated consequences on the well-being of older adults and their ability to cope with everyday life are urgently needed [1]. One resource in this context might be the use of the so-called social robots. According to Anzalone and colleagues [2], social robots can be understood as “machines that humans should perceive as realistic, effective partners, able to communicate and cooperate with them as naturally as possible interestingly enough.” The acceptance of social robots and their potential to promote the well-being of older adults have been explored and demonstrated in several studies [3-8]. Most of the robots studied are animallike, with PARO [9], a seal-shaped robot, being a prominent example [2-5,10,11]. However, animallike companion robots are not multifunctional and their interactions are not sufficient for those who require care and support. A study comparing animallike and humanlike social robots in group settings provided the first evidence that humanlike robots have greater effects on cognitive training than animallike robots [12], which brings humanlike social robots into the focus of research for group activities for older adults. This so-called third generation of social robots, including Nao, Pepper, QT, Sophia, Jack, LOVOT, or Tessa [12-18], continue to evolve, as new software is developed and released into the market [13]. Their humanlike forms [19] and integrated voice capability allow for interactions through facial expression, gestures, and voice. Thus, these robots can support cognitive and physically stimulating exercises, which in combination, achieve the best results in maintaining cognitive abilities in older adults [1].

Few studies [7,12,13,20-25] have investigated whether older adults actively engage in and experience positive moods during these activities. Since mood and engagement are crucial for the effectiveness of such group activities with a humanlike social robot, this study aims to explore these 2 constructs empirically. In doing so, we chose the method of systematic behavioral observation, because self-report data of older adults in nursing homes are often difficult to obtain and might interfere with their experience of the activity itself [9]. As no suitable observational coding scheme could be identified in the literature, a second aim of this study was the development and piloting of an observational coding scheme. In summary, this pilot study addresses the following questions: (1) can the engagement and mood of older adults in a robot-assisted group activity be assessed through systematic behavioral observation? and (2) do older adults actively engage in a robot-assisted group activity and what mood (ie, positive or negative affect) can be observed in the group during such a robot-assisted group activity?

Related Work

A review identified group activities for older adults assisted by social robots in 5 domains: affective therapy, cognitive training,

social facilitation, companionship, and physiological therapy [7]. Three studies [12,13,20] showed a great potential of humanlike robots in group activities, with broader functionalities for physical activities. The first indications that older adults liked to participate in robot-assisted group activities for physical activities are shown in [21,22]. The robot NAO was found suitable to be used in group settings for moving, memory training, entertainment, music, dancing, and games [23]. One study showed that older adults in a nursing home prefer walking with a robot rather than walking alone [24]. Another study showed that older adults actively participated in robot-assisted cognitive therapy and physiotherapy sessions, and a trend toward improved neuropsychiatric symptoms, reduced apathy, and higher quality of life was observed [25]. Although these studies [12,13,20-25] provide first insights into the acceptance of humanlike robots assisting in group activities of older adults, we identified only 1 study that systematically developed and used an observation system for examining the engagement of groups of older adults during activity sessions assisted by a humanlike social robot [13]. Even though this observation system indicates that systematic observation is a fruitful methodological approach in this research context, it does not fully capture the psychological constructs of engagement and mood that are at the center of our pilot study and that are usually captured using self-report surveys.

Observation of Engagement and Mood During a Robot-Assisted Group Activity

Engagement

In the context of group activities providing physical and cognitive stimulation, engagement in exercises is crucial to generate the intended effects [26]. According to Perugia and colleagues [27], engagement is defined as “the psychological state of well-being, enjoyment, and active involvement that is triggered by meaningful activities and causes people with dementia to be absorbed by the activity, more energetic and in a more positive mood.” Studies with children provide evidence that children are just as willing to engage in robot-guided exercises as when a human demonstrates the exercise [28].

Mood

The mood (ie, positive or negative affect) in the group during a robot-assisted activity is of interest to determine if older adults are enjoying themselves in the process, which is relevant to ensure participation beyond curiosity and to assess whether the intended positive effects of such robot-assisted group activities are actually attained. Assessing mood separately from engagement was important also because the stimulus for activities of older adults in the nursing home is a key factor in whether engagement occurs [29]. The general experience is that humanlike social robots, with their ability to express emotions, tend to evoke a notably positive affect. However, the counter hypothesis to this would be that older adults simply want to be polite and participate because something new is happening in

the nursing home, without they actually experiencing the positive affect when interacting with the humanlike social robot.

Assessment of Engagement and Mood

The assessment of engagement and mood during a robot-assisted group activity has not been researched much [27], and collecting data with older adults in terms of reliable outcomes presents a challenge [7]. Several observational studies have provided inspiration for the design of the observation tool used in this study [30-33]. One important observational instrument is the Observational Measurement of Engagement [34], and its further development can be used to gain a broad understanding of engagement in the context of telepresence robots and companion robots [20]. Although this instrument was not directly suitable to measure the predefined behavior of older adults (eg, mimic an exercise) at the group level, it informed our methodological decisions and developments.

Methods

Study Design

We considered this as a pilot study because we developed and tested the applicability of a systematic observation system for rating participants' engagement and mood during robot-assisted group activity sessions for older adults in nursing homes.

Recruitment Strategy

A pool of about 200 nursing homes in the German-speaking part of Switzerland were contacted by telephone and invited to participate in this study. Four nursing homes expressed their interest, and they were selected to participate in this observational field study. All participating nursing homes provide various services for leisure activities and physical and cognitive stimulation. They offer accommodation and care to 50-160 residents and provide specialized dementia care. As part of this study, the management of each nursing home agreed to co-organize a robot-assisted group activity together with the research team and made nursing staff available to accompany residents to the session. Residents of the participating nursing

homes were informed about the robot-assisted group activity and the study procedure, and they were invited to participate on a voluntary basis.

Materials

The robot used for the robot-assisted group activity was the NAO robot from SoftBanks Robotics [35]. We used the software of Avatation [36] developed by Smart Companion [37]. The software was developed in collaboration with experts for leisure activities and physical and cognitive stimulation for older adults, specifically for robot-assisted leisure activities during their care. In this study, we used 3 software modules that support common elements of group activities for older adults: singing, storytelling, and gymnastics.

1. **Singing:** In the first module, the robot animates the residents to sing along with him or her by using friendly verbal communication and gestures. All songs implemented in this module are well-known Swiss songs that are popular with the older generation. The robot sings the songs with a human voice, and the singing is accompanied with suitable gestures. For songs with more complex lyrics, the residents received handouts of the lyrics.
2. **Storytelling:** In the second module, the robot tells a story to the residents. The stories are designed to include biographical aspects. All stories implemented in this module are short and contain elements to imitate movements.
3. **Gymnastics:** In the third module, the robot guides the residents to imitate physical exercises by using friendly verbal communication and gestures. The physical exercises are designed for older adults. For example, the robot shows how to stretch the arms or move the fingers.

Figures 1-2 illustrate the robot-assisted physical exercise sessions in 2 different nursing homes. Photos were taken during 2 robot-assisted group activity sessions in 2 different nursing homes. The pictures show the NAO robot demonstrating movements with its hands and residents participating in this physical exercise by imitating the robot's movements.

Figure 1. An illustration of a robot-assisted group activity in a nursing home.



Figure 2. An illustration of a robot-assisted group activity in another nursing home.



Ethical Considerations

According to Swiss law this study did not require formal ethics approval and was thus exempt from formal ethics review. For more information please see the corresponding section of the Swiss Human Research Act. The participating nursing homes consented to this study and informed the residents in advance about the robot-assisted activity sessions. Participation in the robot-assisted activity sessions was voluntary. Consent was obtained for using the anonymized photographs in this paper.

Study Procedure and Data Collection

Robot-assisted group activity sessions were offered in the participating nursing homes in July and August 2019. Chairs and free spaces for wheelchair users were arranged in a way

that allowed the participants to see the NAO6 robot that was placed on a table. All robot-assisted group activity sessions took place 1 hour before lunch. Participating residents arrived independently. During the session, 2-5 health care professionals were available in the room for the general support of the residents. All group activity sessions in this study were conducted by research team members and lasted 1 hour, with the actual robot-assisted group activity taking about 30 minutes.

The activity session was structured in 3 parts. First, a representative of the research team welcomed the residents, explained the procedure of the session, reminded them that participation was voluntary, informed them about data protection issues, asked for their approval regarding video recording, and introduced the persons involved. Second, a technical expert

from the Smart Companion team started the robot program. The participants first performed a gymnastics exercise, then sang a song together with the robot, and toward the end of the session, they listened to a story. The research team did not interact with the participating residents during these sessions. Third, an additional exercise was conducted by the robot to get the residents in the mood for lunch. This exercise was not recorded and was not part of this study, as it did not aim at their physical and cognitive stimulation. At the end of the activity session, the robot wished the residents bon appétit and said goodbye. Finally, the research team also said goodbye and thanked the residents for their participation.

To systematically analyze residents' engagement and mood in group activities with the robot, sessions were recorded on video. Video recording has the advantage that, for example, behavior can be observed unobtrusively and participants do not have to be bothered afterwards, as they would be when using interviews. Further, for a high number of residents in nursing homes, other forms of data collection such as surveys present an inaccurate form of assessment, since retrieval, reporting, and ranking of relevant information may be compromised. Therefore, almost all assessment techniques for people with dementia rely on behavior observation [27]. Video recording was done in a way such that residents should not be disturbed, and the Hawthorne effect could be reduced [38]. Hence, short video clips of all 3 exercises were filmed as discreetly as possible. The video clips lasted between 30 seconds and 3 minutes and were distributed across the whole duration of the 3 exercises. The time of the start of the clip in the exercise was chosen randomly. For practical reasons, video clips were recorded with a smartphone camera. For ethical reasons, we collected no personal data such as the age of participants as well as the presence and severity of dementia symptoms. The videos only show the number of participants during each session.

Measures

For a structured observation of engagement and mood during a robot-assisted group activity, an observation system was developed. The observation system builds on existing observation systems for engagement and mood of individuals but was adapted for direct observation in a group setting. For example, in studies of children's engagement during one-on-one interactions with robots [30,31], the variables used to measure engagement were direction of gaze, facial expressions, responses, or gestures. Another study related to children with

autism spectrum disorders interacting with social robots [32] used measures of engagement based on nonverbal behavior focusing on social and antisocial behaviors. Another system used for older adults observed in a session with a social robot includes measures of engagement and mood targeted to a setting with small groups and a facilitator. Engagement was measured by someone leaning toward the collaborator, and mood was assessed by movements that were accompanied by a positive or negative affect [27]. Further, we analyzed the Observational Measurement of Engagement. This tool is based on a self-identity questionnaire and the 3 dimensions of observational measurements, namely, duration, attention, and attitude. This instrument did not meet all our needs, as we had a predefined duration of an interaction, and attitude was not the focus of our study. However, attention was in our interest and was included in our observation instrument. Another study measured affect and social interaction during a game [33]. Positive affect included smiling and clapping, and negative affect included sadness and anger [33]. Both studies show the relevance of gaze direction for capturing engagement and of observable behaviors for capturing positive and negative affect.

Engagement

Extending the previous research, we aimed to assess participants' engagement in robot-assisted group activities. We adapted an established rating system that has been used for the observation of students' attention in class [39]. This observation system captures 3 aspects of engagement: (1) direction of gaze (looks toward the teaching center vs looks elsewhere), (2) posture and body expression (oriented toward the teaching center and alert vs averted or flaccid), and (3) activity (performs the activity necessary for the task vs does something else on the side). Since we analyzed groups of nursing home residents and were not interested in individual differences, we assessed engagement of the group as a whole. To do so, we created a 5-point rating scale reflecting the degree of engagement in the group. For example, in the original systematic behavior observation instrument [39], sequences were rated whether a child looks toward the teaching center. We have modified the formulation from "none" of the participants looks (score 1) to "all" participants look to the center of the robot-assisted activity (score 5), and this 5-level rating scale aimed to assess engagement from very low to very high (see Table 1). Therefore, we distributed the number of people who showed the behavior depending on group size on the 5-level scale.

Table 1. Description of the rating system for engagement at the group level.

Rating	Engagement	Direction of gaze	Posture and body expression	Activity
1	Very low	None of the participants look to the center of the robot-assisted group activity (looking elsewhere)	None of the participants turned toward the center of the robot-assisted group activity but turned away and were flaccid	None of the participants perform the activity necessary for the task, for example, performing movements, singing, or listening to the story told by the robot (doing something else on the side)
2	Low	Most participants do not look to the center of the robot-assisted group activity	Most of the participants are not turned toward the center of robot-assisted group activity but turned away and were flaccid	Most participants do not perform the activity necessary for the task, for example, performing movements, singing, or listening to the story told by the robot (doing something else on the side)
3	Medium	Some participants look to the center of the robot-assisted group activity	Some participants are turned toward the center of robot-assisted group activity and their body expression is alert (vs turned away and flaccid)	Some participants perform the activity necessary for the task, for example, performing movements, singing, and listening to the story told by the robot (vs doing something else on the side)
4	High	Most participants look to the center of the robot-assisted activity session	Most participants are turned toward the center of robot-assisted group activity and their body expression is alert (vs turned away and flaccid)	Most participants perform the activity necessary for the task, for example, performing movements, singing, and listening to the story told by the robot (vs doing something else on the side)
5	Very high	All participants look to the center of robot-assisted activity session	All participants are turned toward the center of robot-assisted group activity and their body expression is alert (vs turned away and flaccid)	All participants perform the activity necessary for the task, for example, performing movements, singing, and listening to the story told by the robot (vs doing something else on the side).

Mood

To capture participants' mood during the robot-assisted activities, we developed an observational rating scale based on the German version of the Positive and Negative Affect Schedule (PANAS) [40]. The PANAS is frequently used in studies in which human mood states are of interest. The questionnaire consists of 20 adjectives describing different feelings with 10 adjectives capturing positive affect and the other 10 capturing negative affect. The items of the original

PANAS are shown in [Textbox 1](#) [25]. This survey instrument was chosen because it contains a set of mood variables that describe mood with positive and negative affects with several adjectives that we assumed were observable by a rater. Based on findings by Reizenzein and colleagues [41] that emotions can be detected by observers using a variety of cues (eg, facial expressions, verbal expressions, physical expressions), we transformed the survey instrument PANAS into an observational rating scale for mood at the group level.

Textbox 1. Adjectives of the Positive and Negative Affect Schedule.

<p>Positive affect</p> <ul style="list-style-type: none"> • Attentive • Active • Alert • Excited • Enthusiastic • Determined • Inspired • Proud • Interested • Strong (this mood could not be observed reliably in our study) <p>Negative affect</p> <ul style="list-style-type: none"> • Hostile • Irritable • Ashamed • Guilty (this mood could not be observed reliably in our study) • Distressed • Upset • Scared • Afraid • Jittery • Nervous

The original 5-level response scale contains the gradations “very slightly or not at all,” “a little,” “moderately,” “quite a bit,” and “extremely.” Again, because we were interested in the mood at the group level, we adapted the rating scale to reflect observable indicators of mood in the group, and a 5-point rating scale from “very low” to “very high” was used. For example, “very low” signified none of the participants were attentive in the robot-assisted group activity, and “very high” signified all participants were attentive in the robot-assisted group activity

(see Table 2). To make an objective assessment of group mood during the robot-assisted group activity, sequences from the observation were rated in relation to each adjective from the PANAS. The description of the 5-point rating scale of mood according to the PANAS is shown in Table 2. We considered the observation at group level to be particularly relevant for capturing mood in the group so that situational factors that are an important component in the observation of mental states [41] could be included.

Table 2. Description of the 5-point rating scale of mood according to the Positive and Negative Affect Schedule [35] for a robot-assisted group activity.

Rating	Extent of the perceived states for the measurement of mood in the group activity	Description
1	Very low	None of the participants are ___ ^a in the robot-assisted group activity.
2	Low	Most participants at the robot-assisted group activity are not ___.
3	Medium	Some participants are ___ in the robot-assisted group activity.
4	High	Most participants are ___ in the robot-assisted group activity.
5	Very high	All participants at the robot-assisted group activity are ___.

^aThe rating system was used for every adjective of the Positive and Negative Affect Schedule.

Coding of Video Recordings

Video clips were rated independently by 2 trained observers (rater 1 and rater 2). Rater 1 was present during all robot-assisted

group activities and rater 2 during two randomly selected sessions. Both raters were trained in the observation of nonverbal communication and body language for assessing the items for all 3 aspects of engagement (ie, direction of gaze,

posture and body expression, activity) and for mood (ie, positive and negative affect). Clearly visible signs of dementia and severe physical limitations of the residents had to be considered, and the rating of engagement had to be adjusted to the residents' possibilities of participation (eg, physical limitations). However, no individual was excluded from the analysis, as all ratings were performed at the group level. Each observer rated the group as a whole in every video clip by assessing whether none of the participants, some of the participants, most of the participants, or all of the participants exhibited a particular behavior indicating engagement (eg, direction of gaze, posture and body expression, activity) or positive or negative affect (eg, attentive, scared). To provide specific and context-sensitive anchors for the ratings, we counted the number of participants and distributed them proportionally across the 5-point scale. Thus, it depended on the actual group size what most and some participants meant. During the initial trial, it became apparent that all variables of engagement could easily be observed and rated by both raters. However, for rating the perceived mood in the group of study participants according to PANAS, additional coding rules had to be defined. The items "strong" and "guilty" were difficult to observe and hard to differentiate from 2 other items (eg, proud, ashamed) and thus not considered in the analysis. Each video clip was rated independently by the 2 raters to allow for reliability assessment.

Data Analysis

Interrater Agreement

To evaluate the agreement between 2 raters, we calculated the intraclass correlation coefficient (ICC) with the SPSS statistics

software (version 26; IBM Corp). An ICC higher than 0.61 was considered substantial, and ICC higher than 0.81 was considered an almost perfect agreement [42].

Video Analysis

The number and gender of participants who attended each robot-assisted group activity session was extracted from the videos and presented descriptively. For the analysis of engagement, the mean values, standard deviation, and medians of the aspects direction of gaze, posture and body expression, and activity as well as the overall mean value, standard deviation, and median of engagement were calculated from the observers' ratings. We also calculated the mean value, standard deviation, and median for each item and the positive and negative affect dimensions from the PANAS for each robot-assisted group activity session.

Results

Videos and Study Participants

Of the 34 video clips recorded during 5 robot-assisted group activities, 3 videos had to be excluded because not all participants were visible or the video was too short to be rated. Thus, we finally included 31 video clips. In the 4 participating nursing homes, 85 older residents participated in 5 robot-assisted group activity sessions. Participant characteristics are provided in [Table 3](#).

Table 3. Characteristics of the nursing homes and attendance in the activity sessions.^a

Participating long-term care facilities	Residential spaces (n)	Residents attending the group activity (N=85)
1	160	15
2	140	20
2	140	16
3	82	18
4	48	16

^aIn nursing home 2, we conducted 2 independent robot-assisted group activity sessions.

Interrater Agreement

Agreement between the 2 raters was high for engagement and positive and negative affect. Engagement had an ICC score of 0.83 (95% CI 0.65-0.92). Negative affect reached an ICC of 0.84 (95% CI 0.67-0.93), and positive affect had an ICC of 0.90 (95% CI 0.79-0.96). Individual items, specifically adjectives that belonged to negative affect, received a rather weak ICC. These include the items "ashamed" (ICC 0.37, 95% CI -0.32 to 0.70) and "afraid" (ICC 0.39, 95% CI -1.07 to 0.52).

Engagement

As [Table 2](#) demonstrates, the results show that the engagement of the participants in the robot-assisted group activity was high (mean 4.19, SD 0.47; median 4.0). The direction of gaze was measured as almost very high (mean 4.65, SD 0.49; median 5.0); posture and body expression (mean 4.03, SD 0.71; median

4.0) and activity (mean 3.90, SD 0.65; median 4.0) were also rated as high.

Mood

Overall, no negative affect could be observed (mean 1.13, SD 0.20; median 1.0). The mean value of positive affect was 3.22 (SD 0.55; median 3.2), which indicates the observer perceived a good mood during the sessions. Adjectives of the positive affect such as interested (mean 4.13, SD 0.56; median 4.0), alert (mean 4.39, SD 0.67; median 4.0), inspired (mean 3.87, SD 0.96; median 4.0), attentive (mean 4.19, SD 1.05; median 4.0), and active (mean 4.16, SD 0.64; median 4.0) received high ratings around the value 4, while enthusiastic (mean 2.42, SD 1.03; median 2.0), proud (mean 1.23, SD 0.43; median 1.0), and determined (mean 1.94, SD 0.77; median 2.0) were observed to be very low or low within the group of participants. [Table 4](#) shows the detailed results.

Table 4. Interrater agreement as well as the mean (SD) and median values for the study variables engagement and mood (ie, positive and negative affect) observed during robot-assisted group activities.^a

	Interrater agreement (intraclass correlation coefficient)	Mean (SD)	Median
Engagement	0.831	4.19 (0.47)	4.0
Direction of gaze	0.661	4.65 (0.49)	5.0
Posture and body expression	0.883	4.03 (0.71)	4.0
Activity	0.811	3.90 (0.65)	4.0
Positive affect	0.902	3.22 (0.55)	3.2
Interested	0.842	4.13 (0.56)	4.0
Excited	0.825	2.61 (0.92)	3.0
Enthusiastic	0.840	2.42 (1.03)	2.0
Proud	0.680	1.23 (0.43)	1.0
Alert	0.750	4.39 (0.67)	4.0
Inspired	0.884	3.87 (0.96)	4.0
Attentive	0.901	4.19 (1.05)	4.0
Determined	0.766	1.94 (0.77)	2.0
Active	0.722	4.16 (0.64)	4.0
Negative affect	0.840	1.13 (0.20)	1.1
Distressed	0.842	1.29 (0.59)	1.0
Upset	0.768	1.16 (0.52)	1.0
Scared	0.659	1.06 (0.43)	1.0
Hostile	0.491	1.10 (0.48)	1.0
Irritable	0.649	1.06 (0.25)	1.0
Ashamed	0.365	1.16 (0.37)	1.0
Nervous	0.804	1.29 (0.53)	1.0
Jittery	0.665	1.23 (0.43)	1.0
Afraid	0.390	1.13 (0.51)	1.0

^aThe items “strong” and “guilty” were not analyzed.

Additional Observations

Although we did not collect this information systematically, we observed that more residents participated in the robot-assisted activity sessions than expected by the nursing home staff and the research team. The different types of robot-assisted exercises (ie, singing, storytelling, gymnastics) promoted a variety of cognitive and physical stimulations as would a human instructor. Further, when watching the video recordings, we noted that the nursing home staff took time to assist and support participants individually during the robot-assisted activity session. Conversations took place between the residents and the nursing staff, and it seemed that the robot conducting all the instructions allowed more time for personal care.

Discussion

In robot-assisted group activity sessions for older adults in nursing homes, their engagement and mood (ie, positive affect) can be regarded as preconditions to achieve the intended positive effects of physical and cognitive stimulation. Our observational

pilot study in 4 nursing homes shows that residents actively engage in the leisure activities demonstrated and guided by a humanlike social robot. Overall, the engagement of the older adults in gymnastics exercises, singing with the robot, or listening to the robot telling stories was high. Engagement in the group activity was measured using 3 variables: direction of gaze, posture and body expression, and activity that the robot demonstrated. Almost all participants in the robot-assisted activity sessions kept their gaze directed toward the robot, and most had an active alert posture and actively imitated the movements demonstrated by the robot. We observed a positive mood in the groups during the robot-assisted activity sessions. Overall, the items measuring positive affect received high ratings, and the mood in the groups was mainly interested, alert, inspired, and attentive. The results of our study extend and complement existing laboratory studies as well as studies applied in areas other than the nursing home [13] by systematically using observational data to gain a better understanding of the ways in which residents engage in and experience robot-assisted group activities. From a methodological point of view, the participatory observation with video recording provided new

insights. The systematic coding of video clips using structured observation systems for both study variables allowed us to reliably show whether participants engage with a positive mood. Further, the observation system developed for this study complements existing instruments for measuring engagement and positive and negative affect by focusing on group level measures and the behavior toward a humanlike social robot in a group activity.

In contrast, other instruments [2,27,34] focus on engagement-related behavior, wherein older adults directly interacted in a one-on-one setting with the robot and not within a group activity. During a group activity, it is common for older adults, especially for those with physical limitations and early signs of dementia, to express behavior less consistently and clearly. By observing at group level, it was possible to assess the engagement and the mood of the individual in the situation and context of the group, and the sometimes subtle cues to emotion could be reliably detected by the trained raters. This is important as the technical recognition system still needs to be greatly improved [36]. The added value of the instrument is that it allows for monitoring engagement and mood in a group of participants with limited self-report capabilities and thus broadens the insights gained with the existing instruments. In combination with the initial findings from other field studies [13,21,23,25,43] specifically studying the fostering of well-being in a nursing home setting, our results show the potential of such activity sessions to make a valuable contribution. For example, a memory study program with a humanlike social robot for older adults for cognitive training in a nursing home showed positive trends [44] and could be adapted for fun group activities.

As limitations, the following aspects should be mentioned. First, participants attended the robot-assisted group activity sessions voluntarily and were generally informed about the content beforehand; so, when they joined the session, they may have had a positive attitude toward robots, which could therefore have introduced a bias toward a more positive affect. Moreover, although the reliability of the observation system could be shown with high ICC values for most items measuring affect, some mood items had to be excluded due to difficulties in distinguishing them through observation during short interactions in pretests and some items still have rather low ICC values (eg, ashamed, afraid). This indicates that negative affect was more difficult to assess, which needs to be reflected critically when interpreting our findings. This result matches the findings of a study that measured emotions of individuals with severe intellectual disabilities where positive emotions were also found to be more observable than negative ones [45]. Thus, the investigation of negative affect while participating in robot-assisted activities might be an interesting focus of future studies. Second, we did not collect data as to whether the participants had mild or severe dementia. Although the analysis at the group level allowed consideration of situational factors and the constraints of the individuals were included by the raters, there may be differences in engagement and mood expression depending on the level of dementia as previous research shows [46]. Third, each robot-assisted activity was only performed once per group. Thus, we were unable to assess sequence effects

or analyze which activities are the most engaging or which activities might tire participants more quickly. Moreover, in this study, we did not have the opportunity to study engagement and mood over a long period of time. Future research is needed for this [47]. Thus, novelty effects cannot be excluded. Interestingly, some studies [23] over longer periods of time did not report an attractiveness loss of the robot, but they did mention loss of interest due to usability problems with the robots. The so-called novelty effect [48] theoretically predicts “a decrease in the engagement with a stimulus after its initial novelty has worn off.” Usually, it is seen as a bias that has to be overcome (eg, by repeated interaction with the robot). An experiment with well-controlled repeated interactions showed that perceptions were positively influenced when participants interacted with the robot [48] and reported that a consistently positive interaction was already determined in the first 2 minutes of the conversation with the robot and remained stable over the subsequent sessions. In contrast, perceived threat and discomfort were the dimensions that changed the most during the interactions and decreased until the last session of the experiment [48]. With this in mind, we assume that the engagement and positive mood observed in the initial interaction as in our study are likely to be maintained in a relatively stable manner. Fourth, our pilot study investigates engagement and mood across different exercises within a robot-assisted activity session. In terms of effects on health, a larger study should assess which type of exercise receives the greatest engagement and positive affect, and it is of interest to continuously record the exercises. This allows for a more precise analysis of behavior during exercises, such as fatigue, and facilitates better comparisons of participation in the exercises among themselves. This knowledge would inform future software development and implementation of social robots. Finally, we did not investigate the practicability of the NAO robot for nursing staff and how a robot-assisted group activity can be implemented in a nursing home successfully. Research following a human-centered design approach [49] and an improved understanding of sustainable integration of social robots in leisure activities of older adults during their care are crucial.

Based on the positive findings of our study, questions arise about other application areas for robot-assisted group activities. Group sessions with social robots generate a form of enthusiasm, which is why they may be particularly suitable for group activities with vulnerable groups such as children, older adults, or people with disabilities. For all these potential target groups, interactions need to be designed in a way that results in maximum benefit and does no harm. In the context of the shortage of skilled nursing staff, social robots bring the potential to conduct a leisure group activity where caregivers do not need to be continuously present, thereby enabling older adults to be physically and cognitively engaged with less care effort and with fun. Moreover, if the social robot demonstrates exercises, nursing staff have more time for individual care as well as for personal conversations with the older adults. The literature shows that engagement and mood are prerequisites for health effects to be achieved [26]. Although the generalizability of our results must be established by future research, we found that older adults engage in robot-assisted group activities and that most of them were in a good mood during the

session—interested, alert, inspired, and attentive. Therefore, the positive results on engagement and mood provide clear indications that humanlike social robots can improve the cognitive and physical abilities in older adults. Compared to other technologies, robots with their ability to communicate in

a humanlike manner have a special property of supporting individuals physically and psychologically. Further development of this new technology of social robots is thus worthwhile in terms of promoting the quality of life of older adults in nursing homes.

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Authors' Contributions

All authors contributed to the study conception and design. AT and AU prepared the material, collected the data, and performed the analysis. AT, HS, and TM prepared the first draft of the manuscript. All authors read and approved the final paper.

Conflicts of Interest

None declared.

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Abbreviations

ICC: intraclass correlation coefficient

PANAS: Positive and Negative Affect Schedule

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Original Paper

Expected Health Benefits as the Ultimate Outcome of Information Available on Stroke Engine, a Knowledge Translation Stroke Rehabilitation Website: Web-Based Survey

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Abstract

Background: Electronic knowledge resources are readily available and typically target different audiences, including health professionals and the public, that is, those with lived experience and their relatives. The knowledge-to-action framework, in combination with the information assessment method (IAM), considering both the *value-of-information* construct and the conceptual model of *acquisition-cognition-application*, can be used to support the evaluation process of such resources. As an example, Stroke Engine is an evidence-based knowledge translation resource in stroke rehabilitation (assessments and interventions) for health professionals and students as well as individuals who have sustained a stroke and their relatives. According to Google Analytics, the website is perused >10,000 times per week.

Objective: With the overall aim to improve the content available on Stroke Engine, we documented Stroke Engine users' perceptions of situational relevance, cognitive impact, intention to use, and expected patient and health benefits regarding the information consulted.

Methods: A web-based survey anchored in the IAM was made available via an invitation tab. The IAM is a validated questionnaire that is designed to assess the value of information. Sociodemographic characteristics were also collected, and a space for free-text comments was provided. Descriptive statistics were used, and thematic analysis was used for the free-text comments.

Results: The sample consisted of 6634 respondents. Health professionals (3663/6634, 55.22%) and students (2784/6634, 41.97%) represented 97.18% (6447/6634) of the total responses. The remaining 2.82% (187/6634) of the responses were from individuals who had sustained a stroke (87/6634, 1.31%) and their relatives (100/6634, 1.51%). Regarding situational relevance, *assessments* (including selecting, obtaining, and interpreting results from a test) was the main topic searched by health professionals (1838/3364, 54.64%) and students (1228/2437, 50.39%), whereas general information on stroke rehabilitation was the top-ranked topic for nearly two-thirds of the individuals with stroke (45/76, 59%) and their relatives (57/91, 63%). Cognitive impact was characterized by *learning something new*. Intention to use was high (4572/6379, 71.67%) among the respondents and varied in context (eg, refine a topic, research, class assignments, teaching, and education). Respondents commented on ways to improve content.

Expected patient and health benefits such as improvement in health and well-being was the top-ranked category for all 4 subgroups, followed by the avoidance of unnecessary or inappropriate treatment for health professionals (183/623, 29.4%) and a feeling of being reassured for individuals with stroke (26/75, 35%) and their relatives (28/97, 29%).

Conclusions: Valuable feedback on Stroke Engine was obtained in terms of its accessibility, relevance for informational needs and retrieval, accuracy, and applicability; however, of utmost importance is the potential implementation of its evidence-based content in clinical practice and the perceived expected impact on patients, their relatives, and their health professionals. The feedback received allowed for corrections and the identification of key topics for further development.

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KEYWORDS

crowdsourcing; health-related information; internet; knowledge translation; rehabilitation; stroke

Introduction

Background

In 2020, 92.3% of Canadians aged ≥ 15 years were internet users, including 77.6% of seniors (aged ≥ 65 years) [1]. Health information on the internet is readily available and typically targets different audiences such as health professionals and the public, that is, those with lived experience and their relatives. Indeed, electronic knowledge resources are now readily available and provide information about various health conditions [2,3]. Electronic knowledge resources can facilitate clinical decision-making, increase the understanding of disease of individuals with lived experience and their relatives, or override human memory [4]. In the form of texts, images, sounds, or videos, these resources can originate from different databases [5]; for example, *Google Scholar* is a Google service that can be used by the public to search for scientific articles, identifying those that are approved or not by a peer-review committee [6]. Similarly, *PubMed* is a searchable database that contains >34 million medical citations from scientific journals, web-based books, and biomedical literature. Considering the impact that this information can have on the users of these resources, the knowledge-to-action (KTA) model [7] argues that for this information to be considered a third generation of knowledge, it is essential that the information transmitted is not only reliable and valid but also synthesized in a way that is relevant, understandable, and readily applicable by end users (eg, health professionals and people with lived experience).

The Stroke Engine website [8] was built with the goal of contributing to bridging the gap between available research findings and their application in current clinical practice in stroke rehabilitation [9-13]. Indeed, with >1700 motor- and cognitive-based stroke rehabilitation randomized controlled trials published between 1972 and 2018 [14], stroke rehabilitation is an area where there is an abundance of available scientific evidence. This comprehensive site, available in English and French, includes the most current information about the effectiveness of various interventions in both scientific and lay-language format as well as the psychometric and pragmatic properties [15] of >100 stroke-related assessment tools used in stroke rehabilitation. Stroke Engine's content is derived from multiple sources, including the Evidence-Based Review of Stroke Rehabilitation [16], and extensive reviews of databases such as MEDLINE, CINAHL, the Cochrane Library, HealthSTAR, Health and Psychosocial Instruments,

CANCERLIT, and PsycINFO. The goal is to provide health professionals (physicians and clinicians working with individuals with stroke in any setting), students (in any discipline), and individuals with stroke and their relatives with evidence-based information on stroke rehabilitation. The website is led by the first author (AR), and its content relies on the expertise of a research team (including 5 coauthors [AT, NMS, BV, AM, and LP]). Indeed, a dedicated team of senior researchers, graduate students, and research assistants with expertise in specific areas also contribute to creating reviews for each topic and evaluating their quality. Contributing authors are listed on each page and topic along with the date of the last update.

The website is perused by >10,000 visitors per week. According to Google Analytics, the most popular pages are related to assessment, although the page *Find an intervention* is ranked in the top 10. The visitors can be health professionals, students, or individuals with stroke and their relatives. We wondered about what information they are searching for and what they think about what they find. Obtaining answers to these questions [17] is essential to present *better-than-best* evidence [18]. Indeed, 2-way knowledge translation assumes that information users have the expertise [19] to provide feedback on the relevance, accuracy, and applicability of the available information. Therefore, we created a knowledge translation resource that synthesizes information in a way that is relevant to end users as well as understandable and readily applicable by them. However, unless we apply a rigorous evaluation process, we do not know how this information is applied and whether it has the intended ultimate targeted benefits for health.

Despite the purpose and many benefits of internet resources, including Stroke Engine, it is unclear how the impact of its use by end users should be documented. We argue that outcomes such as internet access as well as information needs and retrieval, as documented in most studies [20,21], are insufficient, whereas the actual implementation in practice and health benefits are most relevant. The information assessment method (IAM) [22] can help to overcome these limitations because it is based on both the *value-of-information* construct and the conceptual model of *acquisition-cognition-application* [23], which was extended to 4 levels of outcomes: situational relevance, cognitive impact, intention to use, and expected patient and health benefits [24]. Thus, this brief, systematic web-based questionnaire can evaluate and document reflection

on health information because it fosters reflective learning, evaluation, and 2-way knowledge translation [25].

Research Questions and Objectives

Our research questions were as follows:

- Who are the visitors?
- Are they mostly health care professionals, students, and individuals with stroke and their relatives?
- What information are they searching for?
- What do they think about what they find?

The objective of this study was to document Stroke Engine users' perceptions of (1) situational relevance, (2) cognitive impact, (3) intention to use, and (4) expected patient and health benefits regarding the information they consulted on the Stroke Engine website.

Methods

Study Design

As the Stroke Engine website is visited by approximately 500,000 individuals yearly, we relied on a crowdsourcing developmental evaluation [26,27], using a web-based survey to obtain feedback on its content. Crowdsourcing is defined as “the practice of obtaining needed services, ideas, or content by soliciting contributions from a large group of people and especially from the online community rather than from traditional employees or suppliers” [28]. Crowdsourcing has been used by search engines such as Google to identify the most useful and most visited internet pages [29], and it has also been used to develop innovative learning networks such as Wikipedia [30,31].

The KTA Cycle

We used the process depicted in the KTA cycle [7] to guide our plan to evaluate Stroke Engine, whereas crowdsourcing was used as a method of data collection for evaluating the website. As the Stroke Engine website disseminates the best available scientific evidence, we needed the survey information to understand and improve how it supports implementation of this evidence in practice and ultimately benefits individuals with stroke and their relatives. The Stroke Engine team members *synthesize the information* about stroke rehabilitation assessment and treatment interventions (corresponding to the knowledge creation funnel at the center of the KTA) and then post it on the website, which enables *diffusion* of information to a large international audience (corresponding to the action and application cycle of the KTA). Visitors or users of this knowledge tool (website) are invited to *assess the information* through a web-based survey built into the website (corresponding to the *evaluate outcomes* step of the KTA); data and feedback are analyzed, and the results are used to *improve content* on the website and help prioritize future content developments (corresponding to the *sustain knowledge use* step of the KTA).

IAM Questionnaire

The web-based survey uses the IAM questionnaire developed by members of our research team (RG and PP) and follows the

reasoned action approach [32]. The IAM is a validated method to assess the value of information in terms of its (1) situational relevance, (2) cognitive impact, (3) intention to use, and (4) expected patient health benefits [18,24]. Two versions of the IAM questionnaire were used: the IAM for clinicians and the IAM for patients and consumers. Both contain 5 questions that can be answered in <2 minutes. A space was provided for optional free-text comments. The items under each question were adapted to the context of stroke rehabilitation using a 2-phase process: consultation of stroke experts (n=5) using the nominal group method, followed by a consultation of users through 2 focus groups (1 with 6 clinicians and 1 with 3 individuals with stroke). Minor modifications were made to both versions of the questionnaire. For the IAM for clinicians, 2 questions were slightly modified, 15 items were modified, 4 were removed, and 3 were added in comparison with the initial version to clarify the statements. In the IAM for patients and consumers, 2 questions were modified to contextualize to stroke rehabilitation, 7 items were modified, and 4 items were added.

Data Collection Procedures

An invitation tab was added to the right side of the website to invite users to a web-based survey using IAM. This method has been successfully used for >15 years in >25 projects, 4 countries, and with various health conditions [22]. Invitation tabs in English or French appeared on the respective language pages of the website. We added an invitation pop-up window that appeared when a user had been on the same page for >30 seconds because health professionals told us that they could not easily find the invitation tab on the right side of the website.

The survey was completed on an anonymous, voluntary basis. It was thus possible for respondents to complete the survey questionnaire more than once. Data collected between October 7, 2020, and May 25, 2021, were used for analysis. According to Google Analytics, for the period during which the survey data were collected, the majority of the visitors (206,017/243,628, 84.56%) came from organic search, 11.75% (28,632/243,628) landed directly, 4.99% (12,165/243,628) were referred, whereas others represented 1.15% (2795/243,628). Following the 5 questions of the IAM, we collected minimal sociodemographic data (eg, age, gender, education, and location) for descriptive purposes. As the survey questionnaire was built into the website, the system also allowed us to collect data regarding the specific page visited when the survey was completed.

Ethics Approval, Informed Consent, and Participation

Respondents provided consent by agreeing to fill in the web-based questionnaire through the following text: “Thank you for your feedback which will be used to improve the website and prioritize future developments. All data are analyzed anonymously. By completing the survey and clicking on the submit button below, you are providing consent. Ethics approval was obtained from the health ethics board of the University of Montreal (Projet 17-157-CERES-D). For any questions, please contact the principal investigator [name and contact information].” There was no compensation for filling in the web-based questionnaire.

Data Analysis

We used descriptive statistics (frequency and percentage) to describe feedback on the information consulted. Optional free-text comments were coded using thematic analysis [33]. We deliberately chose to not perform a content analysis, which typically includes frequency of categories and themes [34], because comments were optional, and these were used in an exploratory manner to deepen our understanding of the answers to the IAM questionnaire. All free-text comments were uploaded into NVivo 10 (QSR International) with ID numbers and coded inductively by the first author with a tag relating to the meaning of the content. It was not possible to split the comments according to the type of respondent, but whenever the content of the comments related to an individual with stroke or their relative, these were tagged as such. In addition, we could retrieve respondent characteristics for a specific quote using the ID number. As such, comments were analyzed for the whole sample. Codes were then grouped according to major themes and are presented following the study objectives. Themes and related associated comments were reviewed by the research team.

Results

Sample Description

A total of 6634 completed questionnaires were available at the time of analysis (refer to [Table 1](#) for sample description). Health professionals (3663/6634, 55.22%) and students (2784/6634, 41.97%) represented 97.18% (6447/6634) of the total responses. The remaining 2.82% (187/6634) of the responses were from individuals who had sustained a stroke (87/6634, 1.31%) and

their relatives (100/6634, 1.51%). Nearly half of the respondents (3182/6518, 48.82%) were aged between 19 and 29 years. Among the health professionals and students, 77.15% (4822/6250) of the respondents were female. Almost all survey respondents (6027/6397, 94.22%) had completed a college degree or higher. The most common geographical locations of respondents were Western Europe (2406/6634, 37.45%) and North America (2203/6634, 34.29%), followed by Eastern Asia (422/6634, 6.57%) and Australia or New Zealand (353/6634, 5.49%). [Tables 2](#) and [3](#) provide an overview of the descriptive results of the IAM for health professionals and students ([Table 2](#)) and for individuals with stroke and their relatives ([Table 3](#)). The main themes emerging from the free-text comments (n=950) for all respondents are presented in the subsections that are presented after the tables according to the study objectives. Regarding situational relevance, the main themes are summarized as 8 subthemes: assessment approach, how to obtain a test, interpretation of the test results, clinical decision-making, empowerment and coping, research purposes, resource for teaching, and educate and inform clients. The main cognitive impact was characterized by the following subtheme: learning something new. Intention to use was composed of 5 subthemes: refine knowledge on a topic with prior knowledge, intention to use a test and looking as to where to obtain it, use information in the context of a class assignment, visual or format and ease of finding needs improvements, and information insufficient and perceived as incomplete. Respondents also left comments identifying important topics to add. The main subtheme under the objective of expected patient and health benefits related to using an assessment to provide feedback on improvements. Respondents also used free-text comments to leave general comments that were overall positive.

Table 1. Respondents' characteristics.

	Health professionals (n=3663)	Students (n=2784)	Individuals with stroke (n=87)	Relatives (n=100)	Total (N=6634)
Age group (years)					
≤18, n (%)	21 (0.59)	73 (2.65)	0 (0)	1 (1.1)	95 (1.46)
19-29, n (%)	957 (26.72)	2221 (80.53)	1 (1)	3 (3.2)	3182 (48.82)
30-39, n (%)	1010 (28.2)	282 (10.22)	9 (11)	8 (8.5)	1309 (20.08)
40-49, n (%)	771 (21.52)	120 (4.35)	14 (17)	12 (12.8)	917 (14.07)
50-59, n (%)	560 (15.63)	42 (1.52)	21 (25)	27 (28.7)	650 (9.97)
60-69, n (%)	214 (5.97)	8 (0.29)	21 (25)	23 (24.5)	266 (4.08)
70-79, n (%)	31 (0.86)	5 (0.18)	13 (15)	16 (17)	65 (1)
≥80, n (%)	18 (0.5)	7 (0.25)	5 (6)	4 (4.3)	34 (0.52)
Missing, n	81	26	3	6	116
Sex					
Female, n (%)	2719 (77.09)	2103 (77.23)	41 (51)	58 (63)	4921 (76.63)
Male, n (%)	711 (20.16)	501 (18.4)	37 (46)	32 (34.8)	1281 (19.95)
Prefer not to answer, n (%)	97 (2.75)	119 (4.37)	2 (3)	2 (2.2)	220 (3.43)
Missing, n	136	61	7	8	212
Language of survey completion					
English, n (%)	2689 (73.41)	1823 (65.48)	71 (82)	78 (78)	4661 (70.26)
French, n (%)	974 (26.59)	961 (34.52)	16 (18)	22 (22)	1973 (29.74)
Level of education completed					
None, n (%)	5 (0.14)	5 (0.18)	0 (0)	0 (0)	10 (0.15)
Primary, n (%)	7 (0.2)	12 (0.44)	1 (1)	2 (2.2)	22 (0.34)
Secondary or high school, n (%)	17 (0.48)	287 (10.5)	23 (28)	11 (11.8)	338 (5.22)
College, n (%)	152 (4.26)	277 (10.13)	22 (27)	16 (17.2)	467 (7.21)
University undergraduate, n (%)	882 (24.69)	1559 (57.02)	16 (20)	21 (22.6)	2478 (38.23)
University postgraduate, n (%)	2461 (68.9)	561 (20.52)	18 (22)	42 (45.2)	3082 (47.55)
I do not know, n (%)	48 (1.34)	33 (1.21)	2 (2)	1 (1.1)	84 (1.3)
Missing, n	91	50	5	7	153
Location					
Western Europe, n (%)	1210 (34.04)	1145 (42.36)	25 (32)	26 (29.2)	2406 (37.45)
North America, n (%)	1365 (38.4)	743 (27.49)	47 (60)	48 (53.9)	2203 (34.29)
Eastern Asia, n (%)	197 (5.54)	220 (8.14)	3 (4)	2 (2.2)	422 (6.57)
Australia or New Zealand, n (%)	233 (6.55)	116 (4.29)	1 (1)	3 (3.4)	353 (5.49)
Central Asia, n (%)	118 (3.32)	101 (3.74)	0 (0)	2 (2.2)	221 (3.44)
Central or South America, n (%)	111 (3.12)	78 (2.89)	0 (0)	0 (0)	189 (2.94)
Eastern Europe, n (%)	75 (2.11)	57 (2.11)	0 (0)	1 (1.1)	133 (2.07)
Western Asia, n (%)	64 (1.8)	67 (2.48)	0 (0)	0 (0)	131 (2.04)
South Africa, n (%)	63 (1.77)	57 (2.11)	1 (1)	3 (3.4)	124 (1.93)
North Africa, n (%)	52 (1.46)	41 (1.52)	1 (1)	2 (2.2)	96 (1.49)
Pacific Ocean, n (%)	32 (0.9)	47 (1.73)	0 (0)	2 (2.2)	81 (1.26)

	Health professionals (n=3663)	Students (n=2784)	Individuals with stroke (n=87)	Relatives (n=100)	Total (N=6634)
Indian Ocean, n (%)	16 (0.45)	24 (0.88)	0 (0)	0 (0)	40 (0.62)
Caribbean, n (%)	13 (0.36)	7 (0.26)	0 (0)	0 (0)	20 (0.31)
Central Africa, n (%)	6 (0.17)	0 (0)	0 (0)	0 (0)	6 (0.09)
Missing, n	108	81	9	11	209

Table 2. Feedback from health professionals (HPs) and students on information consulted regarding situational relevance, cognitive impact, intention to use, and expected patient and health benefits (N=6447).

	HPs (n=3663)	Students (n=2784)
Overall, did you search Stroke Engine for information on...		
General information on stroke rehabilitation, n (%)	894 (26.58)	693 (28.44)
Assessment approach, n (%)	1838 (54.64)	1228 (50.39)
Intervention approach, n (%)	309 (9.18)	143 (5.87)
e-Learning modules, n (%)	171 (5.08)	213 (8.74)
All of the above, n (%)	11 (0.33)	2 (0.08)
Other ^a , n (%)	141 (4.19)	158 (6.48)
Missing, n	299	347
Q1. Why did you do this search for information?^b		
To address a clinical question, n (%)	990 (22.5)	300 (9.8)
To get new knowledge, n (%)	2063 (46.82)	2347 (76.67)
To share information with patient or family, n (%)	348 (7.9)	87 (2.84)
To share information with other HPs, n (%)	1005 (22.8)	327 (10.68)
Q2. Did you find relevant information that partially or completely met your objectives?		
Completely, n (%)	1741 (47.53)	1419 (50.97)
Partially, n (%)	1762 (48.1)	1270 (45.62)
No, n (%)	160 (4.37)	95 (3.41)
Q3. What is the expected impact of this information on you or your practice?^b		
Practice changed or improved, n (%)		
Assessment approach	689 (68.22)	311 (64.9)
Treatment approach	198 (19.6)	115 (24)
Prognostic approach	52 (5.15)	21 (4.4)
Patient or family education	71 (7.03)	32 (6.7)
Learned something new, n (%)	1854 (50.61)	2080 (74.71)
Information confirmed I was doing right, n (%)	1013 (27.65)	463 (16.63)
I am reassured, n (%)	506 (13.81)	320 (11.49)
Reminded of what I already knew, n (%)	750 (20.48)	374 (13.43)
Problem with presentation of information, n (%)	27 (0.74)	15 (0.54)
Disagree with information, n (%)	4 (0.11)	6 (0.22)
Information potentially harmful, n (%)	2 (0.05)	4 (0.14)
Q4. Did you (will you) use this information for a specific patient?		
Yes, n (%)	1503 (42.91)	496 (18.44)
Possibly, n (%)	1237 (35.31)	1167 (43.4)
No, n (%)	763 (21.78)	1026 (38.16)
Missing, n	160	95
If yes, I will use the information to...^b, n (%)		
Modify how I assess this patient	471 (31.3)	138 (27.8)
Modify how I treat this patient	288 (19.2)	95 (19.2)
Make a choice between options	295 (19.6)	108 (21.8)
Manage this patient	480 (31.9)	169 (34.1)

	HPs (n=3663)	Students (n=2784)
Be more certain about management	363 (24.2)	146 (29.4)
Better understand particular issue	398 (19.8)	151 (30.4)
Discuss with this patient	222 (14.8)	59 (11.9)
Discuss with other HPs	304 (20.2)	110 (22.2)
Influence this patient or HP regarding treatment	185 (12.3)	45 (9.1)
Q5. For this patient, did you observe (or do you expect) any health benefits as a result of applying this information?		
Yes, n (%)	623 (42.09)	203 (41.26)
Possibly, n (%)	636 (42.97)	222 (45.12)
No, n (%)	221 (14.93)	67 (13.62)
Missing, n	2183	2292
If yes, I expect the benefits to..., n (%)		
Improve patient's health status, functioning, or resilience	345 (55.4)	89 (43.8)
Prevent disease or worsening of disease	93 (14.9)	32 (15.8)
Avoid unnecessary or inappropriate treatment	183 (29.4)	46 (22.7)
Decrease patient's worries	95 (15.2)	24 (11.8)
Increase patient's or relatives' knowledge	170 (27.3)	36 (17.7)

^aThe *Other* response option was not specified.

^bMultiple answers were allowed.

Table 3. Feedback from individuals with stroke and relatives on information consulted regarding situational relevance, cognitive impact, intention to use, and expected health benefits (N=187).

	Individuals with stroke (n=87)	Relatives (n=100)
Overall, did you search Stroke Engine for information on...		
General information on stroke rehabilitation, n (%)	45 (59)	57 (62.6)
Assessment approach, n (%)	11 (14)	19 (20.9)
Intervention approach, n (%)	3 (4)	10 (11)
e-Learning modules, n (%)	6 (8)	1 (1.1)
All of the above, n (%)	1 (1)	0 (0)
Other ^a , n (%)	10 (13)	4 (4.4)
Missing, n	11	9
Q1. Is this information relevant? n (%)		
Very relevant	34 (39)	50 (50)
Relevant	37 (43)	39 (39)
Somewhat relevant	13 (15)	8 (8)
Not relevant (not the information I had hoped to find)	3 (3)	3 (3)
Q2. Do you understand this information? n (%)		
Very well (I understood)	41 (47)	48 (48)
Well	39 (45)	45 (45)
Poorly	4 (5)	2 (2)
Very poorly (I did not understand much)	3 (3)	5 (5)
Q3. What do you think about this information?^b, n (%)		
Teaches me something new	30 (34)	65 (65)
Allows me to validate what I do or did	25 (29)	26 (26)
Information reassures me	24 (28)	20 (20)
Refreshes my memory	9 (10)	9 (9)
Motivates me to learn	26 (30)	23 (23)
I think there is a problem with the information	3 (3)	0 (0)
I disagree with the information	0 (0)	1 (1)
Information can have negative consequences	1 (1)	0 (0)
Q4. Will you use this information?, n (%)		
Yes	77 (89)	92 (92)
No	10 (11)	8 (8)
If yes, I will use the information to...^b		
Help me better understand	42 (54.5)	57 (62) ^c
Help me do something	10 (13)	22 (24) ^c
Convinced me to do it	14 (18.2)	5 (5) ^c
Do something in a different manner	15 (19.5)	9 (10) ^c
Discuss with health professionals	15 (19.5)	25 (27) ^c
Discuss with relatives and friends	14 (18.2)	28 (30) ^c
Q5. Do you expect any benefit for you and your relative from using this information? n (%)		
Expect no benefits	12 (14)	3 (3)

This information will...	Individuals with stroke (n=87)	Relatives (n=100)
Help improve health or well-being	35 (40)	54 (54)
Help feel reassured	26 (30)	28 (28)
Help prevent a problem or worsening of a problem	10 (11)	20 (20)
Help handle a problem	16 (18)	20 (20)
Prepare better for discussion with health professional	22 (25)	27 (27)
Prepare better discussion with relatives	13 (15)	27 (27)
More confident to make decision with health professional	17 (20)	13 (13)
More confident to make decision with relatives	6 (7)	13 (13)

^aThe *Other* response option was not specified.

^bMultiple answers were allowed.

^cN=92.

Situational Relevance

Assessment approach was the main topic searched by health professionals (1838/3364, 54.64%) and students (1228/2437, 50.39%), followed by general information on stroke rehabilitation (894/3364, 26.57% and 693/2437, 28.44%, respectively), which was the top-ranked topic for nearly two-thirds of the individuals with stroke (45/76, 59%) and their relatives (57/91, 63%), as reported in [Tables 2](#) and [3](#).

Analysis of the free-text comments (n=950) indicated that although some respondents were looking at *how to obtain a test*—as illustrated by the following comments: “Interest in purchase of assessment” (ID3208, occupational therapist looking at the Activity Card Sort) and “Looking for a copy of the assessment” (ID3514, occupational therapist looking at the Wolf Motor Function Test)—others were searching for in-depth information that would allow for an accurate *interpretation of the test results*, as supported by comments such as “I am looking for the scores and the ranges of the scores and what the scores mean” (ID744, family member of a patient with a traumatic brain injury) and “I used the Trails A and B to test a patient and will use the information in this website to interpret the results” (ID1610, kinesiologist). Others were looking for information to assist them in their *clinical decision-making*; examples of comments include “Looking for more info in functional communication assessments in general” (ID1788, speech-language pathologist) and “I need the information found on your website to learn about available assessments as well as their psychometric properties to determine if the assessments are the best and most appropriate for the population I’m seeing” (ID2399, student).

Analysis of the comments from the individuals with stroke and their relatives showed that the information contributed to the *empowerment* of people regarding their own health and decisions and helped them to better *cope* with their situation as illustrated in the following comments: “I would like to prepare therapeutic materials to use while waiting for speech therapy to begin” (ID2701, relative); “I am a recent stroke victim, this information will very greatly help me in my recovery!” (ID3743, individual

with stroke); “[Y]our article, which helped me to feel better about the future—especially since my stroke is cryptogenic” (ID4605, a health professional who had had a stroke); and “Better acceptance of a difficult diagnosis for the patient” (ID4820, relative).

Another case of situational relevance of information that emerged from the free-text comments related to searching information for *research purposes* as illustrated by these comments: “We are considering using the ARAT [Action Research Arm Test] as our primary outcome for a new data science research proposal” (ID245, physical therapist) and “I am using the CDT [Clock Drawing Test] in a research proposal” (ID452, student). In addition, a respondent commented as follows:

It’s really helpful, I am planning to use it for research.
[ID1496, occupational therapist]

Respondents also mentioned consulting the website for educational purposes because it is used as a *resource for teaching*: “I was looking for information to give my students” (ID396, occupational therapist), “I am an instructor and use the site frequently with OT [occupational therapy] students” (ID1238, occupational therapist), and “Using this information to teach students about aphasia assessments” (ID1978, speech-language pathologist). More specifically, other respondents mentioned using the website to *educate/inform clients*: “I use this resource to share with patients, students, and health professionals” (ID2125, librarian); and “[The Stroke Engine website] has become my first recommendation for patients and families who want to have access to reliable information regarding suggested or advertised stroke treatment modalities” (ID3974, rehabilitation medicine).

Cognitive Impact

Of the health professionals and students who answered yes to the question about a change or an improvement in practice ([Tables 2](#) and [3](#)), approximately two-thirds related this change to the assessment approach (689/1010, 68.22% and 311/479, 64.9%, respectively). *Learning something new* was chosen by 74.71% (2080/2784) of the students, 65% (65/100) of the

relatives, 50.61% (1854/3663) of the health professionals, and 34% (30/87) of the individuals with stroke, as exemplified by these free-text comments: “To enhance my knowledge” (ID1533, occupational therapist looking at the Motor-Free Visual Perception Test page), “Love to know more about this” (ID1574, student looking at the Motor-Free Visual Perception Test page), “I want to gain information regarding this topic” (ID1604, nurse looking at the General Health Questionnaire-28), “I will apply the knowledge I get from this questionnaire” (ID3857, physical therapist looking at the General Health Questionnaire-28), and “I don’t know this test yet and I’m looking into it to see with which patient I could use it” (ID5419, speech-language pathologist looking at the Boston Diagnostic Aphasia Examination).

Intention to Use

The majority of the respondents reported an intention to use the information as reflected by the percentages of respondents who selected *no use*: 21.78% (763/3503) of the health professionals, 38.16% (1026/2689) of the students, 11% (10/87) of the individuals with stroke, and 8% (8/100) of their relatives (Tables 2 and 3). The free-text comments suggest that many of the respondents were searching for information to *refine a topic*: “Will help determine remediation strategies and possible problems at home upon discharge” (ID3986, occupational therapist looking at the Bells test), “I believe I will be able to target sedentary behaviour” (ID4078, physical therapist looking at a web-based aerobics course), and “Bookmarking this page for possible future reference once I graduate” (ID917, student looking at the home page). Respondents with *prior knowledge* who were already using an assessment were looking for information on administration procedures or interpretation of the scoring; for example, a respondent commented as follows:

[Information] confirmed improvement in language skills and appropriate home practice to continue on motor speech skills. It was helpful to have this on-line to allow me to analyze a report and score without having to return to the office to look at the manual. [ID3370, speech-language pathologist looking at the Western Aphasia Battery]

Others already had the *intention to use a test* before accessing the website and were searching for information on how to obtain it (refer to the *how to obtain a test* subtheme in the *Situational Relevance* subsection).

Intention to use was high among all 4 subgroups, with the exception of the students: less than one-fifth (496/2689, 18.44%) answered yes to the question about their intention to use the information for a specific patient (Table 2). Indeed, many of the students were looking for information in the *context of a class assignment*: “Researching for assignment on right neglect” (ID289, student looking at the Bells test); “I am using this as a student to understand how depression can be assessed” (ID2002, student looking at the Beck Depression Inventory); “This information will help me on my board exam and when I get a job as an OTA [occupational therapy assistant]” (ID2654, student looking at the Executive Function Performance Test); “I am a PT [physical therapy] student, thank you for this clear

explanation of the comb and razor test!” (ID3060, student looking at the Comb and Razor Test).

Although intention to use was high overall, the free-text comments allowed respondents to make suggestions regarding *how information provided could be improved* either in terms of *visual/format* or in *ease of finding*, as illustrated by comments such as “Not helpful if I can’t download the PDF in Greek” (ID1294, pharmacist looking at the Mini Mental State Examination); “The Patient/family PDF link at the top of the page is linked to the wrong PDF, it is about electrical stimulation instead of positioning” (ID2543, physical therapist looking at Positioning); “I need a link to purchase” (ID2292, occupational therapist looking at the Motor-Free Visual Perception Test); “Make the presentation of information interesting, add pictures or other graphic that can catch people’s attention easier” (ID4523, student; the page visited was not recorded); and “Videos of the assessments are lacking” (ID4984, occupational therapist looking at the Berg Balance Scale). Others left comments asking for *more information* because the information provided was perceived as *incomplete*; for example, a respondent commented as follows:

Did not find any information. I have not found this website easy to use and prefer other websites. [ID2769, nurse; the page visited was not recorded]

The other comments included “Need more information on population aim” (ID1201, student looking at the Chedoke Arm and Hand Inventory), “The info can be a bit more specific with more examples” (ID1732, student looking at the definition of intratester reliability), “There was no information on the frequency of the test” (ID3566, nurse looking at the Clock Drawing Test), “The given information is helpful, but was expecting more detailed information as I am from medical field hence I was looking for depth information” (ID3746, physical therapist looking at the Glasgow Coma Scale), and “Scoring should be more elaborately explained” (ID4511, physical therapist; the page visited was not recorded).

Furthermore, a respondent provided the following comment regarding the information available on the website:

Incomplete information. Procedure required with more meaning. [ID4800, student; the page visited was not recorded]

The respondents also used this opportunity to let us know which *topics they consider important enough to be added*; for example: “You make no mention of Personality changes nor Emotion Lability Episodes, both of which are very common consequences for Stroke survivors” (ID1266, individual with stroke on the *Contact us* page); and “I am trying to find more information on other perceptual difficulties such as construction or other spatial challenges” (ID3912, occupational therapist looking at Unilateral Spatial Neglect).

In addition, a respondent commented as follows:

It would be very useful to have a section for how to approach rehab for patients with Ataxia. Somewhere that summarises the basics of Ataxia management. [ID3188, occupational therapist looking at interventions by topic page]

Expected Patient and Health Benefits

The expectation that the use of the information would result in health benefits was relatively high (more than two-fifths of the respondents: 998/2159, 46.23%; refer to [Tables 2](#) and [3](#)) across all 4 subgroups. Improvement in health and well-being was the top-ranked category of expected benefits for all 4 subgroups, followed by the avoidance of unnecessary or inappropriate treatment for health professionals (183/623, 29.4%) and a feeling of being reassured for individuals with stroke (26/75, 35%) and their relatives (28/97, 29%). Examples of comments supporting expected benefits included “I want to know about benefits or uses of assistive devices for stroke patients” (ID1159, student looking at assistive devices). Other comments were related to the *benefits of using an assessment to provide feedback on improvements*, such as the following comment:

In selecting this assessment, which I've not previously used, I can complete information to provide a patient with post rehab scores to complement the pre rehab score on this test, completed at another facility. This will likely be beneficial to the client in knowing his achievements and also to the community team whom I am referring the patient to nearer his home. [ID2311, occupational therapist looking at the Occupational Therapy Adult Perceptual Screening Test]

Other comments included “It was beneficial” (ID2916, student looking at the Boston Diagnostic Aphasia Examination) and “Using as an outcome measure after rehab to highlight improvement therefore may be of psychological benefit” (ID3016, occupational therapist looking at the Nine-Hole Peg Test).

General Comments

Overall, the free-text comments were positive: “Thank you for raising health care standards!” (ID4180, occupational therapist looking at the National Institutes of Health Stroke Scale), “A useful summary of important information” (ID4563, clinical psychologist; the page visited was not recorded), “Thank you for this wealth of information that improves our practice!!” (ID5014, speech-language pathologist looking at the Bells test), and “Thank you for sharing your work you are always models for us!!!!” (ID5220, stroke pathway facilitator looking at the *Patients and Families* page). In addition, respondents provided the following comments:

Useful to have a variety of topics in one place. Information is brief but reasonably detailed so gives a good idea of what to do and not do. [ID4622, occupational therapist; the page visited was not recorded]

Love Stroke Engine. Thank you for this resource! [ID4777, occupational therapist; the page visited was not recorded]

Hello, I am a medical student and I was learning a course on how to measure motor impairments in people with disabilities, which led me to this site and I was able to find my happiness. Thank you. [ID5830, student looking at the Modified Ashworth Scale]

Discussion

Principal Findings and Comparison With Prior Work

The main goal of this study was to document Stroke Engine users' perceptions of situational relevance, cognitive impact, intention to use, and expected patient and health benefits regarding the information consulted. The main results relating to situational relevance showed that assessments (including selecting, obtaining, and interpreting results from a test) was the main topic searched by health professionals (1838/3364, 54.64%) and students (1228/2437, 50.39%), whereas general information on stroke rehabilitation was the top-ranked topic for nearly two-thirds of the individuals with stroke (45/76, 59%) and their relatives (57/91, 63%). Cognitive impact was characterized by *learning something new*. Intention to use was high (4590/6379, 71.95%) among respondents and varied in context (eg, refine a topic, research, class assignments, teaching, and education). Expected patient and health benefits such as improvement in health and well-being was the top-ranked category for all 4 subgroups, followed by an avoidance of unnecessary or inappropriate treatment for health professionals (183/623, 29.4%) and a feeling of being reassured for individuals with stroke (26/75, 35%) and their relatives (28/97, 29%). Overall, the results of this study highlighted the funnel pattern of the 4 levels of outcomes on information [24] where information can be relevant and have a cognitive impact but may not necessarily be used; conversely, information can be used but does not necessarily lead to health benefits. This illustrates information-related actions and subsequent outcomes regarding information users, including people with lived experience and their relatives. Indeed, although the information searched was deemed relevant and had a cognitive impact for 96.07% (6373/6634) of the respondents, intention to use dropped to 68.92% (4572/6634), and only 27.98% (1856/6634) of the respondents expected patient or health benefits. The drop relating to intention to use can be partially explained by a large representation in our sample of students (2784/6634, 41.97%), who typically use the information for class assignments. It may also be because practice change is a challenging process that requires more than access to knowledge [35,36]. In fact, a positive attitude toward scientific evidence was recently found to be the necessary and sufficient attribute to explain a high use of evidence-based practice among rehabilitation professionals [37]. We may hypothesize that the majority of our subgroup of health professionals (3663/6634, 55.22%) had a positive attitude toward scientific evidence because they initiated the search (they *pulled* the information), which is a different scenario than when the information is *pushed* to facilitate its implementation [38]. As shown by the free-text comments, many of the respondents were already users of the information and were searching for a link that would lead them to a specific assessment or searching for guidance on how to interpret a tool that they were already using in practice.

Interestingly, more than half of the health professionals and students searched for assessments rather than interventions (309/3364, 9.19% and 143/2437, 5.87%, respectively). The reasons for this are uncertain. They may already know how to intervene or be aware of the best treatment options. By contrast,

it is possible that *they don't know that they don't know* (knowledge gap), and therefore they do not initiate a search for interventions, or perhaps they look into clinical practice guidelines for treatments. The generally agreed-upon time lag for scientific evidence to translate into practice is 17 years [39]. If we consider 2008 as the start of the rise in the number of publications of randomized controlled trials in stroke rehabilitation [14], this type of evidence-based knowledge can be arguably considered relatively recent. Looking at our results, we could interpret them as an incentive to further prioritize content on assessment on our website so that we may best meet users' needs. However, this should not be at the expense of interventions because we anticipate that interventions will become an important topic as we strive to bridge the knowledge-to-practice gap [40].

The substantial underrepresentation of individuals with lived experience and their relatives in comparison with health professionals and students was striking, although the website is accessible to all. This may partly be due to the fact that, as scholarly practitioners [41], health professionals may facilitate translation and mobilization and therefore share health-related information with their clientele in practice. Health professionals have told us to provide printable PDF versions of relevant information from our website to their clientele. As such, nearly one-third (170/623, 27.3%) of the health professionals responded that they expected an increase in patients' or relatives' knowledge as a benefit, further supporting their role as a transmission belt of relevant information. It may also be that fewer individuals with stroke and their relatives filled in the IAM questionnaire because they may use our website as 1 resource among many others and also use it less formally compared with the other 2 subgroups.

This website was first created with the aim to narrow the knowledge-to-practice gap and support the evidence-based practice of health professionals. From its inception in 2008, the website has included lay summaries for people with lived experience and their relatives to help them to cope with the consequences of stroke. It was also designed to empower people with lived experience and their relatives to become a transmission belt and request specific interventions or, at the very least, open a dialogue with their therapists. Both quantitative results and free-text comments indicate that we are meeting this aim for individuals with stroke and their relatives who volunteered to complete the web-based survey. One challenge is to reach out to a greater audience of individuals with lived experience and their relatives. We might also question whether the current format and content are sufficient or how to improve both to meet the informational needs of a greater audience. In other words, what do nonrespondents think of the value of this content? What would be the best way or methods to give them a voice?

Finally, using crowdsourcing as a method for soliciting feedback enabled us to realize how important and relevant such a web resource can be not only for practice (its primary mandate) but also for education and research. Indeed, with students representing 41.97% (2784/6634) of the sample and as supported by the free-text comments, our website proved to be a premium resource to learn about stroke rehabilitation. One sector,

however, that might be considered underrepresented would be the policy sector. Incidentally, we are aware that our website is used as a resource for national [42] and provincial [43] guidelines. Despite the website's value for knowledge translation in practice, education, research, and policy, our biggest challenge is to secure recurrent funding to keep its content up to date and to further add innovations. Our hope is to incorporate artificial intelligence (AI; such as a chatbot) to facilitate an open evidence-based practice dialogue by allowing an easy exchange among scientific evidence (actual content of the website), tacit knowledge of health professionals, and experiential knowledge of people with lived experience and their relatives. However, to materialize our vision for incorporating AI, we would first need to secure funding to keep the actual website up to date. Indeed, research funding by national funding agencies proved to be of immense support when we first created this knowledge translation platform, but we do not have access to any funding programs to ensure its survival. Despite its relevance and usefulness for multiple stakeholders, most funding agencies view this resource as *infrastructure* and no longer as research. Given the perennial challenges of evidence-based practice and the intended purpose of knowledge translation, we have serious concerns about such a view. How can best practices be implemented in a sustainable manner without adequate funding? We invite discussion on how the absence of infrastructure funding for knowledge translation initiatives will affect patients and society at large.

Strengths and Limitations

The use of crowdsourcing as a method of data collection can be seen as a strength because it allowed us to obtain valuable feedback from a large sample; however, it can also be seen as a limitation because we used convenience sampling [44]. As such, a first limitation concerns generalizability: the respondents may not be representative of all website users. A second limitation is the inclusion of a survey invitation pop-up window as suggested by users who could not easily find the link to the survey. Although its addition contributed to increasing our survey response rate, we wonder whether the pop-up window was appearing too early because some of the respondents commented about this. We know that too many pop-ups may irritate users by causing a distraction. Nevertheless, we do not know how this may have affected data collection, although visitors had the option to close the pop-up window and return later to complete the survey, which remained accessible at all times. The optional free-text comments to elicit concrete (practical) explanations or illustrations of survey responses is a strength of this study. Indeed, the IAM constitutes a reflexive learning method, thus justifying medical education credits in popular national programs, that stimulates thinking and constructive feedback. Although the option to provide free-text comments helped to collect feedback about areas for improvement, a third limitation lies in the fact that we were unable to analyze this feedback data according to the type of respondent.

Future Directions

In sum, building on these results, first, we would recommend that knowledge translation resources that are comparable with

Stroke Engine perform a similar evaluative process on a periodic basis, using a validated questionnaire such as the IAM. This tool enabled the retrieval of feedback not only on relevance of the information consulted but also on intention to use and expected health benefits, which is the essence of implementation sciences. Second, we would recommend including information in a *ready-to-use* format to minimize any potential barriers to implementation. Third, we would recommend exploring how AI can facilitate interactions among scientific evidence, tacit knowledge (through clinician users), and experiential knowledge (through people with lived experience). Fourth, we would recommend additional exploration as to how well AI can personalize the information searched, especially for people with lived experience and their relatives. Fifth and last—but probably the most important—we would recommend that research funding agencies reflect on current funding opportunities that by and large support new knowledge translation initiatives but do not account for a plan to ensure regular updates and sustained use.

Conclusions

Valuable feedback on Stroke Engine was obtained in terms of its accessibility, relevance for informational needs and retrieval, accuracy, and applicability. The results of this study highlighted the funnel pattern of the 4 levels of outcomes regarding information where information can be relevant and have a cognitive impact but may not necessarily be used; conversely, information can be used but does not necessarily lead to health benefits. In this era of omnipresence of the internet for retrieving various types of information, including health-related information, it becomes of utmost importance to document how information posted on the web is perceived and received. The methods used in this study, including crowdsourcing through the IAM, allowed us to retrieve valuable feedback not only in terms of its accessibility, relevance for informational needs and retrieval, accuracy, and applicability but also, importantly, on the potential implementation of its evidence-based content in clinical practice and perceived expected impact for patients, their relatives, and health care professionals.

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Data Availability

As informed consent did not include a specific data-sharing agreement, the data sets analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

AR is the actual leader of the Stroke Engine website, and AT, NMS, BV, AM, and LP are members of the Stroke Engine research team.

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Abbreviations

AI: artificial intelligence

IAM: information assessment method

KTA: knowledge-to-action

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Original Paper

Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study

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Abstract

Background: Persistent walking impairment following a stroke is common. Although rehabilitative interventions exist, few exist for use at home in the chronic phase of stroke recovery. InTandem (MedRhythms, Inc) is a neurorehabilitation system intended to improve walking and community ambulation in adults with chronic stroke walking impairment.

Objective: Using design best practices and human factors engineering principles, the research presented here was conducted to validate the safe and effective use of InTandem.

Methods: In total, 15 participants in the chronic phase of stroke recovery (≥ 6 months after stroke) participated in this validation study. Participants were scored on 8 simulated use tasks, 4 knowledge assessments, and 7 comprehension assessments in a simulated home environment. The number and types of use errors, close calls, and operational difficulties were evaluated. Analyses of task performances, participant behaviors, and follow-up interviews were conducted to determine the root cause of use errors and difficulties.

Results: During this validation study, 93% (14/15) of participants were able to successfully complete the critical tasks associated with the simulated use of the InTandem system. Following simulated use task assessments, participants' knowledge and comprehension of the instructions for use and key safety information were evaluated. Overall, participants were able to find and correctly interpret information in the materials in order to answer the knowledge assessment questions. During the comprehension assessment, participants understood warning statements associated with critical tasks presented in the instructions for use. Across the entire study, 3 "use errors" and 1 "success with difficulty" were recorded. No adverse events, including slips, trips, or falls, occurred in this study.

Conclusions: In this validation study, people in the chronic phase of stroke recovery were able to safely and effectively use InTandem in the intended use environment. This validation study contributes to the overall understanding of residual use-related risks of InTandem in consideration of the established benefits.

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KEYWORDS

chronic stroke; walking; InTandem; MR-001; neurorehabilitation; human factors engineering; usability; rhythmic auditory stimulation; validation; neurotherapeutic

Introduction

Stroke is a major cause of disability and the second leading cause of death worldwide, with its incidence and prevalence expected to increase due to an aging population [1,2]. Many people in the chronic phase of stroke recovery (commonly defined as ≥ 6 months after stroke) experience walking impairment [3] and consider the ability to walk in their community as “either essential or very important” [4]. Walking rehabilitation can positively impact the well-being of stroke survivors and their families. It can also restore independence—a prospective study in the chronic stroke population reported that better walking ability was positively correlated with quality of life and the ability to live independently [5]. Clinical practice guidelines recommend various interventions for walking impairment, including physical therapy and braces such as an ankle foot orthosis [6-8]. Rhythmic auditory stimulation (RAS) is another clinically effective intervention for the rehabilitation of movements that are naturally rhythmic (eg, walking) [9]. RAS draws on a naturally occurring phenomenon called auditory-motor entrainment. During entrainment, an external auditory rhythm enables subconscious synchronization between the auditory and motor systems to drive coordinated movement patterns [10,11]. RAS has shown clinical benefits related to walking for patients with stroke across the subacute and chronic phases in many studies, several of which are randomized controlled trials (RCTs) [12-18]. In particular, speed, step length, cadence, balance, and dynamic postural stability [12,19,20] have been shown to improve in people who have had a stroke and receive RAS. In addition, the US Department of Veterans Affairs incorporated rhythmic auditory cueing into its clinical practice guidelines for the management of stroke rehabilitation in 2019 [21].

Currently, clinicians administer the RAS protocol in rehabilitation hospitals or clinics, while accessible at-home RAS-based interventions are nonexistent. Rehabilitation at home

can carry benefits including half the risk of readmission, lower caregiver strain [22], reduced cost, and greater patient satisfaction [23] relative to hospital rehabilitation. For those in the chronic phase of stroke recovery, physical therapy and to a greater extent RAS can be difficult to access due to limited insurance coverage and the limited number of neurologic music therapists who deliver RAS. The lack of a solution for at-home walking rehabilitation is a critical gap in chronic stroke recovery, and it is imperative that solutions that are safe and effective to use are developed and delivered to address this unmet need.

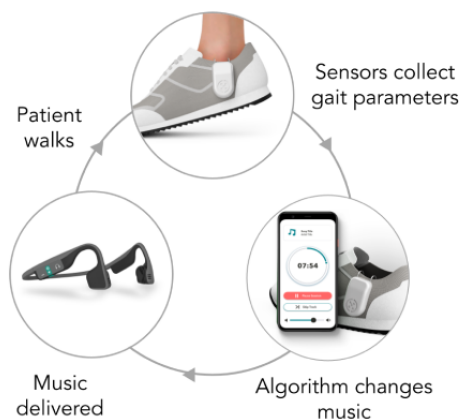
To help close this gap, MedRhythms has designed MR-001 (InTandem, MedRhythms, Inc), a neurorehabilitation system that delivers a RAS-based intervention for chronic stroke walking impairment and is intended to be used independently at home.

Methods

System

The InTandem system (Figure 1) consists of 2 shoe-worn sensors that measure gait parameters, a locked touchscreen device preloaded with proprietary software, a headset, and charging equipment (not shown). The rhythmic stimulation used in InTandem is music. The music supplied has been screened for therapeutic benefit by a proprietary process that ensured the music met requirements for beat prominence and tempo. In developing InTandem, a patient-centered usability engineering process was followed to optimize for safe and effective use of InTandem according to the US Food and Drug Administration (FDA) guidance on human factors and usability engineering for medical device development [24]. Throughout this paper, InTandem might be referred to as “StridePlus” or “MR-001”—these were the nonproprietary names used during the development of the product. The product will be branded and commercialized as InTandem.

Figure 1. InTandem neurorehabilitation system.

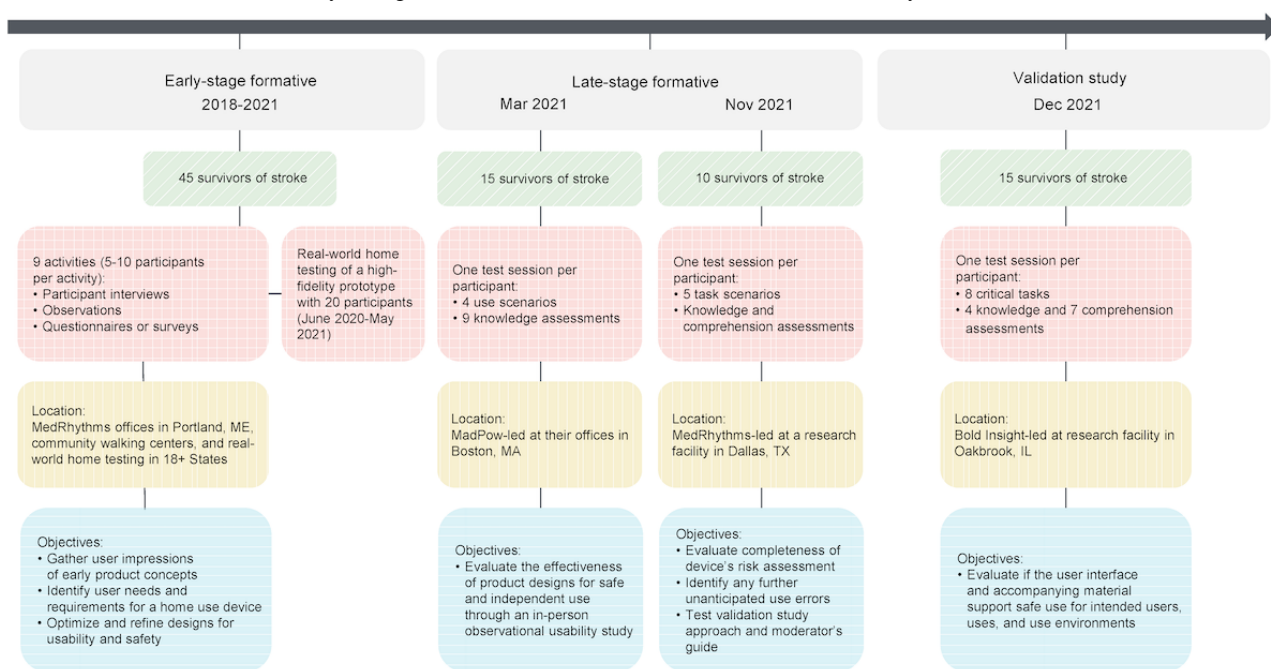


Background on Formative Testing

This paper describes the methods and results of the human factors validation testing, which aimed to validate InTandem for safe and effective use. The testing was preceded by formative research activities across 2 phases to better understand stroke survivors’ needs for a home-use device, identify potential risks to patient safety, and iterate on system designs. A total of 70 unique stroke survivors with varied demographic backgrounds from both urban and rural locations across the United States were involved in the 2 formative research phases (see Figure 2 for more details about formative research activities). Some

examples of learnings and iterations that occurred during the formative phases include (1) the need for improved sensor clips that allowed easier placement on sneakers that required less fine motor skill and hand strength and (2) the identification of which interactions with the product users needed the most education on and were less immediately intuitive out of the box. Examples of results from the late formative phase included the need for improved instructions to walk and experience during the baseline walking part of a session, in which the sensors calibrate and measure cadence. A need for an improved user interface of the “pause” and “skip” buttons was also apparent in the late formative phase.

Figure 2. Overview of MR-001 usability testing across formative research activities and validation study.



The validation study was conducted in December 2021 by an independent user experience and human factors research firm (Bold Insight). Bold Insight was selected to provide an unbiased third-party evaluation of the system’s usability and safety. This study assessed participant performance on all critical safety tasks to validate the usability of InTandem in the intended use population and environment (at home) and demonstrate that the product is not vulnerable to use errors that could lead to serious harm. Here, “critical tasks” are defined as “those that could cause serious harm in the event of a use error scenario or tasks with a severity of ‘moderate’ or greater identified in the use failure mode and effects analysis” (uFMEA; Multimedia Appendix 1). For the purposes of this paper, and in line with ISO 14971:2019 standard [24], “safety” is defined as the “freedom from unacceptable risk,” whereas “risk” is defined as the “combination of the probability of occurrence of harm and the severity of that harm.” In addition, according to IEC 62366 [25], “effectiveness” is defined as the “accuracy and completeness with which users achieve specified goals.” The study design followed a human factors validation protocol, and the study methods implemented were based on industry standards and FDA guidance [25-28]. Multimedia Appendix 1

provides definitions of terminology relevant to the study along with examples from the study [26,29].

Ethical Considerations

The study protocol was reviewed and approved by the Biomedical Research Alliance of New York, an institutional review board (IRB #A20-02-508). Participants were reimbursed for out-of-pocket expenses incurred by being in the study.

Participants, Setting, and System Set-Up

A total of 15 participants, with a mean age of 70 (SD 5.4; range 60-82) years and diagnosed as having had a stroke at least 6 months prior were recruited to meet the intended user population. Bold Insight managed screening and enrollment based on recruiting requirements. A broad group of patients with chronic stroke were recruited to ensure that the results reflected the differences in background and experiences of potential end users. Of note, although all participants reported not needing a caregiver to perform the tasks during screening, at the beginning of the session, 1 participant indicated their caregiver may help them in the real world, so that caregiver was invited into the session. A summary of enrolled patient characteristics can be found in Table 1.

Table 1. Summary of participant characteristics^a.

Variable	Values (N=15)
Age (years), mean (SD)	70 (5.4)
Gender, n (%)	
Male	9 (60)
Female	6 (40)
Education level, n (%)	
General educational development or high school	6 (40)
PhD or higher	1 (7)
Bachelor's degree	5 (33)
Trade school	2 (13)
Master's degree	1 (7)
Time since the last stroke, n (%)	
6 months to <2 years	1 (7)
2 years to <5 years	4 (27)
5 years to <10 years	1 (7)
10 years to <15 years	4 (27)
15 years to <20 years	5 (33)
Comfort level with technology, n (%)	
Basic tasks	3 (20)
Okay	9 (60)
Very comfortable	3 (20)
Caregiver needed, n (%)	0 (0)
Walking impairment, n (%)	13 (87)
Interested in improving the ability to walk, n (%)	14 (93)
Assisted walking devices, n (%)	2 (13)
Neurologic injury other than stroke, n (%)	0 (0)
Lower limb prosthetic, n (%)	0 (0)
Hearing impairment, n (%)	0 (0)
Severe aphasia, n (%)	0 (0)
Speech disorder, n (%)	0 (0)
Able to safely participate in a 5- to 7-minute walk, n (%)	15 (100)

^aFor the demographic variables that have 0%, this was intentional in order to replicate exclusion criteria used for clinical trials of InTandem.

To evaluate MR-001 use in the intended home environment, test sessions were performed at a usability laboratory that simulated a home setting and included items typically found in a personal living space (eg, table, chairs, and indoor ambient lighting). The 2-room research suite was equipped with a 1-way mirror, enabling researchers to observe the testing unobtrusively. The walking portion of the test sessions took place in a hallway outside the testing room that was kept private using screens.

Procedures

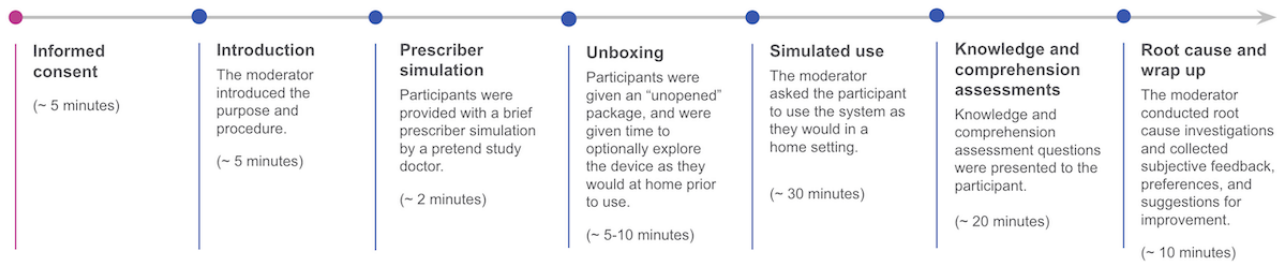
Each study session lasted approximately 90 minutes (see [Figure 3](#) for session flow), and participants were scored on the completion of critical tasks that were assessed via 3 evaluation methods such as simulated use of the product, knowledge

assessments, and comprehension assessments. Knowledge and comprehension assessment questions were used when tasks could not be simulated such as to verify whether the participants understood where they should use the device. Other noncritical tasks were completed as part of the procedure but were not scored. After consent was obtained and an introduction to the session was provided, each participant was provided with a prescribing scenario to simulate the experience of receiving a prescription of InTandem from a qualified health care provider. Specifically, an introduction by a pretend study doctor to highlight that the system was (1) prescribed by a doctor, (2) the system would be mailed to the patient's house, and (3) everything they needed to use the system would come in the box. Then, participants were given the opportunity to unbox

and familiarize themselves with the product and instructions for use (IFU) as they would at home. Throughout the unboxing and simulated use scenarios, participants also had the opportunity to watch a welcome video and had access to a

helpline via a test facility telephone or their phone, with a MedRhythms support representative providing remote assistance.

Figure 3. Session flow.



For simulated use scenarios, participants were observed while they completed realistic task sequences needed for a walking session including system setup, initiating a session, ending a session, and charging the components for future use (Table 2). During this activity, the moderator evaluated performance twice—once with the headset available and once without the headset to evaluate the usability and safety of listening via both

headset and device speakers. Across the 2 conditions, participants were scored on 4 unique critical tasks with the device, resulting in 8 total critical tasks that were scored. All participants completed the 2 conditions in the same order—first with the headset available and again without the headset. The moderator also noted any observations related to usability and safety on participants’ interaction with the system.

Table 2. Description of critical tasks for the simulated use assessment.

Simulated use task	Success criteria
Users clip sensors onto shoes	User puts on sensors from a stable position (such as sitting down)
Adjust the volume so that the volume is loud enough without being uncomfortable	The audio volume is loud enough for the user to hear without being uncomfortable
Stow device—user keeps touchscreen device where it does not impact their environmental awareness and personal stability	The user keeps a touchscreen device where it does not impact their environmental awareness and personal stability
Remove sensors from shoes	Foot sensors are removed from shoes from a stable position (such as sitting down)

As a descriptive example of how a simulated use critical task relates to safety, the “adjusting volume” task in the uFMEA is tied to these hazardous situations and potential harms if a user encountered a use error when (1) the user cannot hear safety cues in their environment, which may lead to the potential harm of kinetic impact, (2) the user is exposed to an acoustic energy condition that could result in hearing discomfort, or (3) the user

is unable to hear instructions and therapy which could result in a delay of therapy.

After the simulated use scenario, participants were asked to use the instructional materials provided (eg, IFU and welcome video) to answer 4 questions to evaluate knowledge of critical information (Table 3). This set of critical tasks assessed the participant’s ability to recall critical information from the materials.

Table 3. Description of the critical tasks for the knowledge assessment. Participants were asked questions that assessed their knowledge of critical information.

Question	Success criteria
According to the materials, what environments are appropriate for using StridePlus in?	Participant mentions: <ul style="list-style-type: none"> • Home; Track; YMCA; or flat outside space such as a sidewalk or park • Flat and level surfaces • Locations where you can walk at least 20 steps in a straight line before turning • Not for use on treadmills
According to the materials, what environments are NOT appropriate for using StridePlus in?	Participant mentions: <ul style="list-style-type: none"> • Treadmill • Places with icy, steep, wet, or dark terrain • Places with obstacles in your path like furniture, many people, traffic, and so on • Loud places that will compete with the device audio or interfere with situational awareness
According to the materials, what is the proper way to put on and take off the foot sensors?	Participant mentions: <ul style="list-style-type: none"> • Sitting down, being in a stable position, or asking someone else to put them on
According to the materials, what footwear should you use with this system?	Participant mentions: <ul style="list-style-type: none"> • Well-fitted, supportive, OR recommended by a physician • Additional acceptable answers include lace-up or Velcro-strap style sneakers. Avoiding wearing flip-flops, slippers, clogs, and any slip-on style shoe

Finally, 7 comprehension tasks were used to evaluate whether participants fully understood key safety information (Table 4) by observing safety icons and demonstrating an understanding of safety statements.

Table 4. Description of critical tasks for comprehension assessment. The participant was asked to demonstrate their understanding of the safety icon and statements.

Statement	Success criteria
<ul style="list-style-type: none"> DO NOT use [InTandem] if any of the system materials are damaged (to prevent risk of electric shock) 	Demonstrates understanding to not use damaged materials
<ul style="list-style-type: none"> To prevent the risk of injury from a slip, trip, or collision: attach and remove the foot sensors from your shoes from a stable position such as sitting down 	Demonstrates understanding to put sensors on from a stable position
<ul style="list-style-type: none"> DO NOT use [InTandem] with the volume very loud or in loud surroundings because it may hide safety cues, such as emergency sirens or cars honking. 	DO NOT use [InTandem] with the volume very loud or in loud surroundings because it may hide safety cues, such as emergency sirens or cars honking
<ul style="list-style-type: none"> Use [InTandem] in a safe walking area. Do not use in poorly lit areas (to avoid potential obstacles) Do not use in areas with obstacles or potential hazards in your walking path, such as tables, chairs, rugs, pets, pedestrians, or traffic Do not use in areas with uneven, wet, or icy terrain 	Demonstrates understanding to not perform walking sessions on uneven surfaces (stairs, ramps, or wet surfaces) or in crowded locations with many obstacles
<ul style="list-style-type: none"> To help [InTandem] work properly and ensure accurate step detection from the foot sensors: <ul style="list-style-type: none"> Use [InTandem] in areas where you can walk at least 20 steps in a straight line before turning. Avoid locations with high noise levels that may limit your ability to hear system instructions and music. Avoid uneven walking surfaces (such as frequent stairs, ramps, or hiking trails) Do not use [InTandem] on a treadmill 	Demonstrates understanding to perform walking sessions in a flat environment, not on a treadmill
<ul style="list-style-type: none"> Do not walk while looking at the [InTandem] touchscreen device 	Demonstrates understanding to not view their device during walking sessions
<ul style="list-style-type: none"> Do not continue using [InTandem] if the walking exercise becomes too difficult. Take breaks as needed. A session can be paused and resumed on the touchscreen device screen at any time throughout the session. If you ever become uncomfortable or feel unsafe with the speed of the music, walk at your natural pace. The speed of the music will adjust back to the starting pace of your walking If you experience muscle or joint pain or discomfort that you normally do not have, stop using [InTandem] and consult a medical professional If you experience any abnormal symptoms such as nausea, shortness of breath, or excessive fatigue, stop using [InTandem] and consult a medical professional 	Demonstrates understanding to not walk if they become too tired or experience a health issue

Performance of user tasks was scored as “success,” “success with close call,” “success with difficulty,” “use error,” or “not applicable” (definitions provided in [Multimedia Appendix 2](#)). Descriptions of use error severity in the uFMEA risk management plan can be found in [Multimedia Appendix 3](#).

Data Management, Collection, and Analysis

Bold Insight carried out the data collection, management, and analysis. Consent for data collection, use, and sharing of data with the study sponsor (MedRhythms), other authorized persons, and regulatory agencies was collected. Data were deidentified and each participant was given a unique participant code for data collection and analysis purposes. Data included demographic and background information (eg, age and gender), personal health information (eg, medical history) and study visit data, such as (1) participant task performance data; (2) instances of test administrator assistance; (3) system device malfunctions; (4) reported root causes; (5) interview responses; (6) completion of noncritical tasks; and (7) use of the instruction manual, setup

video, and helpline during handling scenarios. Sessions were video and audio recorded, and the results were documented and analyzed in a test report formatted to conform to FDA guidance [24].

Use errors were analyzed in two ways: (1) as a percent of participants who successfully completed the critical tasks without use errors for each of the 3 evaluation methods and (2) as the error rates observed out of all opportunities for errors for each of the 3 evaluation methods. For any use errors, close calls, and operational difficulties associated with critical tasks, the moderator probed for underlying root causes of the observed use-related event. Root cause analysis consisted of asking in-depth and open-ended questions to understand the source of any participant confusion or use errors. Documented use-related events were discussed with a cross-functional team to determine if additional design improvements were necessary to mitigate risks. Difficulties and close calls were calculated as the frequency with which they occurred for each task type.

Results

Each participant completed 8 simulated use tasks, 4 knowledge assessments, and 7 comprehension assessments. In total, 93% (14/15) of participants successfully completed the simulated use tasks associated with at-home use of InTandem. Out of the 120 opportunities for error in the simulated use (15 participants \times 8 simulated use tasks), there was 1 error observed, resulting in an error rate of 0.8% (1/120). The 1 use error was observed during the system setup involving the placement of sensors onto shoes. This participant (P01) initially expected that the charging cables should remain attached to the sensors on one's shoes while using the product and attempted to keep the charging cables attached at the beginning of the walking task. The moderator paused the participants to prevent them from walking with the charging hub. Root cause analysis revealed that due to a software bug, the participant was able to hear the welcome video but could not view the video, which describes and demonstrates the proper way to attach the sensors for a walking session. However, this mitigation strategy of watching and listening to the video was not fully available. During the root cause investigation, the participant indicated that the video would have been helpful to see during setup. Therefore, the root cause for this use error was ascribed to the software bug, which was subsequently corrected. The participant also did not review information in the IFU that showed how the sensors should be attached to the shoes. The severity of the associated use error was categorized as moderate, with the possibility of a slip, trip, or fall resulting in harm. Aside from this, all participants were successful in completing the walking task, and no instability or loss of path was observed. During the course of the simulated use evaluation, no new critical tasks were identified, and no issues were experienced with the noncritical tasks.

During the knowledge assessments, 93% (14/15) of participants were able to find and correctly interpret information in the instructional materials, including the IFU and welcome video, to answer the questions. Out of the 60 opportunities for error in the knowledge assessments (15 participants \times 4 knowledge assessments), there was 1 error observed, resulting in an error rate of 2% (1/60). One participant (P013) experienced a use error in which they were unable to specify where the information about appropriate environments could be found in the IFU. The participant assumed that guidance on appropriate environments would be placed toward the end of the IFU after the sections that outlined how to set up the system and did not look for information at the beginning of the IFU where it was located. However, this participant was able to correctly state the appropriate use environments for the system; therefore, after root cause analysis was conducted, the research team determined that additional mitigation strategies were not required for this use error.

Similar to their performance on simulated use tasks and knowledge assessments, participants showed high success with the comprehension assessments. In total, 93% (14/15) of participants understood warning statements associated with critical tasks presented in the IFU. Out of the 105 opportunities for error in the comprehension assessments (15 participants \times 7 comprehension assessments), 1 error was observed, resulting

in an error rate of 1% (1/105). The 1 use error was observed related to the warning: "DO NOT use [InTandem] with the volume very loud or in loud surroundings because it may hide safety cues, such as emergency sirens or cars honking." The participant (P10) believed that the statement was instructing them to use InTandem in quiet places so that outside noises would not interfere with the instructions. However, the task's success criteria required participants to specifically mention the ability to hear safety cues in their environment. Comprehension of this information is important because people need to maintain awareness of their surroundings. If the volume is too high, there could be a risk of not hearing an environmental safety cue such as a potential collision that may be outside of their view. Ultimately, the participant demonstrated their complete understanding of the statement, so no additional mitigations were required to further reduce the risk of a slip, trip fall, or kinetic impact.

With respect to "close calls" and "difficulties," 0 "close calls" and 1 "difficulty" in the knowledge assessment were observed. The 1 "difficulty" was due to a participant (P01) who had trouble understanding the knowledge task question "According to the materials, what is the proper way to put on and take off the foot sensors?" However, the research team categorized this as a "success with difficulty" because during root cause probing, it was evident the participant understood the proper way to put on and take off the foot sensors.

Discussion

Principal Findings

The goal of this study was to validate that participants representative of InTandem's intended use population can safely and effectively use InTandem, through the completion of critical tasks, and demonstration of knowledge and comprehension of materials. Overall, the occurrence of use errors was observed to be extremely low. For the 3 use errors that occurred in the simulated use tasks, knowledge assessments, and comprehension tasks, root causes were attributed to a software bug and expectations about product use and instructional materials. For the software bug-related use error, we cannot be certain that the use error would not have happened even if they had seen the video while the components were attached to the charging cables. However, the order of events as well as the record of the participant having suggested the video would have helped suggest to the research staff that the software bug was the root cause. The software bug was subsequently corrected. Regarding expectations about product use and instructional materials, although 1 participant expected information about appropriate walking environments to be in a different part of the IFU, no additional mitigations were deemed necessary because they were able to accurately state the appropriate environments for use, and this feedback was not prevalent across the study. In addition, for the participant who did not specifically mention the ability to hear safety cues in their environment during the comprehension evaluation, they were ultimately able to demonstrate their understanding of the safety statement, and existing risk mitigations were deemed sufficient. With respect to difficulties and close calls, there was only 1 difficulty

observed in the knowledge assessment. This participant later exemplified that they knew the correct answer during the root cause investigation. The 3 use errors observed for each of the 3 evaluation methods were experienced by 3 different participants, suggesting that all participants showed a high level of performance in critical tasks associated with the safe and effective use of InTandem.

Contextualization With InTandem Formative Research

Leading up to this study, over 2 years and 8000 hours of iterative design and testing were conducted (formative research) that tailored the system for use in the home environment by the intended patient population. The formative research was conducted with participants representative of the intended population to ensure that the patient's voice, needs, and desired experience are represented in InTandem. The formative research also ensured that all tasks associated with potential use errors could be identified and tested, and through design iterations, use errors were reduced to a risk as low as reasonably possible, culminating in a robust product design. The methods of this study align with best practice human factors engineering and user-centered design, which are critical to the development of impactful evidence-based rehabilitative systems that meet an unmet medical need.

Strengths and Limitations

This study contains important strengths in the study methodology. For example, this research was conducted after extensive formative testing that used a patient-centric and iterative design approach with multiple rounds of design refinement, which helped address the needs of the device users. Second, a third party conducted the study to help mitigate potential bias. Related to the device itself, a high percentage of individuals were successful in completing critical tasks, even though the majority of participants enrolled indicated that they were not "very comfortable" using technology, which suggests that InTandem is intuitive to use. These strengths add to the compounding evidence for InTandem to be used by the intended population in the intended environment for use. The accumulated evidence for InTandem includes a feasibility study that resulted in clinically relevant improvements in speed over 1 and multiple sessions [30] and a reduction in the energetic cost of walking along with improved gait asymmetries [31]; a longitudinal RCT of safety and clinical efficacy of InTandem [32]; and a budget impact model that estimates cost savings to payers [33]. Furthermore, MR-001 (InTandem) was designated as a breakthrough device by the FDA in 2020 [34], which underscores both the unmet need to address persistent walking deficits of people who are in the chronic stroke phase of recovery in an accessible and effective manner and the merit and opportunity that InTandem offers them. With the findings presented in this paper and the holistic evidence base of

InTandem to improve walking impairment in the chronic stroke population, there is a convincing rationale for its place as a rehabilitation option available to patients.

This study is not without limitations. For example, this study included a walking component that only lasted for 5 minutes as opposed to the 30-minute sessions that would occur in real-world use. This was intentional since the aims of the study were not to assess the treatment effect of the intervention which was assessed in both the feasibility study and the RCT but rather to assess the usability of the system by the intended population in the intended environment. In addition, this research focused on only critical tasks involved in the use of InTandem, and although noncritical tasks were necessarily experienced as part of the testing protocol, they were not scored. Another limitation is that gait impairment was not included as a screening criterion, which would align the study population even closer to the intended population. However, even without a screening criterion, 87% (13/15) of participants enrolled experienced walking impairment. Given the fact that the focus of this study was on using the product and not on the efficacy of the intervention to improve walking, the need for representative walking impairment may be less critical than if the focus was on walking outcomes. Another limitation of the study is that although all participants were recruited and screened for not needing a caregiver to perform the activities, during the warm-up questions, 1 participant indicated that their caregiver would help with some tasks and was subsequently allowed to have their caregiver join them in the room. InTandem was designed to be used independently without a caregiver present, and none of the critical task performances were affected by the inclusion of the caregiver, suggesting InTandem can be used safely and effectively as designed. Another limitation is that there were no participants who had less than a high school education enrolled in this study, which would have reflected a potentially lower literacy population. Finally, racial and ethnic diversity was not an explicit recruitment criterion, and such data were not captured in this study. Future work on InTandem will benefit from newly implemented product research standards to increase racial diversity in studies.

Conclusions

This paper describes the methods and results of the patient-centered process undertaken to validate the safety and effectiveness of the use of InTandem at home by people living with chronic stroke. In this validation study, people in the chronic phase of stroke recovery were able to safely and effectively use InTandem in the intended setting. This validation study contributes to the overall understanding of residual use-related risks, in consideration of the established benefits of InTandem.

Acknowledgments

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Authors' Contributions

SC was involved in the conception, organization, and execution of the study. KES was involved in writing of the first draft, review and critique, and submission and resubmission preparation and execution of the paper. KL and JU organized, executed, designed, executed the study, and reviewed and critiqued the paper. NF and AD were involved in writing the first draft and reviewing and critiquing the paper.

Conflicts of Interest

SHC and KES are employees of MedRhythms and hold equity. KL and JU are employees of Bold Insight. NF and AD are employees of EVERSANA Canada Inc, which received funding from MedRhythms to prepare portions of this manuscript.

Multimedia Appendix 1

Definitions and examples of common terminology used.

[[DOCX File , 13 KB - rehab_v10i1e50438_app1.docx](#)]

Multimedia Appendix 2

Definition of performance scores.

[[DOCX File , 13 KB - rehab_v10i1e50438_app2.docx](#)]

Multimedia Appendix 3

Severity of potential harm definitions.

[[DOCX File , 12 KB - rehab_v10i1e50438_app3.docx](#)]

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Abbreviations

FDA: Food and Drug Administration
IFU: instructions for use
RAS: rhythmic auditory stimulation
RCT: randomized controlled trial
uFMEA: use failure mode and effects analysis

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Original Paper

A Brain Computer Interface Neuromodulatory Device for Stroke Rehabilitation: Iterative User-Centered Design Approach

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Abstract

Background: Rehabilitation technologies for people with stroke are rapidly evolving. These technologies have the potential to support higher volumes of rehabilitation to improve outcomes for people with stroke. Despite growing evidence of their efficacy, there is a lack of uptake and sustained use in stroke rehabilitation and a call for user-centered design approaches during technology design and development. This study focuses on a novel rehabilitation technology called exciteBCI, a complex neuromodulatory wearable technology in the prototype stage that augments locomotor rehabilitation for people with stroke. The exciteBCI consists of a brain computer interface, a muscle electrical stimulator, and a mobile app.

Objective: This study presents the evaluation phase of an iterative user-centered design approach supported by a qualitative descriptive methodology that sought to (1) explore users' perspectives and experiences of exciteBCI and how well it fits with rehabilitation, and (2) facilitate modifications to exciteBCI design features.

Methods: The iterative usability evaluation of exciteBCI was conducted in 2 phases. Phase 1 consisted of 3 sprint cycles consisting of single usability sessions with people with stroke (n=4) and physiotherapists (n=4). During their interactions with exciteBCI, participants used a "think-aloud" approach, followed by a semistructured interview. At the end of each sprint cycle, device requirements were gathered and the device was modified in preparation for the next cycle. Phase 2 focused on a "near-live" approach in which 2 people with stroke and 1 physiotherapist participated in a 3-week program of rehabilitation augmented by exciteBCI (n=3). Participants completed a semistructured interview at the end of the program. Data were analyzed from both phases using conventional content analysis.

Results: Overall, participants perceived and experienced exciteBCI positively, while providing guidance for iterative changes. Five interrelated themes were identified from the data: (1) "This is rehab" illustrated that participants viewed exciteBCI as having a good fit with rehabilitation practice; (2) "Getting the most out of rehab" highlighted that exciteBCI was perceived as a means to enhance rehabilitation through increased engagement and challenge; (3) "It is a tool not a therapist," revealed views that the technology could either enhance or disrupt the therapeutic relationship; and (4) "Weighing up the benefits versus the burden" and (5) "Don't make me look different" emphasized important design considerations related to device set-up, use, and social acceptability.

Conclusions: This study offers several important findings that can inform the design and implementation of rehabilitation technologies. These include (1) the design of rehabilitation technology should support the therapeutic relationship between the patient and therapist, (2) social acceptability is a design priority in rehabilitation technology but its importance varies depending on the use context, and (3) there is value in using design research methods that support understanding usability in the context of sustained use.

KEYWORDS

user-centered design; stroke; rehabilitation technology; wearable technology; brain computer interface; BCI; mobile app; think-aloud; near live; semistructured interviews

Introduction

Background

Stroke is a major health, socioeconomic, and financial burden that affects over 12 million people worldwide annually [1]. Despite advances in stroke prevention, the incidence of stroke is anticipated to rise due to population growth and aging [2]. Following a stroke, up to 80% of individuals experience difficulty with locomotion [3,4]. Locomotion refers to the ability to move from one place to another [5] and encompasses a wide range of activities such as getting on and off a chair; walking indoors; climbing stairs; and navigating obstacles, terrains, and environments. While most people with stroke regain some ability to walk unassisted, less than 20% achieve unrestricted community locomotion [6,7]. Rehabilitation can reduce locomotor disability following stroke, particularly when delivered in large volumes [8-14], yet observational studies confirm the amount of rehabilitation received is limited, translating into poorer outcomes for people with stroke and consequent lifelong disability [15-20]. Thus, innovative approaches for stroke rehabilitation are required.

The last 2 decades have witnessed the rapid development of rehabilitation technologies, such as robotics, virtual reality, neuromodulation devices, activity monitors, and mobile apps designed to augment rehabilitation after stroke. While there is evidence that these technologies can increase the amount of rehabilitation a person with stroke receives and improve outcomes [13,14,21-26], user adoption and sustained use of such technologies remains low [27-33]. The disconnect between initial efficacy and clinical translation likely relates to the usability of these technologies and their acceptability to users [34,35]. As a result, there has been a call for increased application of user-centered design approaches in the development of rehabilitation technologies [35-37]. Adopting user-centered design approaches can support the development of usable and acceptable technologies by prioritizing user needs, involving users and relevant stakeholders throughout the project life cycle, and modifying the design of the technology based on iterative user-centered evaluation [38,39].

Noninvasive neuromodulatory interventions are rehabilitation technologies with the potential to maximize rehabilitation outcomes and reduce physical disability. Typically, these interventions involve repeated magnetic or electrical stimulation of the central and peripheral nervous systems to induce neural plasticity [40]. Noninvasive neuromodulatory interventions that target movement control have the potential to accelerate stroke recovery when combined with traditional rehabilitation [41-44]. However, such interventions often rely on complex medical devices and user interfaces operated by expert operators, and lack usability and acceptability. To maximize the potential for successful implementation in rehabilitation practice, research and development of noninvasive neuromodulatory technologies

must include a user-centered approach [45]. In this paper, we present a complex neuromodulatory rehabilitation technology (exciteBCI) and its evaluation in a user-centered design research process.

exciteBCI

exciteBCI is a prototype, portable, medical wearable device designed to deliver neuromodulation during locomotor rehabilitation for people with stroke. The device uses a brain computer interface in which a specific electroencephalography signal, which reflects the person's intention to move, is extracted and paired with the afferent stimulus from peripheral electrical stimulation [46,47]. The electrical stimulation is timed to coincide precisely with the electroencephalography signal in the motor cortex to induce neural plasticity [46,47].

exciteBCI evolved from an endeavor to translate a neuromodulatory intervention that had been tested in healthy and stroke populations in a clinical research laboratory setting [46-54] into a rehabilitation device suitable for stroke rehabilitation. Prior feasibility work found that the neuromodulatory intervention, when delivered during simple ankle movements while seated, was not acceptable to people with stroke and was not feasible for rehabilitation [55]. The equipment was deemed cumbersome and uncomfortable, the set-up time was excessive, and the movement tasks were considered meaningless and boring by people with stroke. Given that qualitative evidence indicates that rehabilitation should be centered on meaningful real-world activities that reflect a person's aspirations and should be practiced at progressively higher intensities [56,57], these perspectives have important ramifications for the implementation of the intervention in clinical practice and for ensuring sustained use.

The iterative user-centered design process for developing exciteBCI was guided by the International Organization for Standardization (ISO) 9241-210:2010 standard [38] and was driven by a transdisciplinary team comprising physiotherapists, biomedical engineers, product designers, user experience and user interface designers, and a lived experience researcher. Initial work involved the following three phases: (1) understanding and specifying the context of use, (2) identifying user requirements, and (3) iteratively developing design solutions [58]. This paper reports the fourth stage of the ISO 9241-210:2010 standard [38]: (4) evaluating the design. The aims of this research were to (1) explore users' perspectives and experiences of exciteBCI and how well it fits with rehabilitation, and (2) facilitate modifications to exciteBCI design features.

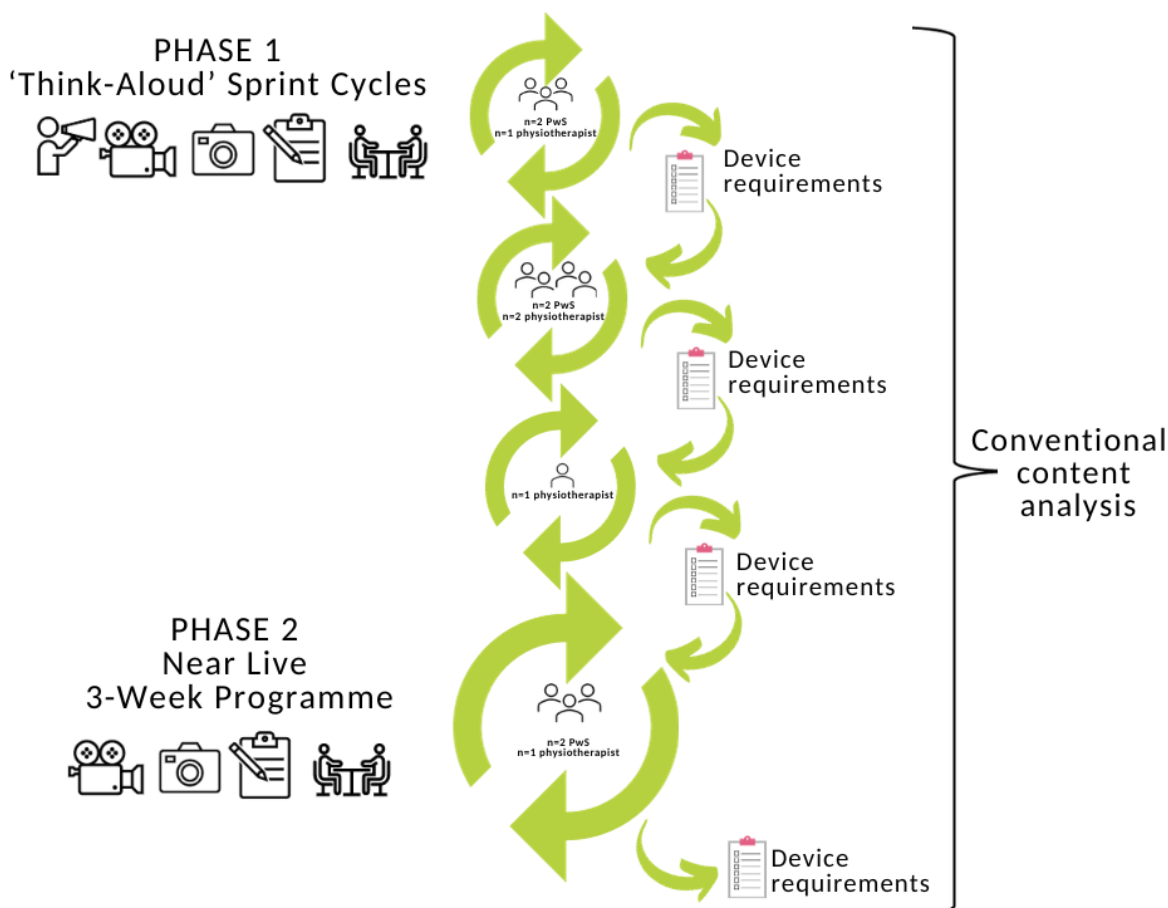
Methods

Study Design

The evaluation phase of an iterative user-centered design approach supported by a qualitative descriptive methodology was used to address the aims of this study. In this study, users

were people who had experienced a stroke and physiotherapists working in stroke rehabilitation. This study consisted of 2 phases. In phase 1, a series of usability testing sprint cycles were conducted [59]. In phase 2, a “near-live” [60] testing approach was used, in which 2 participants with stroke and a physiotherapist undertook a 3-week intervention of locomotor rehabilitation augmented by exciteBCI (Figure 1).

Figure 1. Overview of study design, data collection procedures, and data analysis. PwS: people with stroke.



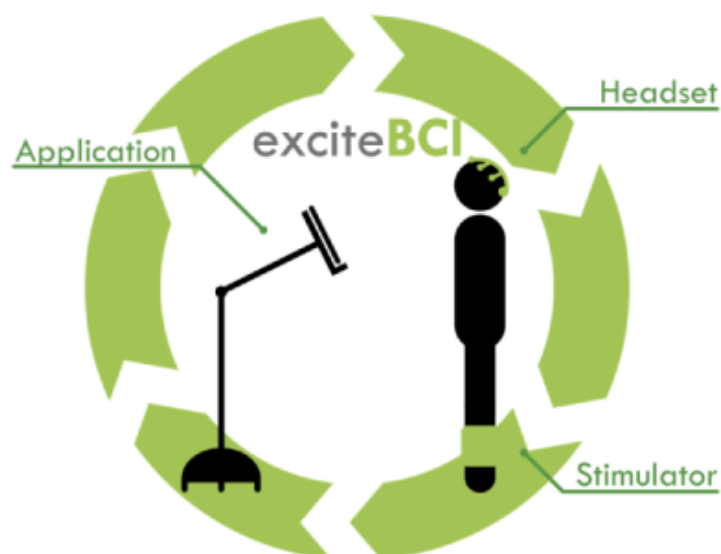
Ethical Considerations

The study was approved by the New Zealand Health and Disability Ethics Committee (17/NTA/177), and locality authorization was endorsed by the Auckland University of Technology Ethics Committee (17/373). Before the study, all participants provided written informed consent. The privacy and confidentiality of participants was protected by secure storage of all data and deidentification of data where feasible. Participants received an NZ \$40 (US \$24) gift voucher for each session they attended in acknowledgment of their contributions.

exciteBCI Prototype

The exciteBCI prototype evaluated in this research is intended for clinical use in collaboration with a qualified physiotherapist in an inpatient, outpatient, or community setting. exciteBCI has 3 components: 2 wearable components, including an electroencephalography headset and a muscle stimulator, and a third component, a mobile app. The 3 components communicate wirelessly (Figure 2).

Figure 2. The exciteBCI consists of 3 components: an electroencephalography headset, a muscle stimulator, and a mobile app, each of which communicates wirelessly.



The electroencephalography headset included 9 gel electrodes capable of recording brain activity that was used to predict when the person with stroke was going to move. The muscle stimulator (NeuroTrac Rehab) was housed within a neoprene sleeve and worn during rehabilitation tasks to deliver electrical stimulation to a lower limb muscle. The muscle stimulator delivered the afferent stimulus which was paired with electroencephalography brain activity to induce neural plasticity. The exciteBCI app was designed to support the delivery of the intervention. It

included locomotor tasks cued with an audiovisual prompt. The locomotor tasks could be selected, and the task parameters such as number of repetitions, movement speed, and rest time manipulated to create an individualized locomotor rehabilitation program. See Figure 3 for example screenshots from the exciteBCI app interface prototype v3.3. This version of the app was presented to participants during the first sprint cycle of phase 1.

Figure 3. Example screenshots from the exciteBCI app interface prototype v3.3. (A) Registering a new patient, (B) the task selection suite where the patient and therapist select tasks that align with the patient’s goals, (C) the parameters that can be manipulated for each task by the therapist to ensure an optimal level of task difficulty, (D) checking the impedance levels of the electroencephalography headset, (E) the muscle stimulator is connected to the app and stimulation amplitude saved, (F) the patient watches a video on how to perform the task, (G-H) the timing signal (auditory-visual cue) to get ready and execute the task, and (I) the patient completes the task difficulty and confidence ratings at the end of the task set.



Participants

People diagnosed with a stroke at least 6 months prior who presented with some restriction of the foot and ankle movement limiting locomotor function were recruited. People with English language limitations, cognitive, perceptual, and communication impairments, who were unable to engage in the research process even with the support of a family member or a health professional, were excluded. New Zealand registered physiotherapists with at least 5 years of professional experience in the field of neurological rehabilitation were recruited. Networking with local health care and rehabilitation providers and community advertising were used to recruit a convenience sample of participants. All participants provided written informed consent before participating in the study.

Procedures and Data Collection

Phase 1: Think-Aloud Sprint Cycles

People with stroke (n=4) and physiotherapists (n=4) participated in a single 1-hour usability testing session, where they interacted with the exciteBCI prototype using a “think-aloud” approach

[61], followed by a semistructured interview [62] (refer to Figure 1). At the end of each sprint cycle, user device requirements were compiled, and changes were made to the user interface and device before the next sprint cycle began. Participants were asked to use a “think-aloud” process by verbalizing their thoughts, observations, and opinions while interacting with the exciteBCI prototype in a planned series of activities (Textbox 1). The researcher’s interactions were kept to a minimum to support participants to fully engage in the “think-aloud” process, but, when necessary, the researcher prompted the participant with phrases like “tell me what you’re thinking now.” Video and audio recordings, photographs, and researcher observations (TB SO, and UR) were used to capture the think-aloud process. Semistructured interviews were conducted by 2 experienced researchers (GA and NS). The interviews were audio-recorded and focused on participants’ experiences and opinions of the device, functionality, design features, and suggested improvements. See Multimedia Appendix 1 for phase 1 indicative interview questions. Consecutive participants participated in the sprint cycles until no new insights or changes to the exciteBCI device's design features were provided [63,64].

Textbox 1. Examples of activities used in phase 1 sprint cycles to facilitate the “think-aloud” process.

Physiotherapists

- Use the tablet to complete the initial client registration (10-15 min).
- Use the tablet to design a task-specific training program for a client (10-15 min).
- Follow the instructions to set-up the headset (10-15 min).
- Follow the instructions to set-up the electrical stimulation and place electrodes on the tibialis anterior muscle (10-15 min).
- Calibrate the system—complete the task-specific training while the headset records your model’s brain signals (10-20 min).
- Complete task-specific training while your model receives the paired intervention (5-10 min).
- Remove the headset and electrical stimulation device (5-10 min).

People with stroke

- Now you are set-up, follow the cue on the tablet to perform the exercises and we will record your brain signals (20-25 min).
- Follow the cue on the tablet screen to complete the exercises while receiving the neuromodulatory intervention (20-30 min).
- Please rate how difficult it was to perform that task and how confident you felt performing the task (5-10 min).
- Donning and doffing of equipment (10-15 min).

As the time spent on each activity varied across participants, a time range (min) has been listed against each activity. Similarly, the number of task-specific training exercises and associated repetitions varied across participants (2-4 exercises 20-80 repetitions per exercise). For the physiotherapist session, the model was a member of the research team.

Phase 2: Near-Live Program of Rehabilitation

A “near-live” testing approach [60] was carried out in which 2 people with stroke engaged in a 3-week program of locomotor rehabilitation augmented by exciteBCI (Soft Headset v2, App v3.6, Electrical Stimulator v.3). Eight 1-hour rehabilitation sessions were conducted in an outpatient clinical setting supervised by a New Zealand registered physiotherapist with 10 years of clinical experience in stroke rehabilitation (GA). Before the rehabilitation sessions, participants attended an initial assessment and planning session to establish locomotor-related goals and completed clinical outcome measures. Clinical measures included the 30-second chair stand test, 10-m walk test; 6-minute walk test; four step square test, and lower limb muscle strength testing of the ankle dorsiflexors, ankle plantar flexors, knee extensors, and hip flexors using a handheld dynamometer [65]. Clinical measures were repeated at the end of the rehabilitation program.

The rehabilitation program was based on current evidence-based practice as recommended in the National and International Clinical Guidelines for Stroke [66-68] and included goal-oriented task-specific training of locomotor-related skills that were deemed important to the participant. The physiotherapist prescribed 3 to 4 different tasks from the suite of tasks within the tablet-based exciteBCI app per session. Informed by the principles of motor learning [69], the rehabilitation tasks were progressed over the program based on the participant’s rating of perceived difficulty for each task using a numerical visual analog scale. Task parameters were manipulated or new tasks were prescribed to achieve a challenge point of 6 to 8 out of 10 on the task difficulty visual analog scale for each task [57]. Participants completed between 30 and 100 repetitions of each task during the 1-hour session. The participants used the exciteBCI throughout the rehabilitation program, which delivered electrical stimulation to the tibialis

anterior muscle to coincide with the person’s intended movement. Approximately 10 minutes of the 1-hour session was attributed to the donning and doffing of the equipment.

All rehabilitation sessions were video-recorded, researcher observation notes (NS and TB) of the participant interactions with the exciteBCI prototype were recorded, and photographs were taken at each session. Following completion of the rehabilitation program, the participants with stroke and the physiotherapist (GA) took part in separate semistructured interviews. Interviews were conducted by 2 experienced researchers (GT and SM) who were not involved in the development of the exciteBCI. The interview focused on the participants’ opinions and experiences of using the device within a rehabilitation context and included specific questions in response to video observations of the rehabilitation program. All interviews were audio-recorded. See the [Multimedia Appendix 1](#) section for phase 2 indicative interview questions.

Data Analysis

“Think-aloud” and interview data were transcribed verbatim. The transcripts and written observation notes were imported into NVivo 12 (Lumivero) computer software package [70]. Data analysis was undertaken in 2 stages. In the first stage, transcripts and videos were descriptively analyzed by the primary researcher (GA) to identify user interface and device requirements within each sprint cycle. This analysis was then discussed with the team to inform the development of the device before the next cycle. This analysis also served as a familiarization process for the second stage of analysis.

The second stage of analysis focused on addressing the aim, exploring users’ perspectives and experiences of exciteBCI, and how well it fits with rehabilitation. This stage used a modified version of conventional content analysis [71] to analyze the data from both phases of the study. Conventional

content analysis allows the researcher to immerse themselves in the data to acquire an accurate description of what participants experienced and understood about the topic at hand [62]. The data were coded inductively by the primary researcher (GA) at the sentence or phrase level, and a semantic coding framework was iteratively developed during the data analysis process [72]. Several activities were used to enhance the understanding of code relationships, such as continuous comparisons within and between codes and data sources, as well as the practice of memoing to capture initial insights about the data and potential interactions among codes [73]. The coded data iteratively informed the development of categories. Categories and representative coded data were visually represented using a mind map in the MIRO Application to support the development

of themes. The coded data, categories, and prototype themes were reviewed and discussed with 2 researchers (NS and GT) in a series of analysis meetings to ensure consistency of interpretation.

Results

Overall

A total of 11 people participated in the study with no reported adverse events. [Table 1](#) presents the demographic and clinical characteristics of the participants, and [Figure 4](#) displays photographs of participants interacting with the device in phases 1 and 2 of usability testing. In the interest of intellectual property protection, the iterative device requirements for the user interface and the device are not presented in this paper.

Table 1. Participant characteristics (n=11).

Demographic and clinical characteristics	Value
People with stroke (n=6)	
Type of stroke, n (%)	
Ischemic	3 (50)
Hemorrhagic	3 (50)
Lesion location, n (%)	
Right hemisphere	4 (67)
Left hemisphere	2 (33)
Time since stroke (y), mean (SD; range)	7 (6.7; 2-19)
Types of impairments, n (%)^a	
Motor	6 (100)
Sensory	4 (67)
Perceptual	2 (33)
Cognition	2 (33)
Communication	1 (17)
Functional ambulation category scores [74], n (%)	
0 ^b	0 (0)
1 ^c	0 (0)
2 ^d	1 (17)
3 ^e	1 (17)
4 ^f	3 (50)
5 ^g	1 (17)
Prior experience of technology components, n (%)	
FES^h	
Clinical	4 (67)
Research	3 (50)
No experience	1 (17)
BCIⁱ	
Clinical	0 (0)
Research	3 (50)
No experience	3 (50)
Mobile app-based interventions	
Clinical	0 (0)
Research	0 (0)
No experience	6 (100)
Sex, n (%)	
Female	3 (50)
Male	3 (50)
Ethnicity, n (%)	
Asian	1 (17)
European	2 (33)

Demographic and clinical characteristics	Value
New Zealander	3 (50)
Age (y), n (%)	
<45	1 (17)
45-65	2 (33)
>65	3 (50)
Physiotherapists (n=5), n (%)	
Years qualified as a physiotherapist	
5-10	1 (20)
10-20	3 (60)
>20	1 (20)
Highest qualification	
Bachelor of Science	4 (80)
Masters	1 (20)
Years of clinical experience in stroke rehabilitation	
5-10	3 (60)
10-20	1 (20)
>20	1 (20)
Prior experience of technology components	
FES^j	
2-12	5 (100)
BCI^k	
3 (research context)	1 (20) ^l
Mobile apps for rehabilitation^m	
3-10	5 (100)
Sex	
Female	5 (100)
Ethnicity	
European	2 (40)
New Zealander	3 (60)

^an>6 due to some participants presenting with multiple impairments.

^bNonfunctional walker (unable to walk).

^cDependent walker requires continuous manual contact.

^dDependent walker requires intermittent manual contact.

^eDependent walker requires verbal supervision or guiding.

^fIndependent walker on level surfaces only.

^gIndependent walker on any surface.

^hFES: functional electrical stimulation (n>6 due to experience in more than 1 category).

ⁱBCI: brain computer interface.

^jYears experience using functional electrical stimulation.

^kYears experience using brain computer interfaces.

^lPrimary author: GA.

^mYears experience using mobile apps for rehabilitation. Video mobile apps to capture patient performance and exercise provision mobile apps.

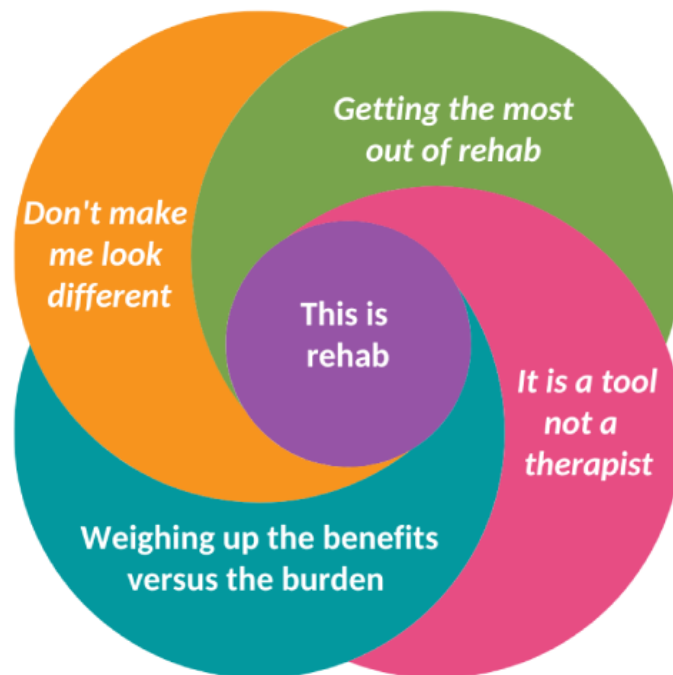
Figure 4. Photographs of participants from phase 1 sprint cycles and phase 2 “near-live” 3-week program interacting with the exciteBCI device. (A) A participant with stroke and physiotherapist work in partnership to select task-specific training exercises in the exciteBCI app, (B) a physiotherapist participant setting up the electroencephalography headset, (C) a physiotherapist setting up the muscle stimulator on a participant with stroke, (D-F) participants with stroke engaging in locomotor rehabilitation while wearing the exciteBCI device and receiving the neuromodulatory intervention with the physiotherapist. (G) a participant with stroke using the app rating scale of perceived rehabilitation task difficulty to inform the physiotherapist about the challenge-point of the task.



Overall, the findings showed that participants with stroke and physiotherapists had positive perceptions and experiences of the exciteBCI intervention and could see it being used in a rehabilitation context. Five themes were generated from the data, as illustrated in Figure 5. Central was the theme (1) This is rehab, which interacted and was influenced by the themes (2)

Getting the most out of rehab, (3) It is a tool not a therapist, (4) Weighing up the benefits versus the burden, and (5) Don't make me look different. Illustrative quotes that corroborated the data have been selected for thematic representation, and pseudonyms have been used.

Figure 5. The relationship of themes associated with the users' perceptions and experiences of exciteBCI, and how well it fits with rehabilitation.



Theme 1: This Is Rehab

At the core of the findings was the theme, “This is Rehab.” Despite being a novel technology incorporating a brain computer interface and app, both physiotherapists and people with stroke identified that the exciteBCI was clearly a rehabilitative tool suitable for supporting and augmenting rehabilitation practice:

At first, I thought, it's not a new treatment [...] we're doing something that's extra, but it's basically just facilitating what we're doing anyway. [Sarah, Physiotherapist, Sprint cycle 2]

For clinical use, the intervention worked brilliantly. [Anni, Age 58, PwS, 3-wk program]

Many expressed surprise at how congruent the technology was with their own clinical practice and understanding of rehabilitation principles. This congruence appeared to enhance perceptions of usability and acceptability. They readily identified ways in which the technology could be integrated into current rehabilitation practices:

It doesn't seem to be over complicated, and once you use it on a daily basis more or less it's actually not that difficult. [Zoe Physiotherapist, Sprint cycle 2]

Participants were easily able to understand the purpose and mechanism of the intervention. Physiotherapist participants drew on their understanding of functional electrical stimulation (FES), a modality commonly used in clinical practice, in understanding the physiological underpinnings of the paired neuromodulatory intervention. They identified that the exciteBCI device could offer benefits over FES, particularly in relation to the way the person's own brain signals are used to drive the delivery of electrical stimulation, and suggested that this would enhance outcomes from rehabilitation:

With an external stimulus like the FES hand switch, I need to try and time it right. So, it's not that it's not inconvenient it's just[...] makes more sense to take the relationship internally rather than externally. It's the patients driving it[...] And I think that will facilitate learning more. [Sarah, Physiotherapist, Sprint cycle 2]

Physiotherapists described how the exciteBCI app would support them in delivering effective rehabilitation by supporting their clinical reasoning process, enabling specificity in the design of rehabilitation programs, and promoting efficiency. They particularly valued how the exciteBCI app aided them in thinking about different aspects of task-specific training. However, they also consistently emphasized the importance of tailoring rehabilitation to individuals.

This prompted them to describe additional app features which might support further personalization:

What this shows [points to video playing task], it's the goal of doing it perfectly well, but it might not look like that for them [the client]. Would be great if the actual client performing the task can be videotaped as well. [Sarah, Physiotherapist Sprint cycle 2]

Shopping bags, washing basket so they are the things that we would [...] quite commonly do, but [...] when I choose secondary tasks, I often choose things that I know this patient is going to do and relates to their goals [...] so a customize option is essential [Zoe, Physiotherapist Sprint cycle 2]

Attention to an efficient workflow, minimizing duplication of information being entered, and system interoperability were also priorities for physiotherapists. They particularly valued how the exciteBCI app could support efficient and

comprehensive clinical record keeping and support handover between therapists:

I would think about a lot of these different parameters, but I might not be as explicit about them in my notetaking [...] this is way more thorough[...] structured[...] easy to follow, easy to pick up on for next time[...] and so much quicker. [Megan, Physiotherapist, Sprint cycle 1]

Physiotherapists identified the challenges associated with the use of clinical terminology and language, calling for app features such as icons and pop-up definitions, which would support users to have a clear understanding of key terms:

Accuracy? so I've got large target, small target, wide path, small path [...] so path I presume means width? [...] I think photos or icons is a really good thing to just clarify stuff- probably more than words. [Megan, Physiotherapist, Sprint cycle 1]

Most physiotherapists also described the need for prior hands-on training opportunities led by an experienced clinical expert, specifically addressing the rehabilitation approach, device set-up, and troubleshooting. This was deemed essential to support the successful uptake of the technology in rehabilitation. In addition, they recommended incorporating training and troubleshooting videos directly into the app.

Theme 2: Getting the Most Out of Rehab

People with stroke and physiotherapists described the ways in which the exciteBCI, and in particular the app, could support people with stroke to engage in more intensive and challenging rehabilitation at higher doses. Participants valued the way exciteBCI supported people with stroke to work hard. This was achieved in multiple ways. First, the app enabled physiotherapists to design specific and challenging rehabilitation programs for patients:

It just was a really nice, structured way of [...] finding that sweet spot to maintain challenge, but for the participants to feel they are making progress and all that hard work is paying off. [Gemma, Physiotherapist, 3-wk program]

Second, the task difficulty rating scales supported both people with stroke and physiotherapists to judge the challenge of each task and served as a prompt to work on more challenging tasks:

[...]and the rating scale is really helpful too. You have a bit more about what's challenging for them and what's not. Gives you a better starting point. [Zoe, Physiotherapist, Sprint cycle 2]

Third, the audiovisual cue that prompted the onset of movement compelled people with stroke to remain focused. By setting the time of task practice, limiting the amount of rest, and promoting attention on the task, large volumes of rehabilitation were achieved:

[...]I think the way that the system has been constructed is quite focus oriented...It's actually keeping the time [...] you get so much more in [the session]. [Anni, Age 58, PwS, 3-wk program]

Together, these factors supported people with stroke to work at intensities and volumes beyond what they would normally achieve during rehabilitation. This supported substantial gains in balance and walking and, in turn, built self-efficacy:

I felt a sense of achievement you know, and that's what's important, I'm still making progress. [Jake, Age 44, PwS, 3-wk program]

These findings illustrate that both people with stroke and physiotherapists discovered a number of features within the app that support fundamental rehabilitation principles.

Theme 3: It Is a Tool, Not a Therapist

Participants with stroke emphasized that developing a trusted relationship with their therapist was fundamental to their rehabilitative journey. They discussed ways in which the app might support or disrupt this relationship. Participants in phase 1 raised the possibility that the app could disrupt the therapeutic relationship:

[...]Physically having the device and therapist there complicates the relationship...so the therapist really needs to make sure their cues show engagement and interest[...] there is a risk here. [Thonia, Lived experience researcher]

While those who participated in the 3-week program did not highlight the same concern, all participants stressed that the app was a therapeutic tool that should not be viewed as a substitute for the therapist:

[...] if you feel I handed over the therapy session to this [app] and I've cognitively left the building, then that is disastrous, to our relationship and their treatment. If I'm not engaged, why would they want to be [Jude, Physiotherapist, Sprint cycle 3]

Most participants indicated that they would be happy to use the app independently; however, the majority indicated a preference for using the device with the physiotherapist present. They described how the physiotherapist offered guidance and feedback about their performance and progress:

So, if I'm not doing a sit to stand correctly [points at app] then who is going to correct me? [...] I like the feedback from the therapist, because at some point the quality of the movement does matter. [Lilly, Age 64, PwS, Sprint cycle 1]

Participants also described how the physiotherapist motivated them to work harder by encouraging them to do their best work, while also understanding their personal limits in a way that the app could not:

The physiotherapist can push you further. They can see that you can be pushed extra. Which is important [...] people get tired, aagh and ready to give up, whereas the therapist goes another 10-minutes. Helps you squeeze out that last little bit. [Bob, Age 84, PwS, Sprint cycle 1]

Consequently, some participants felt that the exciteBCI either should not or could not be used without the support of a physiotherapist. These findings illustrate that attention to the

impact of technology on the therapeutic relationship during both the design and implementation of rehabilitation technologies is essential.

Theme 4: Weighing up the Benefits Versus the Burden

While both people with stroke and physiotherapist participants saw the benefits and potential of exciteBCI, they also called for “real-world evidence” of effect, research-based evidence, or endorsement from a trusted source:

[...] If I knew it was going to bring about a speedier recovery, I would be more likely to use it. [James, Age 74, PwS, Sprint cycle 2]

If my physio turned up with it, I wouldn't mind at all. [Jenny, Age 67, PwS, Sprint cycle 2]

Those who participated in the 3-week program drew on their own experiences of the intervention to generate real-world evidence:

When we visited French festival, I was helped up onto the raised platform advertising electric cars [...] Renault Twizy. I don't think I was pressing down on my husband's hand as much, on 'reaching' up, and managed to squeeze myself into the car-space for a photo or two, [...] great! Extending my reach, even just a wee bit, was brilliant. [Anni, Age 58, PwS, 3-wk program]

Physiotherapists described how they would consider cost, client suitability, set-up time, workflow, and clinical effectiveness when deciding whether to adopt the exciteBCI intervention:

I would need to know it was going to make a really big difference to invest in purchasing it and have a fair amount of clients I could use it with. [...] it's difficult without actually using it in clinical practice as to know sort of who would really benefit. [Megan, Physiotherapist, Sprint cycle 1]

While participants with stroke called for the device to be integrated into their rehabilitation as early after stroke as possible, some physiotherapists saw a tension between the set-up time of both the headset and the app and the decision to implement the device in different clinical contexts:

I don't think[...] you'd use it on an acute ward[...] I think it takes too much time [...] based on how much time[...] physios have based in my experience[...] I just think time and all the equipment there and everything else that goes on. I don't, can't see it working. In a rehab ward maybe. Definitely outpatients. [Jude, Physiotherapist, Sprint cycle 3]

When discussing use of the device in the home, participants with stroke and physiotherapists from phase 1 (single session) viewed the headset as a potential barrier to adopting the device. This was mainly due to the perceived difficulty of setting it up independently for those with upper limb disability and the need for gel to be inserted into the electroencephalography electrodes while wearing the headset. The set-up of the electrical stimulator and app was not viewed in the same light. While people with stroke who participated in the 3-week program expressed similar

concerns, they were eager to offer suggestions to make it a viable option for independent use.

Theme 5: Do Not Make Me Look Different

Almost all participants emphasized how the social acceptability of the device would influence their desire to use it. The need for a socially acceptable device design was less important in a clinical setting or at home than if the device was being used in a public or social context:

It's [the headset] not for glamour it's for results [...] it's the job it's doing, reading the brain. Glamour doesn't matter, does it? If there's certain areas of the brain it can read, it's got to work. It doesn't matter what it looks like [...] not whilst you're doing rehab. You're there for the rehab. [Lilly, Age 64, PwS, Sprint cycle 1]

Nevertheless, most participants called for a device which did not draw attention to themselves or their disabilities:

Many people find it difficult to approach you, when you walk differently, or they treat you differently [...] So, you can understand why I would value a design that doesn't make me look even more different than I already do. [Jenny, 67 years; PwS, Sprint cycle 2]

Participants posited that what constitutes a socially acceptable device might also vary depending on a person's gender, age, and culture. The length of time since their stroke diagnosis and how much rehabilitation was prioritized in their daily lives also appeared to influence the participants' perspectives on whether they would consider using the wearable device in their daily lives:

Initially I would [during inpatient rehab] [...] you're ready to take anything that you think will help but what shifts the balance of that is I think it's about - I'm more progressed now and more - I want people to see me where I'm at now. [James, Age 74, PwS, Sprint cycle 2]

Concerns about the social acceptability of the device largely pertained to the esthetics of the headset and electroencephalography gel. The current headset design was viewed as unacceptable for wearing-out in public, where social perceptions play a role. Minimizing and concealing the device with clothing or incorporating it into something that looked familiar and fits with everyday life, such as a hat or headphones, was seen as an important future design consideration. Participants from phase 1 perceived there to be no issue with the use of electroencephalography gel in a rehabilitation environment. While participants in the 3-week program described the inconvenience of repeated gel use and its impact outside of the rehabilitation context, they perceived that the benefits they experienced from the intervention outweighed this inconvenience. In contrast, participants perceived the electrical stimulator to be more acceptable. It was noted that the electrical stimulator and its neoprene housing resembled sports braces which were considered socially acceptable and in common use.

Discussion

Principal Findings

This study applied a user-centered design approach to explore the perspectives and experiences of people with stroke and physiotherapists when engaging with exciteBCI rehabilitation technology and how well it fits within a stroke rehabilitation context. The results support the acceptability of the exciteBCI intervention and its “fit” with clinical practice and will inform the requirements for future device development. These findings also provide key insights that can inform the design and implementation of rehabilitation technologies more broadly.

Technology and the Therapeutic Relationship

This study highlights the importance of considering the impact of technology on the therapeutic relationship between patients and therapists. The therapeutic relationship refers to the relational process that takes place during clinical interactions and is considered a critical aspect of rehabilitation by both patients and therapists [75-77]. Qualitative research in neurorehabilitation indicates that positive therapeutic relationships are pivotal in supporting patient engagement, positive patient experiences, and in enhancing patient outcomes [78,79]. The “It is a tool, not a therapist” theme identified that both people with stroke and physiotherapists who participated in the phase 1 single usability sessions cautioned that the exciteBCI app could be disruptive to the therapeutic relationship. Similar concerns have been raised in other health technology domains, citing disruptions of the therapeutic relationship as a potential barrier to technology adoption [80-83]. In contrast, in this study, participants who used the exciteBCI app over multiple sessions in phase 2 highlighted how the technology could be successfully integrated into clinical interactions to support and enhance the therapeutic relationship. The participants described how using the rating scales within the exciteBCI app facilitated a shared understanding of the rehabilitative challenge, allowing the person with stroke to take control of their rehabilitation and identify opportunities for progressing rehabilitation challenge in collaboration with the physiotherapist. However, this required the physiotherapist and the person with stroke to be mindful of the role of the technology, its value, and limitations, and to use it purposefully and appropriately.

The current findings combined with previous literature emphasize how crucial it is to take the patient, therapist, and technology triad into account when designing and implementing rehabilitation technology. While research in telehealth has attended to the influence of technology on the therapeutic relationship over time and its implications for usability [84-86], the same attention has not been given to the development of rehabilitation technology devices. Understanding the influence of technology on clinical interactions and workflow, and the ways in which these change over time, is critical. Being attuned to the impact rehabilitation technologies have on therapeutic relationships requires a deep understanding of the role of the therapist and patient and the rationale for the technology. This knowledge should be applied in two ways: (1) designers and developers should explicitly consider how the design of the technology can support and strengthen the therapeutic

relationship, and (2) therapists and health care educators should consider how rehabilitation technologies can be used to support person-centered rehabilitation, ensuring that the therapeutic relationship is preserved and developed throughout the rehabilitation process.

Considerations for Social Acceptability in Rehabilitation Technology Design

The findings from the “Don’t make me look different” theme clearly articulate that people with stroke place weight on the esthetics and social acceptability of a rehabilitation technology device when considering whether to use it. Social acceptability may be particularly important in the design of head-mounted wearable devices [87-89]. This is an important finding given that social acceptability is often a lesser priority in the rehabilitation technology development process. Defining the target user population and understanding their device requirements early in the design and development process may resolve acceptability issues and minimize the need for significant design changes later in the process [90]. This approach has the potential to not only mitigate issues of acceptability and usability but also reduce the impact on development time and costs, while simultaneously increasing the chances of successful adoption and sustained use of the technology [45,91]. Importantly, our findings indicate that the need for a socially acceptable device design is dependent on the context in which the technology is to be used. Therefore, device developers should be cognizant of the use context when prioritizing social acceptability. Given the shift in rehabilitation services to the community [92] and supported self-management programs [93], social acceptability for both users and bystanders [87,89] is likely to be a pivotal consideration in the design of rehabilitation technologies in the future.

User Testing in a Sustained Way

User-centered design approaches are increasingly being encouraged to inform health technology design and development [45,94]. Yet much of the methodological literature describes single-session usability evaluation, where novice users’ perceptions and experiences of the technology inform the next iteration [95]. While this approach can highlight “entry-level” usability issues or novice user frustrations that can often be quick fixes, it is unlikely to identify fundamental usability and acceptability issues or the sources of frustrations that could be barriers to the sustained use of the technology [59,95]. This is an important limitation when using user-centered design methods for the development of rehabilitation technologies intended for sustained use. To ensure that we captured design requirements that support both the adoption and sustained use of the exciteBCI technology, in addition to the iterative single usability evaluation sessions, we conducted “near-live” usability testing over a 3-week period. This approach allowed us to investigate the technology’s “fit” with a program of rehabilitation. Users’ long-term experiences and the ways in which the device’s usability and acceptability evolved over time were elucidated.

An important finding was that user perspectives and usability priorities shifted with sustained use of the exciteBCI technology. Long-term users were less concerned with the practicalities of

the technology, such as the ease of setting up the exciteBCI app and headset. While these inconveniences were noted, they were apparently offset by the benefits users experienced from the intervention itself. It appeared that from engaging in sustained use, they obtained the “real-world evidence” in support of the technology which was desired by participants in phase 1. Long-term users also did not highlight that the technology might disrupt therapeutic relationships. Instead, they were more focused on the pleasure they had from “getting the most out of rehab,” the increase in self-efficacy they experienced, and the gains they made when the technology augmented the rehabilitation process. Similar findings have been previously reported in the literature. When meaningful connections are formed with technology over time, the pleasure derived from its use acquires more weight, and practical limitations become less significant [96]. A single-session usability assessment may not always foresee future satisfaction with the technology since it may be evaluating expectations rather than user experience [97]. In the context of this study, it is critical to remember that the user experience includes not only the technology itself, but also the experience gained from participating in the rehabilitation process, and that this experience occurs within the context of a therapeutic relationship. As a result, explicitly designing technology to support both meaningful rehabilitation and best practice from the physiotherapist to establish and nurture a therapeutic relationship is paramount.

Our findings regarding the sustained use of exciteBCI technology also provide important guidance for its eventual implementation in clinical practice. Current models for implementing rehabilitation technologies often rely on instructional booklets and training and accreditation packages, usually provided by the technology manufacturer. While these strategies are likely to support the adoption of rehabilitation technology, they are less likely to support sustained use. Implementation science literature emphasizes the importance of strategies, such as identifying factors and barriers to sustained use, the use of clinical champions on site, and the use of behavior change strategies to ensure therapists are supported in practice change [98-100].

Limitations of the Study

This study adopted a rigorous approach to qualitative research; however, it is important to acknowledge that we used a convenience sampling method in this study; all participants

were in the chronic stage of stroke (2-19 y since stroke onset), and the physiotherapists worked in an outpatient rehabilitation or community setting. While participants reflected on their prior lived experiences of inpatient rehabilitation closer to the onset of their stroke, when their stroke symptoms were more severe, or when physiotherapists worked in an inpatient setting, future user testing should include participants who are currently undergoing or providing inpatient rehabilitation. This will determine whether their experiences align with or differ from the device features described in this study and help to understand how well it fits in an inpatient rehabilitation setting. In phase 1, while the physiotherapists had extensive experience with the patient cohort and their associated clinical presentation, the model used during the usability evaluation was not an individual with stroke. This may have influenced the usability results. Only 1 physiotherapist (GA) participated in the “near-live” 3-week program. Future research should explore usability testing over periods of time with a range of different users. Another potential limitation of the study design was that it did not capture the initial expectations of phase 2 long-term users. Therefore, we were unable to interpret how their initial expectations may have shaped their experiences of using exciteBCI, and whether their expectations were confirmed or disregarded at the end of the program.

Conclusions

This study presented an iterative user-centered design approach supported by a qualitative descriptive methodology exploring users’ perspectives and experiences of exciteBCI, a complex neuromodulatory rehabilitative technology designed to augment locomotor rehabilitation for people with stroke. The 5 interrelated themes generated from the analysis revealed that overall exciteBCI was perceived and experienced positively by people with stroke and physiotherapists and viewed as technology that could be implemented in a rehabilitation context. These findings provide important insights pertinent to the broader field of rehabilitation technology design, implementation, and sustained use. Notably, these findings highlight that rehabilitation technology design should (1) consider ways to support and enhance the therapeutic relationship; (2) recognize that social acceptability is a design imperative, but its significance varies depending on the use context; and (3) that there is merit in using research design methods that explore device usability within the context of sustained use.

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Data Availability

The data sets generated and analyzed during this study are not publicly available because of ethical approval requirements, which do not permit data sharing. Data may be obtained from the corresponding author upon reasonable request with the approval of the relevant ethics committee.

Authors' Contributions

GA, NS and DT conceptualized the study. GA, NS, DT, and GT designed the methodology, and DT and GA acquired ethical approval. NS, DT, UR, GA, SO, and IKN acquired funding, and GA performed project administration. GA, NS, TB, GT, UR, and SO contributed to data collection. UR and IKN were responsible for the technology. Data analysis was performed by GA and reviewed by NS and GT. Supervision was performed by NS and DT. The original draft was written by GA and NS, and edited by SO. All authors reviewed the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Indicative interview questions.

[\[DOCX File, 29 KB - rehab_v10i1e49702_app1.docx\]](#)

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Abbreviations

FES: functional electrical stimulation

ISO: International Organization for Standardization

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Original Paper

The Effect of a Mobile Health App on Treatment Adherence and Revenue at Physical Health Clinics: Retrospective Record Review

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Abstract

Background: A significant number of patients do not adhere to their prescribed course of physical therapy or discharge themselves from care. Adhering to prescribed physical therapy, including attending physical therapy clinic appointments, contributes to patients achieving the goals of therapy including reducing pain and increasing functionality. Web-based platforms have been demonstrated to be effective means for managing clinical patients with musculoskeletal pain, similar to managing them in person. Behavior change techniques introduced through digital or web-based platforms can reduce nonadherence with prescribed physical therapy and improve patient outcomes. Literature also indicates that a phone-based app provided to patients, which includes a reward-incentive gamification to complement their care, contributed to a greater number of kept appointments in a physical therapy clinic.

Objective: This study aims to compare the rate of provider discharge with self-discharge and the number of clinic visits among patients attending a physical health clinic who did and did not choose to adopt a phone-based app to complement their care. A secondary purpose was to compare the revenue generated by patients attending a physical health clinic who did and did not choose to adopt a phone-based app to complement their care.

Methods: A retrospective analysis of all new outpatient medical records (N=5328) from a multisite physical health practice was conducted between January 2018 and December 2019. Patients in the sample self-selected the 2018 Usual Care, the 2019 Usual Care, or the 2019 Kanvas App groups. Kanvas is a customized private practice app, designed for patient engagement with their specific health care provider. This app included a gamification system that provided rewards to the patient for attending their scheduled clinic appointments. According to their medical record, each patient was classified as completing their prescribed therapy (provider discharged) or not completing their prescribed therapy (self-discharged). Additionally, the total number of clinic visits each patient attended, the total charges for services, and the total payments received by the clinic per patient were extracted from each patient's medical record.

Results: Patients in the 2019 Kanvas App Group exhibited a higher rate of provider discharge compared to patients who did not adopt the app. This greater rate of provider discharges among the patients who adopted the Kanvas app likely contributed to this group attending more clinic visits (13.21, SD 12.09) than the other study groups who did not download the app (10.72, SD 9.80 to 11.35, SD 11.10). This greater number of clinic visits in turn contributed to the patients who adopted the app generating more clinic charges and payments.

Conclusions: Future investigators need to employ more rigorous methods to confirm these findings, and clinicians need to weigh the anticipated benefits against the cost and staff involvement in managing the Kanvas app.

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KEYWORDS

physical health; completion of therapy; phone app; clinic charges and payments; payment; cost; physiotherapy; physical therapy; adherence; attrition; mobile phone; reminder; mobile health; mHealth; health app; mobile app

Introduction

Background

Over 50 million adults (21.8% of the population) in the United States exhibit some form of a disability, while in 2010, the most prevalent disabilities resulted in limitations in mobility. The most common causes of disability were arthritis or rheumatism and back or spine problems [1]. Physical therapy aims to reduce disability and pain and improve functioning, resulting in improving the patients' quality of life [2]. Adhering to prescribed physical therapy, including attending physical therapy clinic appointments, contributes to patients achieving the goals of therapy including reduced pain [3,4] and improved functioning [5,6]. Literature indicates that patients commonly do not adhere to their prescribed course of physical therapy. Previous investigators estimate that between 14% and 70% of patients who have been prescribed physical therapy do not complete their prescribed course of therapy or discharge themselves from care [7,8].

These findings indicate that several different factors contribute to whether a patient adheres to a prescribed course of physical therapy. These factors may either be patient oriented or related to the procedures within the clinic where the therapy is prescribed. Jack et al [8] commented that early research in this area focused on how patient-oriented factors, including low self-efficacy, depression, anxiety, helplessness, poor social support, and greater perceived number of barriers to exercise, contributed to not adhering to a prescribed course of physical therapy. Although related to adhering to prescribed physical therapy, these patient-oriented factors may be challenging to address during a physical therapy clinic visit. Other authors reported that modifying procedures within the clinic along with a personalized approach to physical therapy (Coach2Move) by a physical therapist, including providing more feedback and taking into account individuals' contextual factors, improved adherence to prescribed physical therapy [9]. An early review of the related literature examining clinical procedures concluded that prescribed physical therapy that included cognitive-behavioral change components can improve attendance at physical therapy clinic sessions [10]. After reviewing 10 RCTs, Hajihasani et al [11] concluded that cognitive-behavior change interventions, when added to routine physical therapy, were more effective than physical therapy alone in treating pain and disability and improving functional capacity variables. Recent systematic reviews and meta-analyses concluded that cognitive behavior change techniques oriented to the specific patient, including graded tasks, goal setting, self - monitoring, problem-solving, and feedback, significantly enhanced adherence to prescribed physical therapy for chronic musculoskeletal conditions [12,13]. Thus, cognitive behavior change techniques incorporated with physical therapy appear to increase adherence with a prescribe course of physical therapy.

One approach to administering cognitive behavior change techniques designed to increase adherence with prescribed physical therapy is through a mobile digital platform or a phone-based app. In a recent study, the authors compared adherence with prescribed clinic appointments among patients attending a physical health clinic who did and did not choose to adopt a phone-based app to complement their care [14]. This app employed the cognitive behavior change techniques of reward-incentive gamification for encouraging adherence to prescribed clinic appointments. The investigators reported that the group who adopted the phone-based app had a greater ($P<.05$) number of kept clinic appointments (7.79, SD 0.25) compared to the Usual Care Group (4.58, SD 0.18). Other researchers reported that patients with musculoskeletal conditions exhibited greater adherence to their home exercise programs when the programs were provided on an app with remote support compared to paper handouts [15]. In a review of 11 clinical trials evaluating rehabilitation programs administered online or digitally, the authors concluded that these approaches to administering a rehabilitation program can improve adherence to prescribe plans of care [16]. A similar systematic review and meta-analysis assessed the effectiveness of web-based cognitive behavior change techniques (e-BMT) in the management of patients with chronic musculoskeletal pain [17]. These authors reported that cognitive behavior change techniques administered through a web-based platform is an effective means for managing patients with musculoskeletal pain similar to managing them in person. Thus, directing prescribed physical therapy through web-based or digital platforms appears to be an effective medium by which to administer cognitive behavioral interventions aimed at facilitating adherence with prescribed physical therapy. A limited number of studies have examined whether a phone-based app designed to complement a patient's physical therapy treatment can affect the rates of provider discharge versus self-discharge. Moreover, no study has compared the revenue generated by patients attending a physical health clinic who did and did not choose to adopt a phone-based app to complement their care. The results of this study will indicate the potential of a phone-based app that complements prescribed physical therapy to impact the completion of prescribed therapy and to generate revenue for the clinic.

Objective

The purpose of this study was to compare the rate of provider discharge with self-discharge and the number of clinic visits among patients attending a physical health clinic who did and did not choose to adopt a phone-based app to complement their care. A secondary purpose was to compare the revenue generated by patients attending a physical health clinic who did and did not choose to adopt a phone-based app to complement their care.

Methods

Design

A retrospective analysis of all new outpatient medical records from a multisite physical health practice was evaluated between January 2018 to December 2019. New patients admitted to this physical health practice during 2018 were assigned to the 2018 Usual Care Group. Beginning in January 2019, all new patients admitted to this practice during their initial visit were offered the opportunity to download a phone-based app, Kanvas, to complement their care. The new patients who downloaded and registered on the phone-based app self-selected the 2019 Kanvas App Group. Patients who chose not to download and register on the app self-selected the 2019 Usual Care Group. All eligible patients included in the study during 2018 and 2019 had their medical record accessed to determine if they prematurely terminated treatment against the advice of the provider (self-discharged) or if they completed their prescribed treatment (provider discharged regardless of the duration of prescribed care). The number of clinic visits, the total charges for services, and the total payments received were also extracted from each patient's medical record. This resulted in a quasi-experimental 3-group design in which the medical records of all eligible patients initially presenting for treatment between January 2018 to December 2019 were reviewed and included in the analysis.

Sample

The medical records of new patients who were scheduled for care during 2018 and 2019 at 5 community-based physical health clinics in the greater Washington DC area (N=5844) were initially screened to be included in this study. These clinics specialize in treating pain and increasing functional ability. Of the 5844 patients, 516 (8.8%) were excluded from the analysis because they did not attend their initial clinic appointment, they were referred to another clinic for care, they were employed by one of the targeted clinics, they died prior to completing therapy, or their clinic appointment was for a single-clinic visit (eg, clinical evaluation, massage, etc). This resulted in a total of 5328 patients being involved in the analysis, including 2523 (47%) in the 2018 Usual Care Group, 2006 (37.7%) in the 2019 Usual Care Group, and 799 (15%) self-selecting the 2019 Kanvas App Group. This sample size, employing the 2x3 cross tabulation to calculate a chi-square statistic with type 1 error set at .05 and maintaining statistical power at .8 (1- β) would be able to detect a small effect size $d=0.05$ in the different rates of self-discharge versus provider discharge among the 3 study groups.

During their initial visit, patients seeking care at the clinics in 2019 were informed they could download a free mobile app to their phone, which they could use to compliment the care they were receiving in the clinic. At this time, all patients were told

about the components of the app and the reward structure as a result of using the app. The patients were also told the use of the app was voluntary and would in no way affect their care or relationship with their provider or the clinical agency.

Ethical Considerations

This record review study was approved by the Sport & Spine Rehab Clinical Research Foundation (IRB #SSR.2021.1), which included waivers for informed consent and Health Insurance Portability and Accountability Act requirements. All data extracted from the electronic medical were deidentified, compiled without patient identifiers, and kept secured and confidential. No compensation was provided for any participants involved in the study.

Procedure

During the initial visit at one of the targeted clinics, each patient completed an initial assessment with a practitioner (Doctor of Chiropractic) who prescribed a plan of care, which included home exercises and a series of follow-up clinic visits. During 2019, these practitioners were not blind to the patient's decision to download and register on the phone-based Kanvas app. The plan of care prescribed by the practitioner, including the number and frequency of the follow-up clinic visits, was customized to the type and severity of the patient's condition. The number of treatment sessions was initially determined by the provider, and based upon the patient's clinical progress, may have been reduced or extended during the course of their therapy. When the practitioner prescribed a plan of care, the patients were informed that their account would be charged US \$25 if they did not attend future scheduled visits ("no-show") or did not contact the clinic to cancel the appointment within 24 hours of the appointment ("late cancel").

The Kanvas app is a customized private practice app, designed for patient engagement with their specific clinic. The initial screen includes various tiles in which the patient can engage with the office. These tiles include "contact us," "about us," "refer a friend," "request an appointment," "review us," and "home exercise" (Figures 1 and 2). The app did not provide direct messaging between the patient and the provider. Additionally, the app included the cognitive behavior change technique of a built-in gamification system in the "rewards tile" (Figure 3). This feature was designed to reward the patient for attending their scheduled clinic appointments. This feature is compliant with the Office of the Inspector General, offering an item as a reward that is valued at less than US \$15 once the patient completed 12 prescribed visits or were provider discharged. This feature documented a running total of the number of clinic visits the patient had attended. The feature is patient directed, in which they scan a QR code at the front desk of the clinic at every visit. When the patients reach 12 prescribed visits or are provider discharged, they are eligible for a reward.

Figure 1. Tiles from the Kanvas app.



Figure 2. Additional tiles from the Kanvas app.

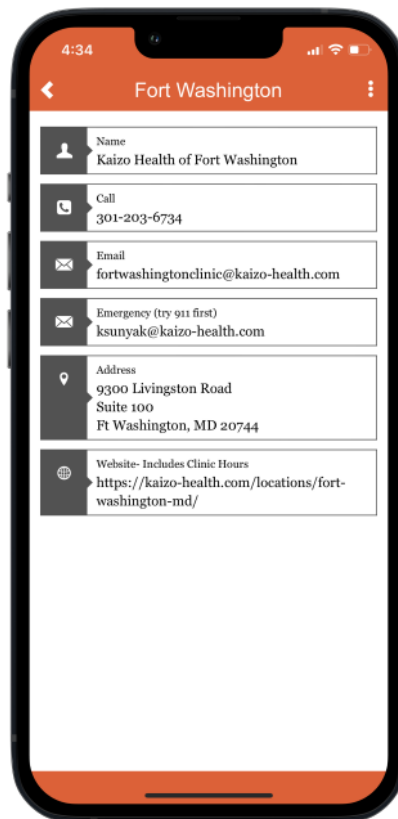
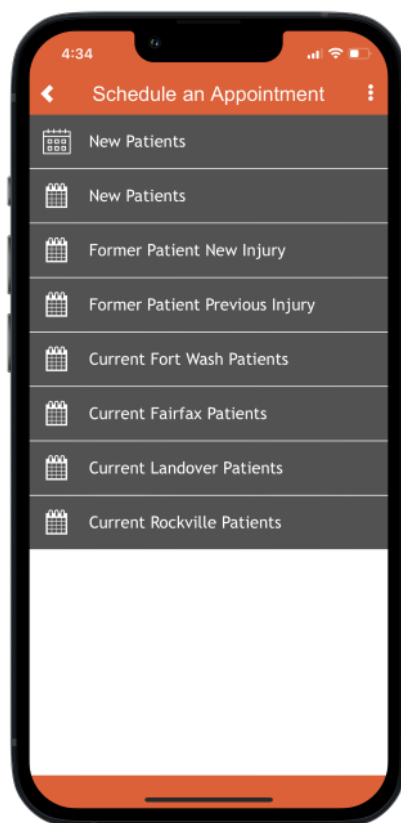


Figure 3. Rewards tile from the Kanvas app.

Outcome Variables

The medical records of all eligible patients who were initially seen in the targeted clinics over the 24-month duration of the study were reviewed during the 4-month period after their initial assessment. Based on the discharge summary documentation on the patients' medical record, patients were classified as completing prescribed therapy and being discharged by their provider (provider discharged) or not completing their prescribed therapy and discharging themselves (self-discharged). Moreover, the total number of clinic visits each patient attended, the total charges for services, and the total payments received by the clinic per patient were extracted from each patient's electronic medical record. Revenue generation was examined as a secondary outcome in this study. When considering the purchase of a new technology, both the return on investment and the clinical impact of the technology need to be evaluated.

Analysis Plan

Data were extracted from the medical records of all patients identified to be eligible for the study and transcribed into an Excel (Microsoft Corporation) spreadsheet and then transferred to an SPSS, version 27 (IBM Corporation) database. These data were validated to include only eligible patients. Eligible patients who visited the clinic during 2018 were grouped into the 2018 Usual Care Group, while eligible patients who visited the clinic during 2019 were grouped into either the 2019 Kanvas App Group or 2019 Usual Care Group based on their decision to self-select to download and register on the phone-based Kanvas app. A chi-square statistic was calculated to compare the proportions of the 3 study groups, who were classified as provider discharged or self-discharged. The remaining outcome

variables, including the total number of clinic visits each patient attended, the total charges for services, and the total payments received by the clinic per patient, were addressed through a 1-way ANOVA comparing the outcome variables among the 3 study groups. Significant main effects ($P < .05$) of these ANOVA equations indicated post hoc comparisons of the group means using the Tukey least significant differences.

Results

A total of 5844 patient records were reviewed, and 5328 (91.2%) were included in the analysis. Of these 5328 patients, 2523 (47.4%) were in the 2018 Usual Care Group, 2006 (37.7%) self-selected the 2019 Usual Care Group, and the remaining 799 (15%) self-selected the 2019 Kanvas App Group. **Figure 4** indicates that 51% ($n=1284$) of the patients in the 2018 Usual Care Group were provider discharged, while the remaining 49% ($n=2523$) were self-discharged. **Figure 4** also indicates that among the 2019 Usual Care Group, 46% ($n=1084$) were provider discharged and 54% ($n=2007$) were self-discharged. Finally, among the 2019 Kanvas App Group, 52% ($n=384$) were provider discharged and 48% ($n=799$) were self-discharged ($\chi^2_2=13.83$, $P < .001$).

Table 1 presents the results of the 1-way ANOVA comparing the 3 study groups on the total number of clinic visits each patient attended, the total charges for services, and the total payments received by the clinic per patient. This analysis indicated that patients who self-selected the 2019 Kanvas App Group had significantly more total patient visits (13.21, SD 12.09; $P < .001$) when compared with the 2018 Usual Care Group (10.73, SD 9.80) and the 2019 Usual Care Group (11.35, SD

11.10). A similar pattern in the data emerged with the 2019 Kanvas App Group exhibiting significantly greater total charges for services (US \$3702, SD US \$3299; $P < .001$) than either the 2019 Usual Care Group (US \$3096, SD US \$3002) or the 2018 Usual Care Group (US \$2920, SD US \$1348). Additionally, post hoc analysis further revealed that the 2019 Usual Care Group exhibited significantly greater charges than the 2018

Usual Care Group. Finally, Table 1 indicates that the clinic received significantly greater total payments per patient ($P = .02$) from the 2019 Kanvas App Group (US \$1513, SD US \$1517) compared to the 2018 Usual Care Group (US \$1348, SD US \$1410), while the total payments from the 2019 Usual Care Group (US \$1415, SD US \$1549) was not statistically different from the other 2 study groups.

Figure 4. Provider vs self-discharge by year and group.

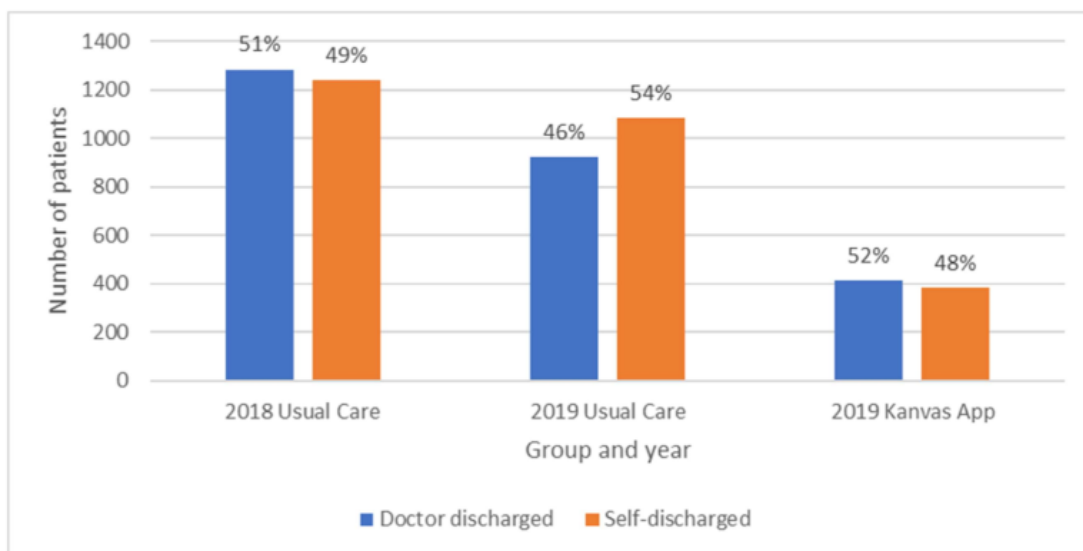


Table 1. Charges, payments, patient visits per patient and group^a.

Variable	2018 Usual Care, mean (SD)	2019 Usual Care, mean (SD)	2019 Kanvas App, mean (SD)	1-Way ANOVA	
				F score	P value
Total patient visits	10.73 (9.80) ^a	11.35 (11.10) ^a	13.21 (12.09) ^a	16.48	<.001
Charges (US \$)	2920.62 (1348.4) ^a	3096.18 (3002.5) ^a	3702.71 (3299.9) ^a	21.94	<.001
Payments	1348.44 (1410.9) ^a	1415.09 (1549.6) ^a	1513.62 (1517.7) ^a	3.81	.02

^aMeans with different letters for an individual variable are significantly different at $P < .05$.

Discussion

Principal Findings

The findings indicate that patients attending a physical health clinic who choose to adopt a phone-based app to complement their care exhibited a higher rate of provider discharge compared to patients who did not adopt the phone-based app. This greater rate of provider discharges among the patients who adopted the phone-based app likely contributed to this group also attending more clinic visits and generating more clinic charges and payments.

The findings of this study are consistent with previous studies and address a number of gaps in the literature. Previous investigators have reported that technology-based health interventions including phone apps can increase adherence with prescribed therapies [18-22]. This study is one of the first to demonstrate the efficacy of a phone app to increase adherence with prescribed physical therapy, resulting in greater revenue for the clinic. These findings may be employed to address the

high rates of patients who do not complete their prescribed course of physical therapy or those who self-discharge from care [23-25].

Strengths and Limitations

This study contains a number of limitations and strengths that may direct future inquiry into this area. The validity of this study is strengthened by the large sample size collected over multiple clinical sites and the use of the electronic medical record as the source of outcome variables. The data employed in the analysis are also clinically valid because charges for services and payments are based on the electronic medical record. Although encouraging, these findings must be interpreted cautiously due to a number of methodological limitations. First, the source of the data for this study was a retrospective review of the electronic medical record. Although a rich source of data, the electronic medical record is limited by the lack of consistency and expertise of individuals entering data into the system and the existence of missing data, which are not easily reconstructed [26]. The second limitation in this study was that

patients in the 2019 study groups had the option to choose whether or not to download the Kanvas app. The decision to self-select the adoption of this mobile app may have been made by patients who were more likely to be provider discharged, attend more clinic visits, and generate more charges and payments. Future studies may wish to randomly assign patients who are initially willing to download the Kanvas app to groups who are and are not provided with the Kanvas app, to minimize the impact of this self-selection bias. Future investigators may also describe the reasons patients self-selected not to download the Kanvas app and address those reasons in future trials. The large sample examined for this study increased the external validity of the findings, although it increased the likelihood of detecting statistical significance of a small effect size.

Future clinicians will need to weigh the anticipated benefits and costs that may accompany providing patients with a phone-based app to complement their care. The costs include not only the phone-based app but also the cost of staff to monitor and interact with patients using the app. The benefits may include higher rates of adherence with prescribed therapy, as well as the return on investment of the technology, including how the technology affects revenue. Patients who self-selected the Kanvas app on average had approximately 2-3 more clinic visits with roughly US \$6000-\$8000 more charges and US \$1000-\$2000 more in

payments than the groups who were not able to access the app (2018 Usual Care) or chose not to download the app (2019 Usual Care). Although numerous studies have reported the clinical efficacy of technology-based health interventions, including phone apps, few studies have consistently found these interventions generate revenue or are at least cost neutral while benefiting patients [25,26]. Finally, the validity of the findings may be limited because the individual patient's use of the Kanvas app was not monitored. The methodology employed in this study did not monitor the type or duration of interaction the patient engaged with the app. Future studies may wish to study the time spent with the app and the type of activities engaged in with the app that contributed to increased patient adherence with prescribe physical therapy treatments.

Conclusion

These findings support the efficacy of the Kanvas app to increase provider discharge rates and increase clinic visits, resulting in greater charges and payments among patients attending a chiropractic and rehabilitation clinic. Future investigators need to employ more rigorous methods to confirm these findings. Clinicians need to weigh the anticipated benefits of the Kanvas app against the cost and staff involvement in managing this app.

Data Availability

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

Conflicts of Interest

None declared.

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Original Paper

An Intensive Exercise Program Using a Technology-Enriched Rehabilitation Gym for the Recovery of Function in People With Chronic Stroke: Usability Study

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Abstract

Background: Rehabilitation improves poststroke recovery with greater effect for many when applied intensively within enriched environments. The failure of health care providers to achieve minimum recommendations for rehabilitation motivated the development of a technology-enriched rehabilitation gym (TERG) that enables individuals under supervision to perform high-intensity self-managed exercises safely in an enriched environment.

Objective: This study aimed to assess the feasibility of the TERG approach and gather preliminary evidence of its effect for future research.

Methods: This feasibility study recruited people well enough to exercise but living with motor impairment following a stroke at least 12 months previously. Following assessment, an 8-week exercise program using a TERG (eg, virtual reality treadmills, power-assisted equipment, balance trainers, and upper limb training systems) was structured in partnership with participants. The feasibility was assessed through recruitment, retention, and adherence rates along with participant interviews. Effect sizes were calculated from the mean change in standard outcome measures.

Results: In total, 70 individuals registered interest, the first 50 were invited for assessment, 39 attended, and 31 were eligible and consented. Following a pilot study (n=5), 26 individuals (mean age 60.4, SD 13.3 years; mean 39.0, SD 29.2 months post stroke; n=17 males; n=10 with aphasia) were recruited to a feasibility study, which 25 individuals completed. Participants attended an average of 18.7 (SD 6.2) sessions with an 82% attendance rate. Reasons for nonattendance related to personal life, illness, weather, care, and transport. In total, 19 adverse events were reported: muscle or joint pain, fatigue, dizziness, and viral illness, all resolved within a week. Participants found the TERG program to be a positive experience with the equipment highly usable albeit with some need for individual tailoring to accommodate body shape and impairment. The inclusion of performance feedback and gamification was well received. Mean improvements in outcome measures were recorded across all domains with low to medium effect sizes.

Conclusions: This study assessed the feasibility of a holistic technology-based solution to the gap between stroke rehabilitation recommendations and provision. The results clearly demonstrate a rehabilitation program delivered through a TERG is feasible in terms of recruitment, retention, adherence, and user acceptability and may lead to considerable improvement in function, even in a chronic stroke population.

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KEYWORDS

rehabilitation technology; stroke; feasibility; intensive exercise; rehabilitation; exercise; motor impairment; feasibility study; telehealth; recovery; telerehabilitation

Introduction

Globally, 2.41 billion people live with conditions that can be improved with rehabilitation [1]. As the leading cause of long-term disability, stroke makes up a considerable proportion of this population [2] and is responsible for the loss of an estimated 18 million years to disability [1]. Evidence-based guidelines for delivering the type of rehabilitation known to improve recovery and reduce disability after stroke are widely available [3]. Globally adopted [4,5], these guidelines recommend an approach that is individually tailored, intensive, and delivered within enriched environments. The overwhelming need for this rehabilitation, however, far outstrips the capacity of most health care systems, which are constrained by dependency on specialist staff, resulting in suboptimal, and often inequitable, rehabilitation. The mismatch between what is required and what can be delivered has been repeatedly documented in the United Kingdom [6] and globally [7,8].

As a potential solution to scaling up intensity, technology has gradually been adopted into practice. Rehabilitation technology like treadmills [9], speech therapy apps [10], virtual reality [11], and telerehabilitation have slowly been put into practice. These changes were accelerated by restrictions on face-to-face therapy during the recent COVID-19 pandemic [12]. Despite promising and consistent evidence of effect, the adoption of rehabilitation technology into practice continues to be patchy without real adjustment to the underlying labor-intensive delivery model [13]. Furthermore, when technology has been trialed, it has typically been done in isolation and not part of a holistic, integrated intervention; an approach considered critical for complex health challenges [14].

Our multidisciplinary rehabilitation research group at the University of Strathclyde (Glasgow, UK) has established a cocreation center for rehabilitation technology [15]. The center offers an 8-week rehabilitation program located in a gym-like space equipped with a range of integrated technology designed to holistically address the motor and communication impairments caused by stroke. Further details of this technology-enriched rehabilitation gym (TERG) can be found in our previous publication [15]. The center and program are supervised by trained staff on a one-to-many basis with individuals encouraged to define their rehabilitation goals and, with support, manage their program.

The aim of this study was to assess whether this supported self-managed approach undertaken in a TERG was feasible and acceptable to a group of chronic stroke survivors and to collect data that would allow an effect size to be estimated for future research.

Methods

Overview

Details of the methods, including participant eligibility, rehabilitation equipment, and example programs, are available in our previous publication [15]. Here, we describe the key elements of the methods according to the CONSORT (Consolidated Standards of Reporting Trials) guideline extension for reporting pilot and feasibility studies [16]; the checklist is provided (omitting the randomization protocol) in [Multimedia Appendix 1](#).

Ethics Approval

This study was approved by the University of Strathclyde ethics board (UEC20/08).

Design

This is a feasibility study of a novel, technology-based, rehabilitation intervention in a group of chronic stroke survivors. Feasibility was assessed through recruitment, retention, attendance, and adherence to the program, safety (incidence and nature of adverse and serious adverse events [AEs]), and participant acceptability using a mixed methods approach including semistructured interviews, attendance, activity, and safety records.

Participants

People living with stroke affecting their mobility or communication but otherwise well enough for light or moderate exercise were invited to participate. Recruitment was through a network run by a medical charity for stroke in Scotland. Individuals expressing an interest in participating registered with the charity and were invited, in the order they registered, to attend an initial meeting where eligibility was assessed and baseline measures of function recorded.

Intervention Details

The intervention was developed from our previous work [15,17-19] and feedback from a pilot with chronic stroke survivors ($n=5$; mean age 51.6, SD 12.1 years; mean 19.6, SD 9.32 months post stroke; 2 females; 2 with aphasia). The small pilot sample size and limited attendance (twice weekly) were related to COVID-19 restrictions in place at the time. Feedback from these participants, through independent interviews, allowed us to implement changes to the intervention, most importantly this included an increase in the number of weekly available sessions from 2 to 5.

The resulting 8-week long rehabilitation intervention was delivered entirely through technology, including virtual reality (immersed and nonimmersed), treadmills, weight suspension and movement resistance, and assistance equipment located in a gym-like space on a university campus (Glasgow, UK). Individual programs were designed, supervised, and reviewed by a physiotherapist using principles of intensity, feedback,

cognitive engagement, and aerobic activity [20] to address the goals identified by the participant and scores from outcome measures at baseline. An example program is detailed in a previous publication [15]. Participants were encouraged to use the exercise equipment on their own, wherever possible, while being supervised and to make alterations to the program, with support from the therapist.

Outcome Measures

Feasibility was assessed by rates of recruitment, adherence, AEs, and participants' perceptions of acceptability from semistructured interviews [21] (see [Multimedia Appendix 2](#) for interview schedule). To reflect the multidomain nature of the intervention, a range of outcome measures were included: 10-meter walk test (10mWT), five times sit to stand test, action research arm test, functional ambulatory category, Rivermead Mobility Index, and the Stroke Impact Scale-16 (SIS-16) [22-26].

Data Analysis

Participant interviews were analyzed using the 6-stage thematic approach described by Braun and Clarke [27]. Initially, an independent researcher generated codes and candidate themes. These were then reviewed by 2 members of the research team.

Through an iterative process of discussing and revising, a consensus was reached. Descriptive statistics were used to assess feasibility (recruitment, retention, adherence, and safety) and outcome data.

Results

Recruitment

Between August 2021 and August 2022, 70 individuals registered their interest in participating in this study. The first 50 were invited to attend an initial meeting to assess eligibility, 39 attended, and 31 met the criteria and consented. In total, 8 individuals were not eligible due to conflict with ongoing rehabilitation (n=2), currently unwell or in pain (n=2), unable to attend at least twice a week due to lack of transport (n=2) or other reasons (n=1), and other (n=1). The first 5 recruited participants participated in a pilot of the intervention with the next 26 participating in the feasibility study. A participant flowchart is available in [Multimedia Appendix 3](#). Since the program continues to be supported through charitable funding, the 20 individuals still on the register will be invited to participate in future cohorts. Full details of the sample, separated into 3-phased participating cohorts, recruited to this feasibility study are provided in [Table 1](#).

Table 1. Participant details separated into the 3 cohorts.

	Age (years), mean (SD)	Gender (female/male), n	Time since stroke (months), mean (SD)	Aphasia, n	MoCA ^a , mean (SD)	Attendance, mean number of sessions (SD)
Cohort 1 (n=9) ^b	57.4 (17.7)	3/6	51.1 (34.8)	2	26.7 (2.1)	15.4 (3.3)
Cohort 2 (n=7)	61.9 (12.9)	4/3	20.9 (17.3)	4	21.17 (8.6)	20.1 (0.8)
Cohort 3 (n=10)	62 (9.1)	3/7	42.6 (26.6)	4	21.2 (9.8)	21.3 (6.9)
Total (N=26)	60.4 (13.3)	9/17	39.0 (2.2)	10	23.1 (8.3)	18.7 (4.9)

^aMoCA: Montreal Cognitive Assessment.

^bOne participant withdrew completely from this group after 3 weeks, citing a lack of transport.

Program Adherence

All participants set individual goals in partnership with a physiotherapist, including the number of weekly sessions. A total of 493 total sessions were attended representing 986 hours of therapy. In total, 5 individuals achieved, or exceeded, their target number of sessions, and there was, overall, an average adherence rate of 82% (number of attended sessions or number of sessions planned). In total, 21 participants missed a total of 91 (18% of total) planned sessions for the following reasons: illness (n=13), hospital appointment (n=4), weather (n=15), work (n=5), vaccination (n=5), holidays (n=8), personal (n=24), child care (n=7), and transport (n=12).

Safety

No serious AEs were reported during this study. There were, however, a number of AEs reported (n=19) considered to be related to the study: joint or muscle soreness (n=6), viral illness (including COVID-19; n=5), cardiovascular (dizziness; n=3), fatigue (n=3), and skin irritation (n=2). These all resolved within 1 week without intervention.

Semistructured Interviews

Overview

Participants from cohorts 1 and 3 (n=19) were invited to be interviewed remotely by a researcher not directly involved in the delivery of the therapy after their participation. In total, 12 (63%) individuals agreed. The interviews explored the acceptability of the intervention including the usability of the equipment, perceptions of technology-based feedback, and the need for supervision. Participants were also asked if they achieved their overall goal and whether they perceived any changes in their quality of life. The potential for home use, future plans, and areas for improvement were also explored. Six themes emerged from the analysis.

Equipment Usability

The majority of interviewed participants (9/12) found all the equipment used in the TERG to be easy to use with 1 participant commenting "there was nothing I particularly struggled with." There was some variability in usability, for example, the Shapemaster power-assisted rowing machine, GripAble, Motek Medical "Cube," and "Functional Squat" were identified as

being “highly useable.” The majority of participants (7/12) did find some activities challenging, for example, P15 stated, “It was all quite difficult for me, I think it had to do where you are in stroke journey but everything was useful, it pushed you further. I enjoyed it.” Difficulty in customizing equipment was highlighted as a specific problem by some individuals, particularly in the use of standard grip sizes, which could not always accommodate the range of hand spans and degree of spasticity.

Movement Feedback and Gamification

The majority of participants (9/12) valued the use of games and performance feedback provided during the exercises by the technology, with the feedback provided by the equipment to being both helpful (“the treadmill was very innovative, especially with video where I could see myself” [P7]) and motivating (“because it gave a figure to try and better next time” [P4]). The game-based feedback was not, however, universally approved with some participants finding the games a “distraction” and not fully understanding the meaning of the feedback, in particular, how it related to their impairment.

Goal Achievement

Half the participants (6/12) felt that they had achieved their overall goal, but for 2 participants, this related to initial goals being too ambitious: “I think there was a degree of progress, maybe not as much as I had hoped but there was progress” (P4) and “I wasn’t expecting to achieve my goals, but it has improved my balance and I can walk faster for longer and with more confidence” (P3). Confidence improved for 8 out of 12 participants, for example, “confidence was improved and external gyms now seem like something that I could try” (P8).

Need for Professional Supervision

Almost all participants (11/12) indicated the need for supervisory support for safety and guidance with the equipment and felt the presence of a trained rehabilitation professional to be valuable. This was particularly the case during the treadmill training as this was an area of focused attention for many participants. Two participants voiced a desire to have support from staff reduced over the time of the program to nurture greater independence in the use of the equipment.

Potential for Home or Community Use

In total, 11 of 12 participants thought the smaller pieces of equipment (eg, GripAble and Neuroball) were good candidates

for home-based rehabilitation. The larger pieces of gym equipment (treadmill and resistance training equipment) were considered to be potentially useful if available in local leisure centers. In total, 11 of 12 participants planned to continue with activity-based rehabilitation.

The smaller pieces of equipment (eg, GripAble and Neuroball) were seen as good candidates for home-based rehabilitation. The larger pieces of gym equipment (treadmill and resistance training equipment) were considered to be potentially useful if available in local leisure centers but with participants being more varied in their confidence using them, given issues of balance and need for support getting in and out of some systems. Participants were also wary of specialist equipment being available for general public use as this would have an impact on availability. Participants also expressed a desire to be independent when using gym equipment.

Overall Impression and Rehabilitation Continuation

All participants considered the TERG to have made a very positive impact on their recovery and an experience that helped restore confidence in their physical abilities:

every stroke survivor needs this [TERG] in their life as it was just so positive. [P2]

All interviewed participants expressed clear plans to continue their rehabilitation, including home-based work, purchasing rehabilitation equipment, walking outside more, using fitness trackers for motivation, and joining a local gym. While cost issues were highlighted as a potential barrier to these plans, most of the participants (8/12) felt more confident in their physical abilities and were motivated to continue the progress they had made. One participant commented on the potentially negative psychological effect of the program ending, expressing a need for an individual continuation plan.

Outcome Measures

All participants were able to complete the measurements taken before and after the program. Consistent with previous studies [28], there was considerable variation in group characteristics. In general, there was a positive effect on scores of physical ability with all outcome measures showing a mean improvement (Table 2). Differences were, however, not tested for statistical probability since this study was not set up for this reason; instead, they are reported here as 95% CI and effect size to allow sample size estimations for future studies.

Table 2. Mean of outcome measures before and after the program, mean difference, and effect size.

	RMI ^a	SIS-16 ^b	FAC ^c	FTSTST ^d	10mWT ^e	ARAT ^f
Before the program, mean (95% CI)	11.0 (9.9 to 12.2)	61.2 (57.9 to 65.6)	3.8 (3.4 to 4.3)	26.8 (17.0 to 36.6)	30.4 (16.6 to 44.2)	29.8 (20.1 to 39.6)
After the program, mean (95% CI)	12.7 (11.9 to 13.6)	66.5 (63.1 to 69.9)	4.5 (4.2 to 4.8)	21.7 (15.5 to 27.8)	21.4 (14.1 to 28.7)	30.8 (20.4 to 41.2)
Difference, mean (95% CI)	1.9 (1.3 to 2.6)	5.5 (3.5 to 7.5)	0.7 (0.4 to 1.0)	-8.0 (-15.4 to -0.6)	-10.6 (-19.4 to -1.7)	3.1 (0.9 to 5.3)
Effect size (Cohen <i>d</i>)	0.74	0.60	0.66	-0.41	-0.38	0.13

^aRMI: Rivermead Mobility Index.

^bSIS-16: Stroke Impact Scale-16.

^cFAC: functional ambulatory category.

^dFTSTST: five times sit to stand test.

^e10mWT: 10-meter walk test.

^fARAT: action research arm test.

Discussion

Principal Findings

This study assessed the feasibility of a novel model of stroke rehabilitation designed to deliver evidence-based stroke rehabilitation through the scalable model of a TERG and a self-management, supervised, approach.

Feasibility

The participant's variability in age (SD 13.3 years), cognition (Montreal Cognitive Assessment: SD 23.1), communication ($n=10$, 38% aphasic), severity of motor impairment (action research arm test: SD 23.1 and 10mWT: SD 34.1), and overall impact on their lives (SIS-16: SD 9.6) reflect both the heterogeneity of this population [29] and the broad inclusion criteria. The findings can therefore be applied to the general stroke population with some confidence, albeit with the limitation that participants needed to be medically well, a criterion that excluded 2 potential individuals.

The intervention can be considered feasible within this highly variable population. Program adherence was generally good at 82%, with an average attendance of 2.4 sessions per week, and only 1 participant dropping out completely for transport reasons. Adherence to rehabilitation programs, in general, is low, ranging from 40% to 71% [30] but may be higher among stroke populations when offered in a structured manner, for example, through exercise facilities such as gyms (eg, Reynolds et al [31] report 81% adherence) or when technology is included, Valenzuela et al [32] reported 91% adherence to a technology-based exercise program in older adults. The number of AEs could be considered high (11 participants reporting 19 AEs) but should be seen in the context of the 493 total sessions attended (986 hours), 1 AE every 51 hours, and the minor nature of the AEs, many of which related to joint and muscle discomfort that could be explained by an increase in exercise and the viral illnesses, which should be seen in the context of the contemporaneous COVID-19 pandemic. AEs are relatively common in the poststroke population, Ostwald et al [33]

reported 50% of 159 patients tracked after stroke experienced at least 1 AE in the first year poststroke.

Recruitment for this study was managed by a partner organization and considered broadly successful without the need to specifically advertise or promote the center. In trying to achieve 10 people for each group, 11 individuals were targeted for the assessment sessions (allowing for 10% attrition); however, across all the groups, 8 potential recruits were deemed ineligible due to an inability to attend frequently enough (transport and other reasons) or current pain or illness that prohibited use of the equipment. This finding suggests 2 improvements for future studies: clearer information at the start of the process (when registering interest) and an increase in the number of people invited to the baseline assessments to ensure that 10 participants start the program.

Barriers to Attendance

These positive findings of feasibility are balanced against continued reports of barriers to access. Although daily attendance was possible (40 sessions available in total) and encouraged, no participant achieved this; 33 was the highest number of sessions attended by a single participant. While unmodifiable barriers (illness, weather, national holidays, and personal) account for at least some of the issues around fully accessing the program, the lack of transport was mentioned frequently and was also reported in the interviews. This is consistent with previous reports of environmental barriers (including transport) to physical activity in stroke populations [34]. The TERG was situated in a city center campus which, for some, meant relatively long and costly travel arrangements that likely limited participation. Our plans to establish the TERG model in community locations could resolve some of these difficulties and have been strongly recommended by the World Health Organization [35].

Motor impairments have previously been reported as barriers to using equipment for exercise or physical activity participation [36]. Reassuringly, in this study, this was only mentioned in relation to grip, suggesting the existing adaptations to the TERG equipment enabled broad participation.

Changes in Outcome Measures

While this study was not designed to test efficacy, positive change to all outcome measures is worth noting, in particular, the changes to gait (mean reduction of 10.6 s in 10mWT) and sit to stand ability (mean reduction of 8 s in the five times sit to stand test) and the moderate effect sizes (0.74 and 0.60) estimated for Rivermead Mobility Index and SIS-16, respectively. The high variability in the change data (eg, the SD for change in 10mWT was 27.5 s) further demonstrates the variability of response to rehabilitation in this population that merits further investigation to understand explanatory factors. Despite this variability, improvements compare well to rehabilitation interventions in stroke [37] and suggest that greater improvements may be possible during the subacute phase and that time since stroke should not be seen as an exclusion factor to this kind of rehabilitation program.

Limitations

A number of limitations should be considered when interpreting these findings. In particular, the lack of a comparator group means that any change recorded in physical ability may relate to natural recovery or a Hawthorne effect [37] and not the intervention. The chronic nature of the participants, however, suggests natural recovery is likely to be a small part of the positive response.

A greater issue, for interpreting feasibility and effect size, is the recruitment process, which is likely to be biased toward individuals with a pre-existing motivation and interest in

rehabilitation. While this cannot be avoided in the context of research or ethics governance, it may mean that metrics like recruitment, retention, and adherence may not be as positive in the real world.

No cost analysis was performed on the intervention. This is recommended for future studies but should include health and societal benefits, including a return to economic and social activity, where appropriate.

Recommendations

Based on the findings of this feasibility study, a number of recommendations are suggested for further study and development: (1) establishing community versions of the TERG to resolve access barriers, (2) statistically powered randomized controlled trial of efficacy, (3) health economics analysis of the intervention, and (4) adaptable gripping systems for exercise equipment.

Conclusions

A novel approach to stroke rehabilitation using a TERG with professional supervision is feasible, with 82% attendance across almost 1000 hours of delivery and with only minor AEs reported. Reassuringly, the intervention was overwhelmingly well received by this diverse group of chronic stroke survivors. This approach has the potential to meet the overwhelming need for greater access to effective rehabilitation but requires an experimental approach, with a statistically powered sample, to confirm the early promising findings.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT (Consolidated Standards of Reporting Trials) extension for pilot and feasibility reporting.

[PDF File (Adobe PDF File), 448 KB - [rehab_v10i1e46619_app1.pdf](#)]

Multimedia Appendix 2

Interview schedule.

[DOC File , 46 KB - [rehab_v10i1e46619_app2.doc](#)]

Multimedia Appendix 3

Recruitment flowchart.

[PDF File (Adobe PDF File), 64 KB - [rehab_v10i1e46619_app3.pdf](#)]

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Abbreviations

- 10mWT:** 10-meter walk test
AE: adverse event
CONSORT: Consolidated Standards of Reporting Trials
SIS-16: Stroke Impact Scale-16
TERG: technology-enriched rehabilitation gym

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Original Paper

Improving Home-Based Scoliosis Therapy: Findings From a Web-Based Survey

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Abstract

Background: Conservative scoliosis therapy in the form of assisted physiotherapeutic scoliosis exercises is supplemented by self-contained training at home, depending on the approach (eg, Schroth, the Scientific Exercises Approach to Scoliosis). Complex exercises, lack of awareness of the importance of training, and missing supervision by therapists often lead to uncertainty and reduced motivation, which in turn reduces the success of home-based therapy. Increasing digitalization in the health care sector offers opportunities to close this gap. However, research is needed to analyze the requirements and translate the potential of digital tools into concrete solution concepts.

Objective: The aim of this study is to evaluate the potential for optimizing home-based scoliosis therapy in terms of motivation, assistive devices, and digital tools.

Methods: In collaboration with the Institute of Physiotherapy at the Jena University Hospital, a survey was initiated to address patients with scoliosis and physical therapists. A digital questionnaire was created for each target group and distributed via physiotherapies, scoliosis forums, the Bundesverband für Skoliose Selbsthilfe e. V. newsletter via a link, and a quick response code. The survey collected data on demographics, therapy, exercise habits, motivation, assistive devices, and digital tools. Descriptive statistics were used for evaluation.

Results: Of 141 survey participants, 72 (51.1%; n=62, 86.1%, female; n=10, 13.9%, male) patients with scoliosis with an average age of 40 (SD 17.08) years and 30 scoliosis therapists completed the respective questionnaires. The analysis of home-based therapy showed that patients with scoliosis exercise less per week (2 times or less; 45/72, 62.5%) than they are recommended to do by therapists (at least 3 times; 53/72, 73.6%). Patients indicated that their motivation could be increased by practicing together with friends and acquaintances (54/72, 75%), a supporting therapy device (48/72, 66.7%), or a digital profile (46/72, 63.9%). The most important assistive devices, which are comparatively rarely used in home-based therapy, included balance boards (20/72, 27.8%), wall bars (23/72, 31.9%), mirrors (36/72, 50%), and long bars (40/72, 55.6%). Therapists saw the greatest benefit

of digital tools for scoliosis therapy in increasing motivation (26/30, 87%), improving home therapy (25/30, 83%), monitoring therapy progress (25/30, 83%), and demonstrating exercise instructions (24/30, 80%).

Conclusions: In this study, we investigated whether there is any potential for improvement in home-based scoliosis therapy. For this purpose, using online questionnaires, we asked patients with scoliosis and therapists questions about the following topics: exercise habits, outpatient and home-based therapy, motivation, supportive devices, and digital tools. The results showed that a lack of motivation, suitable training equipment, and tools for self-control leads to a low training workload. From the perspective of the patients surveyed, this problem can be addressed through community training with friends or acquaintances, a supportive therapy device, and digital elements, such as apps, with training instructions and user profiles.

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KEYWORDS

scoliosis therapy; Schroth therapy; home-based exercise; home program; physiotherapeutic scoliosis-specific exercises (PSSE); adherence; assistive devices; exercise system; digital tools; eHealth

Introduction

Background

The term “scoliosis” is used to describe a structural 3D deformation of the spine with lateral deviations and rotations. Its severity is classified by the Cobb angle (degree of curvature) [1]. In Germany, more than 900,000 people are affected by scoliosis [2]. It is the most common spinal disease in children and adolescents [3], with growth spurts being high-risk phases for the development or worsening of scoliosis [4]. Regarding sex distribution, there is a clear tendency toward the female sex when they have a Cobb angle of 20° requiring treatment. This tendency increases with an increasing Cobb angle. In various studies, ratios (female to male) between 1.5:1 and 11.6:1 have been determined [3,5,6]. In terms of age groups, scoliosis is divided into 4 groups, infantile (1-3 years), juvenile (4-10 years), adolescent (11-18 years), and adult (over 18 years) [3], with adolescent expression being the most common form worldwide with a prevalence of 0.47-5.2 [7]. Depending on the severity of the curvature, symptoms such as back pain [8]; changes in posture in the form of shoulder, chest, and pelvic asymmetries [4]; deformations of the rib cage; and, in the case of pronounced curvatures, restrictions in heart and lung function may occur [4,8-10].

The therapeutic approach depends on the patient’s age and the extent of the deformity. Mild scoliosis (Cobb angle up to 20°) does not require therapeutic measures in most cases, except for education and motivation to be physically active. Moderate scoliosis (Cobb angle 20°-40°) is treated conservatively with scoliosis-specific braces and physiotherapeutic scoliosis-specific exercises (PSSE). In the case of severe scoliosis (Cobb angle of 40° or more), surgical interventions are used depending on the localization of the scoliosis and the patient’s age [10-12]. The most important approach in which patients with scoliosis can actively and independently participate in therapy is PSSE. The International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) guidelines recommend PSSE in the form of outpatient physical therapy or 3- to 6-week scoliosis intensive rehabilitation (SIR) programs in specific facilities, depending on the Cobb angle [12,13]. The core elements of the therapy should be 3D autocorrection, training in activities of daily living (posture while sitting, standing, walking), stabilization of the corrected posture, and education

of the patient [12]. Within the past few decades, various approaches have been developed on this basis, of which Schroth therapy, the Scientific Exercises Approach to Scoliosis (SEAS), side-shift therapy, Lyon, Dobosiewicz’s method (DoboMed), Functional Independent Treatment for Scoliosis (FITS), and the Barcelona Scoliosis Physical Therapy School (BSPTS) are among the most important. For almost all these forms of therapy, complementary, independent, and permanent home-based training can be used [14]. The positive effects of self-contained regular training sessions at home have been proven in various studies [15-18]. Nevertheless, compared to training sessions assisted by therapists, some of the results were worse [19,20]. Particularly critical factors in this context may be patient adherence and inaccurately performed exercises in an unsupervised environment [21]. Especially in home-based training, adherence is significantly influenced by motivation, belief in the benefits of exercise, a lack of monitoring, and complexity of exercises [22,23]. Increasing digitization in the health care sector offers opportunities to address some of these issues.

Study Aims

The aim of this study is to identify the potential for optimizing home-based scoliosis therapy in terms of motivation, assistive devices, and digital tools. To represent the initial situation as holistically as possible, questionnaires were created for both patients with scoliosis (PQ) and scoliosis therapists (TQ). A survey of these target groups in Germany was intended to answer the following 4 core questions:

- How many training sessions are recommended for patients with scoliosis at home (PQ and TQ), and how often do they really exercise (PQ)?
- How motivated are patients with scoliosis to exercise at home (PQ and TQ)? Can their motivation be increased, and if so, how (PQ)?
- Which training devices are primarily used at home (PQ), and which are rated as helpful (PQ and TQ)?
- Is there interest in digital assistance, and if so, which functions would have to be realized (PQ and TQ)?

Methods

Survey Design

In collaboration with the Institute of Physiotherapy at the Jena University Hospital, 2 standardized online questionnaires were created using the LimeSurvey tool in order to survey scoliosis therapists (36 questions) and patients with scoliosis (33 questions) in Germany. All questions were coded for evaluation with regard to the target group surveyed (patient or therapist) and the respective topic (eg, PA01, which means PQ, topic 1 [A], and question 1, and TC02, which means TQ, topic 3 [C], and question 2; see [Multimedia Appendices 1 and 2](#)). The TQ consisted of 16 closed-ended, 14 semi-open-ended, and 6 open-ended questions and comprised 7 topics: patient groups and therapy methods, outpatient therapy, home-based therapy, communication, assistive devices, digital tools, and general questions. The PQ consisted of 21 closed-ended, 5 semi-open-ended, and 8 open-ended questions and comprised 8 topics: general questions about scoliosis, exercise habits, motivation, communication, assistive devices, digital tools, dealing with scoliosis, and general data. When developing the questionnaires, care was taken to keep them as short and simple as possible in order to achieve a high response rate and to make it easier for younger respondents in particular to answer the questions. The structure of the questionnaires had an increasing thematic depth within the survey and within a topic. Furthermore, decision questions were omitted in order to inquire about the personal attitude of the probands to the topics. Five-point Likert scales (19/69, 27.5%, of all questions) with verbally coded response options were implemented for the study of personal attitudes. An odd number of items were chosen so as not to force a decision. Furthermore, partial nonresponse answers were allowed when dealing with topics that could not be answered definitively (eg, evaluation of a form of therapy that the respondent does not know). This was intended to allow extensive content to be evaluated in the shortest time possible. In addition, many questions were linked to personal experiences in order to enable participants to quickly access the thematic focal points. As a time guideline, 10 minutes were provided for the PQ and 15 minutes for the TQ.

Ethical Considerations

This study was reviewed by the data protection officers of the Ethics Committee at the Medical Faculty of Leipzig University and found to be of no concern. Since only anonymized data sets were provided and no re-identification was performed by the users of the data sets, there was no obligation to refer the study to an ethics committee formed according to Saxon state law. On the home page of the respective questionnaire, the topic and objective of the study were presented and the research institution conducting the study was named. The participants were informed that this was a research project and that the survey would be conducted anonymously. Before starting, all participants had to agree to the privacy policy, which was integrated via a macro and provided information about data evaluation, data subject rights, and contact persons, among other things.

Recruitment

The distribution of the questionnaires in the patient and therapist environments was carried out in cooperation with the *Bundesverband für Skoliose Selbsthilfe e. V.* and the Physiotherapeutic Institute of the Jena University Hospital. To reach as broad a spectrum of subjects as possible, the questionnaires were distributed via scoliosis forums, direct contact, flyers with quick response (QR) codes for display in therapeutic facilities, and via the *Bundesverband für Skoliose Selbsthilfe e. V.* newsletter during the period from October 27, 2020, to June 30, 2021.

Statistical Analysis

Data were analyzed based on descriptive statistics. For this purpose, on the one hand, frequency distributions were created, and on the other hand, the Likert scale-coded questions were evaluated using the following approach: The individual item responses of the 5-point scales were assigned point values (from 0="not motivating at all" to 5="very motivating"), and based on this, a sum score was calculated for the overall scale. Subsequently, the percentage of the calculated points (sum score) out of the maximum-possible points was determined. To indicate rejection or agreement as a percentage, some of the items were divided into disagreement items (eg, "not motivating at all" and "rather not motivating") and agreement items (eg, "rather motivating" and "very motivating"), and then their proportion of the total was calculated. All free-text responses were evaluated individually and analyzed with respect to co-occurrence. Depending on the question, the patients with scoliosis were also divided into 5 age categories, inspired by the scoliosis-specific age distribution: 1-10 years (children), 11-18 years (adolescents), 19-30 years (young adults), 31-50 years, and over 50 years. Due to the low participation of those under 11 years of age, the infantile and juvenile groups were combined, while the group of people over 18 years (adults) was further divided due to the large number of participants.

Results

Response

The survey was based on 2 questionnaires with a total of 141 participants. The PQ was filled out by a total of 97 (68.8%) participants, 72 (74.2%) of whom answered all questions. The TQ was filled out by a total of 44 (31.2%) persons, 30 (68.2%) of whom answered all questions. All incomplete questionnaires were excluded from the analysis, so overall, 102 (72.3%) fully completed surveys were analyzed in this study.

Demographics, Health Status, and Therapy

Patients

Of the 72 patients with scoliosis, 62 (86.1%) were female and 10 (13.9%) were male. The average age of the respondents was 40 (SD 17.08) years [PH01]. Broken down by age group, the distribution was as follows: up to 10 years (1/72, 1.4%), 11-18 years (9/72, 12.5%), 19-30 years (14/72, 19.4%), 31-50 years (22/72, 30.6%), and over 50 years (26/72, 36.1%). People between the ages of 7 and 79 years participated [PA02]. Regarding the Cobb angle, patients with scoliosis from all ranges

were represented in our study, with Cobb angles above 50° being the most common (17/72, 23.6%), followed by 11°-20° (11/72, 15.3%). In addition, 12 (16.7%) patients responded with “I don’t know” [PA06]. In addition, of the 72 patients with scoliosis, 12 (16.7%) had already undergone surgery for their scoliosis [PA07] and 18 (25%) wore a brace [PA05].

The majority of patients with scoliosis were in therapeutic treatment for more than 2 years (56/72, 77.8%) [PA03] and attended scoliosis therapy once a week or less (61/72, 84.7%) [PB01]. On average, most patients with scoliosis exercised for up to 45 minutes in 1 physiotherapy session (60/72, 83.3%) [PB04] and up to 30 minutes in 1 home-based session (55/72, 76.4%) [PB05]. The most frequently used therapeutic approach in physiotherapy or at home was Schroth therapy (63/72, 87.5%), followed by spiral dynamics (17/72, 23.6%). The BSPTS, DoboMed, SEAS, FITS, and side-shift therapy were not known to more than 97% (70/72) of patients with scoliosis [PB07]. Other therapy methods mentioned with a maximum of 3 votes each (3/72, ≤4.2%) were yoga, fascial training, Vojta therapy, *Klappsches Kriechen*, Bobath therapy, osteopathy, sling table, manual therapy, fitness training, swimming, climbing, chiropractic, medical training therapy (MTT), proprioceptive neuromuscular facilitation (PNF), *Rota* therapy, Dorn therapy, massage, *fango* therapy, and acupuncture [PB10].

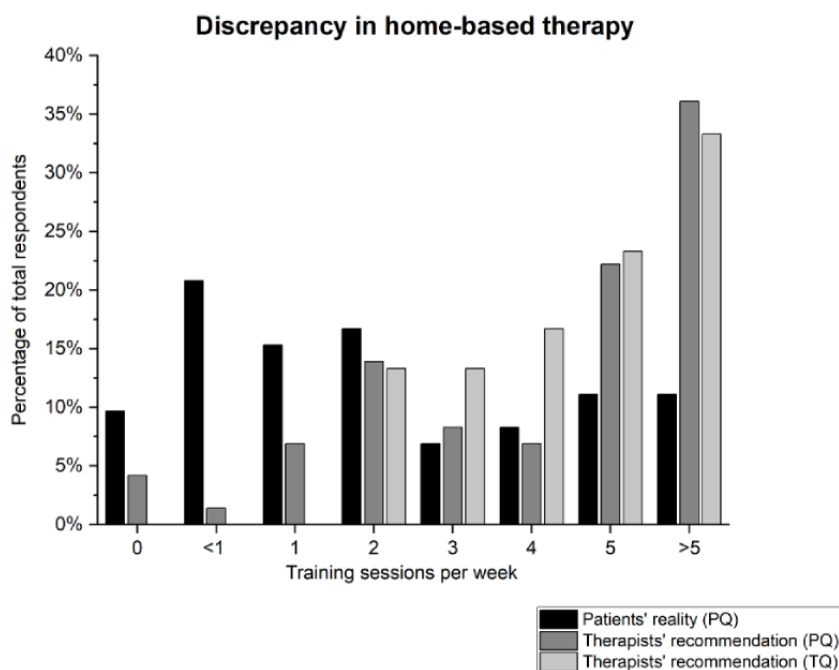
Therapists

The survey of the 30 scoliosis therapists showed that the most common age group of patients with scoliosis in their practices is 10-14 years (25/30, 83.3%), followed by 15-18 years (19/30, 63.3%) and over 50 years (9/30, 30%) [TA01]. The most frequently used therapy methods were Schroth therapy (29/30, 96.7%) and spiral dynamics (6/30, 20%). The following were also mentioned, each with a maximum of 2 votes (2/30, ≤6.7%): stabilization exercises, Vojta therapy, functional training, manual therapy, cupping, functional patterns by Naudi Aguilar, fascia therapy, applied kinesiology, therapeutic climbing, osteopathy, gyrotonic expansion system, yoga, and the Hancke concept [TA04]. The majority of the therapists’ patient base had been in treatment for at least 1 year (16/30, 53.3%) [TB01] and had been in practice on average once a week or more (25/30, 83.3%) [TB02]. A guided training session lasted between 16 and 30 minutes for most therapists (19/30, 63.3%) [TB04].

Home-Based Therapy

In the case of scoliosis home training, there was an opposite trend: Although the majority of patients with scoliosis trained twice or less per week (45/72, 62.5%) [PB02], the majority of therapists recommended at least 3 training sessions per week (PQ: 53/72, 73.6%; TQ: 26/30, 86.7%) [PB03, TC01]; see Figure 1.

Figure 1. Comparison of weekly training sessions performed by patients with scoliosis at home and recommendations of therapists in this regard. To create the figure, the results of 2 questions from PQ (“How often do you do additional therapy exercises at home for your scoliosis?” [PB02; black] and “How often did your therapist recommend you to do exercises at home?” [PB03; dark gray]) and 1 question from TQ (“How often do you usually recommend additional home exercise sessions to your patients for physical therapy?” [TC01; light gray]) were used. PB02: PQ, topic 2, question 2; PB03: PQ, topic 2, question 3; PQ: questionnaire for patients with scoliosis; TC01: TQ, topic 3, question 1; TQ: questionnaire for scoliosis therapists.



For further substantiation, the interviewed therapists were asked to rate the dependence of their recommendations on 4 parameters using a 5-point Likert scale: (1) Cobb angle, (2) age, (3) personal motivation, and (4) cognitive aptitude. The survey of the 30 therapists showed that personal motivation (26/30, 85.3%) and cognitive aptitude (25/30, 82%) were the most important factors from our selection [TC02].

Motivation

We asked how motivated patients with scoliosis were in general to perform their exercises (see Figure 2). Analysis of the data showed that children, adolescents, and young adults in particular are less motivated. This trend reversed with increasing age in our survey. According to their own statements, people aged 50 years and above had the greatest motivation [PC01].

A similar relationship emerged in the therapist survey. According to the therapists questioned, children and adolescents were the least motivated to perform home-based therapy [TB06].

In a second question on motivation, patients with scoliosis were asked to rate a preselection of features in terms of their motivational potential using a 5-point Likert scale. The most popular features (agreement items only) for increasing

motivation were “exercises with friends or acquaintances” (54/72, 75%), “supporting therapy device” (48/72, 66.7%), and “digital profile” (46/72, 63.9%). The worst score was for “digital profile with comparison option” (19/72, 26.4%). The greatest uncertainty was seen in “gamification” (“neutral,” or “neither motivating nor not motivating”; 26/72, 36.1%) [PC02]; see Figure 3.

Figure 2. How motivated are patients with scoliosis to perform their exercises, broken down by age group? The figure is based on the results of 1 question from PQ: “How motivated are you in general to do your exercises?” [PC01]. The disagreement items (“not motivated at all” and “rather not motivated”) are visualized in black and dark gray, respectively, while the agreement items (“rather motivated” and “very motivated”) are visualized in light gray and white, respectively, each stacked. PC01: PQ, topic 3, question 1; PQ: questionnaire for patients with scoliosis.

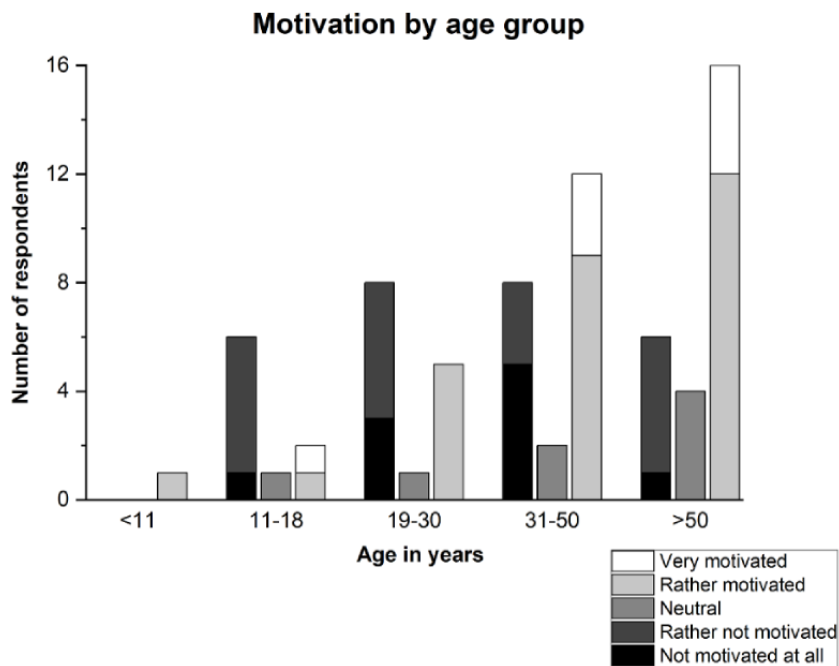
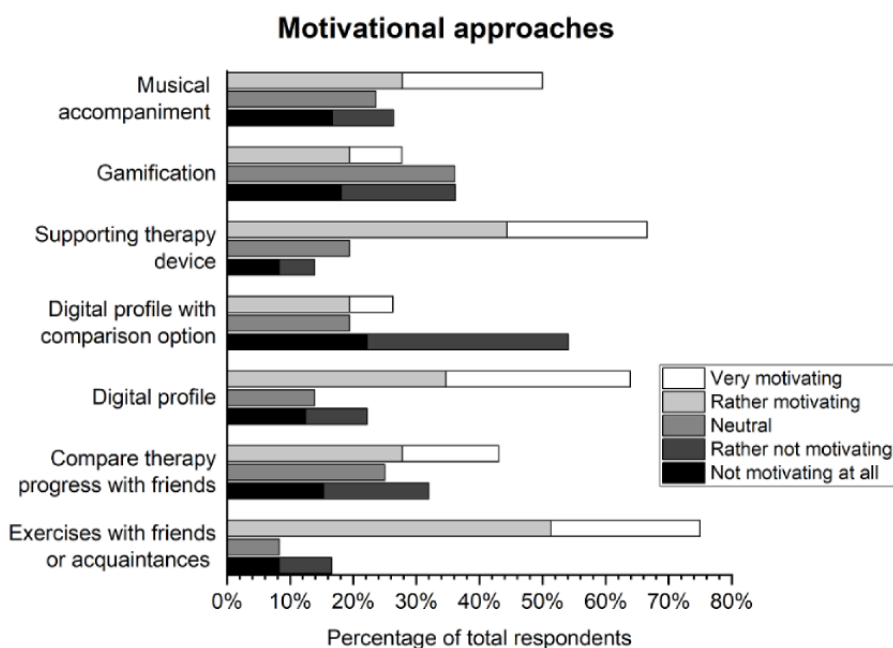


Figure 3. What would motivate patients with scoliosis to perform their exercises? The content of the graph is based on the results of voting from the PQ: “Please indicate how motivating you would find the following features for your scoliosis exercises” [PC02]. Here, the disagreement items (“not motivating at all” and “rather not motivating”) are visualized in black and dark gray, respectively, while the agreement items (“rather motivating” and “very motivating”) are visualized in light gray and white, respectively, each stacked. PC02: PQ, topic 3, question 2; PQ: questionnaire for patients with scoliosis.



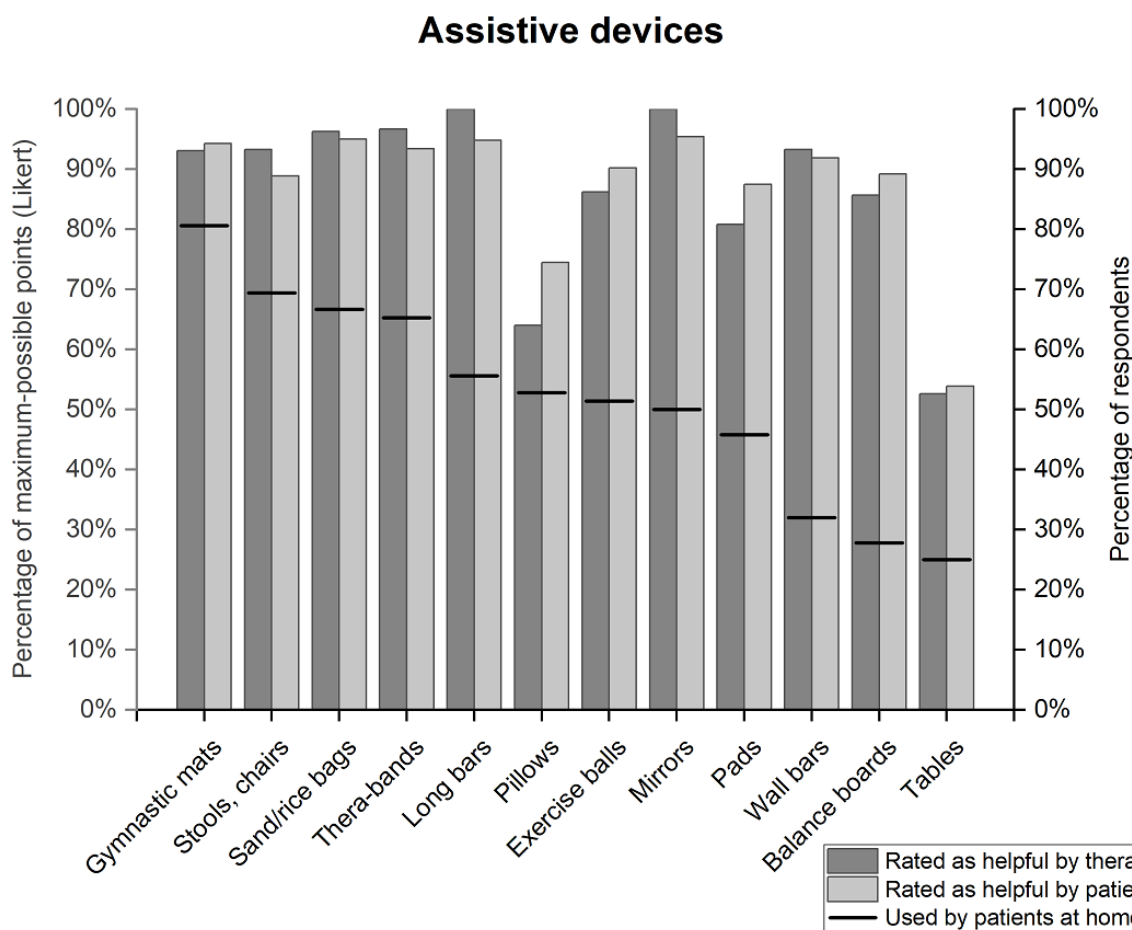
The top 4 features in the 3 age groups of up to 30 years (least motivated) were “exercises with friends or acquaintances” (18/24, 75%), “supporting therapy device” (14/24, 58.3%), “digital profile” (13/24, 54.2%), and “musical accompaniment” (13/24, 54.2%) [PC01].

Assistive Devices

In home-based training, “cushions and gymnastic mats” (58/72, 80.6%), “stools and chairs” (50/72, 69.4%), and “sand and rice bags” (48/72, 66.7%) were used most frequently. “Tables,” in contrast, were used by just a quarter of respondents (18/72, 25%) [PE01].

The 3 most helpful assistive devices for patients with scoliosis were “mirrors” (93.8%), “sand and rice bags” (93.3%), and “wall bars” (93.2%) [PE02]. Note that these percentages refer to the results of the Likert scale, in which scores for the answer “I do not use” were eliminated. A similar picture was shown by the therapists, who rated “mirrors” (98.7%), “sand and rice bags” (94.1%), and “long bars” (92.7%) as most helpful [TE03]. Highly valued (at least 80%) but relatively underused in home-based therapy were “wall bars,” “balance boards,” “mirrors,” “pads” (eg, foam rollers), and “long bars” [PE01, PE02, TE03]; see Figure 4.

Figure 4. Which assistive devices do patients with scoliosis use for training at home, and which do patients and therapists rate as helpful for scoliosis therapy? For the creation of the figure, the results of 2 questions from PQ (“Where do you use, or where would you like to use, which of the predefined tools?” [PE01; black lines] and “How helpful do you find the mentioned devices?” [PE02; light gray]) and 1 voting from TQ (“Please rate how helpful the mentioned assistive devices are for scoliosis therapy” [TE03; gray]) were used. The Likert distribution was calculated excluding the answer “I do not use.” PE01: PQ, topic 5, question 1; PE02: PQ, topic 5, question 2; PQ: questionnaire for patients with scoliosis; TE03: TQ, topic 5, question 3; TQ: questionnaire for scoliosis therapists.



Digital Assistance

Respondents were asked to rate 5 digital tools in terms of their usefulness on a 5-point Likert scale. In patients in the age groups of up to 30 years (24/72, 33.3%, respondents), the digital tools “smartphone or tablet app” (eg, exercise guide; 18/24, 75.8%), “video support” (eg, instructional video; 17/24, 70%), and “music suitable for exercises” (16/24, 67.5%) were the most popular. In patients aged 31 years or above (48/72, 66.7%, respondents), the most popular tools were “video support” (eg,

instructional video; 38/48, 82.1%), “vibration feedback” (vibration when exercises are performed correctly or incorrectly; 35/48, 72.9%), and “smartphone or tablet app” (eg, exercise instructions; 34/48, 72.5%) [PF02]; see Figure 5.

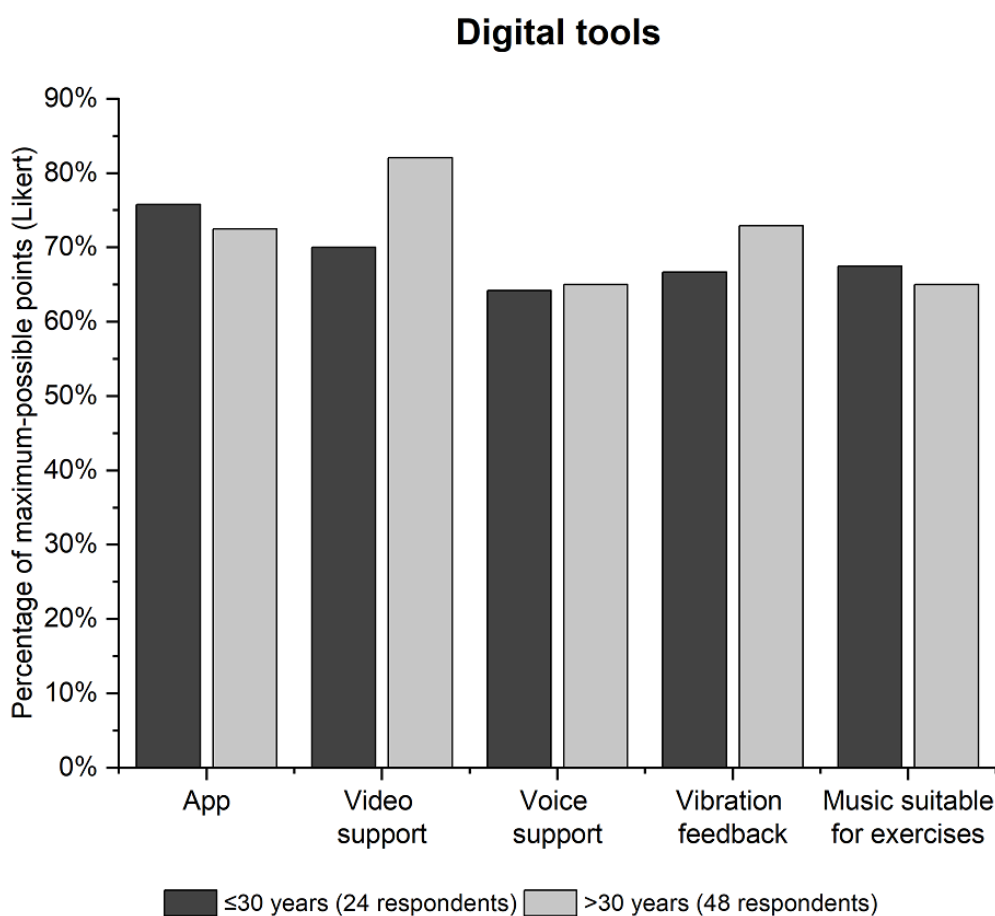
The survey of therapists also revealed that digital tools, such as smartphones (18/30, 60%), watches (9/30, 30%), and tablets (7/30, 23.3%) were already used for scoliosis therapy [TF01]. The most important apps currently included “documentation of therapy progress” (18/30, 60%), “exercise instructions” (16/30,

53.3%), and “communication with the patient” (11/30, 36.7%) [TF02]. Therapists saw the greatest potential in the use of digital tools for “increasing motivation” (26/30, 87%), “improving home therapy” (25/30, 83%), “monitoring therapy progress” (25/30, 83%), and “exercise instructions” (24/30, 80%). The least convincing were “virtual therapy sessions” (15/30, 50%) [TF03].

Based on the survey on the potential of digital tools, therapists were also asked to evaluate necessary parameters for

improvement of home-based therapy. The tracking of “position and movement of certain body parts” (27/30, 90%) was seen as the most important parameter, followed by the measurement of “vital capacity” (13/30, 43.3%) [TF05]. Therapists also preferred the following variants for a therapy-supporting exchange with patients: “exercise instructions as videos” (26/30, 86.7%), “exercise recordings as videos” (24/30, 80%), “sensor data on position and movement” (16/30, 53.3%), and “exercise instructions as pictures” (14/30, 46.7%) [TF07].

Figure 5. Evaluation of digital tools with regard to their usefulness in supporting scoliosis therapy. The results of the question “How helpful do you find, or would you find, the following digital tools in your exercises?” [PF02] from PQ were evaluated for the creation of the graph. The evaluation was carried out using a 5-point Likert scale, divided into 2 age groups. PF02: PQ, topic 6, question 2; PQ: questionnaire for patients with scoliosis.



Discussion

Principal Findings

The aim of this study was to evaluate the potential for optimizing home-based scoliosis therapy in terms of motivation, assistive devices, and digital tools. For this purpose, the topics of training habits, motivation, assistive devices, and digital assistance were addressed in online questionnaires. To gain the most comprehensive insight possible, both patients with scoliosis and scoliosis therapists were surveyed.

In line with the literature, the percentage of female respondents in our patient survey was much higher, with a ratio of 6.2:1 [3,5,6]. Additionally, both questionnaires revealed that Schroth therapy is the most widespread and popular therapy method in

Germany. Its effectiveness as part of conservative scoliosis therapy has been proven in numerous publications [24-26].

In addition to physiotherapeutic treatments, the commitment of patients to deal with scoliosis and to exercise regularly on their own at home is decisive for the success of conservative scoliosis therapy [27]. Depending on age and the Cobb angle, patients with scoliosis are entitled to various types of treatment according to the *Heilmittel-Richtlinie* in Germany, the costs of which are covered by health insurance [28]. These are primarily physiotherapeutic approaches, such as manual therapy, since there are no separate remedy positions for scoliosis therapies [29]. These therapies cover some of the necessary training, yet therapists additionally recommend a continuous and comprehensive home exercise program. Their recommendations

depend on the motivation and cognitive aptitude of their patients. Based on this initial situation, we compared recommendations and the reality for home-based training. A clear trend emerged, which is almost indirectly proportional: patients with scoliosis exercise significantly less at home than therapists recommend. Reasons for this opposite trend may include a lack of time and motivation [23,30], the complexity or number of exercises, forgetting training sessions [23], uncertainty in performing exercises, fear of aggravation, and pain [31].

The survey of therapists showed that children, adolescents, and young adults, especially, undergo physiotherapy treatment for their scoliosis. Because growth is not yet complete, the chances of success of therapy are the highest in this age group [32,33]. However, this is countered by the fact that it is precisely in these age groups that motivation for scoliosis-specific exercises appears to be the lowest, both from the perspective of the patients with scoliosis surveyed and from that of the therapists. This trend may occur because young patients prioritize other aspects in everyday life, which is also reflected in the participation in our survey. An appropriate way to educate children, adolescents, and young adults about age-related problems due to scoliosis has not yet been found. Furthermore, scoliosis-related pain in these age groups is still too low to raise awareness of the importance of training. The increase in pain with increasing age [34] could be a reason for the greater motivation of older-age groups. According to the patients with scoliosis surveyed, motivation could be increased by joint training sessions with friends and acquaintances, a specific therapy device, and a digital profile. In this context, it should be noted that although the digital profile received the most votes for “very motivating,” it only ranked third overall. Half of the respondents still found musical accompaniment motivating. Although community training and musical accompaniment can be partially implemented on their own, new approaches are needed for a specific therapy device and digital profile. The comparison with other patients was not felt to be motivating. Although this can spur one on, it can also be discouraging if one either cannot keep up or one lacks “digital friends” [35]. In addition, a meaningful comparison is difficult to realize due to the high degree of individualization of therapy. The greatest uncertainty was found in the “combining the exercises with a game” approach. The reason for this could be that this approach was seen without a digital reference (gamification) and that the patients with scoliosis surveyed could not imagine combining their current therapy with a game. The question intended to obtain insights into the participants’ opinion on the transfer of training content into a digital environment (eg, an app) with playful elements or visualizations. An increase in motivation can be achieved through the fun of the game as well as through high scores and digital reward systems (eg, badges, points) when completing tasks. The average age (40 years) of the respondents is unlikely to have influenced the answer in this respect, as 44% of people who occasionally or regularly play video games in Germany are aged 40 years or above. The situation is similar with regard to sex and gender, as the ratio between male and female video gamers in Germany is relatively balanced: around 48% are female and 52% are male [36]. Several studies in the past few years have shown that gamification approaches can have a motivating effect in rehabilitation [37]. The literature

identifies personal analyses to progress, data tracking, a competitive environment [35,37], and a sense of community, autonomy, and competence [38] as crucial factors for motivation. Wibmer et al [39] explicitly investigated the potential of gamification in scoliosis therapy. They were able to show that it is possible to increase motivation and precision when performing scoliosis-specific exercises. However, this effect depends on how varied and adaptable the games are designed and thus can also quickly become invalid [39]. A successful gamification approach requires that patients be involved in the development of the game from the beginning and that the possibility of cheating within the game be excluded. Furthermore, different game environments appeal to different groups of people. This should be considered during development [35].

Another influencing factor for the optimization of home-based therapy could be assistive devices that can be used for training. Langensiepen et al [15] reported that the use of side-alternating vibration plates can lead to an improvement in home-based training. Our survey showed that patients with scoliosis mainly use gymnastic mats and bands, sand and rice bags, stools, and chairs at home. These tools are inexpensive, are easy to obtain, and require little storage space. However, patients with scoliosis and therapists found mirrors to be the most helpful of our selection of tools. This offers the advantage of self-control when performing exercises, which is especially important at home [40]. Nevertheless, mirrors were used by only half of the patients with scoliosis we interviewed. One reason for this could be that there is a lack of suitable installation possibilities in private households or that there is not enough space in front of the existing mirrors to perform the exercises. The same applies to wall bars, balance boards, pads, and long poles, which are popular with both patients with scoliosis and therapists but are used relatively little at home. Overall, both groups found 10 (more than 80% approval) of our 12 mentioned tools useful for scoliosis therapy. However, only 1 in 12 devices was used by at least 80% of patients with scoliosis at home. A supportive therapy device that meets the requirements of home training and, if necessary, combines several training options of the aforementioned devices could thus contribute to improving scoliosis therapy. However, it is important that the therapy device not increase the complexity of the training.

After examining motivation and aids, we looked at the potential of digital tools in the last section. Currently, multisensory, smartphone-based systems for improving adherence [41], pressure sensor systems for adapted corsets [42], and apps for Cobb angle measurement [43-45] and therapy support [46] are used in scoliosis therapy. These can be used advantageously for rehabilitation, especially in the areas of visualization [47], networking, information exchange, monitoring [48], and motivation increase [49]. Based on this, we asked patients with scoliosis and therapists which digital tools they thought would be helpful for scoliosis therapy. Our preselection of 5 tools revealed different preferences, depending on the age group. Although a suitable smartphone or tablet app (eg, with exercise instructions) was most preferred by patients in the age groups of up to 30 years, those over 30 years old would particularly like video support (eg, in the form of instructional videos).

Overall, the response was predominantly positive for all tools that serve to support correct exercise execution. Training can lead to incorrect loads or incorrect execution, particularly at home without the presence of a therapist, which can have a negative effect on therapy. In addition to mirrors, which patients with scoliosis can use during therapy, there is a lack of opportunities for self-monitoring at home. In our questionnaire on home-based therapy, the therapists therefore stated that the tracking of positions and movements of the body is a priority. They also saw great potential in increasing motivation, monitoring therapy progress, and optimizing exercise instructions through digital tools. Due to the COVID-19 pandemic, we also sought opinions on virtual therapy sessions. This approach was considered useful by only half of the therapists.

Limitations

Our survey consisted of online questionnaires that were distributed primarily via digital media (forums, social media, QR codes, etc). It can therefore be assumed that the survey was primarily completed by technically skilled respondents. Some of the patients with scoliosis and therapists may have been excluded. Nevertheless, this methodology allowed a larger sample to be reached. Another limitation of the online questionnaires is that answers may have been given that were not true or that people who neither have scoliosis nor treat it participated. The small sample size of the survey was due to the available boundary conditions. Since the survey was conducted within the framework of a 2-year research project, the capacity for the acquisition of participants and the period for data collection were limited. The goal was to integrate the results into the development process of the research project.

Another potential limitation of this study is that the average age of our patient survey was 40 years. Children, adolescents, and young adults were thus comparatively underrepresented, which is why a downstream study with an adapted design that focuses exclusively on this target group is conceivable. In addition, it is possible that the youngest participants in our survey completed the questionnaires together with their parents. In this case, the answers may have been influenced by the parents. Another limitation is the fact that the study was limited to Germany. This raises the possibility that patients with scoliosis and therapists in other countries might have given different answers to the questionnaires, depending on the health care system or local therapy methods. Furthermore, the fact that significantly fewer therapists than patients with scoliosis participated in our survey had a limiting effect on the study. However, it must be considered that there are also significantly more people with scoliosis in Germany than therapists treating them.

Conclusion

In this study, we investigated whether there is any potential for improvement in home-based scoliosis therapy. For this purpose, via online questionnaires, we asked patients with scoliosis and therapists questions about the following topics: exercise habits, outpatient and home-based therapy, motivation, supportive devices, and digital tools. The results showed that a lack of motivation, suitable training equipment, and tools for self-control leads to a low training workload. From the perspective of the patients with scoliosis surveyed, this problem can be addressed by community training with friends or acquaintances, a supportive therapy device, and digital elements, such as apps, with training instructions and user profiles.

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Authors' Contributions

FG, FS, SH, and SD designed and distributed the questionnaires. FG, JS, FS, SH, SS, and C-EH developed the methodology for data analysis. FG conducted data evaluation, created the graphics, and wrote the original draft. C-EH, JS, SS, FS, SH, SD, and W-GD reviewed and edited the manuscript. C-EH und W-GD supervised the project. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient questionnaire.

[\[PDF File \(Adobe PDF File\), 212 KB - rehab_v10i1e46217_app1.pdf\]](#)

Multimedia Appendix 2

Therapist questionnaire.

[\[PDF File \(Adobe PDF File\), 355 KB - rehab_v10i1e46217_app2.pdf\]](#)

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Abbreviations

BSPTS: Barcelona Scoliosis Physical Therapy School

DoboMed: Dobosiewicz's method

FITS: Functional Independent Treatment for Scoliosis

PQ: questionnaire for patients with scoliosis

PSSE: physiotherapeutic scoliosis-specific exercises

QR: quick response

TQ: questionnaire for scoliosis therapists

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Review

Evidence for the Efficacy of Commercially Available Wearable Biofeedback Gait Devices: Consumer-Centered Review

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Abstract

Background: The number of wearable technological devices or sensors that are commercially available for gait training is increasing. These devices can fill a gap by extending therapy outside the clinical setting. This was shown to be important during the COVID-19 pandemic when people could not access one-on-one treatment. These devices vary widely in terms of mechanisms of therapeutic effect, as well as targeted gait parameters, availability, and strength of the evidence supporting the claims.

Objective: This study aimed to create an inventory of devices targeting improvement in gait pattern and walking behavior and identify the strength of the evidence underlying the claims of effectiveness for devices that are commercially available to the public.

Methods: As there is no systematic or reproducible way to identify gait training technologies available to the public, we used a pragmatic, iterative approach using both the gray and published literature. Four approaches were used: simple words, including some suggested by laypersons; devices endorsed by condition-specific organizations or charities; impairment-specific search terms; and systematic reviews. A findable list of technological devices targeting walking was extracted separately by 3 authors. For each device identified, the evidence for efficacy was extracted from material displayed on the websites, and full-text articles were obtained from the scientific databases PubMed, Ovid MEDLINE, Scopus, or Google Scholar. Additional information on the target population, mechanism of feedback, evidence for efficacy or effectiveness, and commercial availability was obtained from the published material or websites. A level of evidence was assigned to each study involving the device using the Oxford Centre for Evidence-Based Medicine classification. We also proposed reporting guidelines for the clinical appraisal of devices targeting movement and mobility.

Results: The search strategy for this consumer-centered review yielded 17 biofeedback devices that claim to target gait quality improvement through various sensory feedback mechanisms. Of these 17 devices, 11 (65%) are commercially available, and 6 (35%) are at various stages of research and development. Of the 11 commercially available devices, 4 (36%) had findable evidence for efficacy potential supporting the claims. Most of these devices were targeted to people living with Parkinson disease. The reporting of key information about the devices was inconsistent; in addition, there was no summary of research findings in layperson's language.

Conclusions: The amount of information that is currently available to the general public to help them make an informed choice is insufficient, and, at times, the information presented is misleading. The evidence supporting the effectiveness does not cover all aspects of technology uptake. Commercially available technologies help to provide continuity of therapy outside the clinical setting, but there is a need to demonstrate effectiveness to support claims made by the technologies.

KEYWORDS

wearables; technologies; walking training; rehabilitation; biofeedback; mobile phone

Introduction

Background

Gait is one of the most frequently assessed attributes in clinical settings because gait impairment is the hallmark of several different health conditions [1,2]. Prevalence of poor gait and gait-associated impairments is on the rise because people are living longer, with multimorbidity of chronic conditions such as obesity, diabetes, and arthritis, and because of a global increase in the proportion of neurological conditions [3-5]. Gait impairments and walking limitations from aging, disease, or injury increase the risk of falls, joint damage, and a sedentary lifestyle, leading to a vicious cycle toward further deterioration [6,7]. To illustrate, gait and balance impairments have been shown to increase with age—from 10% among individuals aged between 60 and 69 years to >60% in individuals aged >80 years [8]. Gait and mobility challenges are among the main concerns for older adults and people with neurological conditions and are a major reason for seeking rehabilitation services. There is considerable evidence to support the effectiveness of gait training in older adults and people with neurological conditions [9-15]. Although traditional therapist-led gait training strategies are well-accepted and effective in improving gait patterns, the effects abate with cessation of training [16,17]. Hence, traditional therapist-led gait training alone will not translate into sustained neuromuscular change nor lead to the behavioral change needed for physical activity guidelines to be met.

Effective and accessible treatments for gait impairments will increasingly be needed with the aging of the population and as people with health conditions live longer. Skilled therapy professionals are a limited resource, and therapy is rationed; furthermore, rehabilitation is a global target of the World Health Organization's 2030 strategy, with key areas for action to increase affordable services and use technology to address this need to assess and reassess how individuals mobilize and move and implement long-term training programs [18]. Increasingly, people with gait vulnerabilities and their family members will turn to technological solutions to supplement and extend rehabilitation services [19,20]. Technological innovations are poised to close the gap between demand and supply [21]. There is no doubt that older adults and people living with health conditions would benefit from focused gait training beyond what is offered during a clinical visit [22,23]. Technology can provide people with opportunities to practice gait-related skills outside the clinical environment and gain *ownership* over their therapy [24]. There is evidence to support that technology alone can influence positive behavior and that smartphone apps have been shown to reduce sedentary time by 41 minutes per day [25,26]. These effects are thought to be a result of the user's ability to self-monitor and self-correct, thus providing them with more control and responsibility for their own therapy [26]. Given the unmet need for access to rehabilitation services and

the need to continue therapy outside clinical settings, the commercialization of technology is timely and necessary.

Available devices range in sophistication from nonelectronic shoe insoles and walking aids to inertial or pressure sensors. Most of the technologies used have gait assessment functionality, but there is now increasing interest in harnessing the capacity of wearable sensors for providing biofeedback. The literature is rich in supporting the effectiveness of biofeedback in improving gait patterns in healthy and clinical populations [27-30].

There is an increasing number of devices that claim to improve gait impairments through biofeedback. However, it is still rare for these devices to be available to the consumer; most are still tied to a laboratory setting. There is an urgent need to move technological innovations from research laboratories to the people who would benefit the most—those with gait impairments. The COVID-19 pandemic has alerted us to the vulnerability of seniors and people living with chronic health conditions when they were no longer able to access clinical and community resources [31-37]. In addition, the growing size of the older population means that one-on-one treatment will no longer be feasible, and a self-management strategy facilitated by technologies will be needed [31-33,38].

The market of people needing gait training technologies is huge. As a result of direct access of the general public to several technologies, the impact of evidence presented on the websites could affect purchasing behavior. A study on the purchasing intention of consumers who shop on the web found that “high involvement” consumers, defined as people living with health conditions who need to improve their gait to meet functional demands or mobility needs and are intently looking to purchase something specific, were more likely to purchase a product if the number of quality reviews was high [39]. Individuals with gait impairments may be considered “high involvement” consumers and, therefore, may purchase related products based solely on available reviews that may or may not have evidenced research quality.

Gait training technologies must be appealing with features such as product attractiveness, functionality, and price, as well as be supported by robust research demonstrating usability, reliability, efficacy, and effectiveness. All these features are equally important; an attractive product that does not work or a product that does work but is expensive would not be appealing. Although the attractiveness of technologies is often featured on websites, the evidence for efficacy could be hard to locate. Furthermore, the public is not likely to have access, time, or training to find the scientific literature and critically appraise the content to guide the decision to purchase such products.

Objectives

The objectives of this customer-centered review were to create an inventory of devices targeting improvement in gait pattern

and walking behavior and identify the strength of the evidence underlying the claims of effectiveness for devices that are commercially available to the general public [40].

Methods

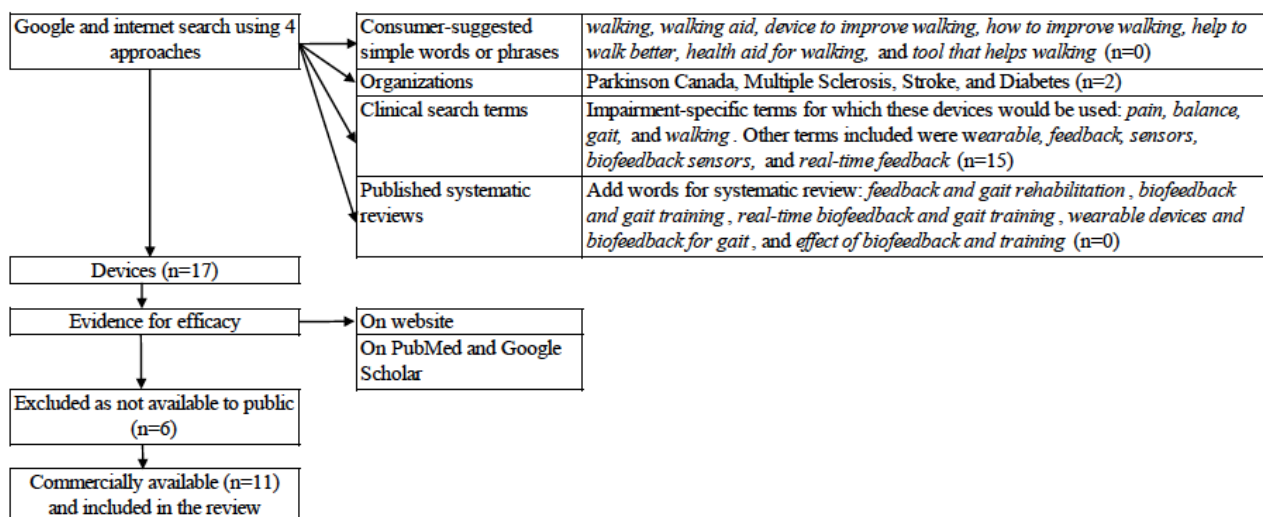
Pragmatic, Iterative Approach

As there is no systematic or reproducible way to identify technologies available to the public to help improve gait, we used a pragmatic and iterative approach. Our search strategy involved a search of gray literature as well as published literature. Figure 1 shows the 4 approaches used to identify a list of commercially available biofeedback devices. We used simple words, including those suggested by laypersons. Our focus was on devices that provided feedback, but this would not be thought of by the consumer. Therefore, we supplemented this strategy by searching for condition-specific organizations or charities because they might endorse such devices. This search yielded 2 feedback devices. We also performed a search using clinical impairment-specific search terms, and this yielded

another 15 feedback devices. Finally, we searched for systematic reviews covering gait but found no new devices [41-45]. The search was first conducted in October 2021 and repeated in December 2022. Once we had a list of devices, we searched for evidence of efficacy published on the device web page as well as on PubMed and Google Scholar using the device name to search.

A findable list of technological devices targeted to health conditions was extracted separately by 3 authors and compared for completeness. For each device identified, the evidence for efficacy or effectiveness was extracted from material displayed on the websites, and full-text articles were obtained from the scientific databases PubMed, Ovid MEDLINE, Scopus, or Google Scholar. This step was carried out by MM, AA, MW, OS, SG, DG, and HD; any conflicts were resolved in consultation with KM and AA-S. Finally, KM and NEM organized the results into tables and reverified all data and assigned levels of evidence. A level of evidence was assigned to each study involving the device using the Oxford Centre for Evidence-Based Medicine scale [46,47].

Figure 1. The steps taken to identify commercially available biofeedback devices to improve gait pattern and walking behavior.



Levels of Evidence

The *levels of evidence* rating system is a method of quantifying the best clinical evidence that is available about the efficacy and safety of treatment approaches that are destined to be implemented in clinical care [46,47]. The Oxford Centre for Evidence-Based Medicine scale was used because it provides the best granularity of evidence arising from the majority of trials of new technologies that usually are not included in meta-analyses and do not have randomized clinical trials with large sample sizes producing narrow CIs. Multimedia Appendix 1 shows the Oxford Center for Evidence-Based Medicine levels of evidence.

Information on the target population, mechanism of feedback, evidence for efficacy or effectiveness, and commercial availability was obtained from the published material or websites. Only devices that claimed gait rehabilitation or gait quality improvement through any sensory feedback mode—visual, auditory, haptic (tactile or kinesthetic), or

vibration—were included. The devices were excluded if the technology was not targeted to any health condition or if it targeted high-functioning populations such as athletes or healthy individuals. The term *feedback* is defined as a physiological or performance signal arising as a result of human movement that, in turn, generates an output (error or correct performance) that is relayed back to the user and that has the potential to modulate (enhance or diminish) subsequent movement.

Results

Overview

The search yielded 17 wearable devices that claimed to target improvement in gait quality through various types of feedback: 11 (65%) were commercially available, and 6 (35%) were at various stages of research and development. Of the 11 commercially available devices, 2 (18%) were sold under the trademark WalkWithPath: Path Finder Laser Shoes and Pathfeel. The inclusion of the devices was appraised by KM and NEM. Table 1 presents a brief description of the devices (grouped into

insoles, wearable sensors, and vests or walking aids), feedback type, target condition, and components. The devices are organized according to availability: directly available to clients or only for research purposes and thus not commercially available. Among the 11 commercially available devices, there were 6 (55%) insoles, 4 (36%) wearable sensors, 1 (9%) vest, and 1 (9%) walking aid; for example, BalancePro insoles, which provide only passive sensory feedback, and FeetMe insoles, which have embedded sensors to provide different types of feedback, including electrical stimulation or an auditory signal. All technologies used a variety of biofeedback (positive,

negative, and continuous) and offered options for choosing or providing a single preset sensory stimulus—auditory, haptic, visual, or vibration—enabling users to set individual preferences. A few of the devices offered practitioners and consumers a choice to select the feedback frequency and type of stimuli. Regarding choosing the type of sensory stimulus, there is no information available on the efficacy of one sensory stimulus compared with that of another. Most devices target gait improvement for people with neurological conditions, specifically people with Parkinson disease.

Table 1. Description of gait training devices (1) available to consumers and (2) for research only.

Gait rehabilitation devices	Feedback type	Condition	Interface
Targeted: directly available to clients			
BalancePro: insoles with raised edges that provide passive sensory feedback on soles to enhance proprioception [48,49]	Haptic (continuous feedback)	Older adults, impaired circulation, and neuropathy	None
FeetMe Stimulate or Insole or Rehab: insoles with embedded sensors that collect gait and balance data and provide electrical stimulation at the foot or ankle to correct the gait pattern [50,51]	Auditory + ^a , haptic +, and visual +	Neurological conditions, obesity, chronic obstructive pulmonary disease, and older adults	Pressure and IMU ^b sensors in insoles, electrodes, and Android app
WalkWithPath (Pathfeel): insoles with embedded pressure sensors that provide vibration corresponding to the pressure detected to enhance sensory information coming from the foot [52,53]	Haptic vibration (continuous feedback)	Parkinson disease and peripheral neuropathy	Pressure sensors and Bluetooth connection to smartphone app
Vibrating Insoles (Wyss Institute): insoles that provide subthreshold vibration continuously to enhance natural sensory information coming from the foot to improve balance and step consistency [54,55]	Vibration (continuous feedback)	Recreational athletes, older adults, and neurological conditions	None
Voxx Human Performance Technology socks and insoles: socks or insoles with embedded tactile pattern under the ball of the foot that stimulates the neural system to encourage the brain into a state of homeostasis [56,57]	Tactile (continuous feedback)	Poor balance and fall risk	None
Walkasins: insoles attached to ankle unit that detect pressure under the foot and provide vibration just above the ankles to improve balance and gait [49]	Haptic vibration +	Asymmetric gait (stroke) and neuropathy	None
Heel2Toe: sensor worn over the shoe that provides real-time auditory feedback on making “good steps” in which the heel strikes first [58]	Auditory +	Parkinson disease and older adults	IMU sensor and Android app
MEDRhythms: 2 wearable sensors attached to each shoe that provide rhythmic auditory feedback based on gait parameters to improve gait [59,60]	Auditory +	Neurological conditions	Headphones, IMU sensor, and smartphone app
CuPiD/Gait Tutor: 3 wireless sensors that evaluate real-time quality of gait and provide vocal message to walk safely, effectively, and smoothly [61]	Auditory and visual – ^c	Parkinson disease	Smartphone, IMU sensor, and docking station
WalkWithPath (Path Finder Laser Shoes): lasers attached to shoes bilaterally activated by body weight on the stance foot emit a horizontal light line on the floor on the opposite side for user to step on or over [52,53]	Visual (continuous feedback)	Parkinson disease	None
ReMoD V5.0 Type 1: vest with attached sensors that detect postural deviations and provide electrical stimulation at the anterior shoulders to correct trunk position when the user deviates past the set threshold [62,63]	Electrical –	Stroke, scoliosis, poor posture, and sensory or vestibular dysfunction	None
Isowalk: self-propulsive cane that guides user’s step forward [64]	Haptic (continuous feedback)	Fall risk	None
Research only, not commercially available			
Artistic 2.0: insoles that detect asymmetries and use a smartphone app display, high or low tone beeps, or long or short vibrations at the ankle to encourage symmetry	Auditory, visual, and vibration –	Neurological conditions and amputations	Silicon insoles with force sensors, a microcontroller, Bluetooth, and Android app
Walk-Even: insoles detect uneven weight distribution and use a speaker on the waistband to signal to the user to change weight distribution (auditory cue), or nociceptive electric stimulation is given on the thigh of the unaffected leg to encourage faster movement of the paretic limb	Auditory – and nociceptive –	Asymmetric gait (stroke)	Hard wired
AmbuloSono: wearable sensor worn on the leg provides auditory feedback (music) once a preset threshold is reached; if steps are too small, the music will stop	Auditory +	Parkinson disease	IMU sensor, audio speaker, iPod Touch, and Bluetooth

Gait rehabilitation devices	Feedback type	Condition	Interface
CueStim: electrical stimulation unit with electrodes on the quadriceps or hamstrings that continuously ramp up and down to overcome shuffling and freezing of gait	Electrical (continuous feedback)	Parkinson disease	Electrostimulation device, Bluetooth, smartphone app, and electrodes
VibeForward: 2 vibratory tactors placed inside the user's shoes, a small electronics box containing a battery and an IMU sensor strapped around the ankle, and Bluetooth connection to a smartphone app; when activated by a switch on the device or a remote, the tactors provide vibration cycling from the hind foot to the forefoot in synchrony with the user's step; the smartphone app acts as a remote control for the vibration	Vibration –	Parkinson disease	Tactors, IMU sensor, Bluetooth, and smartphone app
Walk-Mate: wearable sensor that provides auditory feedback on foot-ground contact; used as a gait compensation device to promote consistent cadence and gait symmetry	Auditory –	Neurological conditions	IMU, computer, headphones, and hard wired

^{a+}: positive feedback.

^bIMU: inertial measurement unit.

^c–: negative feedback.

Effectiveness of Gait Training Devices

Textbox 1 presents information on population, intervention, control, outcomes, time, training, results, usability, and level of evidence with study design. Of the 11 commercially available devices, 4 (36%) have published evidence of efficacy reported in 10 studies with sample sizes ranging from 6 to 40: CuPiD/Gait Tutor, BalancePRO, Heel2Toe, and WalkWithPath [58,65-67]; for example, the BalancePro insoles are plastic insoles with a raised ridge around the perimeter that provide continuous haptic feedback and are targeted to people with Parkinson disease and older adults. The insoles are available for direct purchase on

the company website, and the design patent application is under review. The evidence supporting the BalancePro technology comes from 2 crossover study designs and 1 randomized controlled trial, all at level 2b of evidence using the Oxford Center for Evidence-Based Medicine scale.

Textbox 2 outlines some important areas that would help judge the usefulness of technologies targeting gait from the perspective of consumers. These areas emerged from this review because the needed information was either absent from the papers or inconsistently presented. The list of technology-relevant items presented in **Textbox 2** would be applicable for inventors publishing in the scientific literature.

Textbox 1. Evidence supporting the effectiveness of gait training devices.

BalancePro (studies: 3; level of evidence: 2b)

- Authors, year: Jenkins et al [66], 2009
 - Population: individuals with Parkinson disease, n=40: 16 women and 24 men; age-matched controls, n=40: 25 women and 15 men
 - Intervention: facilitatory shoe insole
 - Control: conventional flat insole
 - Outcome: spatiotemporal gait parameters measured using GAITRite mat and muscle activity measured using electromyography (in 20 people with Parkinson disease and 20 controls)
 - Time: concurrent trials
 - Training: 10 walking trials: 5 with facilitatory insoles and 5 with conventional insoles
 - Results: group effect on velocity, step length, and step length variability
 - Usability: not reported
 - Level of evidence, study design: 2b, crossover (website and PubMed)
- Authors, year: Maki et al [68], 1999
 - Population: older adults, n=14: 6 women and 8 men; 7 healthy controls
 - Intervention: modified insoles
 - Control: none
 - Outcome: center of mass displacement and stepping reactions using force plates
 - Time: concurrent trials
 - Experimental condition: multiple transient perturbations and continuous perturbations: 40 and 16, respectively, for older adults and 56 and 24, respectively, for controls
 - Results: facilitation reduced the number of forward step reactions to perturbations
 - Usability: not reported
 - Level of evidence, study design: 2b, crossover (website and PubMed)
- Authors, year: Perry et al [67], 2008
 - Population: older adults, n=40: 19 women and 21 men aged 65 to 75 years
 - Intervention: facilitatory insole
 - Control: conventional insole
 - Outcome: lateral displacement of center of mass in relation to base of support during single-support phase
 - Time: 12 weeks
 - Training: 12 trials on 4 uneven surfaces wearing each sole
 - Experimental: 12 weeks of wearing randomly assigned sole
 - Results: outcome effect for 2 of the 4 uneven surface conditions
 - Usability: lower fall rate in intervention (25% vs 45%); mild discomfort occurrences reported for 17 out of 240 wear-weeks; 17 out of 20 participants would continue wearing
 - Level of evidence, study design: 2b, randomized trial (website and PubMed)

Walk With Path (studies: 3; level of evidence: 2b)

- Authors, year: McCandless et al [69], 2016
 - Population: individuals with Parkinson disease, n=20: 14 men and 6 women; mean age 68 years; independently ambulatory indoors, with freezing of gait
 - Intervention: laser cane, sound metronome, vibrating metronome, and vibrating walking stick
 - Control: no cueing
 -

Outcome: frequency of freezing of gait episodes over 3-meter walk, first step length, second step length, forward center of mass velocity, sideways center of mass velocity, number of forward and backward sways and number of sideways sways, and forward center of pressure velocity (meters per second) and side-to-side center of pressure velocity

- Time: concurrent trials, 3 per device and 3 control (total: 15 trials per participant)
- Training: none
- Results: 12 out of 20 participants contributed 100 freezing and 91 nonfreezing trials; laser cane was most effective for freezing of gait and for movement strategies to reinitiate movement, whereas vibrating walking stick was second most effective; vibration metronome disrupt movement compared with the sound metronome at the same beat frequency
- Usability: not reported
- Level of evidence, study design: 2b, crossover (website and PubMed)
- Authors, year: Barthel et al [70], 2018
 - Population: individuals with Parkinson disease with freezing of gait, n=21: 5 women and 15 men
 - Intervention: visual cueing using laser shoes
 - Control: no cueing
 - Outcome: duration and number of freezing of gait episodes
 - Time: concurrent trials, 5 trials each during on medication and off medication periods
 - Training: (1) walking back and forth over 10 meters; (2) task 1 plus counting down from 100 in steps of 7 or 3; (3) turning on command while walking, including 180° and 360° right and left turns; (4) walking to pick up a cone at 7 meters and then back carrying the cone; and (5) walking around obstacles placed on the walkway
 - Results: cueing reduced the number of freezing of gait episodes, both off (45.9%) and on (37.7%) medication, reduced the percentage of time frozen during the off period by 56.5% (95% CI 32.5-85.8), and reduced the percentage of time frozen during the on by 51.4% (95% CI -41.8 to 91.5)
 - Usability: not reported
 - Level of evidence, study design: 2b, crossover (website and PubMed)
- Authors, year: Velik et al [71], 2012
 - Population: individuals with Parkinson disease with freezing of gait, n=7: 1 woman and 6 men
 - Intervention: 3 cueing conditions: no cue, visual cue on for 10 seconds whenever freezing occurred, and continuous visual cue
 - Control: no cues
 - Outcome: average duration and number of freezing episodes under 3 conditions
 - Time: concurrent trials
 - Training: 6 tasks to be performed: (1) standing up from a chair and getting a glass of water from the kitchen, (2) going with the glass of water to the bathroom and leaving it on the washbasin, (3) walking to the bedroom and picking up a clothes hanger from the cupboard, (4) carrying a clothes hanger to the washing room and leaving it there, (5) going back to the chair, and (6) performing tasks 1 to 5 in reverse order, starting with task 5
 - Results: continuous cueing: mean duration of freezing reduced by 51%, with 43% fewer freezing of gait episodes; on-demand cueing: mean duration of freezing reduced by 69%, with 9% fewer freezing of gait episodes
 - Usability: not reported
 - Level of evidence, study design: 2b, crossover (website and PubMed)

Heel2Toe (studies: 2; level of evidence: 2b)

- Authors, year: Mate et al [58], 2020
 - Population: older frail and prefrail persons, n=6: 4 women and 2 men
 - Intervention: supervised training with the Heel2Toe sensor, 5 sessions over 2 weeks
 - Control: none
 - Outcome: spatiotemporal gait parameters and system usability
 - Time: immediate and posttest feedback; end of training without and with feedback
 - Training: supervised gait training and walking practice with the Heel2Toe sensor providing feedback for good steps; prescription of 5 exercises, 1 per walking component

- Results: immediate and posttraining response: 5 of the 6 participants displayed meaningful changes in terms of good steps, angular velocity, and coefficient of variation, whereas 1 high-functioning person showed no change
- Usability: 38-item responses: 25/38 (66%) were at optimal levels, and 9/38 (24%) were at the poorest levels
- Level of evidence, study design: 2b, sequential pretest-posttest design (website and PubMed)
- Authors, year: Carvalho et al [72], 2020
 - Population: individuals with Parkinson disease, n=6: 4 women and 2 men
 - Intervention: supervised training with the Heel2Toe sensor, 5 sessions over 2 to 3 weeks
 - Control: none
 - Outcome: spatiotemporal gait parameters and system usability
 - Time: immediate pretest and posttest feedback; end of training without and with feedback
 - Training: supervised gait training and walking practice with the Heel2Toe sensor providing feedback for good steps; prescription of 8 mobility exercises
 - Results: immediate and posttraining response: of the 6 participants, 3 displayed meaningful changes in terms of good steps, 4 improved on angular velocity, and 1 reduced coefficient of variation
 - Usability: 24-item responses: 17/24 (71%) were at optimal levels, and 9/24 (37%) were at the poorest levels
 - Level of evidence, study design: 2b, randomized clinical trial (website and PubMed)

CuPiD/Gait Tutor (studies: 2; level of evidence: 2b)

- Authors, year: Ginis et al [65], 2016
 - Population: individuals with Parkinson disease, n=40: 8 women and 30 men independently ambulatory for at least 10 minutes, with freezing of gait
 - Intervention: supervised weekly visits for 6 weeks plus recommendation to walk at least 3 times per week for 30 minutes with feedback and cues provided separately
 - Control: walking training with no feedback
 - Outcome: gait speed, stride length, and double support time for comfortable gait and dual-task gait conditions; balance evaluated using Mini Balance Evaluation Systems Test; Four Square Step Test; Falls Efficacy Scale-International; 2-minute walk test; freezing of gait; Unified Parkinson's Disease Rating Scale, part III; cognition; and quality of life
 - Time: pretest-posttest training (6 weeks) and retention (4 weeks)
 - Training: weekly home visits for 6 weeks
 - Results: single-task and dual-task gait speeds improved within group at posttest and follow-up assessments; intervention group improved on balance at posttraining assessment
 - Usability: not reported
 - Level of evidence, study design: 2b, randomized clinical trial (website and PubMed)
- Authors, year: Ginis et al [52], 2017
 - Population: individuals with Parkinson disease, n=28: 5 women and 23 men; 14 age matched
 - Intervention: 4 walks (continuous and intelligent cues, intelligent feedback, no information) over 6 weeks with at least 1 week between walks
 - Control: no information
 - Outcome: cadence, stride length, and fatigue
 - Time: concurrent trials
 - Training: comfortable 1-minute reference walk before testing
 - Results: decrease in cadence in participants with Parkinson disease without cues or feedback; participants with Parkinson disease reported more fatigue with continuous cueing and intelligent feedback; increase in coefficient of variation in cadence in participants with Parkinson disease; and less variation in cadence with continuous and intelligent cueing in participants with Parkinson disease
 - Usability: reported
 - Level of evidence, study design: 2b, crossover (website and PubMed)

Textbox 2. Suggested content for reporting guidelines for the clinical appraisal of devices targeting movement and mobility.

<p>Problem to be addressed: gap that the technology is filling</p> <ul style="list-style-type: none"> • Functionality: assessment, treatment, or both • Technology type: implant, robot, exoskeleton, biosensors, virtual or augmented reality, assisted living technologies, wearables, smart devices, trackers, remote monitoring, and chatbots • Technology: describe in a way that it can be pictured without an image • Level of technology: technology readiness level (levels 1 to 9) [48] • Population: (1) health condition and special selection criteria and (2) level of technology readiness • Technology: country-specific regulatory authority classification of the medical device; mechanism of action: actual or hypothesized; reliability of algorithm used in the technology; and comparability with existing methods: (1) comparing assessments: competing technologies and (2) comparing treatments: sham, nothing, usual care, alternative form of technology, alternative intervention, and attention control • Experimental protocol: as per Consolidated Standards of Reporting Trials (CONSORT) or other reporting guidelines [50] or as per the Template for Intervention Description and Replication (TIDieR) and other reporting guidelines [56] • Outcomes: biofunctional model linking the technology to proximal and distal outcomes: <ul style="list-style-type: none"> • Proximal (explanatory) outcomes: technological metrics and impairment level from the patient's perspective • Primary (confirmatory) outcomes: clinically assessed activity outcomes (capacity) • Distal (exploratory) outcomes: real-world assessed activity outcomes (performance) and health-related quality of life <p>Source of information: patient-reported outcomes, self-reported outcomes, performance outcomes, and technologically assessed outcomes [64]</p> <ul style="list-style-type: none"> • Results: as per CONSORT or other reporting guidelines; distributional parameters presented for every outcome, every time point, and every transition • Safety: symptoms (new or aggravated), allergies, injuries, abrasions, and falls • User experience: qualitative and quantitative information on positive and negative experiences with the technology; actions taken to remedy negative experiences <ul style="list-style-type: none"> • Usability: quantitative measure of perceived usability • Adoption: data on short-term uptake and data on long-term use • Level of evidence: level of evidence classification system specified

Discussion

Principal Findings

This review identified a total of 17 wearable biofeedback devices targeting gait patterns and walking behavior. Of these 17 devices, 11 (65%) are commercially available to the public and have a dedicated website for direct purchase. Of these 11 devices, 4 (36%) had published evidence on effectiveness at level 2b according to the Oxford Centre for Evidence-Based Medicine scale (Textbox 1). There was no searchable evidence available for the efficacy or effectiveness of the feedback from the remaining gait training technologies (7/11, 64%). Evidence is primarily generated for 1 health condition, but the claims are generalized to other health conditions with similar gait impairments. There was limited to no data available on accuracy, reliability, usability, and safety. Almost all websites presented user reviews or testimonials, which are likely to be selective in favor of supporting the technology. It is important for clinicians to be aware that some scientific evidence supporting the technology may exist, but a consumer is most likely unable to access the published material. A consumer may be driven to purchase a device or not merely by reading reviews or testimonials.

This review provides a summary of commercial wearable gait training technologies that are currently available in the market or the development phase. A unique feature of this review is that it was conducted from a consumer's perspective and then augmented by summarizing the evidence from scientific publications. Although the strength of the evidence supporting the effectiveness of these technologies is low or moderate at best, the claims on the website often outweigh the evidence. The results of our review can also be used by professionals involved in gait rehabilitation to direct their clients to promising technologies based on available evidence. These technologies can also be incorporated into treatment plans.

Comparison With Prior Work

Several of the papers (9/10, 90%) that contributed evidence toward the efficacy and effectiveness of the wearable sensors failed to capture or report patient-centered outcomes or declared level of evidence. In summary, the quality of evidence was low. Only 36% (4/11) of the devices had searchable evidence for efficacy potential, with all studies being small-sample sized (Textbox 1). This calls into question the strength of the evidence and the generalizability of the findings outside the study population. Although the mechanism of action and information on spatiotemporal gait parameters have been reported for all

devices, it is important to provide information on walking speed, distance, physical function, and walking behaviors such as step count or walking bouts. Overall, the approach to statistical analysis is rudimentary, and inference is mainly based on within-group *P* values rather than CIs. Lack of raw data in the published manuscripts, such as mean, median, SD, and range, prevented a calculation of between-group effects, effect sizes, and reliable change among other metrics that can potentially provide more interpretable information. Sample sizes are typically small, leading to a high degree of uncertainty in the results. Very few papers (4/10, 40%) reported information on missing data or steps taken to account for missing data and the potential impact on the conclusions.

Strengths and Limitations

There is a challenge in searching for information on technology. A 2022 review evaluated the type and quality of information available on the web for aquatic physiotherapy targeted to people with Parkinson diseases [59]. The authors used a commercial *social listening* service Awario that searches social media platforms (eg, Twitter and Instagram) and the web for investigator-selected keywords [59]. The strategy used here was a form of *snowball* sampling where systematic reviews served as the source, and the web was searched for any devices named in these reviews.

Many commercial technology companies reported ≥ 1 clinical trials that are underway; yet, there is a lack of trial-specific information. A potential consumer is unlikely to track these details. It is important to consider the transparency and accessibility of scientific evidence when making evidence-based recommendations to consumers. There is limited research in this area, specifically from a consumer's perspective. Although there is a need to provide therapy outside clinical settings, it is critical that companies marketing technologies do not *scam* people into buying products that are possibly noneffective or even harmful and that clear reporting standards for consumers are made mandatory for these technologies, similar to those now standard for food.

The approach taken here may not have yielded complete results, and, because new technologies are continually developed and added to or removed from the market, the results can quickly become out of date. Many technologies are developed in research settings and are not given a proprietary name until there is evidence to support commercialization. Hence, searching for earlier information is impossible. In addition, the inventors, the authors of the papers, and the entrepreneurs commercializing the technology may not be the same people; hence, an author search will also be fruitless. CuPiD/Gait Tutor is an example of a name change [61,65]. Finally, there is no *gold standard* for rigorous, systematic gray literature search methods, and there are few resources on how to conduct this type of search; for example, the Cochrane Handbook, often cited as the gold standard for conducting systematic reviews, provides limited guidance and specificity for gray literature search methods [62]. In addition, the reporting of gray literature search methods in systematic reviews is often not held to the same high standards in transparency and reproducibility as the academic database search methods.

Therefore, the findings of this review are only valid based on the search conducted at the time. Given the difficulty in searching for gait training technologies, the search method reported here may be difficult to reproduce. Nevertheless, the information presented on the technologies discovered in this search uncovers existing gaps in the evidence and the reporting.

Future Directions

As newer technologies for gait training are continually developed, it is important that the evidence supporting their efficacy and effectiveness is quickly made available to people to make an informed choice. Often, the published literature is unavailable to the general population because of journal paywalls. There was also a lack of consistency in reporting information related to usability, safety, or user feedback. Standards for reporting on research involving technological devices, in the form of reporting guidelines, seem to be a critical need to ensure that the data needed by the potential consumer are communicated.

There are several reviews on the efficacy and effectiveness of gait training technologies. One objective of the research is to build capacity and empower patients who wish to take charge of their health. By equipping people living with gait impairments with the opportunity to improve walking outside clinical settings through biofeedback is a step in the right direction, given the limited access to rehabilitation services. A few technological innovations were initiated along the commercialization path but were abandoned at different stages. Despite the many benefits of at-home therapy, some challenges exist, including device maintenance, battery life, and technological literacy. One study suggests that the most effective devices are those that have a "user-centered design," meaning patients or practitioners are involved in the design process [30]. Many of the devices included in this review use this approach by consulting patients for feedback on comfort, ease of use, and preferred feedback modes, when applicable, during pilot studies.

Although there is strong interest from academic institutions and government agencies to transfer technologies from laboratories to clients, there is a need for due diligence on the part of both the institutions and industry to accurately report all the findings that not only support the science but will also influence a client's or an organization's decision to purchase the technology.

Research in the field of technology development seems to lack the rigorous research method standards required for drug testing, allowing some devices to enter the market based mainly on safety rather than efficacy. Almost all commercial devices overclaim the efficacy of the technology to other populations not supported by their research; for instance, a website will claim effectiveness for people with gait impairments when the device was tested only in people with Parkinson disease. Finally, it would truly benefit the general public to have a summary of the research in layperson's terms similar to food standards.

The field of technology evaluation would benefit from reporting guidelines to extend the guidelines for reporting on randomized clinical trials (eg, Consolidated Standards of Reporting Trials [CONSORT]), such as are available for many different types of experimental studies, including pilot and feasibility studies

and crossover designs, all of which can be found on the Enhancing the Quality and Transparency of Health Research (EQUATOR) website [54]. There are also guidelines for reporting on the features of the intervention (Template for Intervention Description and Replication [TIDieR]), which would be helpful to fully understand the intervention protocol and encourage replication [56]. For technology, it would be useful to provide additional information on user experience using both closed- and open-ended formats to identify challenges that users encounter with the technology.

Conclusions

This review is the first of its kind from a consumer's perspective that critically appraises wearable biofeedback gait devices found on the internet, the literature available on the respective websites, and the strength of evidence supporting the claims. The review highlights the need for providing standardized reporting of device capabilities as information accessible to the public when marketing commercialized devices. This review provides the public and health care practitioners with a summary of information that can be used to choose wearable biofeedback gait technologies or decide not to adopt them. The review covers 17 wearable devices that provide 1 form of feedback to improve

gait and outlines the mechanisms claimed to underlie gait improvement. There was no predominance for biofeedback type (positive, negative, or continuous). A variety of biofeedback modes have been used (auditory, visual, or haptic), with auditory and vibratory haptic being the most common. The strength of the evidence supporting these devices from scientific sources was at 2a (lower randomized controlled trial) or 2b (prospective controlled trial—not randomized) level. Gaps in reporting all needed information for the consumer were uncovered. The propensity of small trials and heterogeneity of studies and conditions highlight the requirement for standardizing reporting of feedback intervention measures and doses to enable meta-analyses to move gait technological rehabilitation forward. Of note, there is a lack of evidence for motor learning interventions even in the field of sport, with a need for current evidence to be extended by theory-driven, high-quality studies to allow for more consolidated and evidence-based recommendations. Technology has the potential to advance the rehabilitation space and enable a better understanding of optimal interventions for learning and maintaining skills. Taken together, our findings target the need for clear reporting standards for gait interventions.

Conflicts of Interest

KKVM, AA-S, HD, and NEM are cofounders of the start-up PhysioBiometrics Inc, with the Heel2Toe sensor as a flagship product.

Multimedia Appendix 1

Oxford Centre for Evidence-Based Medicine levels of evidence. <https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009>.

[PNG File, 151 KB - [rehab_v10i1e40680_app1.png](#)]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials

EQUATOR: Enhancing the Quality and Transparency of Health Research

TIDieR: Template for Intervention Description and Replication

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Review

Models of Telehealth Service Delivery in Adults With Spinal Cord Injuries: Scoping Review

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Abstract

Background: In Canada, approximately 86,000 people live with spinal cord injury (SCI), and there are an estimated 3675 new cases of traumatic or nontraumatic etiology per year. Most people with SCI will experience secondary health complications, such as urinary and bowel issues, pain syndrome, pressure ulcers, and psychological disorders, resulting in severe chronic multimorbidity. Moreover, people with SCI may face barriers in accessing health care services, such as primary care physicians' expert knowledge regarding secondary complications related to SCI. Telehealth, defined as the delivery of information and health-related services through telecommunication technologies, may help address some of the barriers, and indeed, the present global COVID-19 pandemic has emphasized the importance of integration of telehealth in health care systems. As a result of this crisis, health care providers have increased the usage of telehealth services, providing health services to individuals in need of community-based supportive care. However, the evidence on models of telehealth service delivery for adults with SCI has not been previously synthesized.

Objective: The purpose of this scoping review was to identify, describe, and compare models of telehealth services for community-dwelling adults with SCI.

Methods: This scoping review follows the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines. Studies published between 1990 and December 31, 2022, were identified by searching the Ovid MEDLINE, Ovid Embase, Ovid PsycINFO, Web of Science, and CINAHL databases. Papers with specified inclusion criteria were screened by 2 investigators. Included articles focused on identifying, implementing, or evaluating telehealth interventions, including primary health care services and self-management services delivered in the community and home-based settings. One investigator performed a full-text review of each article, and data extraction included (1) study characteristics; (2) participant characteristics; (3) key characteristics of the interventions, programs, and services; and (4) outcome measures and results.

Results: A total of 61 articles reported telehealth services used for preventing, managing, or treating the most common secondary complications and consequences of SCI, including chronic pain, low physical activity, pressure ulcers, and psychosocial dysfunction. Where evidence exists, improvements in community participation, physical activity, and reduction in chronic pain, pressure ulcers, etc, following SCI were demonstrated.

Conclusions: Telehealth may offer an efficient and effective option for health service delivery for community-dwelling individuals with SCI, ensuring continuity of rehabilitation, follow-up after hospital discharge, and early detection, management, or treatment of potential secondary complications following SCI. We recommend that the stakeholders involved with patients with SCI consider the uptake of hybridized (blend of web-based and in-person) health care delivery models to optimize the care continuum and self-management of SCI-related care. The findings of this scoping review may be used to inform policy makers, health care professionals, and stakeholders engaged in establishing web-based clinics for individuals with SCI.

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KEYWORDS

community-dwelling adults with spinal cord injury; models of telehealth services; remotely delivery of health care; SCI; scoping review; spinal cord injury; telehealth; telemedicine; telerehabilitation; web-based care

Introduction

Background

In Canada, approximately 86,000 people live with spinal cord injury (SCI), with an additional 3675 new cases each year [1]. SCI leads to a full or partial loss of sensory, motor, and autonomic function that can be severe and often life-threatening [2]. SCI is commonly classified by distinct characteristics of the injury, such as the mechanism of injury (traumatic or nontraumatic), type of injury (complete vs incomplete), level of neurological spinal injury (cervical-, thoracic-, lumbar-, and sacral-level injuries), and the severity of injury widely rated by American Spinal Injury Association Impairment Scale [3].

SCI may result in severe chronic morbidity from secondary complications that can be chronic in nature [4] and include respiratory concerns, urinary and bowel issues, chronic pain, pressure ulcers, psychosocial complications, bone fracture, and osteoporosis [4]. These may lead to decreased functional independence, health-related quality of life, and community participation, as well as increased rates of hospitalization and loss of employability [5]. Thus, despite the relatively low incidence and prevalence rates of SCI, the associated health conditions contribute to a significant economic impact and financial burden for the patients and their caregivers [6]. In Canada, the net lifetime cost of a person with SCI is estimated to vary between CAD \$1.5-\$3 million (US \$1.10-2.21) [6], and evidence suggests that the direct health care cost of people with SCI is 8 times that of their non-SCI age-matched peers [6]. Therefore, strategies that focus on prevention, early detection, and management of the sequelae of SCI are critical to improve functional level and quality of life of community-dwelling adults with SCI [5,7,8]. Improved self-management skills, rehabilitation, and access to proactive multidisciplinary health care teams are needed to reduce the morbidity and mortality rates associated with chronic conditions in patients with SCI, as well as alleviate the economic burden [9,10].

People with SCI may face several barriers in accessing health care services, including lack of transportation, physical obstacles, lack of preventative health screenings, and primary care physician's expert knowledge regarding secondary complications and preventative care issues related to SCI [11,12]. Research suggests that adequate access to primary health care services may reduce the risk of developing long-term secondary complications associated with SCI as well as chronic illnesses [11,12]. However, a scoping review by McColl et al [12] found that despite patients with SCI being significantly dependent on primary care, their various medical needs, especially those related to rehabilitation services, are poorly met [12].

Telehealth is a strategy that may help to fill unmet care needs among individuals with SCI. Telehealth is defined as the delivery of information and health-related services through telecommunication technologies [13]. Moreover, the present

global COVID-19 pandemic has further emphasized the importance of telehealth, facilitating the continuation of primary health care services for patients who need supportive care [14]. Telerehabilitation is a growing application of telehealth that involves the remote delivery of rehabilitation services, including training, education, self-management, compensatory strategies, and monitoring, to patients with impairments and disabilities [14]. Literature suggests that several telerehabilitation and telehealth programs exist, particularly for patients with SCI, ensuring continuity of rehabilitation and follow-up after discharge to prevent secondary complications [11]. As telehealth is increasingly used to help with the delivery and follow-up of health care services, especially during the present global COVID-19 pandemic, there remains a need to determine the status of telehealth for community-dwelling adults with SCI.

Objectives

With the increasing use of telehealth for delivery and follow-up of health care services for patients with SCI, a scoping review was conducted to systematically review and identify the gaps in the literature. The scoping review is an emerging literature synthesis method that emphasizes covering broad, comprehensive objectives and research questions rather than a particular standard of evidence [15]. This methodological approach is particularly useful when addressing a concept with emerging evidence that applies to telehealth research targeting the SCI population. The purpose of this scoping review was to identify, describe, and compare models of remotely delivered rehabilitative interventions and health services for patients with SCI living in the community. The research question guiding this scoping review was "What models of telehealth and telerehabilitation services are available to community-dwelling adults with SCIs?" Through this review, we identified (1) characteristics (eg, types of telerehabilitation services provided, format, delivery, intensity, frequency, duration, technology component, underlying framework or theories, etc) of distinct telehealth interventions and services used to prevent, treat, and manage secondary complications of SCI; (2) characteristics of the target population (eg, age, sex, level of injury, time since injury, related secondary complications, etc); (3) characteristics of studies conducted (eg, qualitative, quantitative, mixed methods, systematic reviews, scoping reviews, etc); and (4) outcomes examined. The findings of this scoping review would be tailored toward informing the key stakeholders who are involved in establishing a web-based clinic for community-dwelling adults with SCI in a postpandemic world in Ontario, Canada, which is the ultimate goal of this project.

Methods

This scoping review was performed in accordance with the framework from Arksey and O'Malley [15]. The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) was also used

to guide the reporting of this scoping review (see [Multimedia Appendix 1](#) for completed PRISMA-ScR checklist) [16].

Eligibility Criteria

To be included in this review, articles needed to focus on the identification, implementation, and evaluation of telehealth and

telerehabilitation interventions, including primary health care services and self-management services delivered in the community and home-based settings. Refer to [Textbox 1](#) for details on the inclusion and exclusion criteria.

Textbox 1. Summary of inclusion and exclusion criteria.

<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Qualitative, quantitative, mixed methods studies, sources of expert opinion, textual and narrative data, and reviews • Community-dwelling adults with spinal cord injury (SCI) • Adults aged 18 years or older • Studies conducted in high-income countries as the results of this research were specifically tailored to the Canadian SCI community based on the North American health care system. • Published between 1990 and December 2022 • Articles reported in English <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Abstracts only, conferences and posters, study protocols without the published full-text article, editorial letters, and 1-page commentaries • Person with SCI who is not living within the community (ie, being treated as an inpatient) • Person who is younger than 18 years • Studies conducted in middle- or low-income countries • Published before 1990 as the majority of research on the topic of telehealth and thus the use of telecommunication technologies to aid the delivery and follow-up of health care services occurred after this date. • Non-English studies

Search Strategy and Information Sources

A comprehensive search strategy was performed by the primary investigator (SM) to include all relevant literature published between 1990 and December 31, 2022, using the following databases: Ovid MEDLINE (1946-Dec 2022), Ovid Embase (1974-Dec 2022), Ovid PsycINFO (1806-Dec 2022), Web of Science, and CINAHL (1985-Dec 2022). Initially, the review was planned to consider the literature for 3 separate themes. Theme 1: primary care services delivered remotely to patients with SCI; theme 2: telerehabilitation services delivered remotely to patients with SCI; and theme 3: self-management interventions delivered remotely to patients with SCI. However, following consultation with a Medical Librarian in Health Sciences at McMaster University, the authors ran 1 overarching search using medical subject headings and text words related to web-based care and SCIs. Investigators reviewed the final search results to ensure all the initial theme-based articles were included in the overarching search result that was planned to be used, followed by the final decision to select the most appropriate search strategy. The final search strategies can be found in [Multimedia Appendix 2](#). A manual search of the reference lists of recent studies was conducted to ensure the inclusion of all relevant articles in the scoping review. Previously published systematic, narrative, and scoping reviews of related topics were reviewed for related results to ensure all relevant references were included in this review.

Study Selection

Eligible articles were identified using a 3-step process. In step 1, one reviewer (SM) collected the search results and then removed the duplicates. In the second step, 2 reviewers (SM and AM) independently reviewed the titles and abstracts of the identified articles that appeared to meet the inclusion criteria. In step 3, the same reviewers evaluated the full texts of the remaining publications identified by our searches to include potentially relevant publications. Covidence software was used to support and synthesize the process of scoping review production [17]. Discrepancies were resolved through discussion between the reviewers. If reviewers failed to reach a consensus, a third expert reviewer (JR) was consulted for the final decision about inclusion.

Data Extraction

Data from eligible studies were extracted using data extraction forms developed by the research team (refer to the [Multimedia Appendix 3](#)). Two separate data extraction tools were designed for qualitative and quantitative studies. Information extracted from studies included study characteristics (eg, year of publication, country of study, purpose of the study, and study design), participant characteristics (eg, age, sex, time since injury, detail of SCI, and secondary complications related to SCI), key characteristics of the interventions, programs, and services (eg, description, the format of delivery, facilitator, duration, frequency, intensity, underlying theories for the intervention, types of intervention, and the type of technology modality), outcome measures, and results. The extracted results

were examined to determine trends in telehealth service components and characteristics among community-dwelling adults with SCI. For qualitative studies, themes and findings were collated by the lead reviewer (SM).

Data Synthesis

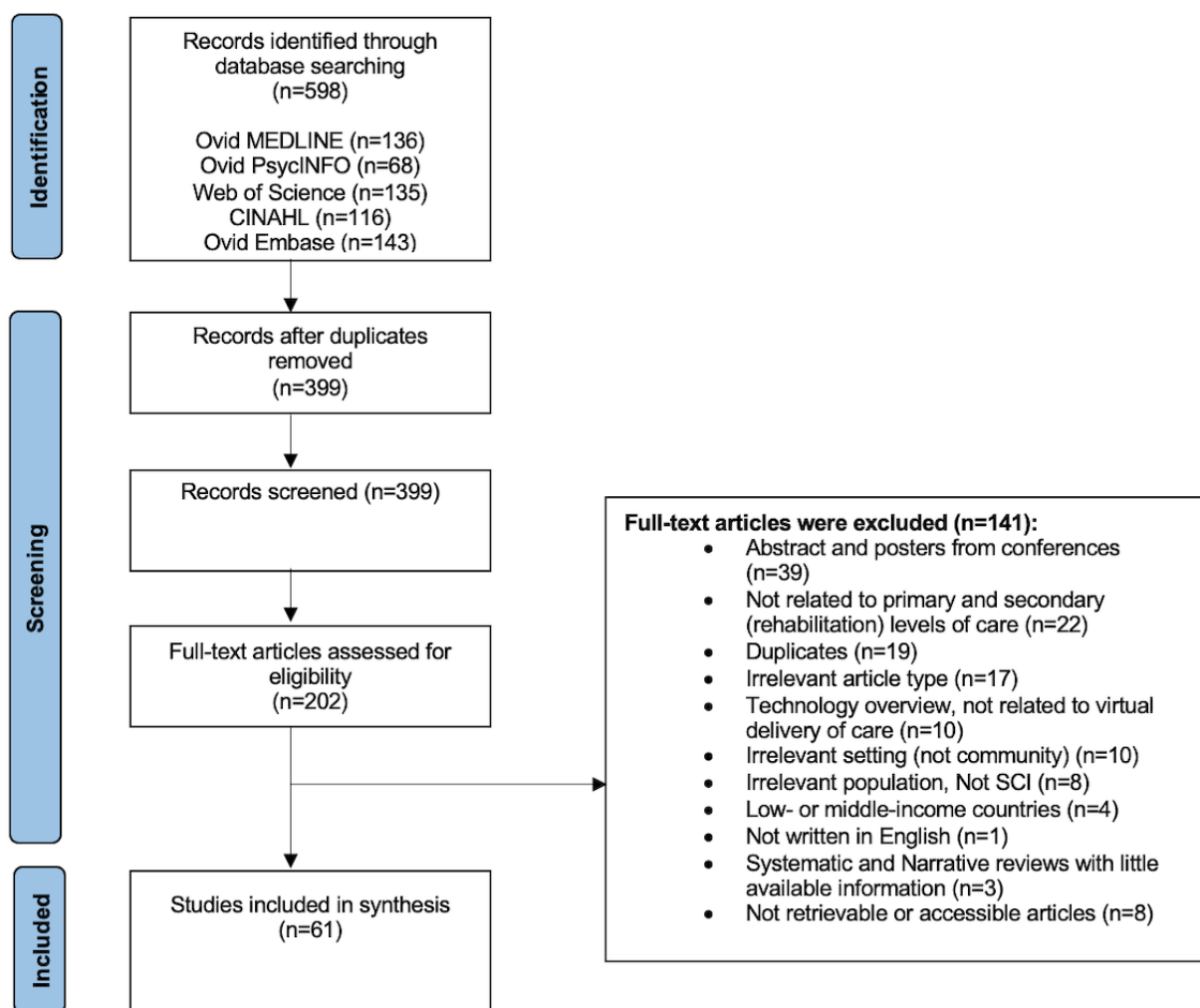
In this review, the extracted results were classified under the main categories for which the services were delivered. In this study, the extracted data were synthesized using both numerical and descriptive analysis, providing both a narrative description of the quantity of articles that address particular issues and a descriptive overview of the types of evidence available on this topic of interest.

Results

Source of Evidence

Initially, 598 studies were imported into the Covidence software. After duplicates were removed, 399 citations were detected from searches of electronic databases and article references. After the title and abstract screening, 202 articles were included for the full-text review process. Of these 202 articles, 141 were excluded (see [Figure 1](#) for reasons), and 61 studies met the inclusion criteria. Data extraction was completed for the remaining 61 studies, which were considered eligible for this review. The PRISMA flowchart is shown in [Figure 1](#).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart. SCI: spinal cord injury.



Study Characteristics

A descriptive summary for each experimental and nonexperimental study is included in [Multimedia Appendices 4 and 5](#), respectively [7,11,13,14,18-75].

The included papers consisted of 14 qualitative studies, 29 quantitative studies conducted in one-on-one format, 4 mixed method studies, 4 systematic reviews, 2 scoping reviews, 5 conceptual reviews, 2 narrative reviews, and 1 meta-analysis.

These studies were conducted in 9 countries: the United States (n=32), Canada (n=13), Australia (n=7), Italy (n=2), South Korea (n=2), the United Kingdom (n=1), the Netherlands (n=1), Sweden (n=1), and Norway (n=2). The first article on telehealth for SCI community-dwelling adults with SCI was published in 1997, with an upward trend starting in 2015 with 51 related articles published on this topic in the last 18 years.

Participant Characteristics

The mean sample size of the included articles was relatively small, with an average of 59 participants, but ranged from 1 to 15,028 across quantitative (n=29) and qualitative (n=13) studies that specified sample size. The age of participants ranged from 18 to 85 years.

SCI Type

Approximately, only half of the included studies (n=34) reported the injury characteristics of the participants. The type of SCI was indicated by 2 studies, where participants had both traumatic and nontraumatic injuries [20,21]. Injury levels (ie, cervical, thoracic, and lumbar spine injuries), neurologic completeness, and paralysis (paraplegia and tetraplegia) varied among the participants of the included studies, indicating heterogeneous nature of participants under investigation.

Outcomes

Physical Activity and Leisure Time Physical Activity Motivation and Participation

A total of 14 articles focused on improving physical activity (PA) and leisure time physical activity (LTPA) participation, motivation, and exercise endurance [18,20,21,23-25,27,36,43,45-47,49,50]. There were 11 articles that quantitatively assessed the effectiveness of interventions and services to improve motivation and participation in PA and LTPA (Multimedia Appendix 4) [18,20,21,23-25,27,36,43,45,46]. Of the 11 studies, 3 (27%) used telephone counseling sessions [21,24,43], 4 (36%) studies applied web-based applications or platforms providing contents (ie, modules, homework, videos, and email or phone support from a provider, coach, or peer) [18,23,45,46], 1 (9%) study employed wearable sensors connected to a mobile phone, transferring collected data to a server [25], and the remaining 3 (27%) studies used videoconferencing software (video-telehealth) as a means of delivering home-based exercise interventions [20,27,36]. The duration of the interventions ranged between 2 and 6 months. A total of 9 (82%) [18,21,23-25,27,36,43,45] of the 11 studies described the planned frequency of contact with the provider, ranging from once a week to once a month, while only 1 (9%) study did not report the frequency of peer and provider interaction [46]. All 11 studies provided a combination of services aimed at monitoring, providing feedback, and providing motivational and informational support to the target population. Overall, 6 studies [18,21,27,43,46,47] indicated that an exercise, PA, or LTPA counselor provided the intervention, whereas 2 studies [43,46] reported registered kinesiologists who were trained in motivational interviewing techniques and behavioral change theories and facilitated the service provision. In contrast, 4 studies [23,24,49] reported that an experienced physiotherapist monitored the self-regulatory interventions. Only 1 study [36] reported that the telehealth coordinator monitored the training of the participants involved in the videoconference program. The outcomes most frequently used for measuring PA and LTPA were the 7-day Self-report LTPA Questionnaire and World Health Organization Quality of Life BREF Scale. In most of the studies (n=10) [18,21-23,25,27,36,43,45,46], the interventions had favorable outcomes, elevating the participant's

engagement in LTPA and PA levels. One pilot randomized controlled trial (RCT) [46] was designed to pilot-test a telehealth intervention, grounded in the self-determination theory, to improve PA and quality of life among patients with SCI. The results of this pilot RCT [46] showed that telephone counseling represents a promising way to decrease health care use during the first year following SCI. Another pilot RCT [24] was conducted to test the effectiveness and feasibility of telephone counseling interventions compared to standard care of increasing physical fitness and reducing medical complications in patients with SCI, indicating no improvement in LTPA and PA levels but decreased depressive symptoms [24].

Chronic Pain

A total of 2 quantitative pre-post studies [32,38] and 1 qualitative study [52] focused on self-management strategies for reducing chronic pain in adults with SCI (see Multimedia Appendices 4 and 5). Of the 2 quantitative studies, 1 used a web-based chronic pain program, while the other used videoconferencing software (video-telehealth) to educate participants on self-management skills and exercise training to reduce pain, respectively [32,38]. In both studies, an experienced physiotherapist monitored and contacted participants if needed [32,38]. All studies reported the duration of the intervention, which ranged between 8 weeks and 6 months. By contrast, only 2 studies noted the frequency of contact, which ranged from 3 times per week to 2 calls per month [32,52]. The 2 quantitative studies reported on the measures used to assess chronic pain, including the Pain Disability Index [38], Pain Self-efficacy Questionnaire [38], and the Shoulder Rating Questionnaire [32], which measures upper extremity function and pain intensity. The 2 quantitative studies demonstrated reduced pain and improved pain-related disability among adults with SCI [32,38]. Both chronic pain and psychosocial outcomes were targeted by 1 study, resulting in a reduction in pain and depression and improved life satisfaction [38]. The qualitative study, which explored peer health coaches' role as provider, highlighted the important role of peer health coaches in promoting chronic pain self-management strategies among peers with SCI [52].

Pressure Ulcers, Sores, Injuries, and Skin or Wound Care

Overall, 11 articles specifically focused on prevention, treatment, or self-management of pressure ulcers and wound care (see Multimedia Appendices 4 and 5) [30,34,37,53-59,72]. Out of the 11 articles, 4 (36%) studies used a videophone (Picasso AT&T) modality to transmit still images and audio over a standard telephone line and to hold audio-video consultation sessions with the SCI population [30,37,53,54]. All 4 studies provided monitoring, wound and pressure ulcers management services, and informational support. The frequency of contact with providers varied, with an average of 7 visits per month. The duration of interventions varied from 6 weeks to 12 weeks. The only outcome measure used to assess pressure ulcers was the Pressure Ulcer Scale for Healing tool version 3.0 [53]. All the interventions demonstrated favorable results in successfully managing pressure injuries and wounds through telehealth. One recent RCT [72] on health-related quality of life and satisfaction of patients with SCI and pressure injuries

receiving real-time multidisciplinary videoconference consultations (video-telehealth) found videoconference-based care to be a safe and efficient way of managing pressure injuries, particularly for those individuals requiring long-term follow-up care and living far from the wound specialists. A total of 2 systematic reviews [55,56] and 1 scoping review [57] identified evidence to inform the development of telehealth techniques used to prevent, treat, and self-manage pressure ulcers in patients with SCI following discharge. One qualitative study that used semistructured interviews [34] and 1 modeled analysis [58] reported on patients' experience using an educational mobile app for pressure ulcer prevention and evaluated costs and savings associated with telehealth services for preventing and treating pressure ulcers, respectively. The results of the modeled analysis found that telehealth services were less expensive than standard care when low-cost technology was used but more expensive in cases where high-cost interactive devices were applied in patients' home settings [58].

Psychosocial Function

A total of 8 articles focused on the effects of telehealth services in reducing psychosocial problems such as depression, anxiety, life satisfaction, community participation, and reintegration (see [Multimedia Appendices 4 and 5](#)) [13,28,40,41,51,60-62]. Telehealth modalities and delivery methods included telephone counseling through simple telephone lines [13,61,62], mobile apps [28], video-based counseling sessions using videoconferencing software (video-telehealth) [13], and web-based applications on any devices accessing internet networks [40,41,51]. In 2 studies involving telephone and video counseling sessions, interventions were provided by a trained nurse and peers who have lived experience with SCI trained in motivational interviewing techniques [13,28]. In 2 studies, patients used the web-based interventions independently without facilitator involvement or supervision [40,41]. The most frequent measures used to assess psychosocial functioning were Depression, Anxiety, and Stress Scale-Short Form [40,41], the Quality of Well-Being Scale [13,41], Craig Handicap Assessment and Reporting Technique Short Form 10 assessing community participation [26,29,41,42], and Patient Health Questionnaire-9 measuring depression severity [28]. The results from the 4 studies were inconsistent in the effects of psychosocial treatments on depressive symptoms, life satisfaction, and quality of life. Improvements in depressive symptoms were demonstrated in 2 studies, such as improved sleep and psychomotor symptoms, positive appetite changes, and increased energy [40,41]. In contrast, 2 studies, including an RCT [28], exploring the use of the mobile app (iMHere) on psychosocial outcomes, showed no improvement in psychosocial and health-related quality of life outcomes [13,28]. Overall, 2 qualitative studies reported on models of service delivery supporting community reintegration and efficiency of psychological interventions delivered by telephone on emotional outcomes [51,60]. One meta-analysis and 1 systematic review evaluated the impact of remotely delivered psychological interventions on the psychological functioning of adults with SCI [61,62]. The systematic review [62] results indicated telecounseling enhanced management of common comorbidities following SCI, including pain and sleep difficulties. The

meta-analysis [61] results demonstrated significant enhancement in coping skills and strategies, depression, and community reintegration following SCI. Ten studies used a cognitive behavior change theory and psychological principle in addressing cognitive behavioral aspects of psychosocial conditions following SCI [20,21,26,38,40,41,43,46,50,51].

Addressing Multiple Secondary Complications

Twenty studies focused on multiple secondary complications, including pressure ulcers or wound care, urinary tract infections, a range of psychosocial problems, and community participation, instead of addressing a single complication (see [Multimedia Appendices 4 and 5](#)) [7,11,14,22,26,29,31,39,42,44,48,63-66,69,70,73-75]. From the 7 studies [7,26,29,31,42,44] which evaluated interventions for multiple secondary complications, telehealth delivery included videoconferencing software (video-telehealth) (n=2) [31,44], web-based application (n=1) [39], mobile apps (n=1) [42], telephone (n=1) [29], and automated calls using interactive voice response system (n=2) [7,26]. The duration of the interventions ranged from 4 months to 9 months. Only 3 studies reported the frequency of interventions, ranging from once a week to biweekly interactions [29,31,44]. The multicomponent interventions were either provided by registered nurses (n=1), physiotherapists (n=2), occupational therapists (n=1), SCI specialists (n=1), or primary care physicians (n=1). Study results varied from no improvement to significant positive outcomes. Narrative reviews (n=2) [63,65], a systematic review (n=1) [66], conceptual review (n=1) [64], and qualitative studies (n=2) [11,48] reported the use of telehealth for patients with SCI who had multiple secondary complications. The patient-provider's perspective about the potential effects of telehealth services regarding the occurrence of secondary complications as well as higher levels of engagement with web-based peer support components, respectively, was described in the qualitative studies [11,48]. In a recent mixed methods study comparing videoconferencing to in-person peer support, most participants felt socially connected with web-based peer support [73]. Overall, 2 conceptual reviews [14,69] and 2 qualitative studies [74,75] discussed how, in the time of COVID-19, telerehabilitation services addressing multiple secondary complications maintained patient-provider interaction and access to essential health care services. These services may otherwise have been interrupted by physical isolation and social distancing regulations in place during the global COVID-19 pandemic [14,69,74,75]. A recent qualitative study [75] explored experiences of persons with SCI with tele-SCI services during the COVID-19 pandemic in British Columbia, Canada, suggesting the presence of benefits from blended models of health care delivery (combination of web-based and in-person care) for the SCI community in a postpandemic world. This qualitative study also explored the expected benefits (ie, increased accessibility and convenience) and challenges (ie, poor infrastructure and limitations in hands-on physical examination performance) of telehealth applications from the perspective of the SCI community [75]. In addition, 1 cross-sectional descriptive study [22], 1 qualitative study [19], and 1 literature review [70] investigated the models of telehealth use provided by United States Army Veterans programs,

particularly veterans with SCI. These 3 studies mainly discussed the important role of leadership support merged with telehealth technologies allowing for follow-up of long-term self-management of patients with SCI [19,22,70].

Oral Health

A total of 2 quantitative studies reported participants' satisfaction with, adaptability of, and user friendliness of home oral care telecare programs, leading to improved oral and gingival health in patients with SCI [33,35]. Both studies used videoconferencing software (video-telehealth) requiring high-speed internet connections as remote modalities facilitated by occupational therapists. These studies reported factors enabling the implementation of telehealth services to address oral care and described ways to integrate tele-oral care services into routine clinical practice [33,35].

Discussion

Principal Findings

This scoping review mapped the literature about the telehealth services provided to community-dwelling adults with SCI. In this review, the extracted results are classified under the main categories for which services were delivered. These included PA or LTPA motivation and participation, chronic pain, pressure ulcers or sores, skin or wound care, psychosocial dysfunction, and oral health. There were 61 articles included in this scoping review; 29 of the articles were quantitative studies, 14 qualitative studies, 4 mixed method studies, and the remainder were different review types (ie, narrative reviews, scoping reviews, systematic reviews, and conceptual reviews), mainly to explore how the existing telehealth services focus on self-management of different SCI-related secondary complications. The results of this paper also highlighted the importance of telerehabilitation services in the time of COVID-19 to increase access to health care services for community-dwelling adults with SCI.

There was inconsistency in reporting the demographic characteristics of participants, particularly the level and type of injury, time since injury, and the SCI-related secondary complications present at the time of participation in the included studies. In addition, most of the included articles needed to identify and describe the theories and frameworks used to construct telehealth services. In most of the included articles with human participants, sample size sufficiency reporting was often considered poor, characterized as a relatively small sample size, and discussed in the context of study limitations. Insufficient and relatively small sample sizes are known to undermine the validity and generalizability of the study results [76]. There was an upward trend in the number of publications since 2015. This upward trend may reflect an increase in the need for telehealth interventions, together with the availability, acceptability, and increased competency with telehealth technologies by health care professionals and patients with chronic neurologic conditions, particularly community-dwelling adults with SCI [2-5,7-9,11,14,17-19,21-24,26-28,30,33,35,37,40-46,48-51,54,56,59,62,64,67,69]. Additionally, there was inconsistency in reporting the duration of interventions and frequency of contact with the providers.

Recent studies conducted during the COVID-19 pandemic support the need for telerehabilitation and telehealth for patients with neurological deficits such as SCI [14,68]. The most recent research indicates that community-dwelling adults with chronic conditions are becoming more engaged with using cost-efficient, easy-to-use technologies to access essential health care services, especially during the current pandemic [14,68]. For example, telehealth has been used to provide indirect contact between psychiatrists and patients, enhancing access to psychological wellness, which may be interrupted due to pandemic-related physical and social isolation [14]. Recent studies suggest hybridized health care delivery models, blending remote- or telecare with in-person care, are promising approaches to create more accessible and patient-centered care for people with SCI who live in more remote areas with limited access to in-person health care services [74,75].

A number of articles in this review evaluated the effectiveness, implementation, and use of existing telehealth services to address secondary complications. A limited number of RCTs were designed to evaluate the effectiveness and use of telehealth interventions among patients with SCI. Various formats and means of remote service delivery were used, such as web-based platforms and applications with contents such as modules, homework, educational videos, and email or phone support from a provider or facilitator, videoconferencing software, telephone counseling sessions, and automated calls using simple telephone lines. Our findings suggest greater patient-reported satisfaction levels and better interaction occur when video modalities are used rather than telephone communications during remote- or televisits [29,75]. Video-based telehealth tools improve remote care by enabling patients to see their providers, fostering therapeutic and clinical rapport, and building interpersonal relationships.

This scoping review suggests that remote, live, peer, or coach support increases patient engagement in their health, promoting health behaviors and outcomes among adults with chronic neurologic conditions. Patients with SCI appreciated being able to have face-to-face remote- or tele-interaction with their health care providers and especially highlighted the importance of designing peer-led interventions (eg, My CareMy Call peer-led interventions). They also acknowledged peer mentors' powerful role in promoting self-management strategies to prevent secondary complications in adults with SCI. Furthermore, peer mentors are widely accepted as a source of social support while fulfilling the roles of role model, advisor, and supporter by promoting self-management skills through educating, strategizing, and more importantly, emotionally connecting and building trust with adults with SCI [52]. Telehealth expands access to care for those requiring specialty care or long-term follow-up care, allowing more frequent encounters and coaching that could facilitate patients' active participation in their self-management of SCI-related care [42].

The findings of this review suggest that most telehealth interventions and services carried out in the home and community were combined with at least one behavioral technique and training [20,21,26,38,40,41,43,46,50,51]. Behavioral training incorporated into the interventions included goal setting, identification of barriers, problem-solving, feedback

about performance, emotional support, and decision-making, which primarily resulted in the development of self-management skills and reduction or control of secondary conditions. These findings confirm the findings from the conceptual review conducted by Dobkin [50] that telerehabilitation technologies offer ways to remotely include behavioral training to self-coordinate (self-navigate and self-manage) their primary care services, resulting in reduced impairment and disability after SCI.

Additionally, the qualitative studies and conceptual reviews included in this scoping review indicate that leadership support and accepted management in health care facilities influence the implementation and maintenance of telerehabilitation use in routine practice. This finding is consistent with a study conducted by Moehr et al [71], which reported that continuous coordination and guidance by management teams lead to successful incorporation of telerehabilitation in clinical routine.

Finally, our study demonstrates that most qualitative studies reported high acceptability and satisfaction with telehealth services in patients with SCI, mainly attributed to the accessibility, convenience, and interpersonal interaction with telecare coaches and providers who have expert knowledge in preventing and treating secondary complications following SCI. The findings of this scoping review highlight the advantages of using telehealth to complement traditional in-person care when transitioning from inpatient care to community settings. Most telehealth interventions have been developed to support people with SCI during their transitions from acute rehabilitation to the community by providing psychosocial adjustments and assisting with other unexpected challenges [51,60,61]. The vast majority of articles published before and after the onset of the COVID-19 pandemic suggest that future telehealth services should be offered and delivered through blended (hybridized) models of care, enhancing access to care while still providing in-person care for those needing hands-on operations and treating and managing their SCI-related secondary conditions [74,75].

Future Directions

The findings of our scoping review indicate that telehealth technologies are potentially effective strategies for addressing disparities in providing quality care and managing multiple health concerns for patients with SCI. The results highlighted the need for future research in the following areas: (1) increased involvement of multidisciplinary teams to facilitate interventions for managing secondary complications, as there were no intervention-based studies reported using multidisciplinary team approaches; (2) implementation of underlying theory or model to inform telehealth services supporting the intended outcomes of the intervention, as majority of the included studies lacked

underlying theories or frameworks; (3) present more consistent details about population characteristics, mainly related to SCI; and (4) address gender differences in user needs and engagement with SCI.

Limitations

First, many of the studies were conducted in the United States and Canada, where health care systems vary from other countries, limiting the generalizability of the results to a North American context. Second, this review only included studies conducted in high-income countries and thus does not reflect telehealth delivery models for patients with SCI in low-income countries. This was mainly because the research was required to be guided toward the North American health care system context to fulfill our ultimate goal of informing key stakeholders involved in establishing a web-based clinic for community-dwelling adults with SCI in Ontario, Canada. Following this study, future research needs to consider the inclusion of middle- and low-income countries to reflect telehealth delivery models for patients with SCI in an international context. Third, the mean sample size of the included articles was relatively small, affecting the generalizability of the study findings to the whole SCI population. As a result, more research with larger sample sizes is required in this field of research to improve the validity and generalizability of the study results. Last, this review was limited to English-written articles. Therefore, it is possible there may be missing studies available in other languages. Accordingly, a systematic review is needed to obtain a more accurate view on the effectiveness of telehealth models of service delivery for community-dwelling adults with SCI.

Conclusion

This scoping review mapped the existing literature on what is known about the telehealth services provided to community-dwelling adults with SCI. Telehealth interventions and services carried out in the home and community of persons with SCI result in the development of self-management skills to reduce or control the secondary conditions following SCI. Moving forward, we expect to see a significant rise in the delivery of telehealth services through hybridized models of care, enhancing access to care while still providing in-person care for those needing hands-on care in managing SCI-related secondary conditions. Additionally, we anticipate an expansion in access to more specialty care by increasing the contact with providers who have expert knowledge in preventing and treating secondary complications following SCI. Findings from this scoping review will be used to inform the policy makers, health care professionals, and local and national stakeholders who are engaged in the planning, implementation, and funding process of establishing a web-based clinic for the SCI population.

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Data Availability

The data sets, filled-in data extraction forms for all the included articles, generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist. [[PDF File \(Adobe PDF File\), 100 KB - rehab_v10i1e41186_app1.pdf](#)]

Multimedia Appendix 2

Final search strategies.

[[DOCX File , 33 KB - rehab_v10i1e41186_app2.docx](#)]

Multimedia Appendix 3

Developed quantitative and qualitative data extraction forms.

[[DOCX File , 24 KB - rehab_v10i1e41186_app3.docx](#)]

Multimedia Appendix 4

Complete quantitative data set.

[[XLSX File \(Microsoft Excel File\), 38 KB - rehab_v10i1e41186_app4.xlsx](#)]

Multimedia Appendix 5

Complete qualitative data set.

[[XLSX File \(Microsoft Excel File\), 20 KB - rehab_v10i1e41186_app5.xlsx](#)]

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Abbreviations

LTPA: leisure-time physical activity

PA: physical activity

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

RCT: randomized controlled trial

SCI: spinal cord injury

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Review

Supporting Collaboration in Rehabilitation Trajectories With Information and Communication Technologies: Scoping Review

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Abstract

Background: Despite a surge in health information and communication technology (ICT), there is little evidence of lowered cost or increased quality of care. ICT may support patients, health care providers, and other stakeholders through complex rehabilitation trajectories by offering digital platforms for collaboration, shared decision-making, and safe storage of data. Yet, the questions on how ICT can become a useful tool and how the complex intersection between producers and users of ICT should be solved are challenging.

Objective: This study aims to review the literature on how ICTs are used to foster collaboration among the patient, the provider, and other stakeholders.

Methods: This scoping review follows the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines. Studies were identified by searching MEDLINE (OVID), Embase (OVID), CINAHL (EBSCOhost), AMED (EBSCOhost), and Scopus. Unpublished studies were extracted from OAIster, Bielefeld Academic Search Engine, ProQuest Dissertations and Theses, NARIC, and Google Scholar. Eligible papers addressed or described a remote dialogue between stakeholders using ICT to address goals and means, provide decision support, or evaluate certain treatment modalities within a rehabilitation context. Due to the rapid development of ICTs, searches included studies published in the period of 2018-2022.

Results: In total, 3206 papers (excluding duplicates) were screened. Three papers met all inclusion criteria. The papers varied in design, key findings, and key challenges. These 3 studies reported outcomes such as improvements in activity performance, participation, frequency of leaving the house, improved self-efficacy, change in patients' perspective on possibilities, and change in professionals' understanding of patients' priorities. However, a misfit between the participants' needs and the technology offered, complexity and lack of availability of the technology, difficulties with implementation and uptake, and lack of flexibility in setup and maintenance reduced the value of ICT for those involved in the studies. The low number of included papers is probably due to the complexity of remote collaboration with ICT.

Conclusions: ICT has the potential to facilitate communication among stakeholders in the complex and collaborative context of rehabilitation trajectories. This scoping review indicates that there is a paucity of research considering remote ICT-supported collaboration in health care and rehabilitation trajectories. Furthermore, current ICT builds on eHealth literacy, which may differ among stakeholders, and the lack of sufficient eHealth literacy and ICT knowledge creates barriers for access to health care and rehabilitation. Lastly, the aim and results of this review are probably most relevant in high-income countries.

KEYWORDS

rehabilitation; shared decision-making; ICT system; decision support systems; remote dialogue; patient participation

Introduction

The World Health Organization (WHO) defines rehabilitation as a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment. The WHO states that rehabilitation is highly person-centered, highlighting individual goal setting and preferences. WHO emphasizes the interdisciplinary workforce involved and the diversity of arenas for rehabilitation (from home or school to inpatient or outpatient hospitals) [1]. Rehabilitation is regarded as a complex and social process that requires coordinated collaboration. Information and communication technology (ICT) holds the potential for offering digital platforms for information exchange between stakeholders, collaboration, shared decision-making (SDM), and safe data storage [2].

Globally, 2.4 billion people are currently living with a health condition that could potentially be improved by rehabilitation. Due to global population growth and the rise of noncommunicable and long-lasting diseases, the estimated need for rehabilitation will gradually increase [1]. In addition, health and social care systems around the world face an increasing gap between needs and demands, a shortage of qualified staff, limited financial resources, and calls for reorganization of services [3]. Low- and high-income countries face different challenges and have to create context-specific strategies and solutions.

In high-income countries, ICT can add value to a person-centered rehabilitation process for all parties involved by using digital platforms for information exchange, collaboration, SDM, and safe data storage [2]. Despite a widespread optimism that ICT can facilitate better health and social care in terms of access, clinical outcomes, and cost-effectiveness, evidence supporting such effects is limited at best [4-7]. This may be attributed to the differences in interests and knowledge between users and producers of ICT and that some ICT solutions in health and social care processes may have none-foreseen and nonplanned effects. For example, organizational processes, roles, standards, access to information, privacy protection, and legislation may work as drivers or barriers to the implementation of ICT in health and social care services, and thus making ICT a useful tool implies considering human resources, cultures, and legal issues [8].

Barriers and drivers of access to public health care described by Levesque et al [9] illustrate the complexity of health care as a common good, as an organization, and as a personalized face-to-face service. Globally, getting access to and benefits from health and social care demands access to knowledge and resources on the individual and societal levels. The performance of health care systems is a result of the interface between the characteristics of persons, households, as well as social and physical environments, and those of health systems,

organizations, and providers [9,10]. Levesque et al [9] describe dimensions and determinants of access to health care that integrate demand and supply-side factors; 5 dimensions of accessibility of services (approachability, acceptability, availability and accommodation, affordability, and appropriateness) interacting with 5 corresponding abilities of persons to generate access (ability to perceive, seek, reach, pay, and engage). There are support mechanisms and barriers in each of the phases, according to how the health care system is organized on the one side and the abilities of the patients on the other side [9]. These barriers and drivers can be used as analytical perspectives to understand why implementing ICT is complicated and expensive, and why we need to consider health and social care as interdependent [11]. ICT solutions in health care should aim at lowering barriers and facilitating drivers for access to health care and rehabilitation.

The use of ICT in health and social care services not only requires access to technology but also implicitly puts demands on the user's eHealth literacy. Active engagement with digital services, usage of digital platforms and user interfaces, correct processing of information, engagement in own health, and preferably a feeling of safety and control are dimensions of eHealth literacy [9,12], which is affected by socioeconomic and cultural factors. Consequently, such factors should be considered in the development and implementation of ICT in health care [11]. The complexity of access to health care [9] must be considered in parallel with the complexity [12] of eHealth literacy if ICT solutions are to be useful and cost-effective.

Designing a user-friendly digital interface between patients and health care personnel is challenging, considering the diversity in eHealth literacy, access to relevant platforms, and the range of distribution in needs between staff and patients [9,12]. Among other challenges, two major problems persist: (1) integration between different ICT solutions and (2) lack of profit realization and personal satisfaction with patient-provider communication and intersection [13-15].

Patient-provider communication is a prerequisite of patient-centeredness and patient satisfaction in a variety of health care settings. Information exchange and coordination are important for the effect of treatment [16,17] and also in rehabilitation [18-25]. SDM is considered the crux of patient-centered care [26] and is dependent on information exchange and data access for everybody involved throughout the process. The SDM process is characterized by information provision and deliberation support and is a process where patients become aware of choices and their consequences. They need to understand options and have time and support to consider the most important factors for themselves. This process may require several contacts between parties, not necessarily face-to-face, including the use of decision support systems [27]. Both information provision and deliberation support can be done digitally; hence, digitalization of the SDM process in

rehabilitation can be an interesting approach. eHealth literacy affects this process [12].

The complexity of patient-provider communication and collaboration, demands on eHealth literacy, and barriers and drivers for access to and usage of health care imply unresolved challenges in developing and implementing ICT to amend or support SDM processes in rehabilitation. Therefore, the aim of this review was to examine how ICT can be or become a useful tool in SDM processes in rehabilitation trajectories, where collaboration among patients, providers, and eventually others is a necessary requirement.

This paper presents and discusses findings from a scoping review of research on ICT platforms for communication, collaboration, planning, and evaluation of rehabilitation trajectories [28]. The fields of ICT, access to health care, eHealth literacy, and SDM in rehabilitation are wide ranging as fields of practice, research, and development, and a scoping review of ICT in rehabilitation trajectories is pertinent. However, acknowledging the uncertain nature of ICT development and implementation as both a resource and a challenge in literature searches and reviews opens abundant possibilities for future design thinking and action.

Rehabilitation is a contested topic where all health and social care professions have vested interests. The common denominator between rehabilitees is a need for coordinated and cross-professional assistance and services; otherwise, their needs and wants may vary greatly [29-31]. A scoping review would help us map the terrain with a broad scope, grasping patients' and professionals' perspectives alike.

Methods

Overview

The methodology for this scoping review was based on the stages in the methodological framework defined for scoping reviews [32], which has been further revised by Peters et al [33] into five phases: (1) identify aim and research questions, (2) search for relevant literature, (3) literature screening and selection, (4) data extraction, and (5) summarize and report the results. The plan for the study, including title, aim, research questions, screening process, and inclusion and exclusion criteria for the inclusion of literature, were specified in a protocol published on the internet [34]. This scoping review follows the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines [35] (see [Multimedia Appendix 1](#)).

Aim

The aim of this scoping review was to gain knowledge about how ICT is used to address the collaboration among the patient, provider, and other stakeholders (eg, next-of-kin, home-care services, welfare technology personnel, or landlords) through the treatment process in rehabilitation. Studies describing a remote dialogue between patients and other stakeholders using technology aiming to address SDM or goals and means, provide decision support, and evaluate treatment were of particular interest.

Search for Relevant Literature

A search strategy was developed in collaboration with a reference librarian. Literature search strategies were developed using medical subject headings and text words related to “ICT system,” “shared decision-making,” and “rehabilitation” processes. The search strategy for MEDLINE (OVID) can be accessed digitally.

The search was initially run on February 22, 2022, and rerun on March 22, 2022. The following databases were searched: MEDLINE (OVID), Embase (OVID), CINAHL (EBSCOhost), AMED (EBSCOhost), and Scopus (see [Multimedia Appendix 2](#)). Searches were limited to studies conducted from 2018 to March 22, 2022. With the aim to locate unpublished studies, the following sources were searched: OAIster, Bielefeld Academic Search Engine, ProQuest Dissertations and Theses, NARIC, and Google Scholar. These searches were limited to studies conducted from 2018 to July 7, 2022. We limited the searches to include studies from 2018 and newer due to the fast development in this area. Furthermore, only studies in the English language were included.

Literature Screening and Selection

Eligible papers were those which addressed or described a remote dialogue between these parties using ICT to address goals and means, provide decision support, or evaluate certain treatment modalities within a rehabilitation context. We included papers describing the development of such digital solutions, their implementations, and evaluation of the outcomes of their usage. Studies focusing on ICT solutions only for 1-way communication between patients and health care providers or papers covering only prototypes or development of some technical features without implementation in clinical work were excluded. Digital solutions in general and their influence on organizations were not of interest either. Studies about collaboration through the rehabilitation process without digital support were not included [34].

We imported identified papers into the reference manager EndNote (version 20.4.1; Clarivate Analytics) for screening of titles and abstracts to detect and eliminate duplicates. The remaining references were uploaded to Distiller SR (version 2.38; DistillerSR Inc, 2022). For further screening, 2 authors (JIG and RJ) separately screened all paper titles and abstracts for inclusion against eligibility criteria (level 1 screening). Subsequently, all eligible papers underwent full-text review by 2 authors (JIG and RJ) to confirm whether the inclusion criteria were met (level 2 screening). All discrepancies between reviewer 1 and reviewer 2 were discussed among themselves and the third (IH) and fourth authors (TS) were consulted for making decisions in case of continued disagreement. All authors fully agreed upon which articles to include in the study.

Data Extraction and Synthesis

Data extraction forms developed by the research team were used. Two of the authors extracted data independently to ensure that all relevant information was included. Data extraction was facilitated using Distiller SR. The main focus of the analysis was the collaboration among stakeholders through ICT. The information extraction included the title of the study, author,

country of authors, year published, country of selected research study, the health sector studied, size and type of selection of study sample, the technology used, type of patient focus or participation, type of decision support, type of collaboration, type of digital user interface, and key findings. After level 2 screening, data extraction was completed, and 3 papers were identified. The reviewers completed the process of data synthesis, which involved identifying important findings and noting areas with gaps in knowledge. The PRISMA-ScR flowchart for the scoping review is shown in the *Results* section.

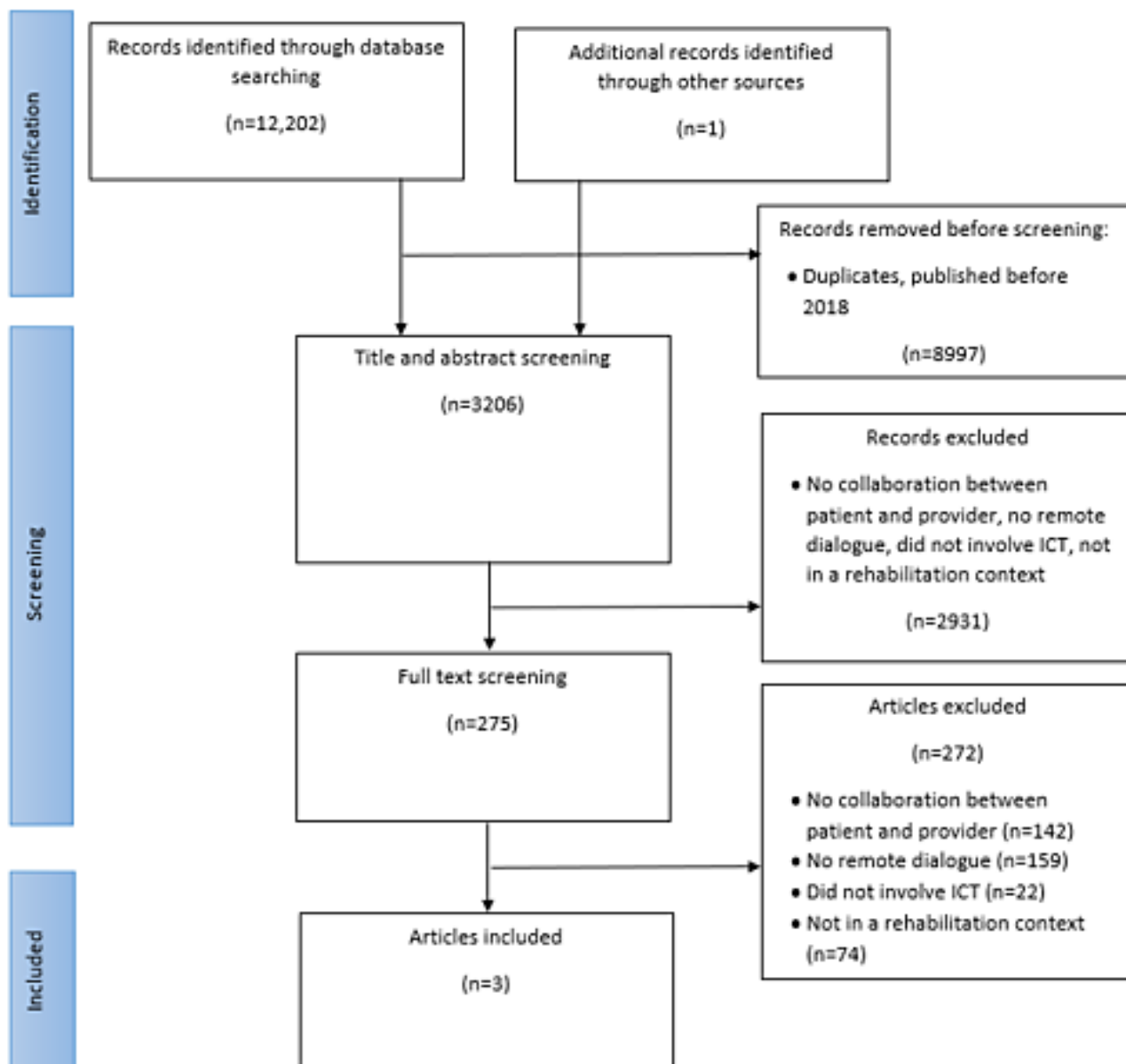
papers remained for screening of titles and abstracts. In this level 1 screening, many studies were excluded because they did not include the use of ICT, there was no reference to a dialogue based on shared information to address goals and means, they did not provide decision support, did not evaluate treatment, or they were not carried out in a rehabilitation setting. Much of the literature was about digital 1-way communication. It could be applications for patients' self-monitoring (and reporting) of functioning, activity, or physical parameters. Others were about applications, text messages, or websites, which health care professionals could use to send instructions, training programs, or reminders to patients. Thus, these papers did not focus on dialogue and SDM involving both patients and practitioners. After the level 1 screening, 275 papers remained for the full-text screening, of which 3 papers met the eligibility criteria and were included in qualitative analysis. The screening process is summarized in [Figure 1](#).

Results

Overview

The literature search yielded 12,203 papers. After the removal of duplicates and papers published before 2018, a total of 3206

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews flow diagram. ICT: information and computer technology.



Characteristics of Included Studies

Table 1 shows the characteristics of the 3 included studies.

These 3 studies were highly different in design and technology or ICT used, sample characteristics, and key findings.

Table 1. Characteristics of the included studies (n=3).

Authors (year); country	Aim	Design and technology	Sample	Data collection and analysis	Type of impairment	Key findings that relate to the scoping review questions
Beit Yosef et al [36] (2022); Israel	Pilot an RCT ^a to explore the clinical efficacy of the tele-cognitive orientation to daily occupational performance intervention for adults in the chronic phase after ABI ^b	Pragmatic exploratory partial RCT pilot study with a waitlist control crossover design examining the use of video to execute tele-cognitive orientation to daily occupational performance	16 patients, median age of 65.5 years, 3 women, 13 men, home setting. Fifteen significant others; 15 spouses; number of clinicians not given	Ratings of and scores on activity performance and participation from 3 instruments were analyzed statistically with comparisons between groups	ABI; 12 with ischemic stroke, 2 with hemorrhagic stroke, and 2 with TBI ^c	Significant improvements in activity performance on trained and untrained goals, participation reported from the participants, clinicians and significant other, and frequency of leaving the house. Partially maintained at follow-up
Strubbia et al [37] (2021); New Zealand	Describe experiences of health professionals and patients in the use of the English-language version of the iPad app aid for decision-making in occupational choice to facilitate collaborative goal setting in rehabilitation	A qualitative descriptive study using an iPad app	Eight health professionals: 7 female, 1 male participants; 6 aged 18-34 years, 2 aged ≥35 years. Eight patients: 3 female and 5 male; 6 in the age group of 18-64 years, 2 were aged ≥65 years; inpatient setting	Individual semistructured interviews conducted in person or on the internet about the understanding of aid for decision-making in occupational choice; what they liked or disliked, thoughts or feelings about using it in the clinic. Reviewed independently by 2 researchers with goal to ensure credibility, transferability, and dependability	Stroke (n=3), TBI (n=1), skin graft (n=1), chronic leg ulcer (n=1)	Changed patients' perspective on what was possible, changed health professionals' perspective on what was important. Facilitated shared decision-making. Lack of guidance for users. Logistical and organizational barriers, app-related and technical problems
Ali et al [38] (2021); Sweden	Evaluate the effects of person-centered care through a combined digital platform and telephone support for patients with chronic obstructive pulmonary disease and chronic heart failure	A multicenter 2-arm randomized trial examining the use of phone calls and a digital platform versus usual care	222 patients: 112 in a control group, and 110 in an intervention group. Overall, 119 were male, 103 were female; home setting	Data from questionnaires and medical records were analyzed statistically to compare groups including analyses of intention-to-treat and per-protocol	115 with COPD, ^d 85 with CHF, ^e 22 with both COPD and CHF	Patients who actually used the digital platform showed an improvement in general self-efficacy 3 months after the intervention. Improvements were not maintained at 6-month follow-up

^aRCT: randomized controlled trial.

^bABI: acquired brain injury.

^cTBI: traumatic brain injury.

^dCOPD: chronic obstructive pulmonary disease.

^eCHF: chronic heart failure.

Two of the studies used quantitative methods [36,38], while the third had a qualitative approach [37]. Ali et al [38] had the highest number of participants (N=222) in their multicenter randomized trial exploring the use of a digital platform and phone calls to promote person-centered care in patients with chronic obstructive pulmonary disease and chronic heart failure. The quantitative study by Beit Yosef et al [36] piloted an RCT

and included 16 patients with acquired brain injury. Occupational therapists remotely guided patients through video in the use of a global problem-solving strategy to focus on function and individual goal setting. Strubbia et al [37] included 8 health professionals and 8 patients in their interview study on the use of an iPad app to facilitate SDM with patients with stroke, traumatic brain injury, skin graft, or chronic leg ulcer.

Technology was used to address collaboration in different ways in the 3 studies. Beit Yosef et al [36] combined physical meetings and video sessions between occupational therapist and patients with acquired brain injury, with an initial meeting in person to establish a therapeutic relationship and complete a baseline assessment. Weekly video sessions over a period of 3 months were conducted before a second assessment was carried out [36]. Strubbia et al [37] also combined physical meetings and digital collaboration. In their study on health care professionals and rehabilitation patients, the professionals and patients chose up to 20 images on an iPad app representing goal topics from the activity and participation domain of the International Classification of Human Functioning, Disability and Health and rated them by importance for the patient. The patient and the health care professional then discussed the urgency of the chosen activities, and together they selected a maximum of 5 activities to focus on [37]. In contrast, Ali et al [38] only used digital collaboration in their study on patients with chronic obstructive pulmonary disease and those with chronic heart failure. In this study, the patient and the health care professional cocreated and followed up on a health plan through an optional number of phone calls. In the first telephone conversations, the health care professional established a partnership using communication skills such as listening to the patients' narratives about daily life events and how they were affected by their condition. A health plan, including patient goals, resources, and needs, was then cocreated through discussion and agreement. A digital platform was used to support communication between phone calls, provide access to shared documentation (health plans and self-ratings), and access to reliable information sources. The digital platform was developed using participatory design including patients, patient partners, experts, and researchers [38].

The 3 studies used different measures to evaluate outcomes or experiences. Beit Yosef et al [36] used the Canadian Occupation and Performance Measure (COPM) to identify 5 functional goals and to measure activity performance in their study on patients with acquired brain injury. Activity performance was also measured through the Performance Quality Rating Scale (PQRS). Participation was measured using the Mayo-Portland Adaptability Inventory-Participation Index [36]. Strubbia et al [37] used semistructured interviews to collect and analyze health professionals' and rehabilitation patients' perspectives on using an iPad app for prioritizing goals. In Ali et al's [38] study on patients with chronic obstructive pulmonary disease and patients with chronic heart failure, the primary end point was a composite score of general self-efficacy changes and hospitalization or death 6 months after randomization into usual care or the intervention group.

Key Findings of the Included Studies

Beit Yosef et al's [36] study with video sessions for persons with brain injuries showed significant improvements in COPM scores compared to the waitlist control group for both trained and untrained goals following the intervention. Significant improvements were also found in the PQRS and Mayo-Portland adaptability inventory-participation index scores and the patients left the house more often after the intervention. Improvements were partially maintained at follow-up. It was concluded that

the intervention was feasible or effective for focusing on function and individual goal setting for adults in the chronic phase after acquired brain injury. The results gave reason to believe that strategies of problem solving learned through the intervention had a spill-over effect on other tasks. Similarly, the data from the participants' significant other and the clinician valued the intervention as having a positive impact [36].

In the study by Strubbia et al [37] on health professionals and rehabilitation patients, the aid for decision-making in occupational choice (ADOC) app was seen as a valuable addition to the rehabilitation process by both professionals and patients because it facilitated conversations around personally meaningful goals and person-centered goal setting. The application enabled patients to understand what they could expect from the rehabilitation process and provided them access and a tool for involvement in decisions about their care. The professionals stated that the application promoted a more patient-centered approach compared to usual goal-setting practice as it gave them a better understanding of their patients' preferences and priorities [37].

In Ali et al's [38] study on follow-up of patients with chronic obstructive pulmonary disease and patients with the use of phone calls and a digital platform to focus on patient-centered care, no differences in composite scores were found between usual care and the intervention groups 3 and 6 months after the intervention. However, when analyzing data from participants who actually used the digital platform and the structured telephone support, there was a significant difference between groups in composite scores 3 months after the intervention but not at the 6-month follow-up [38].

Key Challenges of the Included Studies

According to Beit Yosef et al [36], there were several methodological weaknesses in the video study with persons with brain injuries, small sample size, partial randomization, no active treatment control group, heterogeneity in goal-setting complexity between groups, wrong use of the PQRS, and nonblinded second and third assessment. The lack of improvement in general self-efficacy was assumed to be caused by the intervention's focus on specific goals, which leads to effects on self-efficacy improvements specific to each goal. The lack of effect of the intervention on executive function in daily activities and caregiver burden was explained by the mentioned sample size and relatively high baseline scores. The authors discuss a potential ceiling effect with independent participants in need of only mild assistance in basic activities of daily living [36].

Strubbia et al [37] discuss several methodological weaknesses in their study of the ADOC application. Few participants, an exploratory study design, possible selection bias, and mandatory access to iPad to use the application were emphasized. Furthermore, the authors also discussed challenges related to implicit demands on users and the user interface with the ADOC app. Although the ADOC application was reported to be intuitive and instruction was given at the beginning of the study, both professionals and patients expressed the need for a user manual to keep up its use in clinical practice. Moreover, several logistical and organizational barriers were uncovered such as

the availability of iPads in the clinic, challenges in incorporating a complex application in a pressured timetable, and lack of integration with the health care system. There were also app-related problems and technical issues with the ADOC app; a lack of possibility to create personalized goals and images in the application, no way to access a PDF treatment plan, incompatible email systems, and no print options within the organization [37].

In the study by Ali et al [38] on phone calls and a digital platform for follow-up at home, an explanation for the lack of results was a ceiling effect. The study included participants with a high initial score on general self-efficacy and feeling of disease stability, which might have reduced their need for the intervention. The effect of the intervention after 3 months was explained by the participants' initial high degree of communication with the health care personnel and that the increase in global self-efficacy would attenuate over time independent of the intervention. The authors acknowledge that there could have been richer insights if they had explored the motivation and development of disease or rehabilitation needs through the project period. The authors also consider the need for tailoring interventions to the wants and needs of the user, to identify those persons who would benefit the most from it. The study concluded that person-centered care implies tailoring digital interventions to each patient's unique needs [38].

Discussion

Principal Findings

The aim of this scoping review has been to gain knowledge about how ICT is used to support collaboration between the patient, provider, and other stakeholders (eg, next-of-kin, home-care services, welfare technology personnel, or landlords) through a rehabilitation process. Our review process suggests four different strands for discussion: (1) A low number of papers that matched the inclusion criteria; (2) the studies presented in the included papers differ in research design, sample sizes, type of technology used, and how they frame and address collaboration, effects, and limitations; (3) the complexity of ICT design and implementation in health and social care is striking; (4) there is an unaddressed implicit demand for eHealth literacy and access to health and social care.

First, since information exchange and data access for all stakeholders are prerequisites for patient-centered care, 1 potential challenge is the lack of technological solutions to support data access and exchange when needed. Lack of access complicates remote dialogue and may result in a fragmented information flow between stakeholders [13]. This was reported by Strubbia et al [37] in their study of the ADOC app on health professionals and rehabilitation patients. In their study, the lack of integration with the health care system, for example, electronic health records, logistics, problems with personalization of the application, and the lack of ability to access and distribute results, were major drawbacks with the solution [37]. These challenges might have been experienced differently by the stakeholders, even though they were unanimous in their critique.

Second, even without restrictions on data and information flow, there are numerous possible pitfalls concerning digitalizing dialogue between stakeholders in rehabilitation. As illustrated by Levesque et al [9], there are many different processes or situations a potential patient has to navigate to be able to engage in a health care encounter, for example, perceive, seek, reach, pay, engage, and interact with on the institutional or professional side to gain access. For instance, the capacity to seek health care services depends on the patient's personal and social values, culture, gender, autonomy, socioeconomic position, and living conditions. On the societal side, cultural and social factors influence the possibility for people to accept the aspects of the service (eg, the gender or social group of providers and the beliefs associated with systems of medicine) [9]. The engagement of the patient in health care may depend on the fit between services and the patient's needs, its timeliness, the amount of care spent in assessing health problems and determining the correct treatment, and the technical and interpersonal quality of the services provided. ICT designers are embedded in their own context and have their prejudices and knowledge gaps, like all people. To avoid what has been called "Script by design" [39-41], that is, cultural stereotypes and prejudices reiterated in the technology, ICT must incorporate a vast number of personal factors concerning the patients' access and equivalent dimensions on the provider side through health care. This complexity can be a possible explanation for the paucity of research found in this study. The 3 included studies also report several methodological challenges. In the study by Beit Yosef et al [36] on persons with brain injuries where OTs used video to remotely guide patients in the use of a global problem-solving strategy, an initially high baseline score probably explained the lack of effect in part of the intervention. The same was the case in the study by Ali et al [38], where people with chronic obstructive pulmonary disease and patients with used a digital platform and phone calls. Ali et al [38] suggest that a high initial score on general self-efficacy and feeling of disease stability reduced the need for the intervention. This highlights the complexity described above, and as Ali et al [38] concluded, "person-centered care implies tailoring digital interventions to each patient's unique needs." Based on the authors' methodological critique, we would argue that there is no best fit between the participants' needs and wants, the baseline tests, and the outcome. Given a different methodological approach, with a systematic inclusion of participants in planning and carrying through of the studies and an explicit use of patient-reported outcome measures or experiences (where COPM sits), different outcomes might have been produced.

Third, there is a need to design digital health solutions that meet people's needs and wants, take the users' contexts into consideration, as well as embedding a range of possibilities for adaption to impairments or disabilities [42]. User-friendly and adaptable design is important for all stakeholders, whether it be patients, providers, and other stakeholders' needs in different contexts. Technology development has been driven by technical possibilities to a greater extent than the needs of the different stakeholders [40,41,43]. Technology can act as a barrier against access if the design does not fit the context of use [11]. Traditional design science has not recognized the role of the

organizational context in the development and implementation of technology, where a suitable demonstration context is selected after building the artifact [44]. A consequence may be that the shaping of the IT artifact condones the interests, values, and assumptions of the user end of the artifact. One can assume this is another factor influencing the paucity of research on digital collaboration in rehabilitation. The 3 included studies in this review point to this. The ceiling effect, mentioned by both Beit Yosef et al [36] and Ali et al [38], indicates that interventions are not tailored to the patient's wants and needs. Both studies explained the lack of effects caused by initial high scores on several measures. In addition, in the study by Strubbia et al [37], several conditions were reported that indicate a lack of adaptability of the technology to individual needs. Both the need for user manuals, challenges in incorporating a complex application in a pressured timetable, and lack of personalization possibilities highlights unmet individual requirements for technology [37]. The authors do not address the most obvious lack in their methodology, including those concerned to a greater extent, probably at odds with what is recognized as the best and promising practice [30,31].

Fourth, the differences in design, results, and challenges in the included studies can also be attributed to the complexity of health care and the situations where ICT is assumed to help. Video, an iPad application, a digital platform, and phone calls are technologies used in the included studies in this review. However, what technologies are eligible for addressing the patients' and other stakeholders' wants and needs? This can be seen in the challenges reported in the studies, with a complex fit between methodological challenges and challenges in providing individual access for patients and the match with the provision of access from the supply side. None of the included studies are addressing the implicit knowledge demand put on users, whether these are professionals, patients, or other stakeholders. ICT research in health has shown that to be able to maximize the use of ICT in this sector all users need digital skills, dexterity, cognitive capacity, user interfaces, access to support (eg, introduction, guidance, maintenance), basic knowledge about health and health and social systems, and access to safe storage. ICT for health has been driven by technology architects and commercial interests, which creates unnecessary barriers to both commercial success and access.

Limitations

It is important to acknowledge the limitations of this scoping review, despite following the appropriate methodology. First, the strict eligibility criteria resulted in a limited number of included studies, which may have caused the omission of important information relevant to the study's objective. In addition, restricting the search to a 5-year period starting from 2018 could have hindered the identification of relevant literature. Moreover, the decision to only include papers in English may have resulted in the exclusion of important information from non-English sources.

The search strategy for this study was developed by selecting relevant subject headings, text words, and their combinations from a larger pool of potential terms. Despite careful quality assurance measures taken during this process, there is still a

chance that some crucial elements may have been inadvertently excluded from the search.

However, the low number of included papers illustrates the key finding of this study. The most salient feature of the subject matter of the study is the complexity of human and technological interfaces and collaboration, which is difficult to research.

Conclusions

The use of ICT has been proposed as a solution to address and to support the individual management of the rise in noncommunicable diseases. Furthermore, a lesson learned after the COVID-19 pandemic is that ICT can be a valuable tool for shifting the tables among the stakeholders in rehabilitation to better meet the needs and wants of rehabilitees and other stakeholders and to provide remote support and care. Despite the widespread optimism that ICT can better access, clinical outcomes, and cost-effectiveness, evidence supporting such effects is limited. Technology use is rising globally, but there is an urgent need to include consideration about global differences not only in health burdens but also in socioeconomic factors and living conditions [45,46]. A low-tech user-friendly technical solution might have a much larger global potential to aid the rehabilitees' process, support those concerned and their families, and reduce the demands on professional staff both in low-income and high-income countries. Low-tech and intuitive user interfaces are also paying heed to the necessity for universal design, which increases access for all.

There is an inherent contradiction between the hallmark of rehabilitation; individually tailored and complex intervention; and the study design's lack of thorough assessments of the rehabilitees' wants and needs, and the project's wish for homogeneity, simplicity, and standardized goals. The understanding of a rehabilitation process is always embedded in a treatment plan, and henceforth in a research design. If these perspectives are at odds, the likelihood of success is lower.

Based on this scoping review, we still argue that ICT holds the potential to facilitate communication between stakeholders in the complex and collaborative process of rehabilitation. However, a prerequisite for eliciting this potential is to systematically include those concerned in the design and implementation process and to consider simplicity, low-tech, and low cost to lower barriers for successful user experiences and outcomes.

Potential Implication for Information and Communication Technology Design and Further Research

Critical appreciation of the 272 papers read in full text uncovered implicit biases toward end users (rehabilitees, next-of-kin, and professionals), for example, a top-down approach, fragmented approach, or high demands on eHealth literacy. This probably creates barriers for the stakeholders' participation in rehabilitation processes. Systematic feedback to designers seems lacking. There is an urgent need for more research on how implicit biases can be uncovered and how end users' experiences and needs can be systematically fed back to designers. Implicit bias creates barriers to a strength-based, empowering professional relationship or needs-based inclusive

design [40,41]. Critical rehabilitation studies [31] and critical disabilities studies [30,47] have repeatedly shown that if rehabilitation is to be successful, persons with disabilities must be acknowledged as competent and creative actors and included in the process of technology development and implementation from the launch of the ideas to commercialization.

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Conflicts of Interest

JIG is an industrial PhD candidate financed by the Norwegian Research Council. He works part-time at Carasent Norge AS, where he is involved in the development of a commercial web platform (Ad Voca) for communication between stakeholders in rehabilitation. Ad Voca's development and adaptation to stakeholders' wants and needs is also the research interest in his PhD study.

Multimedia Appendix 1
PRISMA-ScR checklist.

[DOCX File, 108 KB - [rehab_v10i1e46408_app1.docx](#)]

Multimedia Appendix 2

Detailed search strategy for each database searched.

[PDF File (Adobe PDF File), 157 KB - [rehab_v10i1e46408_app2.pdf](#)]

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Abbreviations

ADOC: aid for decision-making in occupational choice

COPM: Canadian Occupation and Performance Measure

ICT: information and computer technology

PQRS: Performance Quality Rating Scale

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

SDM: shared decision-making

WHO: World Health Organization

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Review

Methodologies for Evaluating the Usability of Rehabilitation Technologies Aimed at Supporting Shared Decision-Making: Scoping Review

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Abstract

Background: The field of rehabilitation has seen a recent rise in technologies to support shared decision-making (SDM). Usability testing during the design process of SDM technologies is needed to optimize adoption and realize potential benefits. There is variability in how usability is defined and measured. Given the complexity of usability, a thorough examination of the methodologies used to measure usability to develop the SDM technologies used in rehabilitation care is needed.

Objective: This scoping review aims to answer the following research questions: which methods and measures have been used to produce knowledge about the usability of rehabilitation technologies aimed at supporting SDM at the different phases of development and implementation? Which parameters of usability have been measured and reported?

Methods: This review followed the Arksey and O'Malley framework. An electronic search was performed in the Ovid MEDLINE, Embase, CINAHL, and PsycINFO databases from January 2005 up to November 2020. In total, 2 independent reviewers screened all retrieved titles, abstracts, and full texts according to the inclusion criteria and extracted the data. The International Organization for Standardization framework was used to define the scope of usability (effectiveness, efficiency, and satisfaction). The characteristics of the studies were outlined in a descriptive summary. Findings were categorized based on usability parameters, technology interventions, and measures of usability.

Results: A total of 38 articles were included. The most common SDM technologies were web-based aids (15/33, 46%). The usability of SDM technologies was assessed during development, preimplementation, or implementation, using 14 different methods. The most frequent methods were questionnaires (24/38, 63%) and semistructured interviews (16/38, 42%). Satisfaction (27/38, 71%) was the most common usability parameter mapped to types of SDM technologies and usability evaluation methods. User-centered design (9/15, 60%) was the most frequently used technology design framework.

Conclusions: The results from this scoping review highlight the importance and the complexity of usability evaluation. Although various methods and measures were shown to be used to evaluate the usability of technologies to support SDM in rehabilitation, very few evaluations used in the included studies were found to adequately span the selected usability domains. This review

identified gaps in usability evaluation, as most studies (24/38, 63%) relied solely on questionnaires rather than multiple methods, and most questionnaires simply focused on the usability parameter of satisfaction. The consideration of end users (such as patients and clinicians) is of particular importance for the development of technologies to support SDM, as the process of SDM itself aims to improve patient-centered care and integrate both patient and clinician voices into their rehabilitation care.

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KEYWORDS

usability; technology; rehabilitation; shared decision-making; mobile phone

Introduction

Background

Shared decision-making (SDM), the collaborative process involving active participation from both patients and providers in health care treatment decisions, reflects an important paradigm shift in medicine toward patient-centered care [1,2]. SDM facilitates information exchange and discussion of treatment options that involve the best scientific evidence and consider patient preferences [3,4]. The readiness for using SDM may be enhanced through its accessibility to individuals with limited health literacy or those with disabilities [5]. In the context of rehabilitation, SDM typically occurs during goal setting by selecting and agreeing upon behavioral objectives that patients, caregivers, and the rehabilitation team work together to achieve [6]. The development of mutual trust, 2-way communication, and sharing of power are conditions that influence patients' capacity and confidence to participate in SDM in musculoskeletal physiotherapy [7] and in the treatment of depression [8]. As a result, SDM assists patients in making individualized care decisions, and health care providers can feel confident in the presented and prescribed options [3,4]. SDM is important to increase satisfaction with care among both patients and providers, may improve individuals' quality of life and clinical outcomes, and fosters a better patient-provider relationship [9]. Furthermore, SDM encourages patient participation in their rehabilitation, supporting self-efficacy, empowerment, and ownership over the decisions [6].

Despite the listed benefits, it has been difficult to implement SDM in clinical practice because of barriers such as time constraints, accessibility to information and effective SDM tools, and limited technical and organizational resources [3]. It has been reported that only 10% of face-to-face clinical consultations involve SDM [10,11]. Advances in digital health technologies (eHealth) have resulted in tools that can bridge this SDM gap by allowing increased access to shared information and support for patient-provider communication [12]. Accessible, cost-effective, web-based decision-making is supported by use across various platforms such as the internet, tablets, or smartphone apps [13,14]. Such SDM technologies include patient decision aids that clarify options and values for personalized decision support, leading to reduced decisional conflict and increased participation in treatment choices that are consistent with the patient's values [13]. Patient portals reflect another technology that can support SDM, providing patients with secure access to their health information profile and communication with their care provider [15-17].

Although studies have been conducted to introduce and investigate the acceptance of rehabilitation technologies, research into the usability of technology systems is limited [18,19]. A technology system in rehabilitation is defined as an environmental factor that incorporates aspects of the physical and social environments that may affect communicative participation [20]. Technology systems need to be evaluated in terms of their usability to maximize their acceptance and benefits. The International Organization for Standardization (ISO) 9241 defined usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [21]. Evaluation of usability is key to guiding the development of efficient and effective technologies that end users will readily adopt by providing information about how a user uses the technology system and the challenges they find while interacting with a system's interface [22]. Different usability models have been proposed for evaluating software usability. Gupta et al [23] proposed a comprehensive hierarchical usability model with a detailed taxonomy, including 7 usability parameters: efficiency, effectiveness, satisfaction, memorability, security, universality, and productivity. Evaluating these usability parameters throughout the design process can allow for continuous improvement of ease of use and can predict the user's acceptance or rejection of the product [24]. Therefore, including input from individuals who will use the technology (in the case of SDM technologies, clinicians, patients, and caregivers) through usability testing is a necessary component in designing relevant, understandable, and usable technologies.

Objectives

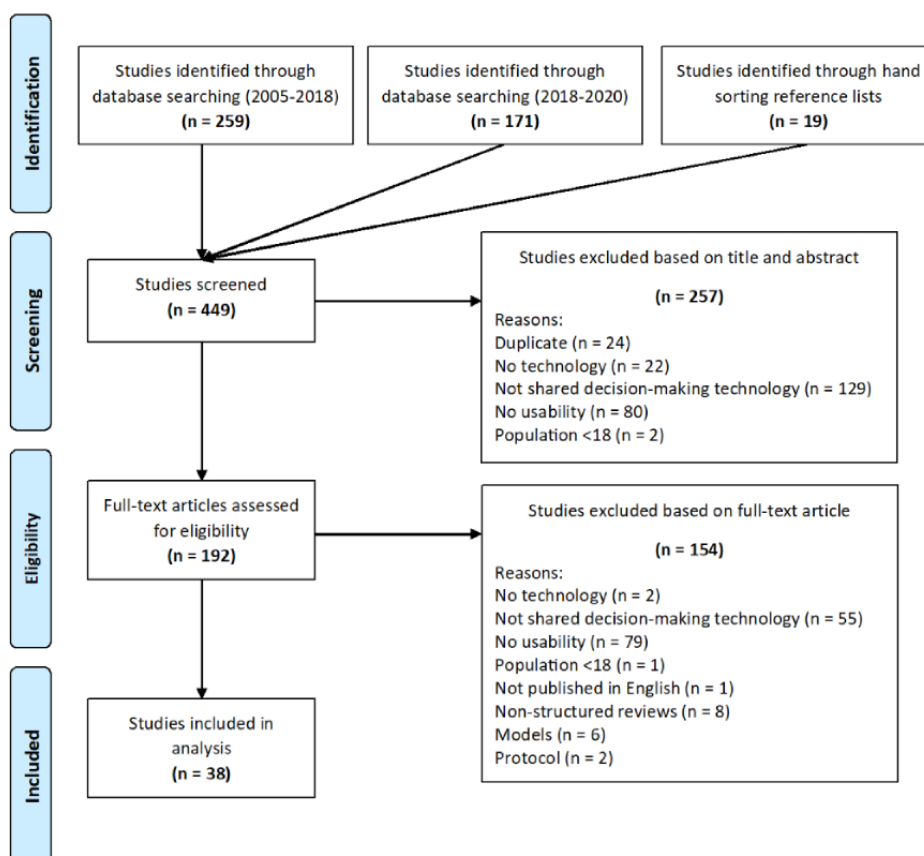
The field of rehabilitation science is defined as a multidimensional person-centered process targeting body functions, activities and participation, and the interaction with the environment aiming at optimizing functioning among persons with health conditions experiencing disability [25]. It has seen a recent rise in the development and implementation of technologies aimed at supporting SDM between clinicians, patients, and their caregivers [26]. However, it is unclear how user input or usability testing is integrated into the design process of these rehabilitation health technologies, including how usability is conceptualized, what measures are used, and at what stage of design usability is evaluated. To date, few studies, and no systematic or scoping reviews that we are aware of, have addressed how usability is measured among rehabilitation technologies supporting SDM. Given the complexity of usability, a thorough examination of the methodologies used to measure usability in this context is required to comprehensively map what has been done and

inform future research efforts. A greater understanding of how the parameters of usability are measured will guide future usability testing to inform further development of SDM technologies designed to enhance patient-centered care in rehabilitation. Therefore, this scoping review was conducted to provide knowledge about the methods and measures used to determine the usability of rehabilitation technologies aimed at supporting SDM at different phases of technology development and implementation.

Methods

This scoping review followed the methodology described by Arksey and O'Malley [27] and was reported according to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines [28] (Figure 1).

Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) flow diagram.



Identifying the Research Questions

This scoping review aimed to answer the following research questions: (1) which methods and measures have been used to produce knowledge about the usability of rehabilitation technologies aimed at supporting SDM at the different phases of development and implementation? (2) Which parameters of

usability have been measured and reported in studies focusing on rehabilitation technologies aimed at supporting SDM?

Eligibility Criteria

The eligibility criteria for this scoping review are outlined in [Textbox 1](#).

Textbox 1. Inclusion and exclusion criteria.**Inclusion criteria**

- Articles published in peer-reviewed journals, including quantitative (randomized controlled trials or nonrandomized controlled trials), qualitative, and mixed methods studies
- Articles including different groups of people, such as health care practitioners and individuals seeking rehabilitation services (ie, patients and their caregivers) or case managers
- Articles that focused on the usability of technology in making decisions
- Articles reporting a clear objective to evaluate the usability of shared decision-making (SDM) technologies in rehabilitation

Exclusion criteria

- Nonstructured reviews, protocols, descriptive reviews, nonhuman studies, and gray literature
- Articles not focusing on or measuring the usability of technologies in SDM and groups not related to the health care sector (ie, students)

Search Strategy

The search strategy was developed in collaboration with a health science librarian. As health system issues often change with models of care delivery, the economic climate, and the environment [29], we decided to narrow the scope of the search (2005 to 2020). The following electronic databases were searched in both English and French: Ovid MEDLINE, Embase, CINAHL, and PsycINFO. A combination of Medical Subject Heading terms, subject headings, and keywords was used and covered five concepts: (1) *usability* OR *user* friendl* OR eas* to use* OR *useful* OR user* perspective* OR patient* perspective* OR client* perspective* OR user* experience** AND (2) *rehabilitation* OR *telerehabilitation* OR *tele rehabilitation* OR *disabled* OR *disabilit** OR *physical limitation** OR *mental limitation** OR *psycho* limitation** OR *adaptation** OR *mobility* OR *occupational therap** OR *physiotherap** OR *physical therap** OR *speech languag* pathol** OR *speech therap** OR *language therap** OR *communication disorder** AND (3) *think* aloud* OR *focus group** OR *interview** OR *Wizard** OR *Empathy map** OR *Persona** OR *Questionnaire** OR *instrument** OR *scale** OR *tool* OR *tools* OR *measurement** OR *survey** OR *drama* OR *deliberation** OR *evaluation** OR *assessment** OR *video confrontation** OR *photo voice** AND (4) *technolog** OR *gerontotechnolog** OR *smart** OR *intelligen** OR *ambient assisted living* OR *virtual reality* OR *virtual rehabilitation* OR *telemonitoring* OR *telehealth* OR *telemedicine* OR *telerehabilitation* OR *ehealth* OR *tele monitoring* OR *tele health* OR *tele medicine* OR *tele rehabilitation* OR *e health or sensor** OR *biosensor** OR *mobile app** OR *product** OR *internet* OR *web* OR *computer** OR *software** OR *device** OR *self-help* OR *wheelchair** OR *wheelchair** OR *communication aid** AND (5) *shared decision making* OR *Decision-Making* OR *patient-provider communication* OR *decision aid* OR *decision support*. This was followed by hand searches of the reference lists of the included studies (the search strategy for Ovid MEDLINE is presented in [Multimedia Appendix 1](#)).

Study Selection

All identified studies were uploaded into EndNote X9.1 (Clarivate Analytics), and duplicates were removed. In total, 2 independent reviewers conducted the selection of abstracts starting with a pilot phase involving the examination of the first

10 titles and abstracts to screen and decide on retention of the abstract based on the inclusion criteria. Interrater agreements were assessed using the κ statistic [30]. Interrater agreement of <75% resulted in a clarification of the eligibility criteria and a revision if needed. The process was repeated twice between the reviewers until an agreement of 75% was reached, which is evidence of excellent agreement [30]. Finally, all eligible studies and those classified as unclear (ie, requiring further information to make a final decision regarding their retention) were independently reviewed as full-text articles. Disagreements at this stage were resolved through consensus. The PRISMA-ScR flow diagram [28] was used to guide the selection process.

Data Extraction

In total, 2 reviewers independently extracted data from the included articles to avoid missing relevant information. The data extracted included information corresponding to study design, rehabilitation technology intervention used (ie, setting, content, and detail of the type of user interface), population studied (participant demographics and target conditions), characteristics of the measures, and the development stage.

Data Synthesis

Descriptive statistics were used to describe the characteristics of the included studies, study design, characteristics of the study population, and geographical location. Findings were categorized based on study designs, parameters of usability, types of technologies, stage of development of the technology, and usability evaluation methodologies.

Types of SDM technologies and usability evaluations were mapped to parameters of usability based on a comprehensive hierarchical usability model presented by Gupta et al [23]. The usability parameters include efficiency, defined as “enables user to produce desired results with respect to investment of resources”; effectiveness, defined as “a measure of software product with which user can accomplish specified tasks and desired results with completeness and certainty”; satisfaction, defined as “a measure of responses, feelings of user when users are using the software i.e., freedom from discomfort, likeability”; memorability, defined as “the property of software product that enables the user to remember the elements and the functionality of the system product”; security, defined as “the degree to which risks and damages to people or other resources

i.e. hardware and software can be avoided”; universality, defined as “the accommodation of different cultural backgrounds of diverse users with software product and practical utility of software product”; and productivity, defined as “the amount of useful output with the software product” [28] (Textbox 2).

The usability evaluation methodologies were mapped based on the framework by Jacobsen [31]. The categories of the usability

evaluation methods included (1) empirical methods, based on users’ experience with the technology in a systematic way; (2) inspection methods, conducted by experts who examined usability-related aspects of a user interface without involving any users; and (3) inquiry methods, based on the information about users’ needs, likes, and understanding of the technology through interviews or focus groups, observation, and verbal or written questions [31].

Textbox 2. Usability parameters based on a comprehensive hierarchal usability model presented by Gupta et al [23].

Efficiency

- Resources
- Time
- User effort
- Economic
- Cost

Effectiveness

- Task accomplishment
- Operability
- Extensibility
- Reusability
- Scalability

Satisfaction

- Likability
- Convenience
- Esthetics

Memorability

- Learnability
- Memorability of structure
- Comprehensibility
- Consistency of structure

Security

- Safety
- Error tolerance

Universality

- Approachability
- Utility
- Faithfulness
- Cultural universality

Productivity

- Useful user task output

Consulting and Translating Knowledge

This scoping review is part of an initiative (*Réseau provincial de recherche en adaptation-réadaptation-RS6 Technologies de readaptation* [Quebec Rehabilitation Research Network]; [6]) to create an interactive directory of methodological tools for measures of the usability of rehabilitation technologies. Stakeholder consultations with members of the *Réseau provincial de recherche en adaptation-réadaptation-RS6* group were held at the beginning of the process (requesting feedback to refine the research question for data extraction and synthesis), during the study (validating the data extraction and deciding on the best way to align the information with stakeholders' needs), and when the final results were available (knowledge mobilization).

Results

Study Selection

A total of 430 studies were identified from electronic searches, and a total of 19 were identified through hand sorting reference lists. We excluded 57.2% (257/449) of the studies at the title and abstract stage, resulting in 192 full-text articles. Of these 192 studies, 154 (80.2%) were excluded at the full-text stage, resulting in 38 (19.8%) studies. The search strategy was updated in November 2020 and followed the PRISMA-ScR flowchart of the selection process. Reasons for exclusion of studies are provided in [Figure 1](#). Interrater agreement reached $\geq 75\%$, which is evidence of excellent agreement. Disagreements were resolved through consensus.

Characteristics of the Included Studies

The characteristics of the included studies are presented in [Multimedia Appendix 2](#) [32-69]. Overall, the 38 included studies

were published between 2008 and 2020 as peer-reviewed studies. Studies were published in the United States (17/38, 43%), Europe (14/38, 37%), Canada (5/38, 13%), and Asia (2/38, 5%). The study designs of the included studies were mixed methods (20/38, 53%), qualitative (12/38, 31%), and quantitative (6/38, 16%).

Characteristics of the Included Participants

[Multimedia Appendix 2](#) presents the characteristics of the included participants. The number of participants across all the included studies was 2138, with age ranging between 18 and 86 years. Participants of usability evaluations included patients (38/38, 100%); clinicians (32/38, 84%); caregivers or family (12/38, 32%); and others (6/38, 16%), including case managers, drug advisory committees, computer scientists, behavioral scientists, communication scientists, clinical administrators, service providers, and social service providers. The target end users of the developed SDM technologies were mainly patients and clinicians (24/38, 63%). The recruitment methods and settings varied across the included studies, including hospitals (24/38, 63%), the community (10/38, 26%), and universities (4/38, 11%).

Usability Definitions and Parameters

[Table 1](#) presents usability definitions and parameters provided by the authors across the included studies. Notably, only 50% (19/38) of the included studies provided an a priori definition of usability or listed parameters of usability. Usability parameters were categorized as effectiveness (9/38, 23%), efficiency (8/38, 21%), memorability (11/38, 29%), satisfaction (14/38, 37%), security (5/38, 13%), universality (4/38, 10%), and productivity (10/38, 26%) based on Gupta et al [23].

Table 1. Usability definitions and parameters.

Study	Definition of usability ^a	Usability parameters ^a	Gupta et al [23] framework
Bauerle Bass et al [34], 2018	User testing was completed to assess the extent to which the tool was understandable, how easily it could be navigated, and its relevance to patients taking HCV ^b +methadone.	<ul style="list-style-type: none"> • Understandable • Navigation • Relevance 	<ul style="list-style-type: none"> • Memorability • Memorability • Productivity
Berry et al [35], 2015	Usability testing is the evaluation of information systems through testing by representative users, enabling evaluation of social acceptability, practicality, and usability of a technology.	<ul style="list-style-type: none"> • Social acceptability • Practicality • Navigation • Content comprehension • Sociocultural appropriateness 	<ul style="list-style-type: none"> • Satisfaction • Productivity • Memorability • Memorability • Universality
Bogza et al [36], 2020	NR ^c	<ul style="list-style-type: none"> • Acceptability • Satisfaction 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction
Chrimes et al [39], 2014	Refers to commentary on the perceived effectiveness, efficiency, and ease of use, or lack thereof, of the ADAPT ^d Toolkit.	<ul style="list-style-type: none"> • Effectiveness • Efficiency • Ease of use 	<ul style="list-style-type: none"> • Effectiveness • Efficiency • Satisfaction
Cox et al [40], 2015	Usability describes the quality of a user's experience with software or an IT considering their own needs, values, abilities, and limitations.	<ul style="list-style-type: none"> • Quality of experience 	<ul style="list-style-type: none"> • Productivity
Cuypers et al [41], 2019	NR	<ul style="list-style-type: none"> • Layout • Language • Content • Amount • Value clarification • Summary 	<ul style="list-style-type: none"> • Effectiveness • Memorability • Memorability • Memorability • Effectiveness • Memorability
Danial-Saad et al [43], 2016	Usability is defined by the ISO ^e 9241 as the "extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use."	<ul style="list-style-type: none"> • Learnability • Efficiency • Memorability • Errors • Satisfaction • Visibility • Affordance • User control • Consistency • User-friendliness 	<ul style="list-style-type: none"> • Memorability • Efficiency • Memorability • Security • Satisfaction • Memorability • Universality • Productivity • Memorability • Satisfaction
De Vito Dabbs et al [42], 2009	The measure of the ease with which a system can be learned and used, including its safety, effectiveness, and efficiency.	<ul style="list-style-type: none"> • Learnability • Effectiveness • Efficiency • Errors • Flexibility • Memorability • User satisfaction 	<ul style="list-style-type: none"> • Memorability • Effectiveness • Efficiency • Security • Satisfaction • Memorability • Satisfaction
Fleisher et al [44], 2008	Whether patients found the tools easy to use and navigate, as well as the readability and usefulness of the physician report. Usability protocol based on NCI ^f guidelines.	<ul style="list-style-type: none"> • Ease of use • Readability • Usefulness 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Productivity
Fu et al [46], 2020	Usability is defined by the ISO 9241-11 as the extent to which a product can be used by a specific person in a specific context to achieve realistic goals of effectiveness, efficiency, and satisfaction.	<ul style="list-style-type: none"> • Help and documentation • Error prevention • Esthetic and minimalist design • Flexibility and efficiency of use • Recognition rather than recall • Match between app and the real world • User control and freedom • Consistency and standards • Feedback and visibility • Helps recover from errors 	<ul style="list-style-type: none"> • Productivity • Security • Satisfaction • Efficiency • Memorability • Efficiency • Universality • Universality • Effectiveness • Productivity

Study	Definition of usability ^a	Usability parameters ^a	Gupta et al [23] framework
Goud et al [47], 2008	NR	<ul style="list-style-type: none"> • Ease of system use • Information quality • Interface quality 	<ul style="list-style-type: none"> • Satisfaction • Memorability • Efficiency
Grim et al [48], 2017	Usability refers to commentary. Understandability and usefulness are 2 major constructs when talking about usability. Understandability refers to the extent to which the descriptive texts and items are comprehensible. Usefulness refers to commentary on the extent to which the features in the decision aid are perceived as supporting decision-making processes on the perceived effectiveness, efficiency, and ease of use, or lack thereof, of the decision aid.	<ul style="list-style-type: none"> • Understandability • Usefulness 	<ul style="list-style-type: none"> • Memorability • Productivity
Kallen et al [52], 2012	Usability was considered an incorporation of system effectiveness, efficiency, and user satisfaction. Usability was defined in the context of the assessment and review of tasks assigned to study participants.	<ul style="list-style-type: none"> • System effectiveness • Efficiency • User satisfaction 	<ul style="list-style-type: none"> • Effectiveness • Efficiency • Satisfaction
Li et al [53], 2013	A usability issue was defined as (1) when a participant was not able to advance to the next step because of the decision aid design or a programming error or (2) when a participant was distracted by a particular design or content of the web tool.	<ul style="list-style-type: none"> • Errors • Design 	<ul style="list-style-type: none"> • Security • Effectiveness
Rochette et al [55], 2008	The term “usability” is defined as the effectiveness, efficiency, and satisfaction with which users can achieve tasks in a particular environment. High usability means that a system is easy to learn and remember, efficient, visually pleasing, and fun to use and enables quick recovery from errors.	<ul style="list-style-type: none"> • Effectiveness • Efficiency • Satisfaction • Ease of use • Visually pleasing • Fun to use • Few errors 	<ul style="list-style-type: none"> • Effectiveness • Efficiency • Satisfaction • Satisfaction • Memorability • Satisfaction • Security
Span et al [60], 2014	NR	<ul style="list-style-type: none"> • User-friendliness • User acceptance and satisfaction • Participants’ appraisal of the DecideGuide for Making Decisions 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Productivity
Støme et al [61], 2019	NR	<ul style="list-style-type: none"> • Feasibility • Ease of use • Tasks on time • Utility 	<ul style="list-style-type: none"> • Efficiency • Satisfaction • Productivity • Universality
Van Maurik et al [65], 2019	Clinicians were asked to complete the SUS ^g after using the tool.	<ul style="list-style-type: none"> • Applicability • User-friendliness • Reliability 	<ul style="list-style-type: none"> • Effectiveness • Satisfaction • Memorability
Williams et al [67], 2016	NR	<ul style="list-style-type: none"> • Learnability • User control • User empowerment • Navigation • Consistency • Actionable feedback and available help 	<ul style="list-style-type: none"> • Memorability • Productivity • Productivity • Memorability • Memorability • Memorability
Zafeiridi et al [68], 2020	Usability is measured as the user-friendliness (eg, ease to learn) and perceived usefulness in addressing users’ needs.	<ul style="list-style-type: none"> • Usefulness • Ease of use • User satisfaction 	<ul style="list-style-type: none"> • Productivity • Satisfaction • Satisfaction

^aAs defined by the authors.

^bHCV: hepatitis C virus.

^cNR: not reported.

^dADAPT: Avoiding Diabetes Through Action Plan Targeting.

^eISO: International Organization for Standardization.

^fNCI: National Cancer Institute.

^gSUS: System Usability Scale.

Technology for SDM

Table 2 presents the type of SDM technologies that were used across the included studies. Technologies for SDM included clinical decision support systems (9/33, 27%), mobile health apps (9/33, 27%), and web-based aids (15/33, 46%). The SDM context was mainly between clinicians and patients (32/36, 89%). The types of technology for SDM were mapped to

usability parameters, including effectiveness (10/38, 26%), efficiency (11/38, 29%), memorability (20/38, 53%), satisfaction (27/38, 71%), security (5/38, 13%), universality (4/38, 10%), and productivity (16/38, 42%) based on Gupta et al [23]. The most common SDM technologies evaluated for usability were web-based aids. Satisfaction was the most common usability parameter mapped to types of SDM technologies.

Table 2. Technologies to support shared decision-making (SDM).

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
Anderson et al [32], 2014	STOP ^a Tool	Web-based user interface for adaptive clinical decision support integrated into electronic health record	Preimplementation	Framework based on usability engineering	SDM between patients and clinicians for self-management and secondary stroke prevention	<ul style="list-style-type: none"> • Ease of use • Fun to use • Navigation • Understandability • Visually pleasant • User-friendly • Efficient interaction 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Memorability • Memorability • Memorability • Satisfaction • Efficiency
Barrio et al [33], 2017	SIDEAL ^b	Mobile app	Developmental laboratory	MI ^c was the main source of guidance throughout the development process.	SDM between patients and clinicians related to self-management of alcohol dependence	<ul style="list-style-type: none"> • Simplicity • Ease of use • User-friendly • User control 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Satisfaction • Productivity
Bauerle Bass et al [34], 2018	“Take Charge, Get Cured”	mHealth ^d decision support tool	Development	Model of illness self-regulation, information-communication theory, and formative evaluation framework	SDM between patients and clinicians related to initiating hepatitis C treatment	<ul style="list-style-type: none"> • Visibility • Ease of use • Learnability • Comprehensiveness 	<ul style="list-style-type: none"> • Memorability • Satisfaction • Memorability • Memorability
Berry et al [35], 2015	P3P ^e	Web-based decision aid	Preimplementation	NR ^f	SDM between patients and clinicians about prostate cancer management options	<ul style="list-style-type: none"> • Ease of use • Readability 	<ul style="list-style-type: none"> • Satisfaction • Memorability
Bogza et al [36], 2020	Web-based decision aids	— ^g	Development	User-centered approach; Center for eHealth and Wellbeing Research guidelines	SDM between patients and clinicians	<ul style="list-style-type: none"> • Acceptability • Satisfaction 	<ul style="list-style-type: none"> • Satisfaction
Burns and Pickens [37], 2017	NR	Technology-based CDSS ^h for app-based assessments	Preimplementation	NR	SDM between providers, client, and family for home evaluation and modifications	<ul style="list-style-type: none"> • Efficiency • User control • Consistency • Feedback 	<ul style="list-style-type: none"> • Efficiency • Productivity • Memorability • Productivity
Canally et al [38], 2015	NR	GUIs ⁱ	Developmental laboratory	NR	Shared decision support system that integrated biophysiological information obtained through multiple noninvasive monitoring for home care	<ul style="list-style-type: none"> • User-friendly • Usefulness • Feedback • Navigation • User control 	<ul style="list-style-type: none"> • Satisfaction • Productivity • Productivity • Memorability • Productivity

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
Chrimes et al [39], 2014	ADAPT ^j	Clinical decision support tool integrating evidence-based shared goal-setting components into electronic health record	Developmental laboratory	ADAPT framework	SDM between patients and clinicians for behavior changes to manage prediabetes	<ul style="list-style-type: none"> Ease of use Visually pleasing 	<ul style="list-style-type: none"> Satisfaction Memorability
Cox et al [40], 2015	eCODES ^k	Web-based decision aid integrated into data entry and management system	Developmental laboratory	NR	SDM between clinicians and surrogate decision makers of patients receiving prolonged mechanical ventilation	<ul style="list-style-type: none"> Ease of use Simplicity 	<ul style="list-style-type: none"> Satisfaction Satisfaction
Cuypers et al [41], 2019	Web-based decision aid system	—	Development	On the basis of existing evidence-based Canadian decision aid, developed by Feldman-Stewart et al [70-74]	SDM between patients and clinicians	NR	NR

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
Danial-Saad et al [43], 2016	OSCAR ^l	Interactive CDSS	Development laboratory	LUCID ^m framework	Server-client system to recommend and select optimal pointing device	<ul style="list-style-type: none"> • Visibility • Minimizing errors • Consistency • Efficiency • Memorability • Affordance • Feedback • Effective use of language • User control • Flexibility • Navigation • Ease of use • Naturalness • User-friendly • Ease of performance 	<ul style="list-style-type: none"> • Memorability • Security • Memorability • Efficiency • Memorability • Universality • Productivity • Effectiveness • Productivity • Productivity • Memorability • Satisfaction • Satisfaction • Satisfaction • Satisfaction
De Vito Dabbs et al [42], 2009	Pocket PATH ⁿ	IHT ^o through handheld computer device	Preimplementation	User-centered design	SDM between patients of lung transplant and their transplant team about self-monitoring of critical values	<ul style="list-style-type: none"> • User control • Action feedback • Ease of use 	<ul style="list-style-type: none"> • Productivity • Productivity • Satisfaction
Fleisher et al [44], 2008	CONNECT ^p	Interactive web-based communication aid	Preimplementation	C-SHIP ^q model	SDM between patients and clinicians about treatment decisions supported through communication skill development modules	<ul style="list-style-type: none"> • Readability • Simplicity • Visually pleasing 	<ul style="list-style-type: none"> • Memorability • Satisfaction • Memorability
Flynn et al [45], 2015	COMPASS ^r prototype	User interface with decision analytical model developed on iPad mobile device	Developmental laboratory	Decision analytic model predictions developed from S-TPI ^s	SDM between clinicians and patients about patient-specific treatment options for acute ischemic stroke and personalized information to patients	<ul style="list-style-type: none"> • User-friendly • Effective use of language • Visibility • Efficient interaction 	<ul style="list-style-type: none"> • Satisfaction • Effectiveness • Memorability • Efficiency
Fu et al [46], 2020	Mobile apps	—	Testing	Nielsen heuristics	Unclear	<ul style="list-style-type: none"> • Satisfaction • Effectiveness • Efficiency 	<ul style="list-style-type: none"> • Satisfaction • Effectiveness • Efficiency
Goud et al [47], 2008	CARDSS ^t	Guideline-based computerized decision support systems	Implementation	Clinical guidelines	SDM between clinicians and patients for patient-specific care for cardiac rehabilitation and patient management	<ul style="list-style-type: none"> • Effectiveness • Minimizing errors 	<ul style="list-style-type: none"> • Effectiveness • Security
Grim et al [48], 2017	NR	Interactive web-based software	Preimplementation			<ul style="list-style-type: none"> • Ease of use • User-friendly 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
				The team followed published evidence on the consensus guidelines for development of decision aids and SDM.	SDM between patients and clinicians about care in psychiatric services		
Holch et al [49], 2017	e-RAPID ^u	Integrated electronic platform for patient self-report	Preimplementation	Translational research model	SDM between patients and clinicians for management of events during cancer treatment	<ul style="list-style-type: none"> • User interface • Action feedback • Visually pleasing 	<ul style="list-style-type: none"> • Productivity • Productivity • Memorability
Jameie et al [50], 2019	Cardiac telerehabilitation platform	—	Development	BACPR ^v	SDM between patients and clinicians	NR	NR
Jessop et al [51], 2020	“Take Charge, Get Cured”	mHealth treatment decision support tool embedded in Articulate 360 app	Preimplementation	NR	SDM between patients and physicians about hepatitis C treatment	NR	—

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
Kallen et al [52], 2012	PRO ^w -based Palliative and Hospice Care Management System—prototype	Electronic PRO system	Implementation	User-centered design approach	SDM between patients in palliative care and treating physician or nurse	<ul style="list-style-type: none"> • Efficiency • Interface quality • Navigation • Simplicity • Visually pleasing 	<ul style="list-style-type: none"> • Efficiency • Efficiency • Memorability • Satisfaction • Memorability
Li et al [53], 2013	ANSWER ^x	Web-based decision aid with educational modules	Preimplementation	The International Patient Decision Aid Standards and the Jabaja-Weiss edutainment decision aid model	SDM between patients and clinicians about using methotrexate	<ul style="list-style-type: none"> • Visually pleasing • Efficient interaction 	<ul style="list-style-type: none"> • Memorability • Efficiency
Murphy et al [54], 2020	CP-PDA ^y	Web-based algorithmic intervention	Development	International Patient Decision Aid Standards criteria checklist, SUNDAE ^z checklist, and the EQUATOR ^{aa} CONSORT ^{ab} checklist	SDM between patients and clinicians about post-prostatectomy care regarding continence product choice	<ul style="list-style-type: none"> • Visibility • Clarity • Ease of use • Usefulness • Comprehensibility • Acceptability 	<ul style="list-style-type: none"> • Memorability • Memorability • Satisfaction • Productivity • Memorability • Satisfaction
Rochette et al [55], 2008	StrokEngine-Family	Stroke rehabilitation layperson website	Implementation	NR	SDM between patients and clinicians	<ul style="list-style-type: none"> • Ease of use • Simplicity 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction
Setiawan et al [57], 2019	iMHere ^{ac} 2.0	Adaptive mHealth system with mobile app modules (client app, caregiver app, web-based clinician portal, back-end server, and 2-way communication protocol)	Development	User-centered design	Monitoring and support of self-management for people with chronic conditions and disabilities and allowing for personalized and adaptive treatment strategies	<ul style="list-style-type: none"> • Error prevention • User satisfaction • Ease of use • Usefulness 	<ul style="list-style-type: none"> • Security • Satisfaction • Satisfaction • Productivity
Schön et al [56], 2018	Digital interactive decision support tool	—	Development	The decision support tool is based on the theoretical framework of SDM.	SDM between patients and clinicians	<ul style="list-style-type: none"> • Ease of use • User-friendly 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction
Snyder et al [58], 2009	PatientViewpoint prototype	Web-based system to collect PROs linked with electronic medical record	Preimplementation	NR	SDM between patients and clinicians for cancer management	<ul style="list-style-type: none"> • Ease of use • Efficient interaction 	<ul style="list-style-type: none"> • Satisfaction • Efficiency
Span et al [60], 2014	DecideGuide	Interactive web tool	Developmental laboratory	NR			

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
					SDM in dementia care networks between patients, care managers, and informal caregivers	<ul style="list-style-type: none"> • Simplicity • Ease of use • Functionality • Visibility • User control • Readability • Social acceptability 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Universality • Memorability • Productivity • Memorability • Universality
Span et al [59], 2018	DecideGuide	Interactive web tool	Preimplementation	The 5 phases of the CeHRes ^{ad} road map	SDM made by care network of people with dementia (patients, care managers, and informal caregivers)	<ul style="list-style-type: none"> • Social acceptability • Minimize error • Efficiency • Action feedback 	<ul style="list-style-type: none"> • Universality • Security • Efficiency • Productivity
Støme et al [61], 2019	Vett interactive mobile app	—	Implementation	NR	Unclear	<ul style="list-style-type: none"> • Feasibility • Ease of use • Tasks on time • Utility 	<ul style="list-style-type: none"> • Efficiency • Satisfaction • Productivity • Universality
Tony et al [62], 2011	EVIDEM ^{ae} decision support framework	MCDA ^{af} and HTA ^{ag}	Developmental laboratory	EVIDEM framework	SDM between patients and clinicians to appraise health care interventions	<ul style="list-style-type: none"> • Learnability 	<ul style="list-style-type: none"> • Memorability
Toth-Pal et al [63], 2008	EviBase	CDSS through internet-based application	Implementation	Clinical guidelines (1 Swedish and 2 European)	SDM between clinicians and patients through integration of individual patient data with guidelines for management of chronic heart failure	<ul style="list-style-type: none"> • Flexibility • Ease of use 	<ul style="list-style-type: none"> • Effectiveness • Satisfaction
Tsai et al [64], 2019	MagicPlan	Mobile app with laser distance measurer	Preimplementation	NR	Clinical home evaluations with virtual floor plan for DME ^{ah} recommendations	<ul style="list-style-type: none"> • Visibility • Ease of use • Error prevention • Usefulness • Satisfaction 	<ul style="list-style-type: none"> • Memorability • Satisfaction • Security • Productivity • Satisfaction
Van Maurik et al [65], 2019	Web-based diagnostic support tool named ADappt	—	Development	NR	SDM between patients and clinicians	<ul style="list-style-type: none"> • Applicability • User-friendliness • Reliability 	<ul style="list-style-type: none"> • Effectiveness • Satisfaction • Memorability
Welch et al [66], 2015	MedMinder	Cellular pill-box monitoring device	Implementation	NR	SDM between clinicians and patients related to treatment and adherence support	<ul style="list-style-type: none"> • Efficient interaction • Action feedback • Readability 	<ul style="list-style-type: none"> • Efficiency • Productivity • Memorability
Williams et al [67], 2016	NR	Clinical decision support on mHealth app	Developmental laboratory	User-centered design approach (user interface and user experience design)	SDM between clinicians and patients for patient-specific recommendations for cardiovascular disease		

Study	Title of developed technology	Technology overview	Stage of development of technology intervention	Framework followed or guidelines by the authors	Description of SDM context or type of decision-making	Usability parameters measured	Gupta et al [23] framework
						<ul style="list-style-type: none"> Actionable feedback Interface quality Information quality User empowerment Simplicity Ease of use Readability Efficiency Practicality 	<ul style="list-style-type: none"> Productivity Efficiency Memorability Productivity Satisfaction Satisfaction Memorability Efficiency Effectiveness
Zafeiridi et al [68], 2018	CAREGIVER-SPRO-MMD ^{ai}	Web-based platform	Development	User-centered design	Social network for sharing information, tips, and support across peers and health professionals	<ul style="list-style-type: none"> Usefulness Ease of use User satisfaction 	<ul style="list-style-type: none"> Productivity Satisfaction Satisfaction
Zheng et al [69], 2017	NR	mHealth app with PROs	Preimplementation	User-centered design principles	SDM between patients and clinicians for knee arthritis treatment	<ul style="list-style-type: none"> Action feedback Interface quality Interface information Visually pleasing 	<ul style="list-style-type: none"> Productivity Efficiency Effectiveness Memorability

^aSTOP: Self-Management to Prevent Stroke.

^bSIDEAL: Soporte Innovador al paciente con Dependencia del Alcohol, Innovative Support to the Alcohol Dependent Patient.

^cMI: motivational interviewing.

^dmHealth: mobile health.

^eP3P: The Personal Patient Profile-Prostate.

^fNR: not reported.

^gData not available.

^hCDSS: clinical decision support system.

ⁱGUI: graphical user interface.

^jADAPT: Avoiding Diabetes Through Action Plan Targeting.

^keCODES: Electronic Collaborative Decision Support.

^lOSCAR: Ontology-Supported Computerized Assistive Technology Recommender.

^mLUCID: logical user-centered interaction design.

ⁿPATH: Personal Assistant for Tracking Health.

^oIHT: interactive health technology.

^pCONNECT: web-based communication aid.

^qC-SHIP: Cognitive-Social Health Information Processing.

^rCOMPASS: Computerized Decision Aid for Stroke Thrombolysis.

^sS-TPI: Stroke-Thrombolytic Predictive Instrument.

^tCARDSS: Cardiac Rehabilitation Decision Support System.

^ue-RAPID: Electronic Patient Self-Reporting of Adverse-Events: Patient Information and Advice.

^vBACPR: British Association for Cardiovascular Prevention and Rehabilitation.

^wPRO: patient-reported outcome.

^xANSWER: Animated, Self-Serve, Web-Based Research Tool.

^yCP-PDA: Continence Product Patient Decision Aid.

^zSUNDAE: Standards for Universal Reporting of Patient Decision Aid Evaluations.

^{aa}EQUATOR: Enhancing the Quality and Transparency of Health Research.

^{ab}CONSORT: Consolidated Standards of Reporting Trials.

^{ac}iMHere: Interactive Mobile Health and Rehabilitation.

^{ad}CeHRes: Center for eHealth Research and Disease Management.

^{ae}EVIDEM: Evidence and Value: Impact on Decision-Making.

^{af}MCDA: multicriteria decision analysis.

^{ag}HTA: health technology assessment.

^{ah}DME: durable medical equipment.

^{ai}CAREGIVERSPRO-MMD: Caregivers Patient-Reported Outcome-Mild Mental Disorder.

Usability Evaluation Methods

The usability evaluation methods were categorized, based on the framework by Jacobsen [31], into (1) empirical (think-aloud protocol, 14/38, 36%; user tracking, 3/38, 8%; performance measures, 4/38, 10%; field test, 2/38, 5%; video recording, 1/38, 2%; and screen capture, 2/38, 5%), (2) inspection (cognitive walk-through, 1/38, 2% and *Near live* clinical situation, 1/38, 2%), and (3) inquiry (focus groups, 3/38, 8%; workshops, 2/38, 5%; semistructured interviews, 16/38, 42%; structured interviews, 1/38, 2%; questionnaires, 24/38, 63%; observations, 5/38, 13%; and comments, 3/38, 8%; [Table 3](#)). An important point to emphasize is the frequency with which researchers used 1 (13/38, 34%), 2 (15/38, 39%), 3 (7/38, 18%), 4 (2/38, 5%),

and 6 (1/38, 2%) methods from the framework by Jacobsen [31], presented in [Figure 2](#) [32-69]. Most (28/38, 73%) used 1 or 2 methods of evaluation. Usability was assessed during development (18/38, 47%), preimplementation (13/38, 34%), or implementation (7/38, 18%) through a variety of measures, including usability questionnaires (15/38, 39%), tailored tools developed by the authors (17/38, 45%), and acceptance and satisfaction questionnaires (6/38, 16%). The usability evaluation parameters identified by the authors were mapped to the usability parameters explained by Gupta et al [23], including effectiveness (13/38, 34%), efficiency (12/38, 31%), memorability (13/38, 34%), productivity (2/38, 5%), security (2/38, 5%), and satisfaction (32/38, 84% [Figure 3](#) and [Table 4](#)).

Table 3. Usability evaluation methods.

Study	Method	Jacobsen [31] framework	Details
Anderson et al [32], 2014	<ul style="list-style-type: none"> Think-aloud protocol Structured interview 	<ul style="list-style-type: none"> Empirical Inquiry 	<ul style="list-style-type: none"> Think-aloud method using prototype and scripted test case scenario Structured interview with open-ended questions (feedback on barriers and facilitators and usefulness)
Barrio et al [33], 2017	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> USE^a questionnaire
Bauerle Bass et al [34], 2018	<ul style="list-style-type: none"> Think-aloud protocol Semistructured interview Questionnaire 	<ul style="list-style-type: none"> Empirical Inquiry Inquiry 	<ul style="list-style-type: none"> Think-aloud method when following navigational steps (audiotaped with observation notes) Semistructured interviews (feedback on graphics, voiceover, content, and purpose) Usefulness and relevance survey
Berry et al [35], 2015	<ul style="list-style-type: none"> Think-aloud protocol Questionnaire 	<ul style="list-style-type: none"> Empirical Inquiry 	<ul style="list-style-type: none"> Think-aloud session while interacting with website, with probing questions Acceptability questionnaire
Bogza et al [36], 2020	<ul style="list-style-type: none"> Think-aloud protocol Questionnaire 	<ul style="list-style-type: none"> Empirical Inquiry 	<ul style="list-style-type: none"> Think-aloud method while reviewing web-based decision aid (probing questions) Ottawa Acceptability Questionnaire and SUS^b questionnaire
Burns and Pickens [37], 2017	<ul style="list-style-type: none"> Semistructured interviews 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> Semistructured interview on perceptions of process and technology needs
Canally et al [38], 2015	<ul style="list-style-type: none"> Semistructured interviews Think-aloud methodology Video recording of computer screen Focus groups 	<ul style="list-style-type: none"> Inquiry Empirical Empirical Inquiry 	<ul style="list-style-type: none"> Open-ended questions about functions and areas of improvement Think-aloud method with prototype using simulated case developed with clinician Video recording of screen interactions Series of focus groups to refine the instrument
Chrimes et al [39], 2014	<ul style="list-style-type: none"> Think-aloud protocol through scripted scenario “Near live” clinical stimulation Screen capture recording 	<ul style="list-style-type: none"> Empirical Inspection Empirical 	<ul style="list-style-type: none"> Think-aloud session with scripted navigation instructions for prediabetes counseling scenario Clinical stimulation without navigational guidance mimicking clinical workflows Motion screen capture for onscreen recordings
Cox et al [40], 2015	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> SUS and ASQ^c
Cuyper et al [41], 2019	<ul style="list-style-type: none"> Think-aloud protocol Semistructured interviews 	<ul style="list-style-type: none"> Empirical Inquiry 	<ul style="list-style-type: none"> Think-aloud method while navigating the decision aid Semistructured interview following 30 minutes of navigating the decision aid
De Vito Dabbs et al [42], 2009	<ul style="list-style-type: none"> Think-aloud protocol Field test Screen capture technology Use tracking 	<ul style="list-style-type: none"> Empirical Empirical Empirical Empirical 	<ul style="list-style-type: none"> Think-aloud session with paper prototype and scenarios (iterative testing of features) Field test to assess the percentage of features that users accessed Data capture and use tracking of tool features (hits per feature, percentage of measurements recorded and transmitted, and times users contacted clinicians when prompted by message) ASQ and PSSUQ^d
Danial-Saad et al [43], 2016	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> SUS questionnaire
Fleisher et al [44], 2008	<ul style="list-style-type: none"> Think-aloud protocol Interviews Use tracking 	<ul style="list-style-type: none"> Empirical Inquiry Empirical 	<ul style="list-style-type: none"> Think-aloud session while reviewing the site, with observations Interview questions Use tracking of program (use of “help” button and number of warning messages)

Study	Method	Jacobsen [31] framework	Details
Flynn et al [45], 2015	<ul style="list-style-type: none"> Interactive group workshops 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> Interactive group workshops with stroke clinicians and patients or relatives with paper prototype and functional prototype (feedback on appearance, layout, and features)
Fu et al [46], 2020	<ul style="list-style-type: none"> Performance measure Questionnaire 	<ul style="list-style-type: none"> Empirical Inquiry 	<ul style="list-style-type: none"> Checklist for intuitive design modified for diabetes apps, originally adapted from the 10 heuristics by Nielsen used for a healthy eating app evaluation SUS questionnaire
Goud et al [47], 2008	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> CSUQ^e questionnaire
Grim et al [48], 2017	<ul style="list-style-type: none"> Think-aloud protocol Semistructured interviews 	<ul style="list-style-type: none"> Empirical Inquiry 	<ul style="list-style-type: none"> Think-aloud method with paper prototype, with observation of behavior (video recording and field notes) Semistructured interview following protocol guide
Holch et al [49], 2017	<ul style="list-style-type: none"> Semistructured interviews Written comments 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Semistructured interviews about the experience Written comments about logging in, navigating the system, and accessing features
Jameie et al [50], 2019	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> SUS questionnaire
Jessop et al [51], 2020	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> PrepDM^f scale with added items on perceived usefulness and user-friendliness
Kallen et al [52], 2012	<ul style="list-style-type: none"> Interviews Questionnaire 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Interviews with physicians or nurses and patients or caregivers to understand their needs and requirements as to the use of a computer system to help them manage their daily clinical activities, especially regarding the use of PRO^g assessments in patient care Providers used the prototype system to complete 2 assessments, the Memorial Delirium Assessment Scale and the Edmonton Classification System for Cancer Pain; patients and caregivers used the electronic PRO system to complete the Edmonton Symptom Assessment System and the Cut down, Annoyed, Guilty, and Eye-opener assessments
Li et al [53], 2013	<ul style="list-style-type: none"> Think-aloud protocol Questionnaire Performance measure 	<ul style="list-style-type: none"> Empirical Inquiry Empirical 	<ul style="list-style-type: none"> Think-aloud method when navigating decision aid, with probing questions (audio recorded and field notes) SUS questionnaire Time to complete the tool (minutes)
Murphy et al [54], 2020	<ul style="list-style-type: none"> Questionnaire Semistructured interview 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Questionnaire developed for the study for feedback on prototype for alpha testing Semistructured interviews with clinicians about usefulness and usability of final prototype in clinical practice
Rochette et al [55], 2008	<ul style="list-style-type: none"> Questionnaire Open-ended questions 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Questionnaire developed for the study combining open-ended questions whenever a score of dissatisfaction was given on a closed-ended question
Schön et al [56], 2018	<ul style="list-style-type: none"> Semistructured interview 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> Semistructured interview guide followed in focus groups (feedback on use of tool, usability, and impact on care planning and decision-making)
Setiawan et al [57], 2019	<ul style="list-style-type: none"> Questionnaire Semistructured interview 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> PSSUQ following requested tasks on app Semistructured interview for further comments and suggestions
Snyder et al [58], 2009	<ul style="list-style-type: none"> Semistructured interviews 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> Semistructured interview while presenting a mock-up of the web application (feedback on features)

Study	Method	Jacobsen [31] framework	Details
Span et al [60], 2014	<ul style="list-style-type: none"> Focus group sessions Cognitive walk-through Think-aloud method Field test Semistructured interviews Observation 	<ul style="list-style-type: none"> Inquiry Inspection Empirical Empirical Inquiry Inquiry 	<ul style="list-style-type: none"> Sketches using paper-based mock prototype presented to focus group Cognitive walk-through of interactive prototype to identify possible user problems Think-aloud method while using tool on tablet at home Field test of final prototype to assess user-friendliness, satisfaction, and value placed on tool Structured interviews throughout field-testing In-person observation of use of tool during field-testing
Span et al [59], 2018	<ul style="list-style-type: none"> Semistructured interviews Observations Use tracking 	<ul style="list-style-type: none"> Inquiry Inquiry Empirical 	<ul style="list-style-type: none"> Semistructured interviews (feedback on satisfaction, usefulness, user-friendliness, and use for decision-making) Observations of use during case manager home visits with people with dementia Use tracking of logged information (frequency of use and topics)
Støme et al [61], 2019	<ul style="list-style-type: none"> Questionnaire 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> Usability questionnaire developed for the study administered to patients
Tony et al [62], 2011	<ul style="list-style-type: none"> Workshop sessions 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> NR^h
Toth-Pal et al [63], 2008	<ul style="list-style-type: none"> Semistructured interviews Observation 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Semistructured interviews after training and field test Field observations of patient visits following predefined guide (use and communication)
Tsai et al [64], 2019	<ul style="list-style-type: none"> Questionnaire Performance measure 	<ul style="list-style-type: none"> Inquiry Empirical 	<ul style="list-style-type: none"> Questionnaires developed for the study for lay participants and clinicians Time needed to finish a floor plan using the mobile app
Van Maurik et al [65], 2019	<ul style="list-style-type: none"> Interviews Questionnaire 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Interviews about prototype with patients and caregivers with software developer (feedback on storyline and graphics) Usability questionnaire developed for the study (administered to providers) and SUS questionnaire
Welch et al [66], 2015	<ul style="list-style-type: none"> Questionnaires 	<ul style="list-style-type: none"> Inquiry 	<ul style="list-style-type: none"> Patient questionnaire on remote home monitoring device usability, patient satisfaction with the diabetes telehealth program, primary care provider feedback on the clinical decision support report, and telehealth nurse satisfaction with the program Questionnaires developed for the study for patients (feedback on device usability and satisfaction), primary care providers (feedback on clinical decision support), and telehealth nurse (feedback on satisfaction)
Williams et al [67], 2016	<ul style="list-style-type: none"> Think-aloud protocol Unstructured comments Questionnaire 	<ul style="list-style-type: none"> Empirical Inquiry Inquiry Inquiry 	<ul style="list-style-type: none"> Think-aloud method one-on-one for test cases (audio recording of verbal feedback) Immediate unstructured comments provided via email, telephone, or SMS text message Open-ended questions about use (amount, type of visits, and components used) SUS questionnaire
Zafeiridi et al [68], 2018	<ul style="list-style-type: none"> Questionnaire Open-ended comments 	<ul style="list-style-type: none"> Inquiry Inquiry 	<ul style="list-style-type: none"> Questionnaire developed for the study Open-ended questions about the improvement of the platform were asked when participants provided low scores for a feature or function
Zheng et al [69], 2017	<ul style="list-style-type: none"> Focus groups Interviews Questionnaire 	<ul style="list-style-type: none"> Inquiry Inquiry Inquiry 	

Study	Method	Jacobsen [31] framework	Details
			<ul style="list-style-type: none"> • Patient focus groups (feedback on experience, assessment of interface, preferences on presentation, and use for treatment decision-making) • Clinician interviews (feedback on expectations from individualized PRO report) • Survey developed for the study on perception of easiness and usability of interfaces

^aUSE: Usefulness, Satisfaction and Ease of Use.

^bSUS: System Usability Scale.

^cASQ: After-Scenario Questionnaire.

^dPSSUQ: Post-Study System Usability Questionnaire.

^eCSUQ: Computer System Usability Questionnaire.

^fPrepDM: Preparation for Decision Making.

^gPRO: patient-reported outcome.

^hNR: not reported.

Figure 2. Usability evaluation methods [32-69].

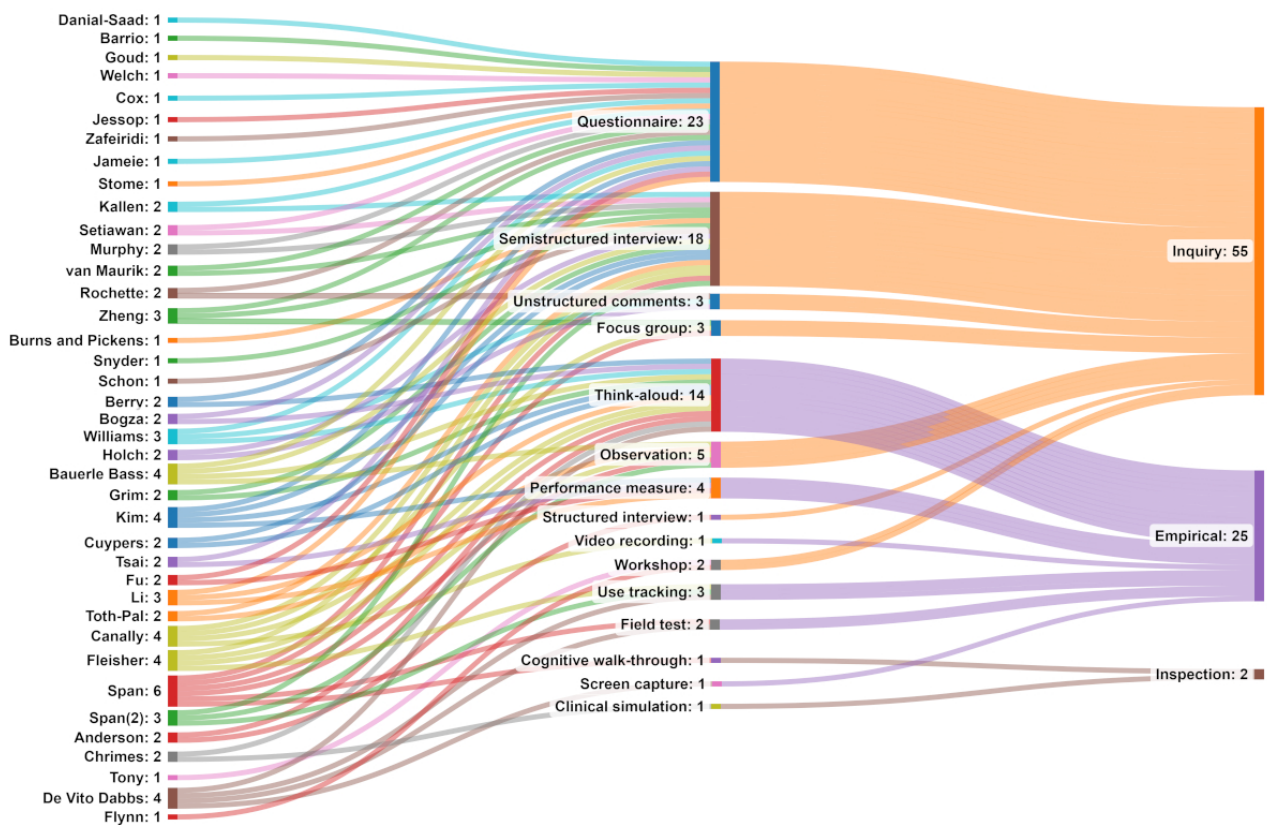


Figure 3. Mapping the usability evaluation methods to usability parameters based on a comprehensive hierarchal usability model presented by Gupta et al [23].

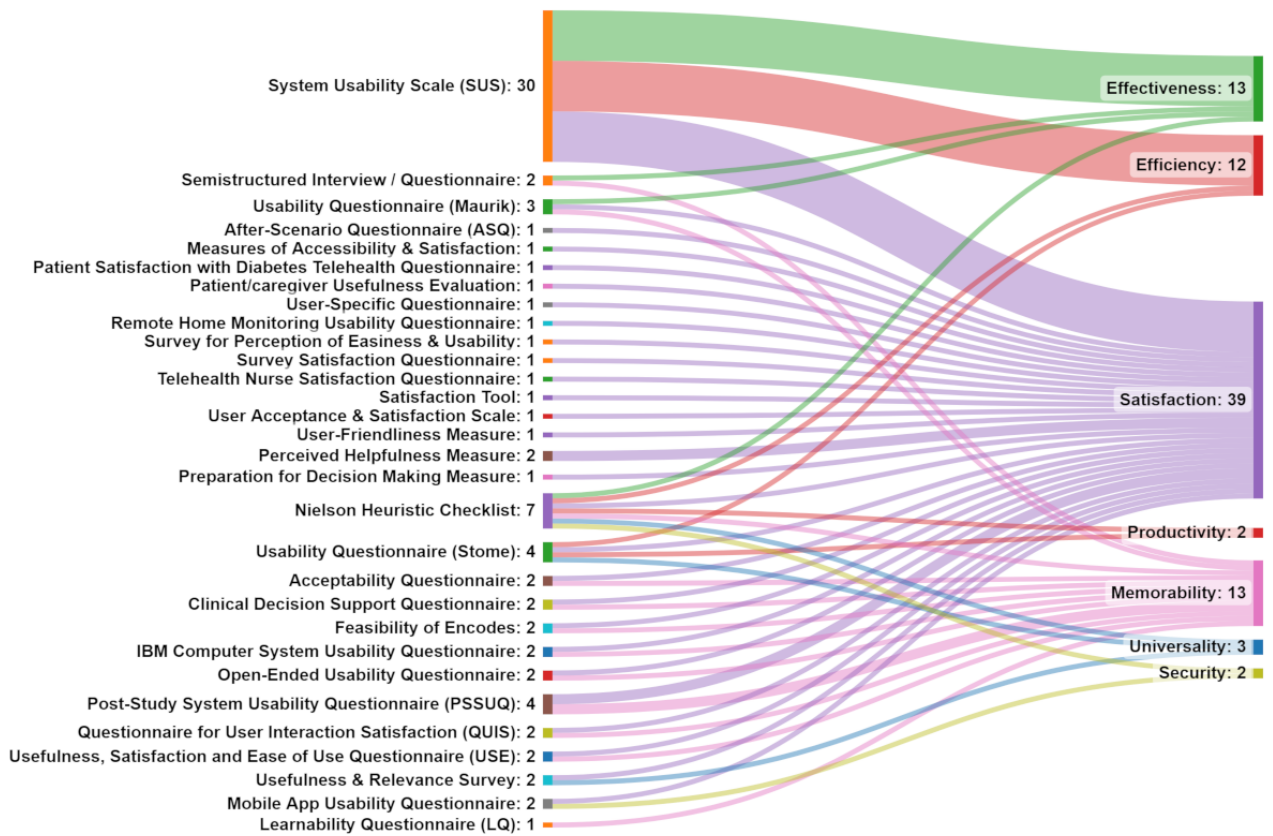


Table 4. Usability measures.

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
Acceptability questionnaire [56]	5-point Likert scale	<ul style="list-style-type: none"> • How easy was the program for you to use? • How understandable were the questions? • How much did you enjoy using the program? • How helpful was it to complete the program? • Was the amount of time it took to complete the program acceptable? • How valuable was the information? • Overall, how would you rate your satisfaction with this program? • Please rate the usefulness to you of: “your part in the decision” section. • Please rate the usefulness to you of: “information topics” section. • Please rate the usefulness to you of: “information on statistics” section. • Please rate the usefulness to you of: video clips. • Please rate the usefulness to you of: prostate cancer internet sites. 	<ul style="list-style-type: none"> • Ease of use • Learnability 	<ul style="list-style-type: none"> • Satisfaction • Memorability
ASQ ^a [45]	7-point Likert scale	<ul style="list-style-type: none"> • Ease of completing tasks in scenario • Time to complete tasks • Support when completing tasks 	<ul style="list-style-type: none"> • Ease of use 	<ul style="list-style-type: none"> • Satisfaction
Clinical decision support report questionnaire [53]	5-point Likert scale	<ul style="list-style-type: none"> • Clear and easy to understand: <ul style="list-style-type: none"> • Medication adherence percentages • Medication adherence calendars • BG^b graphs • BP^c graphs • Detailed logs of BP and BG readings • Clinically useful: <ul style="list-style-type: none"> • Medication adherence percentages • Medication adherence calendars • BG graphs • BP graphs • Detailed logs of BP and BG readings • For my patients, I want this report in the EMR^d • For my patients, I want this report in hard copy 	<ul style="list-style-type: none"> • Ease of use • Visibility 	<ul style="list-style-type: none"> • Satisfaction • Memorability

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
Feasibility of encodes [55]	___ ^e	<ul style="list-style-type: none"> • What did you like most about the encodes program? <ul style="list-style-type: none"> • Easy information, particularly if you have no experience in this situation • Easy to use • It puts it in black and white • It focuses the question at hand on the patient • User-friendly • I liked how patient- and family-centered it was • Informative • Interactive • iPad is a familiar platform • Wording is simple • What did you dislike most about the encodes program? <ul style="list-style-type: none"> • Touch screen • Sensitive topic • Does not make decisions for you • Simplistic • Delay • How could the encodes program be improved? <ul style="list-style-type: none"> • Would like even more information about prognosis • Make [the information] more complex • Make forward button more obvious • Even more illustrations • Make more options focusing on each specific patient's case 	<ul style="list-style-type: none"> • Ease of use • Visibility • User-friendly 	<ul style="list-style-type: none"> • Satisfaction • Memorability • Satisfaction
IBM CSUQ ^f [39]	7-point Likert scale		<ul style="list-style-type: none"> • Satisfaction • Visibility • Ease of use 	<ul style="list-style-type: none"> • Satisfaction • Memorability • Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • Satisfaction and ease of use <ul style="list-style-type: none"> • Overall, I am satisfied with how easy it is to use this system • It is simple to use this system • I can effectively complete my work using this system • I am able to complete my work quickly using this system • I am able to efficiently complete my work using this system • I feel comfortable using this system • It was easy to learn to use this system • I believe I became productive quickly using this system • Quality and clarity of information <ul style="list-style-type: none"> • The system gives error messages that clearly tell me how to fix problems • It is easy to find the information I need • The information provided with the system is easy to understand • The information is effective in helping me complete my work • The organization of the information on the system screens is clear • System’s interface <ul style="list-style-type: none"> • The interface of this system is pleasant • I like using the interface of this system • This system has all the functions and capabilities I expect it to have 		
LQ ^g [32]	6-point Likert scale	<ul style="list-style-type: none"> • The system reminded me of the important information needed for the pointing device adaptation process for people with disabilities • The organization of the information helped me arrange the stages of prescribing a pointing device for people with disabilities • The organization and the display of the information helped my clinical reasoning • The system provided me with new information for the pointing device adaptation process for people with disabilities • The system offered me information that made me change my pointing device adaptation plan • The system concentrated the professional language and terminology used in the pointing device adaptation process 	<ul style="list-style-type: none"> • Learnability 	<ul style="list-style-type: none"> • Memorability
Measures of accessibility and satisfaction [55]	5-point Likert scale		<ul style="list-style-type: none"> • Satisfaction • User-friendly 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> Acceptability <ul style="list-style-type: none"> I was able to answer the questions in the program I was able to complete the computer program Satisfaction <ul style="list-style-type: none"> I was satisfied with the computer program overall I was satisfied with how easy it was to use the program I was satisfied with the layout of the program I was satisfied with the instructions Feasibility <ul style="list-style-type: none"> Prefer printed version of decision aid 		
Mobile app usability concept questions [64]	5-point Likert scale	<ul style="list-style-type: none"> Please rate the user interface Please rate the ease of use Please rate the clarity of error messages Please rate how useful the mobile app is overall How likely would you recommend using this mobile app for home evaluation? 	<ul style="list-style-type: none"> Visibility Ease of use Error prevention Usefulness Satisfaction 	<ul style="list-style-type: none"> Memorability Satisfaction Security Productivity Satisfaction
Nielsen heuristic checklist [46]	Likert scale	<ul style="list-style-type: none"> The heuristic checklist has 10 intuitive design principles, and the severity of each violation is rated as minor, moderate, major, or catastrophic (1-4). 	<ul style="list-style-type: none"> Help and documentation Error prevention Esthetic and minimalist design Flexibility and efficiency of use Recognition rather than recall Match between app and the real world User control and freedom Consistency and standards Feedback and visibility Helps recover from errors 	<ul style="list-style-type: none"> Productivity Security Satisfaction Efficiency Memorability Efficiency Universality Universality Effectiveness Productivity
Open-ended questionnaire for usability [32]	—	<ul style="list-style-type: none"> Would you use the system to support your clinical decision reasoning process? Describe 1 or 2 new things you have learned following the use of the system Suggest 1 or 2 features you would add to the system Please add your comments and suggestions 	<ul style="list-style-type: none"> Learnability Ease of use 	<ul style="list-style-type: none"> Memorability Satisfaction
Patient satisfaction with diabetes telehealth program questionnaire [53]	5-point Likert scale		<ul style="list-style-type: none"> Satisfaction 	<ul style="list-style-type: none"> Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • Happy with RHM^h device training before program • Felt supported by diabetes care team • Nurse phone calls were helpful • Nurse calls lasted a good amount of time • Liked getting help at home over the phone • Would recommend program to other patients with T2Dⁱ • Would keep using this program at home 		
Perceived general helpfulness and value [51]	3-point Likert scale	<ul style="list-style-type: none"> • How helpful was the material? • Would you recommend it to others? • How clear was the information? 	<ul style="list-style-type: none"> • Usefulness 	<ul style="list-style-type: none"> • Productivity
Perceived helpfulness [51]	10-point Likert scale	<ul style="list-style-type: none"> • The information about hepatitis C was helpful • The video of other people talking about their experiences was helpful • The part where I was able to choose questions to talk with my doctor about was helpful • The voiceover information with pictures about HCV^j was helpful • The part where I mark how likely I was to be treated was helpful • The summary at the end was helpful 	<ul style="list-style-type: none"> • User-friendliness • Usefulness 	<ul style="list-style-type: none"> • Satisfaction • Productivity
Perceived usefulness [51]	10-point Likert scale	<ul style="list-style-type: none"> • App provided new information • App helped me feel prepared to talk with doctor • App helped with my emotional concerns • App increased my knowledge • App help me be less anxious 	<ul style="list-style-type: none"> • Usefulness 	<ul style="list-style-type: none"> • Productivity
PSSUQ ^k [45,57]	7-point Likert scale	<ul style="list-style-type: none"> • Easy-to-use system • Simple-to-use system • Effectively complete tasks and scenarios • Quickly complete tasks and scenarios • Efficiently complete tasks and scenarios • Comfort using system • Easy to learn to use system • Belief one could become productive using the system • Error messages were clear • Easily recover from mistakes • Information about system was clear • Easy to find needed information • Easy-to-understand information • Information helped complete the task • Information was clearly organized • Interface was pleasant • Enjoyed using interface 	<ul style="list-style-type: none"> • User satisfaction • Ease of use • Learnability • Visibility • User-friendly 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Memorability • Memorability • Satisfaction
PrepDM ^l scale [51]	5-point Likert scale		<ul style="list-style-type: none"> • Usefulness 	<ul style="list-style-type: none"> • Productivity

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • App helped—recognize that a decision about HCV treatment needs to be made • App prepared—to make a better decision about HCV treatment • App helped—think about the pros and cons of HCV treatment • App helped—know that decision about treatment depends on what matters most to me • App helped—organize your own thoughts about the HCV treatment decision • App helped—identify questions you want to ask your doctor • App prepared—to talk to your doctor about what matters most to you • App prepared—for a follow-up visit with your doctor 		
Remote home monitoring device usability questionnaire [53]	5-point Likert scale	<ul style="list-style-type: none"> • Pillbox: <ul style="list-style-type: none"> • Easy to use • Helped organize medications • Using it easily fit into daily routines • Ability to set it up in a convenient place at home • Easy to understand how to refill • BG meter: <ul style="list-style-type: none"> • Easy to use • Display was clear and easy to read • Using it easily fit into daily routines • Ability to set it up in a convenient place • BP meter: <ul style="list-style-type: none"> • Easy to use • Encouraged me to take BP more often • Using it easily fit into daily routines • Ability to set it up in a convenient place 	<ul style="list-style-type: none"> • Ease of use 	<ul style="list-style-type: none"> • Satisfaction
Survey for perception of easiness and usability of the 6 interfaces [43]	5-point Likert scale	<ul style="list-style-type: none"> • Vertical response options (user interface 1) • Horizontal response options (user interface 2) • Vertical response options with a movable slide (user interface 3) • Horizontal response options with a movable slide (user interface 4) • 3-point multimapping (user interface 5) • 6-point multimapping (user interface 6) 	<ul style="list-style-type: none"> • Ease of use 	<ul style="list-style-type: none"> • Satisfaction
Survey satisfaction questionnaire [46]	Likert scale		<ul style="list-style-type: none"> • Satisfaction 	<ul style="list-style-type: none"> • Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • Preconsultation survey <ul style="list-style-type: none"> • How much time on the internet per week? <1 hour, 1-4 hours, 5-7 hours, 8-14 hours, and >14 hours • Length of survey: reasonable, a little long, and much too long • Satisfaction with survey: not very satisfied, slightly satisfied, moderately satisfied, and extremely satisfied • Where they completed the survey: home, work, friend and family, public computer, resource education center on-site, and other • Postconsultation survey: not at all, a little, moderately, quite a lot, and extremely <ul style="list-style-type: none"> • How helpful was the survey to the consultation • How helpful was the module to the consultation • Did you feel the survey affected how you communicated with your physician? • Did you feel the skills module survey affected how you communicated with your physician? • Which was more helpful? • Did you feel that taking part in the program helped your communication with your doctor? 		
Telehealth nurse satisfaction questionnaire [53]	5-point Likert scale	<ul style="list-style-type: none"> • Device training • Web-based dashboard training • Ability to contact patients by phone • Ability to track DSM^m of patients • Ability to work as a team with PCPsⁿ • Overall satisfaction with telehealth program 	<ul style="list-style-type: none"> • Satisfaction 	<ul style="list-style-type: none"> • Satisfaction
Tool developed by the authors focused on description [52]	5-point Likert scale		<ul style="list-style-type: none"> • Ease of use • User-friendly • Satisfaction 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • Home page <ul style="list-style-type: none"> • Easy to find • Satisfaction with visual presentation (organization or content) • Satisfaction with appearance of text (size, type of writing, and spacing) and satisfaction with colors • Module 1 <ul style="list-style-type: none"> • Easy to find • Satisfaction with visual presentation (organization or content) • Satisfaction with appearance of text (size, type of writing, and spacing) • Usefulness of information • Module 2 <ul style="list-style-type: none"> • Easy to find • Usefulness of information • General appreciation <ul style="list-style-type: none"> • Satisfaction with general appearance • Easy to use • Satisfaction with time required to open pages • How user-friendly • Overall satisfaction 		
Usability questionnaire [61]	100-point Likert scale	<ul style="list-style-type: none"> • Vett on mobile phone is simple and intuitive to use • Reminders of tasks arrive at the agreed-upon time • It is easy and intuitive to answer the reminders • It is easy and intuitive to answer that the task is done 	<ul style="list-style-type: none"> • Feasibility • Ease of use • Tasks on time • Utility 	<ul style="list-style-type: none"> • Efficiency • Satisfaction • Productivity • Universality
Usability questionnaire [65]	10-point Likert scale	<ul style="list-style-type: none"> • Is it clear where ADappt could be used for (scale from 1-10)? • How user-friendly would you rate this tool to be (scale from 1-10)? • How reliable would you rate ADappt to be (scale from 1-10)? • Would you use the final version of ADappt in your daily clinical routine (percentage of “yes”)? 	<ul style="list-style-type: none"> • Applicability • User-friendliness • Reliability 	<ul style="list-style-type: none"> • Effectiveness • Satisfaction • Memorability
Usability scale (SUS) questionnaire [32,36,40,46-48,50,55,57,65]	5-point Likert scale		<ul style="list-style-type: none"> • Effectiveness • Efficiency • Satisfaction 	<ul style="list-style-type: none"> • Effectiveness • Efficiency • Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
USE ^P questionnaire [37]	7-point Likert scale	<ul style="list-style-type: none"> • I think that I would like to use this CDS^o app frequently. • I found the CDS app unnecessarily complex. • I thought the CDS app was easy to use. • I think that I would need the support of a technical person to be able to use this CDS app. • I found that the various functions in this CDS app were well integrated. • I thought there was too much inconsistency in this CDS app. • I would imagine that most people would learn to use this CDS app very quickly. • I found the CDS app very cumbersome to use. • I felt very confident using the CDS app. • I needed to learn a lot of things before I could get going with this app. 	<ul style="list-style-type: none"> • Usefulness • Ease of use • Ease of learning • Satisfaction 	<ul style="list-style-type: none"> • Satisfaction • Satisfaction • Memorability • Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • Usefulness <ul style="list-style-type: none"> • It helps me be more effective • It helps me be more productive • It is useful • It gives me more control over the activities in my life • It makes the things I want to accomplish easier to get done • It saves me time when I use it • It meets my needs • It does everything I would expect it to do • Ease of use <ul style="list-style-type: none"> • It is easy to use • It is simple to use • It is user-friendly • It requires the fewest steps possible to accomplish what I want to do with it • It is flexible • Using it is effortless • I can use it without written instructions • I do not notice any inconsistencies as I use it • Both occasional and regular users would like it • I can recover from mistakes quickly and easily • I can use it successfully every time • Ease of learning <ul style="list-style-type: none"> • I learned to use it quickly • I easily remember how to use it • It is easy to learn to use it • I quickly became skillful with it • Satisfaction <ul style="list-style-type: none"> • I am satisfied with it • I would recommend it to a friend • It is fun to use • It works the way I want it to work • It is wonderful • I feel I need to have it • It is pleasant to use 		
Usefulness and relevance survey [34]	7-point Likert scale	<ul style="list-style-type: none"> • Satisfied with ease • Simple to use • Understand how to go from one screen to another • Easy to choose which parts I want • I felt comfortable using it • Information was clear and easy • Easy to find information I need • Information effective for decision-making • Tablet was easy to use • Length of tool was right • Right amount of information on hepatitis C • Tool slanted toward convincing me • Tool helpful for patients seeking information • Tool helped me talk with doctor • Videos and visuals were helpful 	<ul style="list-style-type: none"> • Usefulness • Relevance 	<ul style="list-style-type: none"> • Productivity • Productivity

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
User acceptance and satisfaction scale [49]	5-point Likert scale	<ul style="list-style-type: none"> All participants valued the tool positively; concerns about guide being too confronting Participants' appraisal of the tool for making decisions—supportive tool Short lines of communication, awareness of the steps in decision-making, and improvements for the tool 	<ul style="list-style-type: none"> User acceptance Satisfaction 	<ul style="list-style-type: none"> Satisfaction Satisfaction
User-friendliness measured with an instrument based on the CeHRes ⁴ assessment of design quality [49]	—	<ul style="list-style-type: none"> Ease of use: chat function easy for all Deciding together function too difficult for all Technical failures: problems with IT and internet connection Nice to have notifications, agenda, photos, memory games, and ability to send message to 1 person 	<ul style="list-style-type: none"> User-friendliness Ease of use 	<ul style="list-style-type: none"> Satisfaction Satisfaction
User-specific evaluation questionnaire for clinicians [47]	—	<ul style="list-style-type: none"> This system could improve our operational efficiency This system could help us improve our quality of patient care This system could help us better use patient assessments in clinical decision-making and patient care This system could help us identify important causal and temporal relationships between care events and outcomes that can aid our clinical decision-making This system could help us monitor patient status and better serve their needs This system will work well with our existing workflow This system will improve patient-provider communication This system could facilitate communication among members of a multidisciplinary team I will recommend our practice to adopt this system when it is fully developed I will recommend other practices to adopt this system when it is fully developed 	<ul style="list-style-type: none"> Usefulness 	<ul style="list-style-type: none"> Satisfaction
User-specific evaluation questionnaire for patients and caregivers [47]	—		<ul style="list-style-type: none"> Usefulness 	<ul style="list-style-type: none"> Satisfaction

Usability measures	Type of scale	Items	Usability evaluation parameters identified by the authors	Gupta et al [23] framework
		<ul style="list-style-type: none"> • I enjoyed using this system to report symptom status • It is easy to complete patient assessments using this system • This system can help me better use patient symptom status reports to communicate with health care providers • This system can help me better use patient symptom status reports in decision-making about patient care • This system can help in the monitoring of patient status to better serve patient needs • It will be easier to use this system to complete patient assessments than to complete assessments using paper and pencil • I would like to be a beta tester of this system when it is ready • I would likely recommend that patient care providers adopt this system when it is fully developed 		

^aASQ: After-Scenario Questionnaire.

^bBG: blood glucose.

^cBP: blood pressure.

^dEMR: electronic medical record.

^eData not available.

^fCSUQ: Computer System Usability Questionnaire.

^gLQ: learnability questionnaire.

^hRHM: remote home monitoring.

ⁱT2D: type 2 diabetes.

^jHCV: hepatitis C virus.

^kPSSUQ: Post-Study System Usability Questionnaire.

^lPrepDM: Preparation for Decision-Making.

^mDSM: diabetes self-management.

ⁿPCP: primary care provider.

^oCDS: clinical decision support.

^pUSE: Usefulness, Satisfaction, and Ease of Use.

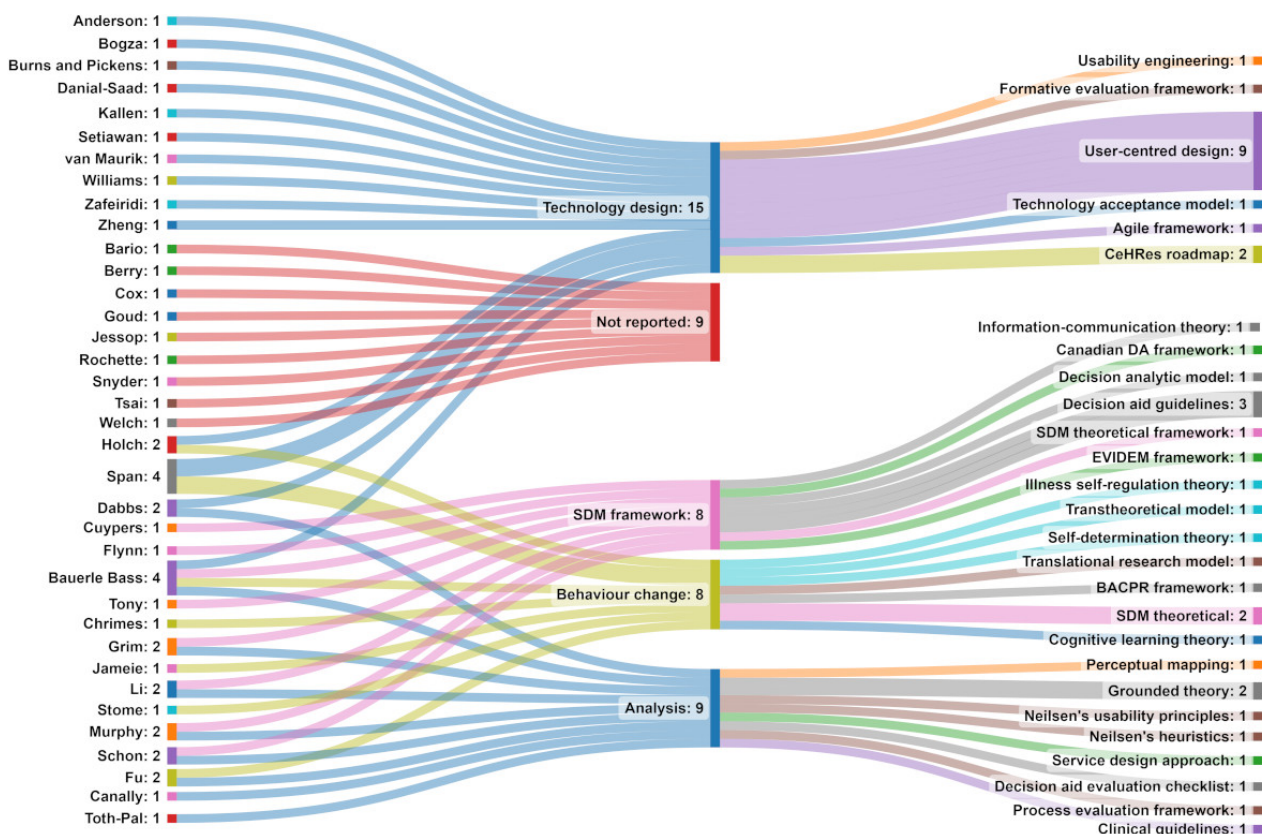
^qCeHRes: Center for eHealth Research and Disease Management.

Frameworks and Theoretical Models

The frameworks and theoretical models reported by the authors during the development, implementation, and evaluation of the technologies to support SDM reflected 5 categories: technology design (15/38, 39%), behavior change (21/38, 21%), analysis (9/38, 24%), SDM framework (8/38, 21%), and not reported

(9/38, 24%; [Figure 4](#)). Notably, 24% (9/38) of the studies did not report using a framework or model during any stage of their research. Authors most commonly reported using a model or framework as a foundation to inform the design of their respective SDM technologies. User-centered design (9/15, 60%) was the most frequently used technology design framework.

Figure 4. Mapping frameworks and theoretical models used during the usability evaluations. BACPR: British Association for Cardiovascular Prevention and Rehabilitation; CeHRes: Center for eHealth Research and Disease Management; DA: decision aid; EVIDEM: Evidence and Value: Impact on Decision-Making; SDM: shared decision-making. [32-41, 43, 45-69]



Discussion

Principal Findings

This scoping review was conducted to provide knowledge about how usability is evaluated when developing or implementing rehabilitation technologies aimed at supporting SDM. The first research question examined the methods and measures used in the context of SDM at different phases of technology development and implementation. Our findings revealed 14 reported methods that can help in evaluating the overall functionalities of the system and whether it fulfills the users' requirements [75] and can be effective for identifying issues with a system [76]. The most frequent reported methods included think-aloud protocols (14/38, 36%), semistructured interviews (16/38, 42%), and questionnaires (24/38, 63%; Table 3). There was a total of 30 usability measures reported (Table 4), with the System Usability Scale being the most frequently used among the included studies. We operationalized the different types of methods used through the model by Jacobsen [31], reflecting empirical methods (based on users' experience with the technology in a systematic way), inspection methods (conducted by experts who examine usability-related aspects of a user interface without involving any users), and inquiry methods (based on the information about users' needs, likes, and understanding of the technology through interviews or focus groups, observation, or comments). Notably, the reported methods were predominantly classified as inquiry and empirical (Figure 2).

The second research question examined the parameters of usability that were measured and reported. We found that the methods used to evaluate different parameters of usability varied according to the a priori framing of usability, demonstrated by the variations in the definitions of usability described by the authors (Table 1). There was an evolution in the definition of usability across the included studies, with more recent studies (published since 2016) using the unified definition proposed by the ISO [43,46,48,57,61,64,65,67]. The usability parameters of the definitions were categorized based on the proposed comprehensive hierarchical model by Gupta et al [23] as effectiveness (9/38, 23%), efficiency (8/38, 21%), memorability (11/38, 29%), satisfaction (14/38, 37%), security (5/38, 13%), universality (4/38, 10%), and productivity (10/38, 26%). These are consistent with the 3 constructs of the ISO standards, which are effectiveness, efficiency, and satisfaction, and allows for a more detailed categorization of usability parameters.

Although the ISO standards [21] and the usability model by Gupta et al [23] provide dimensions that could be considered as primary usability parameters, there remain challenges with measuring usability that emerged in this review. On the surface, usability is a simple concept. In fact, simplicity is at the heart of usability; however, measuring usability is not simple. Paradoxically, the ISO definition of usability is complex. Usability is about the person's experience; however, that experience is influenced by many aspects, such as a person's behavior and social network and the complexity of the technological functionalities. Usability may be viewed as a

feature of the technology or an emergent property of the interaction between the user, the system, and contextual factors. Evaluating usability through these lens leads to using inspection, empirical, or inquiry methods [31]. These can be applied at different stages of development of a technology (ie, in a developmental laboratory, in preimplementation, or during implementation), as described by the included studies (Table 2).

This review revealed that evaluating usability requires a comprehensive approach with several methods to cover multiple usability parameters. Most articles included in this review (36/38, 95%) focused on inquiry methods, relying heavily on questionnaires and semistructured interviews to evaluate usability, and the most frequent empirical method was think-aloud protocols (Figure 2). Although a comprehensive approach is suggested for accurate usability evaluation, this was largely not shown in the included articles. Rather, 73% (28/38) of the included studies only used 1 or 2 methods in total to evaluate usability. Only 2% (1/38) of the studies, conducted by Span et al [59], incorporated multiple methods that covered all 3 dimensions—inquiry, inspection, and empirical [31]. However, some of the included studies (2/38, 5%) described different usability evaluations for the same technology at different stages of development in separate articles (eg, “Take Charge, Get Cured” in the developmental [34] and preimplementation [51] stages). It is believed that the combination of inspection, empirical, and inquiry methods can provide more accurate and complete results in finding usability problems as there is no exact method considered to be the best for usability evaluation [77]. Matera et al [78] developed a systematic usability evaluation framework to address this challenge. They posited that usability can be reliably evaluated by systematically combining evaluation methods [78]. Recent reviews of usability not specific to SDM in software [79], mobile health [80], eHealth [81], user experience [82], and web development [83] mirrored the results of this review in that few studies used a combination of evaluation methods.

However, the lack of reported inspection methods demonstrated in this review may partially be explained by the inherent nature of SDM technologies for rehabilitation rather than a lack of comprehensive evaluation. Very few examples of inspection methods were demonstrated across the included studies, with only 2% (1/38) using cognitive walk-throughs and an additional 2% (1/38) using “near live” clinical situations. Critically, inspection methods refer to evaluations conducted by specific usability experts [31], not by the end users of the technology (eg, patients and clinicians). As the purpose of technology to support SDM in rehabilitation is to improve patient-centered care, the consideration of end users in the development—and, consequently, the usability evaluations—is crucial to ensure that the technology will be understood and adopted by the target population. Therefore, we propose that a comprehensive approach for evaluating the usability of rehabilitation technologies aimed at supporting SDM could focus on empirical and inquiry methods to prioritize the input of the patient and clinician end users.

Although questionnaires were found to be the most common method used overall, the identified measures of usability in the

included studies demonstrated limitations in comprehensiveness, largely mapping to the parameters of satisfaction and memorability (Figure 3). The emphasis on the parameter of satisfaction (demonstrated in 32/38, 84% of measures) may reflect the importance of this parameter when developing technologies for SDM in rehabilitation (eg, the importance of evaluating the usefulness, user-friendliness, and ease of use). However, this may also reflect key missing areas in usability evaluation. Critically, the parameters of usability described by the authors in their a priori definitions of usability were not found to be consistent with the parameters of the measures that were used. Therefore, although individuals may be conceptualizing usability in a comprehensive manner, the measurement itself was not comprehensive. For example, there was a demonstrated lack of measurement of the parameters of effectiveness and efficiency, which were both described in the definition of usability in 34% (13/38) of the included studies, although both were only found to be used in 23% (9/38) of usability measures.

This review uncovered the need for inclusion of theoretical models or frameworks during various stages of SDM usability studies to guide which usability parameter to measure. Theoretical models and frameworks were infrequently reported (Figure 4). Most studies in this review (27/38, 71%) reported using 1 model or framework, whereas some (10/38, 26%) integrated 2. Only 2% (1/38) of the studies, carried out by Bauerle Bass et al [34], exhibited an in-depth application of models and frameworks as underpinnings to their research. The most common (9/38, 24%) and perhaps the most beneficial framework, user-centered design, served as the foundation for designing an SDM technology [21,36,42].

The importance of using theoretical models and frameworks during the development, implementation, and analysis of technologies and evaluation of usability is demonstrated through the implications of poor usability [18,84,85], which discourages users from using the technology systems. Moreover, if the technology systems are not user-friendly, then they can increase the problems experienced by users. Solutions to systems failing to meet the users’ needs include understanding user feedback [86], usability evaluations [75], involving users in the early stages of development [87], and including professionals such as providers [88]. There is a need for flexibility and for friendly, simple, and self-explanatory interfaces that allow users to interact with the system [89]. For the systems to be effective, it is important to assess a system that is easy to use on a daily basis. This would increase the ability of the patients to control their diseases and allow their daily lives to be more satisfying [76]. The technology systems need to be designed for a particular type of user and need to be easy to use to create acceptance. The usability of the technology system is vital as it has a high degree of influence over the success of the system. Thus, the system needs to be designed to provide a friendly environment for the user to develop a positive attitude toward using it and lead to its successful adoption.

It is envisioned that the involvement of end users in the development of SDM technologies will continue to grow and that more applications of existing technology, such as mobile phones, websites, or applications, will be used to benefit

individuals with disabilities. We also anticipate that more companies may show an interest in this market, potentially promoting frequent use of SDM technologies in rehabilitation care. However, there are challenges in the development of SDM technologies, such as tailoring to individuals' capabilities and properly addressing the emotional state of individuals with disabilities or cognitive impairments during everyday tasks. It will be critical to develop these technologies in a way that meets individual variations in needs and abilities of individuals with disabilities so that they really help maintain autonomy, provide meaningful activities, and promote decision-making [18,84,85].

An important area for this growing field will be how to effectively integrate end-user input throughout all stages of development of such SDM technologies, including effective usability testing. An additional challenge for the field of rehabilitation care in supporting SDM technologies would be in integrating the technology into the built environment, such as a client-server system, and into routine care [86]. There is a clear need for new methods of rapid SDM technology appraisal and evaluation to inform deployment to overcome the barriers that will be faced because of the expected further integration of SDM technologies within the built environment.

Limitations

We did not assess the quality of the included articles, consistent with the scoping review methodology [27,90]. Therefore, we included studies with different designs and different quality levels, which allowed for a broad exploration of measures and methods used to evaluate the usability of SDM technologies. In our results, we focused mainly on general usability measures and did not report the psychometric properties and clinical utility of these measures. Future work needs to evaluate the psychometric properties and clinical utility of usability measures through a systematic review methodology with a quality

assessment of the included articles. Another limitation was that we did not include gray literature as this scoping review aimed to examine the reported measures and methods used in peer-reviewed rehabilitation literature on SDM technologies. It could be an area of interest for future work to examine what methods and measures are used in gray literature.

Conclusions

The results of this scoping review highlight the importance as well as the complexity of usability evaluation. Although various methods and measures were shown to be used to evaluate the usability of technologies to support SDM in rehabilitation, very few evaluations used in the included studies adequately spanned the selected usability parameters. This review identified gaps in usability evaluation as most studies relied solely on questionnaires rather than a combination of inspection and empirical methods and most questionnaires simply focused on the usability parameter of satisfaction. We recommend for individuals to adopt a comprehensive approach to usability evaluation of SDM technologies, starting with a clear definition of how usability is conceptualized to guide the structure of the evaluation. In addition, we recommend the use of multiple usability evaluation methods categorized as inspection (eg, questionnaires, focus groups, and interviews) or empirical (eg, think-aloud protocols) to capture a more complete picture of end-user needs and interpretations. The selected methods should span a variety of parameters of usability, not just satisfaction (eg, effectiveness, efficiency, memorability, security, universality, and productivity). The consideration of end users (such as patients and clinicians) is of particular importance for the development of technologies to support SDM as the process of SDM itself aims to improve patient-centered care and integrate both patient and clinician voices into their rehabilitation care.

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Authors' Contributions

All authors contributed to the design of this study, provided critical insights, and contributed to the final written manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Ovid MEDLINE search strategy.

[DOCX File, 15 KB - [rehab_v10i1e41359_app1.docx](#)]

Multimedia Appendix 2

Characteristics of the included studies and participants.

[DOCX File, 24 KB - [rehab_v10i1e41359_app2.docx](#)]

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Abbreviations

ISO: International Organization for Standardization

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

SDM: shared decision-making

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Review

Economic Evaluation of Telerehabilitation: Systematic Literature Review of Cost-Utility Studies

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Abstract

Background: Telerehabilitation could benefit a large population by increasing adherence to rehabilitation protocols.

Objective: Our objective was to review and discuss the use of cost-utility approaches in economic evaluations of telerehabilitation interventions.

Methods: A review of the literature on PubMed, Scopus, Centres for Review and Dissemination databases (including the HTA database, the Database of Abstracts of Reviews of Effects, and the NHS Economic Evaluation Database), Cochrane Library, and ClinicalTrials.gov (last search on February 8, 2021) was conducted in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The inclusion criteria were defined in accordance with the PICOS (population, intervention, comparison, outcomes, and study design) system: the included studies had to evaluate patients in rehabilitation therapy for all diseases and disorders (population) through exercise-based telerehabilitation (intervention) and had to have a control group that received face-to-face rehabilitation (comparison), and these studies had to evaluate effectiveness through gain in quality of life (outcome) and used the design of randomized and controlled clinical studies (study).

Results: We included 11 economic evaluations, of which 6 concerned cardiovascular diseases. Several types of interventions were assessed as telerehabilitation, consisting in monitoring of rehabilitation at home (monitored by physicians) or a rehabilitation program with exercise and an educational intervention at home alone. All studies were based on randomized clinical trials and used a validated health-related quality of life instrument to describe patients' health states. Four evaluations used the EQ-5D, 1 used the EQ-5D-5L, 2 used the EQ-5D-3L, 3 used the Short-Form Six-Dimension questionnaire, and 1 used the 36-item Short Form survey. The mean quality-adjusted life years gained using telerehabilitation services varied from -0.09 to 0.89. These results were reported in terms of the probability that the intervention was cost-effective at different thresholds for willingness-to-pay values. Most studies showed results about telerehabilitation as dominant (ie, more effective and less costly) together with superiority or noninferiority in outcomes.

Conclusions: There is evidence to support telerehabilitation as a cost-effective intervention for a large population among different disease areas. There is a need for conducting cost-effectiveness studies in countries because the available evidence has limited generalizability in such countries.

Trial Registration: PROSPERO CRD42021248785; <https://tinyurl.com/4xurdvwf>

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KEYWORDS

telerehabilitation; cost-effectiveness; quality-adjusted life year; economic evaluation; cost; rehabilitation; systematic review

Introduction

Telerehabilitation

Telerehabilitation refers to the delivery of rehabilitation and habilitation services via a variety of information and communication technologies (ICTs), commonly referred to as “telehealth” technologies. Clinically, the term “telerehabilitation” encompasses a range of rehabilitation and habilitation services that include evaluation, assessment, monitoring, prevention, intervention, supervision, education, consultation, and coaching [1]. This broad definition of Telerehabilitation suggests that the type of ICTs used to support the services is very diverse and is expected to change as technology continues to evolve [2]. Recently, the COVID-19 crisis has increased interest in telerehabilitation and has extended in some countries its perimeter for access and reimbursement [3]. Telerehabilitation is used in several diseases and could benefit a large population in various clinical settings with the aim to improve outcomes by increasing access and adherence to rehabilitation protocols with a positive impact on physical and mental functions and quality of life [4].

Economic Evaluation

Economic evaluation is a set of formal analytical techniques that provide systematic information about the costs and benefits of alternative therapeutic or preventive options and can thereby assist in decision-making. The objective is to contribute to the efficiency of health care spending and to document value for money to support reimbursement of drugs, medical devices, and activities [5,6]. Many countries have introduced this rationale within their regulations regarding reimbursement and negotiation of the price of innovative new medical products. In France, the economic evaluation of medical products has existed by regulation since 2012 [7], which established the principle of evaluating the efficiency for health products within the framework of the market access process. These evaluations are requested from manufacturers submitting economic evaluations of new medical products (including drugs and devices) that have substantially improved clinical benefits and have a significant impact on budget and an organizational impact on patient management and professional practices. More generally, economic evaluations are performed when assessing public health programs at the national or local level and in the management of health care facilities.

It should be noted that an economic evaluation is only appropriate after its effectiveness and safety have been methodologically soundly demonstrated as a first step. In this respect, the effectiveness of using telerehabilitation has been demonstrated in many studies among different disease areas, and several systematic reviews conclude that telerehabilitation was effective, for example, for patients presenting with musculoskeletal conditions, those with multiple sclerosis, those with impaired mobility [8-12], and those in cardiac telerehabilitation [13]. In the case of pharmaceuticals and devices, the market access dossier of innovations is mainly

based on the efficacy and safety results derived from randomized clinical trials. Organizational innovations such as those associated with the use of telerehabilitation raise multiple practical and regulatory issues in the design of interventional studies, which limits their feasibility. In France, as well as in many other jurisdictions including the United Kingdom, Australia, and Nordic countries, the guidelines for manufacturers submitting economic evaluations recommend using cost-effectiveness analysis, where quality-adjusted life years (QALYs) are listed as one of the favored options for measuring effectiveness [14,15]. Over time, QALYs has imposed itself internationally as the gold-standard measure of effectiveness [16,17]. The main reason is the need for consistency in the outcome measures to ensure the usefulness of cost-effectiveness results in decision-making. The existence of a common metric enables the comparison of different kinds of outcomes across disease areas and their comparison with costs in a meaningful way.

Economic Evaluation of Telerehabilitation

In telerehabilitation, multiple types of clinical outcomes can be considered [18]. QALYs include mortality and morbidity in one single measure that qualifies the years lived weighted by their quality of life. Cost-utility analysis (CUA) involves comparing costs and QALYs. Economic evaluations also consider the dimensions of the cost differential associated with the technology of interest as compared to standard of care defined as the situation of reference. The estimation of costs depends on the perspective chosen from a decision-making standpoint: it is important to clearly define who pays the extra costs or benefits from cost savings. The value of saving money for the society at large or engaging additional resources to support an innovative product or service may be viewed differently by public or private third-party payers, health providers, governmental agencies, or individual patients.

The extent of cost measurement may then vary deeply in accordance with the scope of the study, suggesting the difficulties and limitations of comparing the results of economic studies performed at an international level and over various time periods. However, even if the transferability of the results of economic evaluation from one setting to another is not straightforward, it remains interesting to benefit from the international experience gained on the economic evaluation of telerehabilitation and especially in focusing on the most ambitious studies based on randomized controlled trials (RCTs) and cost utility.

Goal of the Study

Despite the existence of 2 systematic literature reviews conducted on cost-effectiveness studies on physical rehabilitation, including telerehabilitation, there is no review about the cost-utility of telerehabilitation to our knowledge [19,20].

The aim of this paper is to review and discuss the use of cost-utility approaches in economic evaluations of

telerehabilitation interventions. It is based on a literature review of all published analyses conducted in this field, which used a CUA methodology.

Methods

This review was planned and conducted in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [21]. It was preregistered on PROSPERO before the search was initiated.

Inclusion and Exclusion Criteria

The inclusion criteria for this systematic review were defined in accordance with the PICOS (population, intervention, comparison, outcomes, and study design) framework: the included studies had to evaluate patients in rehabilitation therapy for all diseases and disorders (population) through exercise-based telerehabilitation (intervention) and had to have a control group that received face-to-face rehabilitation (comparison), and studies had to have evaluated effectiveness through gain in quality of life (outcomes) and used the design of randomized and controlled clinical studies (study). Studies were included if they met the following criteria: they involved synchronous (real-time and interactive) or asynchronous (store-and-forward) telerehabilitation services with health professionals, they were based on RCTs comparing telerehabilitation with usual in-center rehabilitation, and they reported findings on the cost-utility of telerehabilitation in terms of cost per QALY.

Studies were excluded if they only presented the costs of telerehabilitation. Comments, letters, news articles, editorials, correspondence, narratives, systematic reviews, case studies, study protocols, and articles that were not original or published in non-peer-reviewed journals were also excluded. Finally, when a study was available in different formats or published in several versions, the one containing more information was included. The search has been limited to studies published in French and English until February 8, 2021.

Literature Search

The following literature databases were used: PubMed, Scopus, Centres for Review and Dissemination databases (including the HTA database, the Database of Abstracts of Reviews of Effects, and the NHS Economic Evaluation Database), the Cochrane Library, and ClinicalTrials.gov. The references of key full-text articles included in the review were checked to identify any potentially eligible studies, including previously published systematic reviews. Search terms were constructed with 2 themes: cost-utility studies and telerehabilitation ([Multimedia Appendix 1](#)). Related terms under each theme were combined by using the Boolean operator OR, and the 2 themes were combined using the Boolean operator AND. Additional Boolean operator NOT was used to exclude protocols.

Study Selection and Data Collection

All identified studies were subject to a 4-step screening process in accordance with the PRISMA framework (identification, screening, eligibility, and included). The search results were exported to an Excel (Microsoft Corp) spreadsheet for exclusion of duplicates. Two independent evaluators assessed the titles and abstracts of relevant studies for inclusion. In case the title abstract did not provide enough information regarding the eligibility criteria, full-text documents were considered. Discrepancies were resolved through discussion until consensus was reached.

The initially selected studies were manually reviewed to identify additional relevant studies. All the references of the articles selected in the first phase were checked for study selection following the same process described previously before the inclusion of the studies.

Two analysts independently extracted data using a common data extraction form.

The following data were extracted for all selected studies: authors, publication year, country of origin, study perspective, pathology of interest, population targeted, sample size, type of intervention, comparator, setting, clinical outcomes studied, time horizon, type of utility data, cost data, economic outcome measure, and authors' conclusions; QALYs at each time of follow-up, clinical outcomes, and mean differences or standardized mean differences for continuous outcomes with their corresponding confidence intervals; and incremental costs, incremental utility, incremental cost-effectiveness ratio (ICER), and the decision uncertainty is expressed by cost-effectiveness acceptability curves.

Discrepancies in the contents of the full texts of the extracted studies were resolved through discussion.

Quality Assessment

Two authors independently assessed the methodological quality of the selected studies using the Drummond checklist of the French Health Authority [5,17]. The Drummond checklist was designed to guide the critique of economic evaluations and considers (1) the research question, (2) the description of the study or intervention, (3) the study design, (4) the identification of the cost and consequences of each alternative, (5) measurement, and (6) valuation of costs and consequences, (7) whether discounting was carried out, (8) incremental analysis, (9) presentation of results with uncertainty and sensitivity analyses, and (10) discussion of results in the context of policy relevance and the existing literature.

A component approach was used when applying the checklist in [Table 1](#). This approach is advocated in the PRISMA statement and entails assessing each item individually rather than generating a summary score [22,23].

Table 1. Quality assessment of the studies in accordance with the Drummond checklist.

Questions	Studies reporting	Studies, n (%)
The study takes account of both the costs and the outcomes of the intervention.	All studies	11 (100)
The study compares all relevant options on the clinical level.	All studies	11 (100)
A specific viewpoint was adopted, and the study was positioned in a particular decision-making context.	All studies	11 (100)
No important alternative was omitted.	No study	0 (0)
The “do nothing” alternative has been envisaged and studied, if relevant.	N/A ^a	N/A
The alternatives' descriptive elements have been presented (frequency, population analyzed, design of the intervention, etc).	All studies	11 (100)
Effectiveness has been established by a randomized controlled clinical trial, whose protocol reflects what would normally happen in current practice.	All studies	11 (100)
Effectiveness has been established through a summary review of clinical trials of good methodological quality.	N/A	N/A
Effectiveness has been established through observational data or assumptions, with an analysis of biases in the conclusions.	All studies	11 (100)
Have the different relevant viewpoints been examined with regard to costs as well as health effects?	All studies	11 (100)
No important health effect has been omitted. If an important health effect has not been examined, this choice has been justified.	All studies	11 (100)
No important cost has been omitted. If an important cost item has not been examined, this choice has been justified.	All studies	11 (100)
All identified outcomes and cost items have been measured.	All studies	11 (100)
The method used for the quantification of the resources consumed is valid. Unit costs have been detailed (tariffs, market prices, etc) and are suited to the perspective adopted.	All studies except Frederix et al [24]	10 (91)
The measurement of health outcomes is suited to the question posed (life years, event avoided, preference score, etc). The method used to measure the outcomes is valid.	All studies	11 (100)
The sources of information are clearly identified, and the most relevant source has been given priority.	All studies	11 (100)
The costs and outcomes have been discounted at the same rate.	N/A	N/A
The discount rate is known and has been justified.	N/A	N/A
A sensitivity analysis (deterministic and probabilistic) has been presented, covering all uncertain key parameters.	All studies except 3: Frederix et al [24], Frederix et al [25], and Haesum et al [26]	8 (72.7)
In the deterministic analysis, the value intervals have been justified.	Longacre et al [27]	1 (9)
In the probabilistic analysis, the statistical analyses are suited to the nature of the key parameters, and their distribution has been presented and justified.	Longacre et al [27], Kloek et al [28], Fatoye et al [29], Maddison et al [30], Nelson et al [31], and Hwang et al [32]	6 (54.5)
The uncertainty involved in the conclusions of the economic evaluation is known and has been discussed (using CIs, confidence ellipse, or acceptability curve).	Frederix et al [25], Longacre et al [27], Kloek et al [28], Fatoye et al [29], Maddison et al [30], and Hwang et al [32]	6 (54.5)
An analysis of the differences in the costs and health outcomes of the competing alternatives has been conducted and presented.	All studies	11 (100)
If an aggregate indicator has been provided (cost-outcome ratio), it has been correctly interpreted.	All studies except Maddison et al [30] and Nelson et al [31]	9 (81.8)
The alternatives on the cost-effectiveness frontier have been identified.	N/A	N/A
The study is transparent on its limitations.	All studies	11 (100)
The conclusions have been compared, from a critical viewpoint, to those of other studies on the same topic.	All studies	11 (100)

Questions	Studies reporting	Studies, n (%)
The study addresses the issue of generalizing the conclusions for other contexts or different groups of patients.	All studies	11 (100)

^aN/A: not applicable.

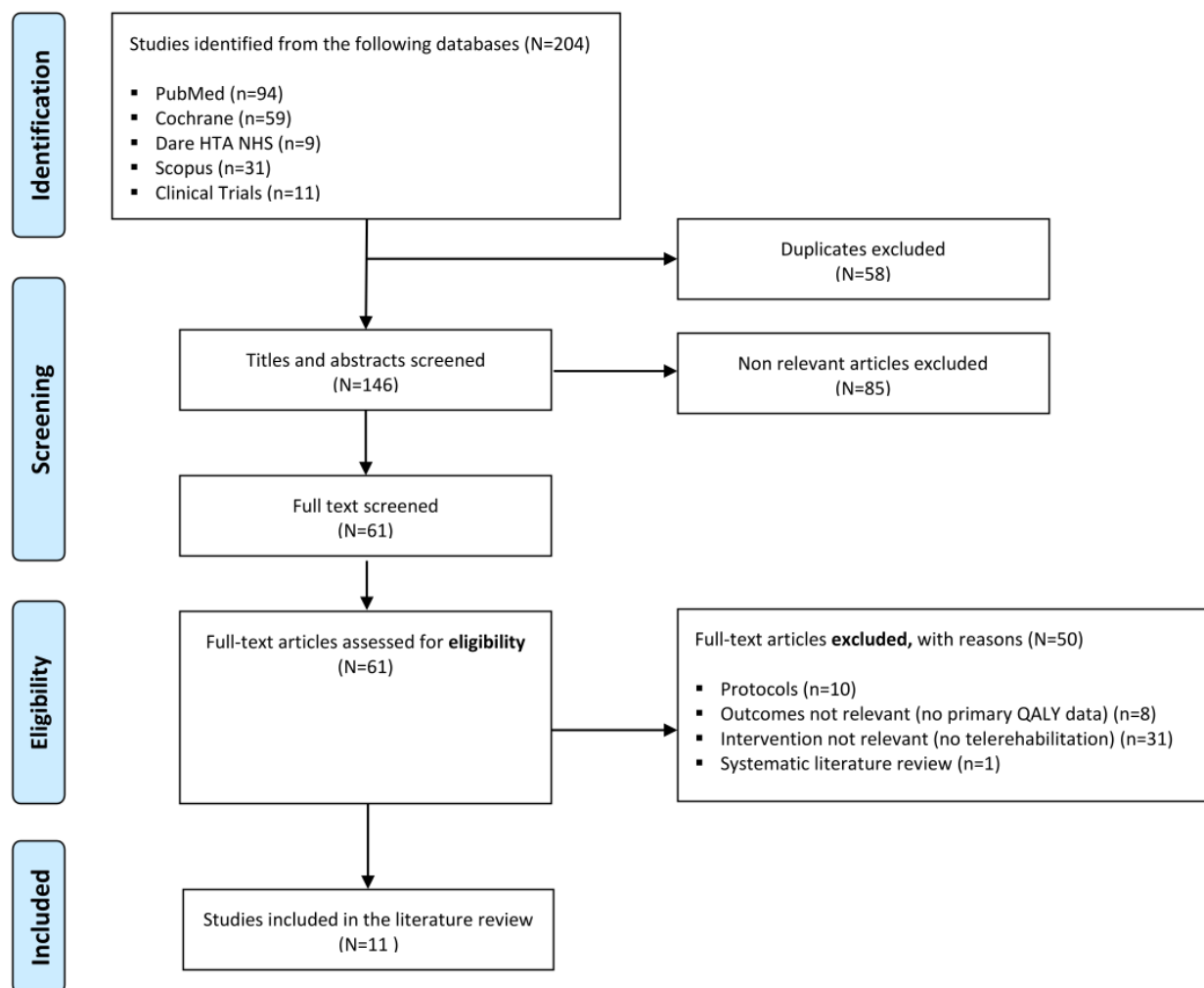
Results

Study Selection

The search across the aforementioned databases retrieved 204 records. The search across ClinicalTrials.gov retrieved 11 records. After removing duplicates, 146 records remained, of

which a further 85 records were excluded as titles and abstracts did not meet the eligibility criteria. During full-text screening, 61 citations were examined in further detail, of which 50 studies were excluded. Finally, a total of 11 economic evaluations were included in the review. The study selection process is shown in [Figure 1](#).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. Dare: the Database of Abstracts of Reviews of Effects; HTA: the HTA database; NHS: the NHS Economic Evaluation Database.



Study Characteristics

The methodology of the selected studies is summarized in [Multimedia Appendix 2](#) and analyzed in [Table 2](#). Regarding the diseases assessed, 6 concerned cardiovascular diseases, 1 concerned chronic obstructive pulmonary disease (COPD), 1 concerned hip or knee osteoarthritis (or both), 1 concerned patients having undergone total hip replacement, 1 concerned nonspecific chronic low back pain, and 1 concerned cancer.

Several types of interventions were assessed as telerehabilitation, consisting in monitoring of rehabilitation at home (monitored by physicians) or a rehabilitation program with exercise and an educational intervention at home alone. All studies met our telerehabilitation criteria with well-specified monitoring frequencies, the use of video for monitoring, and other connected tools. Overall, half of the studies had an intervention duration (usual care and intervention group) of 12 weeks.

Table 2. Characteristics of the selected studies (N=11).

Study characteristics	Studies Citations	n (%)
Region		
Europe	Frederix et al [24], Frederix et al [25], Haesum et al [26], Kloek et al [28], Kidholm et al [33], and Kraal et al [34]	6 (55)
United States and Australia	Longacre et al [27], Maddison et al [30], Nelson et al [31], and Hwang et al [32]	4 (36)
Africa	Fatoye et al [29]	1 (9)
Perspective of cost measurement		
Societal and health care system	Frederix et al [24], Kloek et al [28], and Kraal et al [34]	3 (27)
Health care system	Knapp et al [18], Cochrane et al [19], Liu et al [20], Moher et al [21], Frederix et al [25], Longacre et al [27], Kloek et al [28], and Kidholm et al [33]	8 (73)
Condition		
Orthopedics	Kloek et al [28], Fatoye et al [29], and Nelson et al [31]	3 (27)
Cardiology	Frederix et al [24], Frederix et al [25], Maddison et al [30], Hwang et al [32], Kidholm et al [33], and Kraal et al [34]	6 (55)
Pulmonology	Haesum et al [26]	1 (9)
Cancer	Longacre et al [27]	1 (9)
Sampe size		
<100	Fatoye et al [29], Nelson et al [31], Hwang et al [32], and Kraal et al [34]	4 (36)
100-200	Frederix et al [24], Frederix et al [25], Haesum et al [26], Maddison et al [30], and Kidholm et al [33]	5 (46)
>200	Longacre et al [27] and Kloek et al [28]	2 (18)
Time horizon		
<1 year	Haesum et al [26], Longacre et al [27], Fatoye et al [29], Maddison et al [30], and Nelson et al [31]	5 (45)
1-5 years	Frederix et al [24], Frederix et al [25], Kloek et al [28], Kidholm et al [33], Hwang et al [32], and Kraal et al [34]	6 (55)
Quality of life instruments		
SF-6D ^a or SF-36 ^b	Haesum et al [26], Fatoye et al [29], Kidholm et al [33], and Kraal et al [34]	4 (36)
EQ-5D	Frederix et al [24], Frederix et al [25], Longacre et al [27], Kloek et al [28], Maddison et al [30], Nelson et al [31], and Hwang et al [32]	7 (64)
Number of utility assessments		
2	Frederix et al [25] and Haesum et al [26]	2 (18)
3	Frederix et al [24], Longacre et al [27], Fatoye et al [29], Maddison et al [30], Nelson et al [31], and Hwang et al [32]	6 (55)
4	Kidholm et al [33] and Kraal et al [34]	2 (18)
5	Kloek et al [28]	1 (9)
Intervention duration		
Usual care group		
<12 weeks	Fatoye et al [29] and Nelson et al [31]	2 (18)
12 weeks	Frederix et al [24], Kloek et al [28], Maddison et al [30], Hwang et al [32], Kidholm et al [33], and Kraal et al [34]	6 (55)
>12 weeks	Frederix et al [25], Haesum et al [26], and Longacre et al [27]	3 (27)
Intervention group		
<12 weeks	Fatoye et al [29] and Nelson et al [31]	2 (18)

Study characteristics	Studies	n (%)
	Citations	
12 weeks	Kloek et al [28], Maddison et al [30], Hwang et al [32], Kidholm et al [33], and Kraal et al [34]	5 (45)
>12 weeks	Frederix et al [24], Frederix et al [25], Haesum et al [26], and Longacre et al [27]	4 (36)

^aSF-6D: Short-Form Six-Dimension questionnaire.

^bSF-36: 36-item Short Form survey.

All studies were based on clinical data collected in RCTs. Sample sizes varied from 47 to 516 patients. Only 2 studies had more than 200 participants [27,28].

Four studies had a full societal perspective including health care costs, out-of-pocket patient costs, and productivity loss. Five studies considered only health care costs, 1 included health provider and patient costs, and 1 included only patient intervention costs (Table 1).

All studies carried out a comprehensive cost analysis and included all items of costs relevant to the chosen perspective.

All studies used a validated health-related quality of life (HR-QoL) instrument to describe patients' health states. Four evaluations used the EQ-5D, 1 used the EQ-5D-5L, 2 used the EQ-5D-3L, 3 used the Short-Form Six-Dimension questionnaire (SF-6D), and 1 used the 36-item Short Form survey (SF-36). No direct valuation method was used to obtain health state utilities. Most evaluations reported the method used to transform the scores from the HR-QoL instrument into utility values. Regarding utility estimates, evaluations in several studies calculated QALYs using the area under the curve method or using the change from baseline score [25-30,33]. In some cases, the calculation was explicitly described [27-30], as for example, the one reported by Longacre et al [27], who calculated QALYs with a conversion of incremental utility gain over the 6-month trial period.

Quality Assessment

Quality assessment using the Drummond checklist is shown in Table 1. Two reviewers independently conducted the quality assessment for 10% (2/15) of the selected studies. Disagreements were limited to item 6 ("Were costs and consequences valued

credibly?") on the checklist, and examples in Cartwright's [35] study were consulted to overcome these disagreements. Practical application of item 10 ("Did the presentation and discussion of study results include all issues of concern to the users?") was challenging due to limited guidance; hence, findings from this question were less informative.

Only 6 studies had a time horizon of 1 year or more. All studies except for those of Haesum et al [26] and Fatoye et al [29] conducted sensitivity analyses on important uncertain variables.

Evaluation Outcomes

The results of economic evaluations are summarized in Multimedia Appendix 3 and presented in Table 3. The mean QALYs gained using telerehabilitation services varied from -0.09 to 0.89 in the reviewed studies. Nine studies explicitly performed parametric modeling or nonparametric bootstrapping to calculate uncertainty around the costs and effects estimates. These results were reported in terms of the probability that the intervention was cost-effective at different thresholds for willingness-to-pay values. Two studies reported that the QALY gain was not cost-effective [31,34]. Five studies did not report the CI or P values of QALYs [24,27,28,30]. In more than half of the studies, it was not possible to draw any conclusion about cost-effectiveness based on a willingness-to-pay threshold. These studies reported small positive differences in QALYs at increased or similar costs but failed to report significance. All, except for 3 studies [26,29,30] calculated incremental cost per QALY or net monetary benefit.

The main lessons from the 11 studies are that it is dominant (ie, more effective and less expensive) to offer telerehabilitation, which refers to the delivery of rehabilitation and habilitation services via a variety of ICTs used in several diseases.

Table 3. Permutation plots summarizing the findings of economic evaluations for interventions versus comparators. Numbers in the cells are number of studies relevant to each permutation.

Incremental costs	Incremental quality-adjusted life years		
	+ ^a	0 ^b	- ^c
+	1 (Kidholm et al [33])	0	0
0	0	0	0
-	7 (Frederix et al [24], Frederix et al [25], Haesum et al [26], Longacre et al [27], Fatoye et al [29], Hwang et al [32], and Kraal et al [34])	2 (Kloek et al [28] and Maddison et al [30])	1 (Nelson et al [31])

^aBetter health outcomes and higher costs.

^bUnchanged health outcomes and unchanged costs.

^cPoorer health outcomes and lower costs.

Discussion

Principal Results

This review assesses cost-utility studies of telerehabilitation in comparison with usual care for different diseases and disorders. The general quality of the studies selected in terms of design, statistical methodology, and reporting was quite high. Considering the seminal reviews of telerehabilitation evaluation studies by Bergmo in 2009 [36] and 2014 [37], important progress has been made. However, this may be due to our selection criteria, which were narrower by focusing on telerehabilitation studies based on RCTs.

This review identified 11 economic evaluations with a CUA approach that used QALYs to measure health outcomes. The number of RCTs included in this review might appear quite low compared to the number of studies that use CUA for pharmaceuticals or medical devices.

Most studies originated in northern Europe and Australia, which might be partially explained by extensive expertise in health economics and the request for rigorous evaluations before the widespread adoption of any new health care technology or procedure.

Seven evaluations took the perspective of health providers and intervention costs only and 4 also envisage a societal perspective including costs and benefits for all stakeholders involved.

Most studies showed results about telerehabilitation as dominant, less costly, and with superiority or noninferiority in outcomes. In cases where the incremental utility and ICER were calculated, these values were below the thresholds used in the United Kingdom: the National Institute for Clinical Excellence has recommended that if the ICER is below £20,000-£30,000 (approximately US \$25,000-\$38,000) per QALY, it is cost-effective.

Results obtained in terms of efficiency based on ICER values or dominant situations provide the expected framework to inform resource allocation by using a common metric, which enables the comparison of different kinds of benefits in multiple disease areas and allows a comparison with costs in a meaningful way. In addition to such a global synthetic presentation of CUA results, it may be noted that detailed intermediate results are also informative in any decision-making process. Disaggregating costs by categories, such as direct or indirect, societal or supported by the health care system, reimbursed or out-of-pocket, provide important information to different stakeholders. The same is true for clinical outcomes, especially to convince clinicians of the benefits of telerehabilitation. According to each therapeutic domain considered in this review, primary clinical end points used to define superiority were diverse.

For patients presenting with cardiovascular disease, Frederix et al [25] calculated the sample size based on a 20% effect size of maximum rate of oxygen consumption attainable during physical exertion (VO₂ peak), considering a dropout rate of 30% during follow-up. Maddison et al [30] reported that the RCT sample size was based on the assumption of noninferiority

in the VO₂ peak between groups at 12 weeks. In the same type of patients, in 2017, Kraal et al [34] used a physical activity level score, assessed on the basis of physical activity energy expenditure, estimated from an accelerometer and heart rate measured during a period of 5 subsequent days. Conversely, Kidholm et al [33] did not provide any clinical outcome in their study and focused only on the SF-36 instrument as an end point. In patients presenting with heart failure, Hwang et al [32] used the data from a noninferiority trial based on the 6-minute walk distance.

In both studies addressing telerehabilitation for patient populations either after hip or knee replacement or for presurgical patients with osteoarthritis, the primary outcome measure, recorded at 6 weeks, was physical functioning with the Quality of Life subscale of the Hip Disability and Osteoarthritis Outcome Score questionnaire. Despite this common primary end point, conclusions about sample sizes and follow-up periods were contrasted [38].

In the only study focused on patients presenting with advanced cancers [27], the primary clinical outcome was based on a mobility score on the Activity Measure for Post-Acute Care Computer Adaptive Test, measured at different times during follow-up [39].

Limitations

There are limitations to using QALYs as they might not capture all the benefits of health interventions of interest. Disease-specific HR-QoL instruments are generally more sensitive than generic measures including the EQ-5D or SF-6D in capturing benefits, especially in case of nonsevere conditions [40]. When choosing a utility measure, it is important to consider which instrument is most likely to be sensitive and relevant to changes in health for the specific condition considered. In most studies reviewed, the incremental benefits of QALYs compared to those of standard of care were not statistically significant, which was not surprising considering the limited sample sizes of these RCTs.

One challenge in all economic and clinical evaluations is to balance the need for internal validity against the ability to generalize results to other settings. All studies reviewed were conducted alongside RCTs—a study design associated with specific inclusion criteria for participant inclusion and center selection. Such designs should be discussed for rehabilitation as they may generate bias in the selection of the population enrolled.

Another type of bias, as described in the Cochrane Risk of Bias Tool, is the detection bias resulting from systematic between-group differences in how outcomes are determined [41]. This bias occurs if the knowledge of a patient's assigned strategy influences the outcome assessment. This situation may occur in RCTs where blinding is not feasible and where patient-reported outcomes, and especially HR-QoL, are considered end points. Patients enrolled in the telerehabilitation arm may be positively influenced by the awareness of benefitting from an innovative process and vice versa for the control.

It is the combination of these results, including those of CUA, as a specific aggregated complement that finally constitute the

material of interest for decision-making, letting each stakeholder select the data of primary interest in accordance with their perspective.

Conclusions

During the last decade, we have underlined important progress in rehabilitation studies, notably with the expansion of the use of innovative technologies. This systematic review suggests that telerehabilitation is a cost-utility approach to improve the accessibility of rehabilitation therapies in a large population in

various clinical settings among different areas. This result is important, notably in the recent context of the COVID-19 pandemic, to help determine the appropriate setup for new interfaces for telerehabilitation programs. There were sufficient studies with high levels of evidence on this theme to draw firm conclusions regarding the relative efficiency of telerehabilitation used for several diseases and disorders. There is a need for conducting cost-effectiveness studies in countries because the available evidence has limited generalizability to such countries.

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Authors' Contributions

SB and GK conceptualized the study, curated and analyzed the data, interpreted the results, and drafted and proofread the manuscript. FB extracted the data. NH and CF reviewed the registration information, conceptualized the study, screened and extracted the data, and drafted and proofread the manuscript. AC edited and formatted the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of search terms.

[[DOCX File, 11 KB - rehab_v10i1e47172_app1.docx](#)]

Multimedia Appendix 2

Studies characteristics.

[[DOCX File, 22 KB - rehab_v10i1e47172_app2.docx](#)]

Multimedia Appendix 3

Studies results.

[[DOCX File, 16 KB - rehab_v10i1e47172_app3.docx](#)]

Multimedia Appendix 4

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.

[[PDF File \(Adobe PDF File\), 117 KB - rehab_v10i1e47172_app4.pdf](#)]

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Abbreviations

COPD: chronic obstructive pulmonary disease

CUA: cost-utility analysis

HR-QoL: health-related quality of life

ICER: incremental cost-effectiveness ratio

ICT: information and communication technology

PICOS: population, intervention, comparison, outcomes, and study design

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QALY: quality-adjusted life year

RCT: randomized controlled trial

SF-36: 36-item Short Form survey

SF-6D: Short-Form Six-Dimension

VO₂ peak: maximum rate of oxygen consumption attainable during physical exertion

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Review

Virtual Reality for Pulmonary Rehabilitation: Comprehensive Review

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Abstract

Background: Pulmonary rehabilitation is a vital component of comprehensive care for patients with respiratory conditions, such as lung cancer, chronic obstructive pulmonary disease, and asthma, and those recovering from respiratory diseases like COVID-19. It aims to enhance patients' functional ability and quality of life, and reduce symptoms, such as stress, anxiety, and chronic pain. Virtual reality is a novel technology that offers new opportunities for customized implementation and self-control of pulmonary rehabilitation through patient engagement.

Objective: This review focused on all types of virtual reality technologies (nonimmersive, semi-immersive, and fully immersive) that witnessed significant development and were released in the field of pulmonary rehabilitation, including breathing exercises, biofeedback systems, virtual environments for exercise, and educational models.

Methods: The review screened 7 electronic libraries from 2010 to 2023. The libraries were ACM Digital Library, Google Scholar, IEEE Xplore, MEDLINE, PubMed, Sage, and ScienceDirect. Thematic analysis was used as an additional methodology to classify our findings based on themes. The themes were virtual reality training, interaction, types of virtual environments, effectiveness, feasibility, design strategies, limitations, and future directions.

Results: A total of 2319 articles were identified, and after a detailed screening process, 32 studies were reviewed. Based on the findings of all the studies that were reviewed (29 with a positive label and 3 with a neutral label), virtual reality can be an effective solution for pulmonary rehabilitation in patients with lung cancer, chronic obstructive pulmonary disease, and asthma, and in individuals and children who are dealing with mental health-related disorders, such as anxiety. The outcomes indicated that virtual reality is a reliable and feasible solution for pulmonary rehabilitation. Interventions can provide immersive experiences to patients and offer tailored and engaging rehabilitation that promotes improved functional outcomes of pulmonary rehabilitation, breathing body awareness, and relaxation breathing techniques.

Conclusions: The identified studies on virtual reality in pulmonary rehabilitation showed that virtual reality holds great promise for improving the outcomes and experiences of patients. The immersive and interactive nature of virtual reality interventions offers a new dimension to traditional rehabilitation approaches, providing personalized exercises and addressing psychological well-being. However, additional research is needed to establish standardized protocols, identify the most effective strategies, and evaluate long-term benefits. As virtual reality technology continues to advance, it has the potential to revolutionize pulmonary rehabilitation and significantly improve the lives of patients with chronic lung diseases.

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KEYWORDS

breathing exercise; breathing exercise gaming; pulmonary rehabilitation; respiratory biofeedback; virtual reality

Introduction

Background

Pulmonary rehabilitation focuses on breathing exercises that can help people with chronic lung diseases improve lung function and reduce symptoms of chest tightness, chronic cough, and wheezing. Apart from lung diseases, pulmonary rehabilitation is commonly used for treatments related to hypertension, chronic pain, and cardiovascular disorders, such as coronary artery issues, arrhythmia, and myocardial infarction [1,2]. Breathing exercises may also offer effective and simple solutions for depressive and anxiety episodes, and other mental health-related disorders [3,4].

In recent years, virtual reality (VR) technology has been used in a wide variety of medical applications, including but not limited to areas involving the delivery of treatments for pulmonary diseases, such as asthma [5,6], chronic obstructive pulmonary disease (COPD), [7], and lung cancer [7], and mental health conditions, such as anxiety and stress-related disorders [5,8]. This is because exploration around physiological signals collected in VR can offer holistic breathing guidance options to users and provide them with breathing benefits [8-10]. Nowadays, individuals may explore and seek the assistance of professional coaches or use advanced devices that are specially designed for the purpose of breathing; however, these means often have a high cost and are time-consuming [5,7]. VR technology, on the other hand, is becoming one of the most accessible and low-cost solutions in the health care domain for breathing interventions [8,11]. Further, VR allows users to have full control over the environment they are exposed to. In combination with the use of biosensing technology, which provides acoustic, visual, and biofeedback guidance, VR users are offered the ability to consciously and self-effectively control and monitor their respiratory rate (RR) [2,5,12].

COVID-19 and Pulmonary Rehabilitation

The novel coronavirus SARS-CoV-2 was identified in late 2019. A couple of months later, the World Health Organization (WHO) declared COVID-19 as a pandemic, as it affected 412,351,279 people (5,821,004 deaths) worldwide (February 13, 2022) [13]. The clinical symptoms in patients with COVID-19 included high fever, sore throat, cough, exhaustion, and dyspnea [13,14].

During the COVID-19 pandemic, patients' medical care, including admission to clinics and use of emergency services, was affected owing to the danger of contamination and the limitations of medical service resources [14]. In this situation, clinical visits, nonurgent treatments, and nonurgent clinical issues, especially among vulnerable populations like people with pulmonary diseases, were initially interrupted and later resumed with a diminished scope [15].

Doctors had to confront the quandary of who could be treated at clinical centers or at home, or who could be allocated to the set number of beds in intensive care units [16]. New technologies helped support vulnerable populations during the pandemic, and VR helped overcome a variety of clinical challenges. This technology is quickly changing clinical training,

patient therapies, and rehabilitation [14,15,17]. The pandemic has changed the clinical framework and placed standard methods with virtual telemedicine and software systems to provide clinical benefits for alleviating the effects of COVID-19 [18]. A significant part of the clinical framework involves rehabilitation, and it is significant owing to the pandemic period [19]. This might be driven by telehealth stages, as with the use of VR.

The fundamental objective of pulmonary rehabilitation is to further develop the patient's psychophysical state [19]. Regardless of restricted admittance to hospitals for rehabilitation owing to COVID-19, VR technology can be applied to this group of patients. It can provide extensive help in various areas, including patient management and clinical treatment, monitoring of patient progression in rehabilitation or assessment of changes, and evaluation and advancement of body function, exercise, and consecutive participation [16,19]. Pulmonary rehabilitation is also beneficial after COVID-19 infection, even in patients who are recovering, who need assisted ventilation or oxygen therapy [20]. Additionally, COVID-19 survivors experience stress, depression, and low quality of life, and the symptoms of dyspnea and fatigue can last more than 3 months after infection. Recent evidence has shown that pulmonary rehabilitation can alleviate these symptoms and can improve exercise performance, lung function, and quality of life in COVID-19 patients and survivors [21-23].

However, scientific studies examining and evaluating the opportunities and challenges of VR for breathing remain limited. In this literature review, we introduce state-of-the-art VR technologies relevant to pulmonary rehabilitation and breathing exercises by analyzing recent related articles on the subject. Owing to the lack of studies related to breathing gaming exercises, for this review, we only examined and evaluated 32 available studies from the last decade [5-8,10,24-50]. Evidence from related empirical and experimental studies that comprised several types of breathing exercises and patterns was systematically reviewed to address the following research questions:

- Is VR an effective solution for breathing exercises?
- Which are the most common VR contents used for breathing exercises in gaming?
- How feasible is gamified biofeedback breathing VR for real-world deployment?
- What are the current barriers to biofeedback VR technologies?
- What are the future directions of biofeedback VR technologies?

Methods

Design

This review was conducted according to Bargas-Avila and Hornbæk [51] and the Cochrane methodology [52,53], which involved 5 phases. The phases are described below.

Procedure

Phase 1: Detailed Assessment of Publications

Electronic libraries: The research was conducted with the use of 7 electronic libraries, which cover a balanced choice of multidisciplinary sources. The libraries were as follows: (1) ACM Digital Library (ACM), (2) Google Scholar, (3) IEEE Xplore (IEEE), (4) MEDLINE, (5) PubMed, (6) Sage, and (7) ScienceDirect (SD). The search was delimited to a timeframe of 13 years (2010 to 2023).

Search terms: The following 3 queries were used in all the libraries since the aim was to cover any type of VR technology for breathing:

1. Virtual Reality AND Breath
2. Virtual Reality AND Pulmonary Rehabilitation
3. Virtual Reality AND Breathing games

Search procedure: The search terms were used to examine the publication's title, abstract, and keywords.

Search results: The search results in Phase 1 can be seen in [Table 1](#).

Table 1. Search results (N=2319).

Search terms	ACM ^a (n=524)	Google Scholar (n=678)	IEEE (n=13)	MEDLINE (n=293)	PubMed (n=67)	Sage (n=362)	SD ^b (n=382)
Virtual Reality AND Breath	133	293	11	224	58	162	220
Virtual Reality AND Pulmonary Rehabilitation	220	237	0	32	8	96	77
Virtual Reality AND Breathing games	171	148	2	37	1	104	85

^aACM: ACM Digital Library.

^bSD: ScienceDirect.

Phase 2: Publications Retrieved for Detailed Evaluation

First exclusion: All search results from Phase 1 were imported into Mendeley electronic library. Possible entries with wrong years were excluded (625 wrong-year entries were removed). This elimination decreased the number of papers to 1694.

Second exclusion: Duplicate papers, either extracted from one or more libraries, which either produced or concluded the same outcome, were removed from this review. Moreover, duplicate papers, extracted from one or more similar terms, which either produced or concluded the same outcome, were also removed. A total of 375 duplicate publications were removed, leaving 1319 different papers.

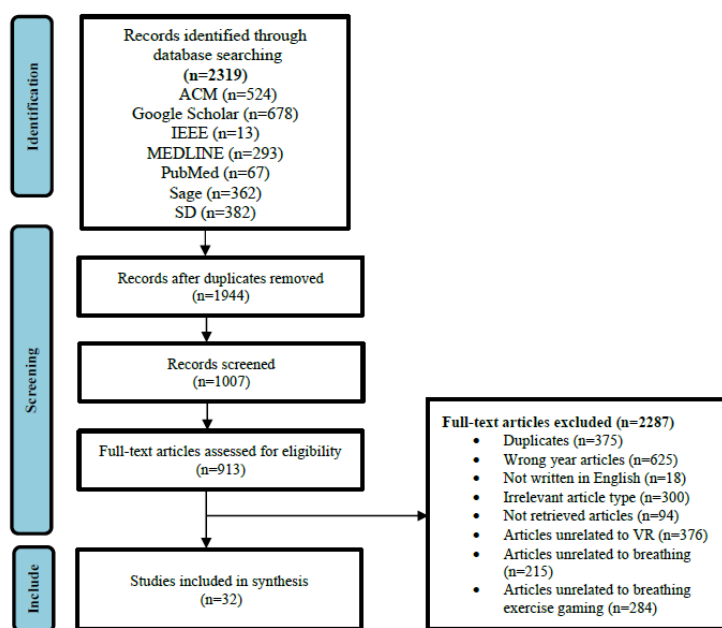
Third exclusion: The entries were narrowed down to original full papers that were written in English. We excluded papers that did not have the full text available (ie, we did not have access to the full text) and papers that were not original full papers, such as workshops, posters, speeches, reviews, magazine

articles, and generally grey literature without formal peer review. As a result, 312 papers were excluded, leaving 1007 papers.

Phase 3: Final Exclusion

Since this review was focused on VR technologies related to breath and breathing exercise gaming, we excluded papers that examined and used other types of technologies that were not related to VR or to breathing exercise gaming. Moreover, research that was only related to breathing without the use of VR was excluded. In this phase and based on these conditions, any irrelevant studies that appeared in Phase 1 and were not removed in Phase 2 were excluded. However, these studies may appear in our findings since relevant words were contained in our research but did not match the specific technical content. Based on these conditions, we removed 376 studies unrelated to VR, 215 studies unrelated to breathing, and 284 studies unrelated to breathing exercise gaming. We ended up with 32 relevant papers (24 journal articles and 8 conference papers; there were no book chapters). The flowchart is presented in [Figure 1](#). All relevant studies were downloaded for examination.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of the literature review. ACM: ACM Digital Library; SD: ScienceDirect; VR: virtual reality.



Phase 4: Data Gathering

All related information from the studies was extracted for examination. An Excel file was created, and the following data were extracted from each paper: sample size of the population studied, methodology, instruments, apparatus, VR content, VR interventions, types of biofeedback sensors, types of biosignals, VR feasibility, key findings, current VR limitations, and VR future directions. Moreover, we categorized each study based on the results as positive (+), negative (-), or neutral.

Phase 5: Data Analysis

The data gathered in Phase 4 were analyzed using descriptive statistics. Consequently, the literature was reviewed to support and enhance the additional knowledge provided by the study. Thematic analysis was used as an additional methodology to classify our findings based on themes. The following themes were considered: VR training, VR interaction, types of virtual environments (VEs), VR effectiveness, VR feasibility, VR design strategies, VR limitations, and VR future directions. Intercoder reliability was assessed between the researcher and research assistant. The Cohen kappa formula was used to calculate the similarity between the researcher and research assistant, and the similarity value was 0.89.

Results

Objectives, Study Design, and Interventions

The search identified 32 studies related to the effective use of VR for breathing exercises. The sample, study design, objective,

and intervention of each study are presented in [Table 2](#). Of the 32 studies, 24 involved healthy individuals [6,8,10,24,26,28-38,40,41,43-48], 1 involved individuals at high risk of developing anxiety disorders [39], 1 involved patients with lung cancer [7], 1 involved patients with pneumonia [49], 2 involved patients with COPD [27,42], 2 involved patients with COVID-19 [49,50], and 1 involved patients with asthma [5]. The breathing exercises were mostly related to breathing therapy (9/32) [5,6,10,25,27,33,48,49,54] and anxiety management (13/32) [8,28,29,32,34,36,37,39-41,43-45]. Most of the reviewed papers based their research on pilot (16/32) or control studies (11/32), while some of the papers (4/32) only described the design and development processes of their systems. Most of the systems (24/32) were designed based on breathing patterns and techniques related to the needs of the populations. For example, for participants who had lung cancer, the VR environments were created for them to perform normal breathing exercises (ie, 10-20 breaths per min) [7], as opposed to the environments for those who had pneumonia or COVID-19 [49], and the VR environments were created to navigate the participants' breathing into a positive expiratory pressure technique (ie, involving breathing with an expiratory resistance that allows air to flow freely when inhaling but harder due to resistance when exhaling) [8]. A different example was provided in a study that included participants who had COPD, and the VR system offered them an avatar assistant, who presented educational content and physical exercises [27].

Table 2. Virtual reality breathing studies: sample, study design, objective, and intervention.

Study	Sample	Study design	Objective	Intervention
Abushakra et al [7], 2014	125 males and females; age not reported	N/A ^a	Develop breathing therapy	Normal breathing with visual feedback
Betka et al [49], 2022	19 males and 7 females; age: 18-55 years	CS ^b (mixed study), randomized, single-blind cross over	Investigate the effect of VR ^c on COVID-19 patients' rehabilitation	Normal breathing with audiovisual feedback
Blum et al [25], 2019	29 males and 31 females; average age: 33.5 years	CS (VR, non-VR)	Investigate the effect of VR and slow-paced breathing on HRV ^d	Slow breathing with visual feedback
Blum et al [10], 2020	16 males and 56 females; age: 18-49 years	CS	Develop VR biofeedback system-based respiratory treatment	Slow diaphragmatic breathing with visual feedback
Brammer et al [41], 2021	9 males and females; age not reported	PS ^e	Develop VR biofeedback scenarios for stress-exposure training	Slow breathing with visual feedback
Charoensook et al [31], 2019	21 males and females; age: 20-24 years	CS (VR, non-VR)	Investigate how VR systems affect HR ^f and RR ^g	Normal breathing with visual feedback
van Delden et al [5], 2020	8 males and 4 females; age: 6-8 years	PS	Develop VR systems based on spirometry for children with asthma	Spirometry test with visual feedback
Feinberg et al [47], 2022	21 males and females; age: 18-34 years	Mixed methods	Design a VR system for meditation	Normal, slow, and diaphragmatic breathing with visual feedback
Gummidela et al [45], 2022	16 males and 14 females; age: 18-35 years	CS (game, nongame)	Develop a VR system for breathing training	Deep breathing with visual feedback
Heng et al [43], 2020	9 participants; gender and age not reported	PS	Integrate a breathing sensor with a VR system for pulmonary rehabilitation	Several breathing techniques with visual feedback
Hu et al [35], 2021	3 males and 3 females; age: 5-8 years	PS	Examine the effectiveness of combining breathing exercises with music rhythm through VR	Several breathing techniques with visual feedback and musical guidance
Jung et al [27], 2020	6 males and 4 females; age: 63-75 years	PS	Pulmonary rehabilitation among participants with COPD ^h	Educational videos and physical exercises with audiovisual feedback
Kluge et al [36], 2021	13 males and 17 females; age: 22-39 years	PS	Develop a VR system for stress management training	Several breathing techniques with visual feedback
Ladakis et al [37], 2021	2 males and 2 females; age: 23-59 years	CS (VR, non-VR)	Examine stress reduction in work environments through VR	Deep breathing exercises with visual feedback
Mevlevioğlu et al [38], 2021	7 males and 4 females; age: 18-30 years	PS	Develop a VR system for height exposure therapy (acrophobia)	Natural breathing with visual respiratory feedback
Michela et al [44], 2022	9 males; age: 26-55 years	PS	Develop a VR system for police officers' breathing performance	Deep and slow diaphragmatic breathing with visual feedback
Patibanda et al [34], 2017	16 males and 16 females; age not reported	PS	Develop a VR system for PLB ⁱ training	PLB with visual feedback
Prpa et al [26], 2018	4 males and 7 females; age: 24-44 years	PS	Investigate breathing patterns according to VR to enhance breath awareness	Slow breathing with visual feedback
Quintero et al [32], 2019	5 males and 6 females; age: 23-32 years	PS	Develop a VR application for HRV analysis	Normal and slow breathing with visual feedback
Rockstroh et al [39], 2021	16 males and 29 females; age: 19-52 years	DD ^j	Develop a mobile VR-based respiratory biofeedback system	Diaphragmatic breathing with visual feedback
Rodrigues et al [50], 2022	22 males and 22 females; age: 18-80 years	CS	Investigate a VR system for the sensation of dyspnea in COVID-19 patients	Not reported
van Rooij et al [40], 2016	52 males and 34 females; age: 8-12 years	PS	Develop a VR breathing system for anxiety in children	Diaphragmatic breathing with visual feedback
Rutkowski et al [42], 2021	9 males and 41 females; age: 45-85 years	CS (VR, non-VR)	Examine the effectiveness of VR for depression and anxiety in participants with COPD	Pulmonary rehabilitation exercises with visual feedback

Study	Sample	Study design	Objective	Intervention
Shih et al [24], 2019	12 males and 31 females; average age: 25.9 years	PS	Develop a mobile app for detecting breathing phases	Normal and slow-paced breathing
Soyka et al [28], 2016	11 males and 10 females; age: 20-45 years	CS	Develop a VR application for stress management	Paced breathing techniques with visual feedback
Desnoyers-Stewart et al [33], 2019	Not reported	DD	Develop a VR application for breathing synchronization between participants	Paced breathing with visual feedback
Tabor et al [8], 2020	N/A	DD	Develop a VR breathing exercise system to support pneumonia rehabilitation	Positive expiratory pressure with visual feedback
Tao et al [46], 2020	3 participants; gender and age not reported	PS	Examine the latent breath input for music instrument performance in VR	Normal breathing with visual and audio feedback
Tatzgern et al [48], 2022	10 males and 2 females; age not reported	DD	Develop a VR system for resistance breathing training	Several breathing techniques with visual feedback
Tinga et al [29], 2018	23 males and 37 females; age: 18-31 years	CS	Examine the effectiveness of respiratory biofeedback through VR meditation	Audio-guided meditation through visual feedback
Tu et al [6], 2020	10 males and females; age not reported	PS	Develop a VR system for breathing training at home	RSA ^k with visual feedback
Zafar et al [30], 2018	100 males; average age: 23 years	CS	Develop a VR system for breathing training	Paced breathing with visual feedback

^aN/A: not applicable.

^bCS: control study.

^cVR: virtual reality.

^dHVR: heart rate variability.

^ePS: pilot study.

^fHR: heart rate.

^gRR: respiratory rate.

^hCOPD: chronic obstructive pulmonary disease.

ⁱPLB: pursed-lip breathing.

^jDD: design and development study.

^kRSA: respiratory sinus arrhythmia.

Various studies involving the treatment of anxiety disorders decided to choose healthy participants for the needs of the experimentations. In particular, among 15 studies, healthy individuals tried several VEs to perform slow (ie, 4-10 breaths per min) [8,10,25,26,41,44,45], normal [7,8,31,32,48], and diaphragmatic breathing exercises (ie, inhale through the nose moving the air toward the lower belly and exhale through the mouth) [39,40,46]. Moreover, healthy individuals participated in studies where VEs were created to guide them on breathing patterns like respiratory sinus arrhythmia (ie, synchronization between heart rate variability [HRV] and RR) [6] and pursed-lip breathing (ie, inhale through the nose with the mouth closed and exhale through tightly pressed lips) [38]. Finally, few studies examined the effectiveness of VR in children for treating asthma

by practicing breathing exercises with the use of spirometry [5] and anxiety by practicing diaphragmatic breathing [40].

Instruments

Self-Reported Data

As mentioned above, most of the studies enhanced conventional breathing training through VR interventions. To evaluate the effectiveness of the VR system, studies used several measures, which are presented in Table 3. All the reviewed studies (32/32) collected participants' demographic information (eg, age, sex, ethnicity, educational level, etc). Half of the reviewed studies (14/32) examined the effect of VR breathing training on mental health (ie, anxiety) [6,25,26,28-30,32,34,36,37,39-41].

Table 3. Virtual reality breathing studies: measures, training, and study duration.

Study	Measures	Training	Study duration
Abushakra et al [7], 2014	<ul style="list-style-type: none"> Physiological data: Lung size, lung capacity, and total lung capacity 	No	Not applicable
Betka et al [49], 2022	<ul style="list-style-type: none"> Quantitative data: GAD-7^a Physiological data: RR^b, respiratory rate variability, HR^c, and SpO₂ 	No	VRE ^d : 5 min; FES ^e : 16 min
Blum et al [25], 2019	<ul style="list-style-type: none"> Quantitative data: VAS^f, STAI^g, Cognitive Interference Questionnaire, State Mindfulness Scale, relaxation self-efficacy, mind wandering, and respiration exercise experience Physiological data: HR 	Yes	VRE: not reported; FES: 10 min
Blum et al [10], 2020	<ul style="list-style-type: none"> Quantitative data: User Experience Questionnaire Physiological data: HR and respiratory sinus arrhythmia 	No	VRE: 7 min; FES: not reported
Brammer et al [41], 2021	<ul style="list-style-type: none"> Physiological data: RR 	Yes	VRE: 15 min; FES: 15 min × 10 sessions, 3 weeks
Charoensook et al [31], 2019	<ul style="list-style-type: none"> Quantitative data: Self-perceived fitness level, gaming experience, and VR^h experience Physiological data: HR and RR 	No	VRE: 15 min; FES: 2 h
van Delden et al [5], 2020	<ul style="list-style-type: none"> Qualitative data: Questionnaire about what happened in the game, what was liked the most, and what was liked the least Quantitative data: VAS Physiological data: Lung function 	No	VRE: not reported; FES: 30 min × 4 sessions
Feinberg et al [47], 2022	<ul style="list-style-type: none"> Qualitative data: Expert meditator interview and qualitative learning assessment (quality of experience) Quantitative data: Quantitative learning assessment 	No	VRE: 5-15 min; FES: 10 sessions × 25 min
Gummidela et al [45], 2022	<ul style="list-style-type: none"> Quantitative data: Stroop Color and World Test Physiological data: RR 	Yes	VRE: 5 min; FES: 20 min × 6 sessions
Heng et al [43], 2020	<ul style="list-style-type: none"> Quantitative data: Game experience Physiological data: Strong breathing, long breathing, and breathing strength control 	No	VRE: not reported; FES: not reported
Hu et al [35], 2021	<ul style="list-style-type: none"> Quantitative data: Game experience Physiological data: Breathing strength 	Yes	VRE: 6 min; FES: 23 min
Jung et al [27], 2020	<ul style="list-style-type: none"> Quantitative data: Patient Activation Measure, GAD-7, Patient Health Questionnaire-9, Short Physical Performance Battery, and Edmonton Frail Scale. Physiological data: HR and oxygen saturation 	No	VRE: 20 min per day × 8 weeks; FES: 75 min
Kluge et al [36], 2021	<ul style="list-style-type: none"> Quantitative data: Nijmegen questionnaire Physiological data: RR 	Yes	VRE: 9 min; FES: 90 min
Ladakis et al [37], 2021	<ul style="list-style-type: none"> Quantitative data: Self-reports and User Experience Questionnaire Physiological data: HR and electrodermal signal 	No	VRE: 2.5 min; FES: 27 min
Mevlevioğlu et al [38], 2021	<ul style="list-style-type: none"> Quantitative data: Igroup Presence Questionnaire and visual height intolerance scale Physiological data: HR, brain electrical activity, electrodermal signal, and RR 	No	VRE: 5 min; FES: not reported
Michela et al [44], 2022	<ul style="list-style-type: none"> Quantitative data: Dutch STAI, prior gaming experience, short self-constructed questionnaire before and after the intervention, and IMIⁱ Physiological data: HRV^j 	Yes	VRE: 15 min; FES: 10 sessions × 15 min, 4 weeks
Patibanda et al [34], 2017	<ul style="list-style-type: none"> Qualitative data: Formal Analysis of Gameplay Physiological data: RR 	Yes	VRE: 3 min; FES: not reported

Study	Measures	Training	Study duration
Prpa et al [26], 2018	<ul style="list-style-type: none"> Qualitative data: Interviews Quantitative data: Music emotion recognition Physiological data: RR 	Yes	VRE: 6 min; FES: 45 min
Quintero et al [32], 2019	<ul style="list-style-type: none"> Quantitative data: Customized questionnaire Physiological data: HRV 	No	VRE: not reported; FES: 30 min
Rockstroh et al [39], 2021	<ul style="list-style-type: none"> Quantitative data: Breath awareness scale, PSS-10^k, and Copenhagen Burnout Inventory Physiological data: RR, inhalation duration, and exhalation duration 	Yes	VRE: 8 min; FES: 46 min
Rodrigues et al [50], 2022	<ul style="list-style-type: none"> Quantitative data: Edmonton Symptom Rating Scale, Borg Scale, HADS^l, and Mini-Mental State Examination Physiological data: HR, RR, blood pressure, and SpO₂ 	No	VRE: 10 min; FES: 40 min
van Rooij et al [40], 2016	<ul style="list-style-type: none"> Qualitative data: Qualitative observations of participants' behavior Quantitative data: STAI, 7-point Likert scale on the experience of playing, self-reported positive and negative affect, and IMI Physiological data: diaphragm expansion and RR 	No	VRE: 7 min; FES: not reported
Rutkowski et al [42], 2021	<ul style="list-style-type: none"> Quantitative data: Perception of Stress Questionnaire and HADS Physiological data: Lung function and expiratory volume 	No	VRE: 20 minutes × 5 times, 2 weeks; FES: 30 min
Shih et al [24], 2019	<ul style="list-style-type: none"> Quantitative data: Self-reports based on 7-point Likert scales Physiological data: Acoustic signal of respiration, inhalation duration, exhalation duration, breathing cycles, and HRV 	Yes	VRE: 6 min; FES: 50 min
Soyka et al [28], 2016	<ul style="list-style-type: none"> Quantitative data: PSS-10 Physiological data: RR, HR, HRV, and blood pressure 	No	VRE: 10 min; FES: 25 min
Desnoyers-Stewart et al [33], 2019	<ul style="list-style-type: none"> Physiological data: RR 	No	VRE: 5 min; FES: not reported
Tabor et al [8], 2020	<ul style="list-style-type: none"> Physiological data: RR, inhalation duration, and exhalation duration 	No	VRE: not reported; FES: not reported
Tao et al [46], 2020	<ul style="list-style-type: none"> Quantitative data: Questionnaire for VR experience and Just Noticeable Difference Physiological data: Exhalation detection 	Yes	VRE: 5 min; FES: not reported
Tatzgern et al [48], 2022	<ul style="list-style-type: none"> Quantitative data: Igroup presence questionnaire, Borg CR10 scale, Paas rating scale, Single Ease Question, and VR questionnaire Physiological data: Inhalation and exhalation 	No	VRE: not reported; FES: 75 min
Tinga et al [29], 2018	<ul style="list-style-type: none"> Quantitative data: VAS for calmness Physiological data: RR, HR, HRV, and electroencephalography data 	No	VRE: 6 min; FES: not reported
Tu et al [6], 2020	<ul style="list-style-type: none"> Quantitative data: Questionnaire for training effectiveness and user experience Physiological data: Breathing duration, movement of the chest, HR, and HRV 	Yes	VRE: not reported; FES: 45 min
Zafar et al [30], 2018	<ul style="list-style-type: none"> Physiological data: RR 	No	VRE: 6 min; FES: not reported

^aGAD-7: Generalized Anxiety Disorder-7.

^bRR: respiratory rate.

^cHR: heart rate.

^dVRE: virtual reality exposure.

^eFES: full experimental session.

^fVAS: visual analog scale.

^gSTAI: State-Trait Anxiety Inventory.

^hVR: virtual reality.

ⁱIMI: Intrinsic Motivation Inventory.

^jHRV: heart rate variability.

^kPSS-10: 10-item Perceived Stress Scale.

^lHADS: Hospital Anxiety and Depression Scale.

To assess the level of anxiety, the following protocols were used: State-Trait Anxiety Inventory (STAI; 3/32 studies) [25,40,44], Generalized Anxiety Disorder-7 (GAD-7; 2/32 studies) [27,49], Hospital Anxiety and Depression Scale (HADS; 2/32 studies) [42,50], Perceived Stress Scale (PSS; 2/32 studies) [28,39], and Edmonton symptom rating scale (1/32 studies) [50]. The STAI is a 4-point Likert scale form, which contains 40 questions measuring pressure, worry, and anxiety [55,56]. GAD-7 is a 7-question screener that assesses participants' psychological well-being status [27,57]. The HADS is a 14-item scale that scores 0 to 3 for each item. The first 7 items relate to anxiety, and the remaining 7 relate to depression. A higher score is associated with greater anxiety and symptoms of depression [42]. The PSS is a 14-item scale with 7 positive and 7 negative items rated on a 5-point Likert scale [58]. The Edmonton symptom rating scale is a questionnaire used to rate the intensity of 9 common symptoms experienced by cancer patients, including pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, well-being, and shortness of breath [59]. Moreover, the Cognitive Interference Questionnaire (CIQ) was used to measure the performance, task-oriented worries, and off-task thoughts of participants through a 22-item questionnaire based on a 5-point scale [5,60]. The Mini-Mental State Examination (MMSE; 2/32 studies) is a set of 11 questions to check if participants have cognitive impairments such as problems with thinking, communication, understanding, and memory [61]. Lastly, the visual analog scale (VAS; 2/32 studies) [5,25] was used to evaluate participants' calmness and relaxation self-efficacy. The VAS is usually used for measuring pain on a 10-point Likert scale, but since the scale is easy to reflect, studies also use it to measure other emotional reflections as well [62].

Some studies (9/32) examined the VR experience [6,10,31,33,38,42,44-46] through self-reported questionnaires. The questionnaires included questions related to the participants' positive and negative emotions, game flow, engagement, ability, capacity, pressure that the said user was experiencing, and challenges that the user perceived [62,63]. Two studies (2/32) also evaluated the motivation of the participants, using a multidimensional self-reported 7-point scale with a Likert-type format called the Intrinsic Motivation Inventory (IMI) [40,44]. The IMI consists of 7 subscales that measure participants' experiences related to a target activity, such as interest/enjoyment, perceived competence, effort, value/usefulness, pressure/tension, perceived choice, and relatedness [64]. The Just Noticeable Difference (JND) was used in a study (1/32) to stimulate the perception level of the user on system latency [46]. Another study (1/32) used the Igroup Presence Questionnaire (IPQ) to assess the sense of presence in different VEs [48]. Lastly, an instrument named the State Mindfulness Scale (SMS; 1/32) [25] was designed for mindfulness assessment with 21 questions self-reported on a 7-point Likert scale. In particular, the SMS counts the level of

present-moment attention to and awareness of activity (mindful or mental) [65].

Biosignals and Physiological Data

Biosignals are physical signals that describe the state of human living. A wide variety of biosignals are regularly used in hospitals and in home monitoring. The most well-known include electrocardiography (ECG), electroencephalography (EEG), and photoplethysmography (PPG). Alternatively, physiological data consist of heart rate (HR), blood pressure, RR, etc.

The studies analyzed the above signals and physiological data in detail. In particular, several studies extracted ECG signals to collect HR data to calculate the average beats per minute [10,25,28,31,37,38,49,50] and HRV to measure the specific changes in time between heart beats [6,29,31,44]. Moreover, a few studies preferred the use of the PPG signal to collect HR [27], blood pressure [50], and oxygen saturation [28,49,50]. Respiration signals were collected by most of the reviewed studies, and they assessed data like lung function [5,36,42], lung volume [8,28], expansion [6,40], and breathing force [48]. Further, respiration signals were used to calculate physiological data, such as RR [8,27,28,30,32,33,35,38-40,45,49,50], and exhalation and inhalation durations [8,39], while accelerometer data were used to identify participants' chest movements [40]. Moreover, EEG data were collected by researchers to reflect participants' brain activity [29,38]. Lastly, electrodermal signals were used by a few studies to record the electric characteristics of the skin and allow researchers to assess participants' stress levels [37,38].

Apparatus

VR Technology

VR allows its users to have full control over the environment they are exposed to. VR technology can provide acoustic, visual, tactile, or olfactory interactions between the user and the system. Based on the above abilities, VR systems can be categorized as nonimmersive, semi-immersive, and fully immersive [66]. Our review found that 21 of the 32 evaluated studies [6,10,25-29,31-33,36,37,39,41,43,45-49] used fully immersive equipment, where the participant's vision is fully enveloped with a head-mounted display (HMD) system and the interactions with the system are based on natural gesture recognition processes. However, 5 of the 32 studies used nonimmersive VR equipment, such as a smartphone [29,44], tablet [5], or laptop [8,34], and these 3D graphical systems allowed users to navigate VEs. Lastly, 6 of the 32 studies did not report the type of VR equipment used [7,8,24,33,39,40].

Biofeedback Equipment

All the reviewed studies used biosignal responses to assess the accuracy of the delivered solutions. In particular, the reviewed biosignals were measurements of the physiological changes in respiration, PPG, ECG, EEG, and electrodermal activity. Most of the studies (27/32) used already existing systems to record

biosignals [5-8,10,24-34,36-41,44,45,47,49,50]. The search results for biofeedback equipment are presented in Table 4. Impressively, only 4 of the 32 studies developed their own systems [35,43,46,48]. Heng et al [43] developed a breathing input sensor consisting of Arduino Uno, a Rev C. Wind Sensor chip, and an ESP8266 ESP-01S Wi-Fi module. The Arduino Uno board acts as the main processor for the breathing input sensor and the power supplier for the whole system. The wind sensor chip picks up the wind signal from human breath and translates it into raw reading data. After that, the Arduino Uno board translates the raw reading data into wind speed. Finally, ESP-01S communicates with the system software through a WebSocket protocol. Moreover, Hu et al [35] used the same

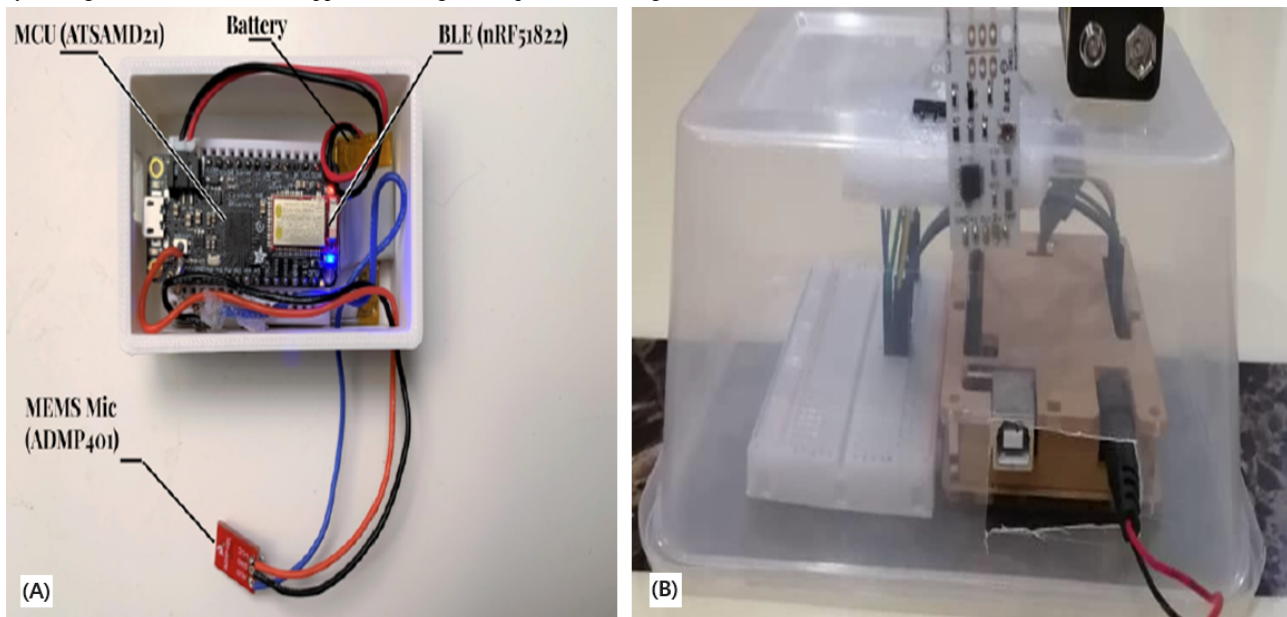
Arduino Uno board as mentioned above but with a different sensor. A gas pressure sensor (XGZP6857A) was applied for respiratory measurements. Tao et al [46] established their own system hardware based on an Adafruit Feather M0 Bluefruit LE board. This board has 2 main features: processing of audio signals with an ATSAMD21G18 ARM Cortex M0 processor and Bluetooth Low Energy communication with an nRF51822 chipset. A MEMS wired microphone was used for the board analog input to read the signal (Figure 2). The system could take breath as input for instrument playing in the VR game. The microphone detected exhalation, which was mapped to the instrument audio in the VR game.

Table 4. Virtual reality breathing studies: biofeedback sensors and interactive devices.

Study	Biofeedback sensors	VR ^a apparatus
Abushakra et al [7], 2014	Unspecified microphone and smartphone	Unspecified apparatus
Betka et al [49], 2022	Go Direct chest strap [67]	Zeiss VR ONEPLUS [68]
Blum et al [25], 2019	Polar H7 chest strap [69]	Oculus Rift CV1 [70]
Blum et al [10], 2020	Polar H10 chest strap [71]	Oculus Rift CV1 [70]
Brammer et al [41], 2021	Unspecified chest strap	Unspecified apparatus
Charoensook et al [31], 2019	Zephyr BioHarness Physiology Monitoring System [72]	HTC Vive [73]
van Delden et al [5], 2020	Air Next (NuvoAir) spirometer [74]	Unspecified apparatus
Feinberg et al [47], 2022	Not reported	Oculus Quest [75]
Gummidela et al [45], 2022	Zephyr BioHarness chest strap [72]	Nexus 6P smartphone [76]
Heng et al [43], 2020	Arduino Uno [77], Rev C. Wind Sensor chip ESP8266 [78], and ESP-01S Wi-Fi module [79]	Unspecified apparatus
Hu et al [35], 2021	Arduino Uno [77], gas pressure sensor (XGZP6857A) [80], and voltage conversion module [81]	Unspecified apparatus
Jung et al [27], 2020	Nonin 3150 probe [82]	VR headset by Pico Interactive Goblin [83]
Kluge et al [36], 2021	EquiVital biosensor [84]	Oculus Rift [85]
Ladakis et al [37], 2021	Scosche Rhythm+ [86] and Moodmetric Ring [87]	Oculus Go [88]
Mevlevioğlu et al [38], 2021	Shimmer device [89] and MyndPlay BrainBand [90]	HTC Vive [73], GeForce GTX Titan X [91] graphics card, and Intel i7-5820k processor [92]
Michela et al [44], 2022	Inductance plethysmography (RIP) belt Plux S.A [93] and Polar H10 chest strap [71]	HTC Vive [73]
Patibanda et al [34], 2017	Breathing+ system sensor [94]	Unspecified apparatus
Prpa et al [26], 2018	Two Thought Technology respiration sensors [95]	Oculus Rift SDK2 [85]
Quintero et al [32], 2019	Samsung smartwatch Gear Sport [96]	Samsung Galaxy S9 [97] and Samsung Gear VR [98]
Rockstroh et al [39], 2021	VR controllers [99]	Oculus Quest VR [75]
Rodrigues et al [50], 2022	Unspecified oximeter and sphygmomanometer equipment	Oculus Realidade Virtual 3D Gamer Warrior JS080 [100]
van Rooij et al [40], 2016	Unspecified stretch sensor	Unspecified apparatus
Rutkowski et al [42], 2021	Unspecified sensor	VR TierOne device [101]
Shih et al [24], 2019	Mindmedia's NeXus respiration sensor [102]	Unspecified apparatus
Soyka et al [28], 2016	g.RESPsensor Piezo-electric crystal respiration effort sensor [103]	Oculus Rift DK1 [85]
Desnoyers-Stewart et al [33], 2019	Biosignalplux breathing sensor [93]	HTC Vive [73] and a projection (6.5×3.66 m)
Tabor et al [8], 2020	Blue Yeti microphone [104]	Unspecified apparatus
Tao et al [46], 2020	Adafruit Feather M0 Bluefruit LE [80], ATSAM21G18 ARM Cortex M0 processor [105], and MEMS microphone [106]	Oculus VR [75]
Tatzgern et al [48], 2022	Sensirion SFM3300 mass flow sensor [107], 3M 6000 series respirator mask [108], and Motor SG-90 servomotor [109]	Oculus Quest 2 head-mounted display [75]
Tinga et al [29], 2018	Respiratory effort transducer SS5LB [110] and BIOPAC System Inc wireless B-Alert X10 system (ABM) [111]	Oculus Rift DK2 [85]
Tu et al [6], 2020	Empatica E4 emp [112] and Hexoskin t-shirt [113]	Google cardboard GGC [114]
Zafar et al [30], 2018	Zephyr BioHarness 3.0 chest strap [71]	LG Nexus 4 smartphone [115]

^aVR: virtual reality.

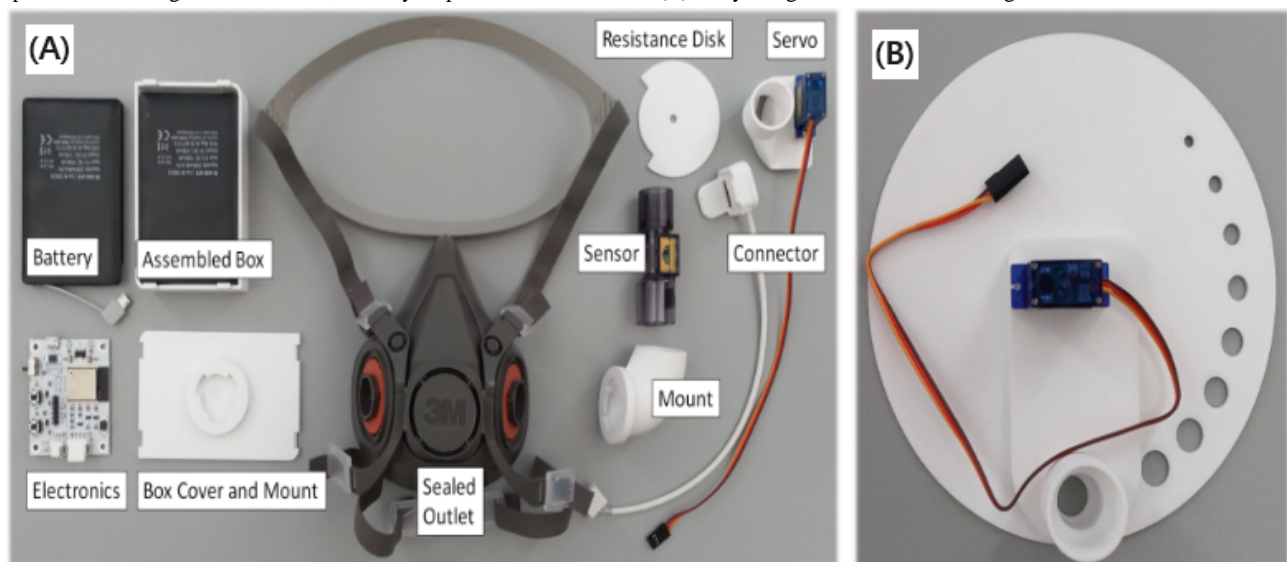
Figure 2. Images of assembled input devices for breathing. (A) The device used a microphone to detect exhalation, which was mapped to the virtual reality (VR) game. (B) The device mapped breathing techniques to the VR game.



Tatzgern et al [48] created the AirRes mask to measure participants' breathing according to VE interactions (Figure 3). The system depends on a Sensirion SFM3300 mass flow sensor 2. This sensor allows the assessment of a participant's airflow with high-precision measurements from both directions (exhalation and inhalation). A protective gear 3M mask frame was used, and the custom-made equipment (electronic circuit

and breathing sensor were added on the frame. Moreover, a disk was applied to the mask to change the amount of air. A Servo Motor SG-90 device was used to rotate and control this disk. A custom circuit board was connected to the airflow sensor and servomotor. The above custom-made system controlled resistance wirelessly in the VR game through an ESP32 Bluetooth module.

Figure 3. Developed system. (A) The first iteration used a common medical oxygen mask, which did not seal the airflow paths sufficiently to be able to experience breathing resistance. Thus, a safety respirator mask was used. (B) Early design of the disk controlling resistance.



VEs and Interventions

As mentioned above, one of the most important advantages of VR is its ability to provide the feeling of being immersed in a simulated environment [66]. Even though the participants of VR technology acknowledge and recognize that the environment

provided by VR is not real, they act as they would in a real environment. The reviewed studies focused on specific types of VEs for mental and anxiety rehabilitation and pulmonary rehabilitation. The study results for VEs are presented in Table 5.

Table 5. Virtual reality breathing studies: virtual environments.

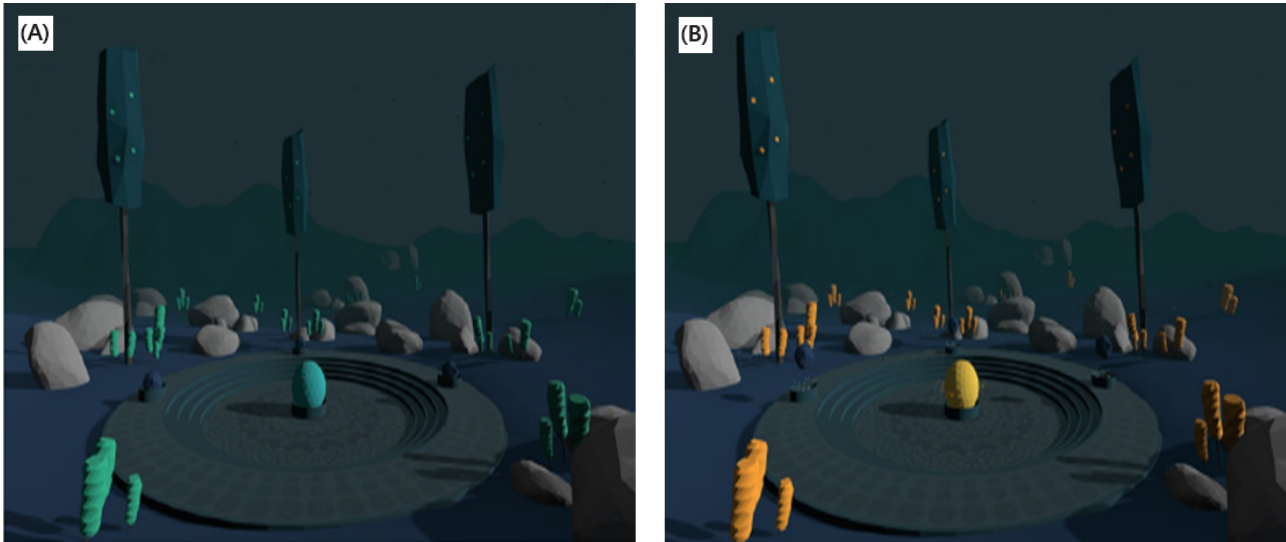
Study	Virtual environments
Abushakra et al [7], 2014	Tissue layers and cells are presented to the participant. Through different types of breathing, the participant diminishes the cancerous lung cells.
Betka et al [49], 2022	A room with a matched-gender virtual body lying on a couch. The virtual body is illuminated synchronously or asynchronously according to the patient's chest movements.
Blum et al [25], 2019	The natural environment of a beach scenery at sunset with palms, rocks, several light sources, and a campfire.
Blum et al [10], 2020	Natural environment with a landscape having hills, flowers, parts of trees, and rocks that change their color according to breathing.
Brammer et al [41], 2021	The trainees must shoot hostile zombies while they leave the benign zombies unharmed.
Charoensook et al [31], 2019	There were 4 games: (1) Beat Saber, (2) Space Pirate Trainer, (3) Gorn, and (4) Final Approach.
van Delden et al [5], 2020	There were 3 games: (1) Popping balloons, (2) Car, and (3) Diving.
Feinberg et al [47], 2022	A dedicated space for meditation with peers and a virtual instructor with an hourglass to track time. There is a bonsai tree that grows to signify progress. The environment changes every few sessions, including weather (sunset or rainstorm).
Gummidela et al [45], 2022	A square arena in which a ball bounces with a randomly initialized direction and location.
Heng et al [43], 2020	There were 8 mini-games: (1) Bubble Gum, (2) Candle Blower, (3) Windmill, (4) Pest Control, (5) Wind Arrow, (6) Table Cleaner, (7) Winter Window, and (8) Steak Gourmet.
Hu et al [35], 2021	There were 2 games: (1) pond scene and (2) ocean scene.
Jung et al [27], 2020	Not reported
Kluge et al [36], 2021	There were 8 discrete modules: (1) emotions, thoughts, and actions; (2) controlled breathing; (3) progressive muscle relaxation; (4) grounding; (5) values and realities; (6) stress reappraisal; (7) managing thoughts/cognitive defusion; and (8) acceptance and avoidance.
Ladakis et al [37], 2021	Fantasy Forest Environment: the participant walks in nature and relaxation sceneries that facilitate recovery from job stress.
Mevlevioğlu et al [38], 2021	There were 2 scenes: (1) nature scene with trees, grass, and flowers moving based on the user's breathing; and (2) elevator scene with a glass elevator outside of a large building in a city, with a height of 6 levels.
Michela et al [44], 2022	A parking garage with friendly and hostile human targets to shoot or not.
Patibanda et al [34], 2017	Life Tree: a tree starts growing through inhalation and exhalation.
Prpa et al [26], 2018	Pulse Breath Water: ocean waves that change their movement according to breathing pace.
Quintero et al [32], 2019	Calm Place: climate sequence that goes from dusk to noon with the appearance of a blue object in the middle of the virtual scene to guide the breathing exercise.
Rockstroh et al [39], 2021	Two types of virtual environments of nature, with elements such as trees, grass, flowers, and rocks.
Rodrigues et al [50], 2022	A relaxed environment.
van Rooij et al [40], 2016	An underwater world in which children can move around freely and explore at their leisure.
Rutkowski et al [42], 2021	Virtual therapeutic garden.
Shih et al [24], 2019	A sailing boat moving backward and forward with the participant's breathing.
Soyka et al [28], 2016	A jellyfish moving up and down in an underwater environment.
Desnoyers-Stewart et al [33], 2019	An underwater world with 2 jellyfish and a growing glass sponge.
Tabor et al [8], 2020	There were 2 games: (1) Bubble Float and (2) Bubble Paint.
Tao et al [46], 2020	A music studio scene, where the participant was asked to practice a virtual reality harmonica instrument.
Tatzgern et al [48], 2022	There were 6 scenarios: (1) blowing all candles on a cake, (2) blowing projectiles through a blow tube, (3) shooting a toy gun, (4) blowing ships, (5) inflating balloons, and (6) playing the harmonica.
Tinga et al [29], 2018	A white cloud moving toward and away in the direction of the participant's mouth.
Tu et al [6], 2020	There were 2 games: (1) Balloon, where the participant could control the movement of a balloon through respiration and (2) Pilot, where the participant's breathing could control a flight's course.
Zafar et al [30], 2018	There were 3 video games: (1) Chill Out, (2) Dodging Stress, and (3) Pacman Zen.

Types of VEs for Mental and Anxiety Rehabilitation

Numerous studies (12/32) used nature scenes, such as scenes of beaches, forests, oceans, and mountains [10,25,26,28,29,33,34,36-40]. Below, we present 4 of the most impressive natural VEs. The first environment was a beach scenery at sunset with several dynamic parameters like lights and clouds, which shifted according to breathing to provide feedback to the participant (Figure 4) [25]. If the participant's

breathing was below the threshold, which was preset by the system, the breathing pace was considered to be correct. As a result of correct breathing, the sky turned clear, and the participant could enjoy a star-spangled sky. A campfire was also included in the said scenario as a dynamic object to make the participant feel more relaxed and to provide the participant with an indication of whether breathing was at the appropriate pace.

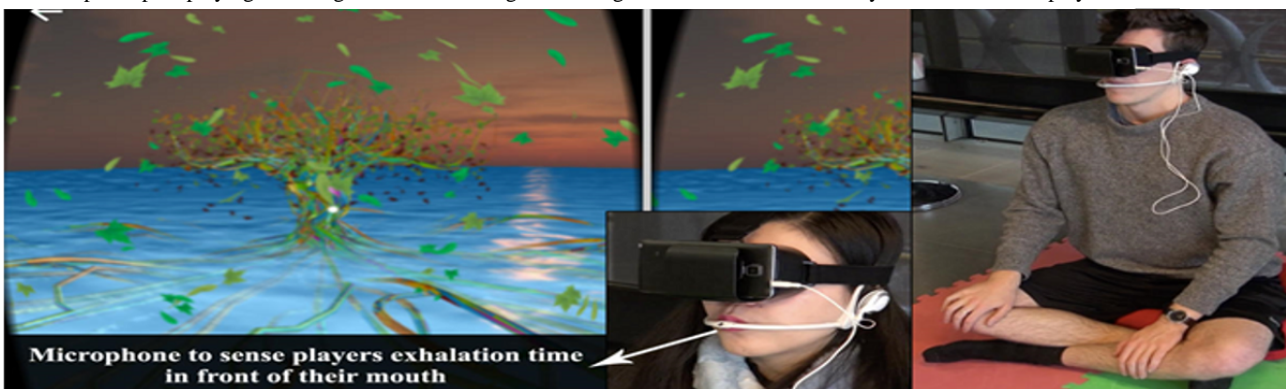
Figure 4. Screenshot of the beach virtual environment in its default state (A) and while exhaling (B).



The second environment was a dynamic scenario with a tree submerged in the middle of water (Figure 5) [34]. The goal of this intervention was to help the participant to practice pursed-lip breathing. The participant was told to wear an unidentified HMD and sit in a comfortable position with the legs crossed. Before the start of the intervention, the participant was advised to go through a breathing exercise introduction. After that, the participant had to follow rhythmic breathing by inhaling and

exhaling until the tree started to expand on inhalation and contract on exhalation. If the participant continued to breathe rhythmically, the tree started to bloom. If the breathing of the participant was nonrhythmic, the view of the participant started to blur in the monitor until the right rhythm was found. Leaves were also used to provide feedback to the participant on the breathing rhythm. More colorful leaves indicated that the participant was following the correct breathing rhythm.

Figure 5. A participant playing the tree game while wearing a breathing headset and a virtual reality head-mounted display.



The third environment was the ZenVR environment, which was a dedicated VE that included an open room in a mountain environment with plants, where the participant could train on different meditation techniques (Figure 6) [47]. The VE contained several objects related to meditation like meditation cushions and candles. Several dynamic parameters, such as the weather and a bonsai tree, changed according to the level of the

breath training. During the duration of the training, the bonsai tree grew to indicate the participant's progress. An hourglass was present as a marker of time for the participant and to indicate that the program continued during the silent meditation. Additionally, numbers appeared with different sizes to illustrate the breathing exercises.

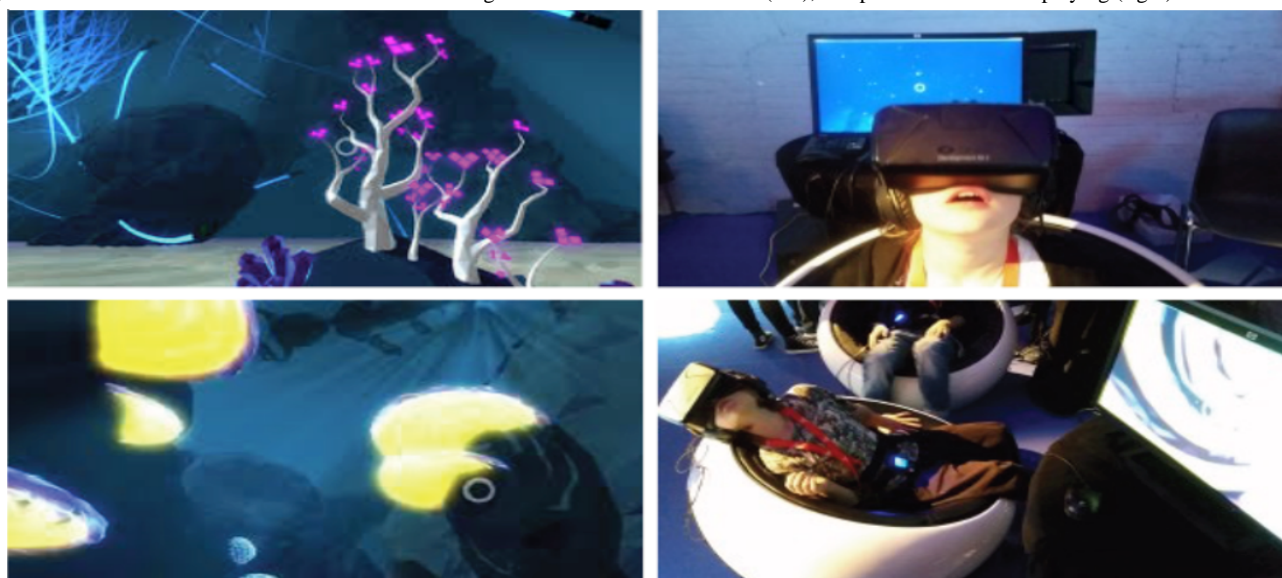
Figure 6. ZenVR learning environment that includes a virtual teacher, an hourglass, a bonsai tree, and numbers to count inhalation and exhalation.



The last environment was an underwater experience for diaphragmatic breathing practiced with children with anxiety issues (Figure 7) [40]. The participant was instantaneously informed of the state of breathing by a dynamic circle in the VE that expanded according to breathing. The system applied gravity to the participant’s avatar if the lung capacity was more than half. The participant’s breathing pace was able to determine

the direction and magnitude of the force. When the participant inhaled, an upward force was applied, and when the participant exhaled, an extra forward force was applied so that the participant was able to dive into the deep ocean. The combination of slow and deep breathing allowed the participant to swim better and have more control in the game. The type of VR equipment was not reported in the study.

Figure 7. Underwater environment. Screenshots showing the virtual underwater world (left), and pictures of children playing (right).



Types of VEs for Pulmonary Rehabilitation

Several studies (10/32) developed different VEs for breathing exercises to improve respiration [5,6,8,29,31,32,34,41,47,49]. In particular, Prpa et al [26] generated a 3D element of a body of water (an ocean) (Figure 8). This minimal environment displayed the ocean and the sky through a variety of grayscale shades. A continuous breathing pattern allowed the participant to control the ocean environment. It started with a light grey sky and a stationary participant position above the ocean surface. When the participant found the breathing flow, the game continued with movements of ocean waves, which were based

on the participant’s breathing pace. The right breathing pattern was mapped to wave movement and musical rhythm. The sky changed from grey to black until the ocean was stationary again, as was seen by the participant at the beginning of the procedure, with the only difference being the color of the sky.

Another study developed a VR intervention for alleviating dyspnea in patients recovering from COVID-19 pneumonia (Figure 9) [49]. Specifically, it created a room with a matched gender body lying on a couch. The goal was to illuminate the virtual body synchronously or asynchronously according to the patient’s chest movements.

Figure 8. Developed virtual environment. Phase 1 starts with a light grey sky at a stationary participant position above the ocean surface. The participant's breath activates the water element in the virtual environment in phases 2 and 3.

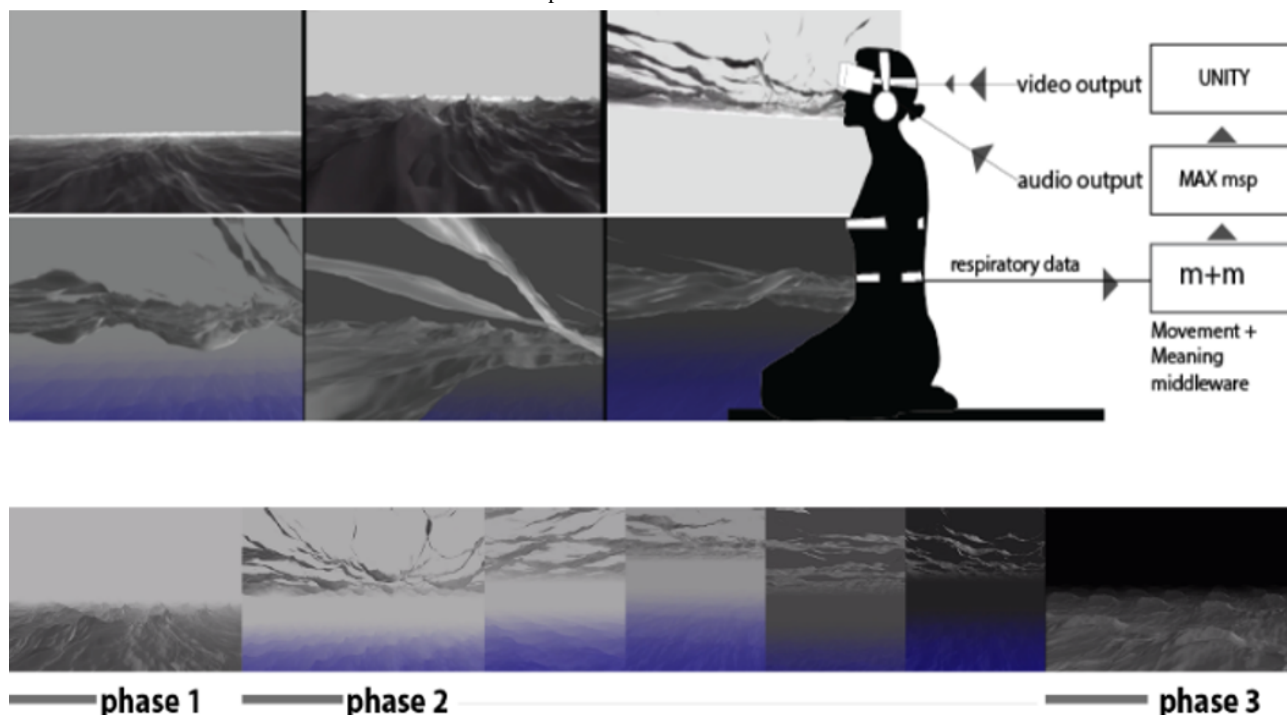
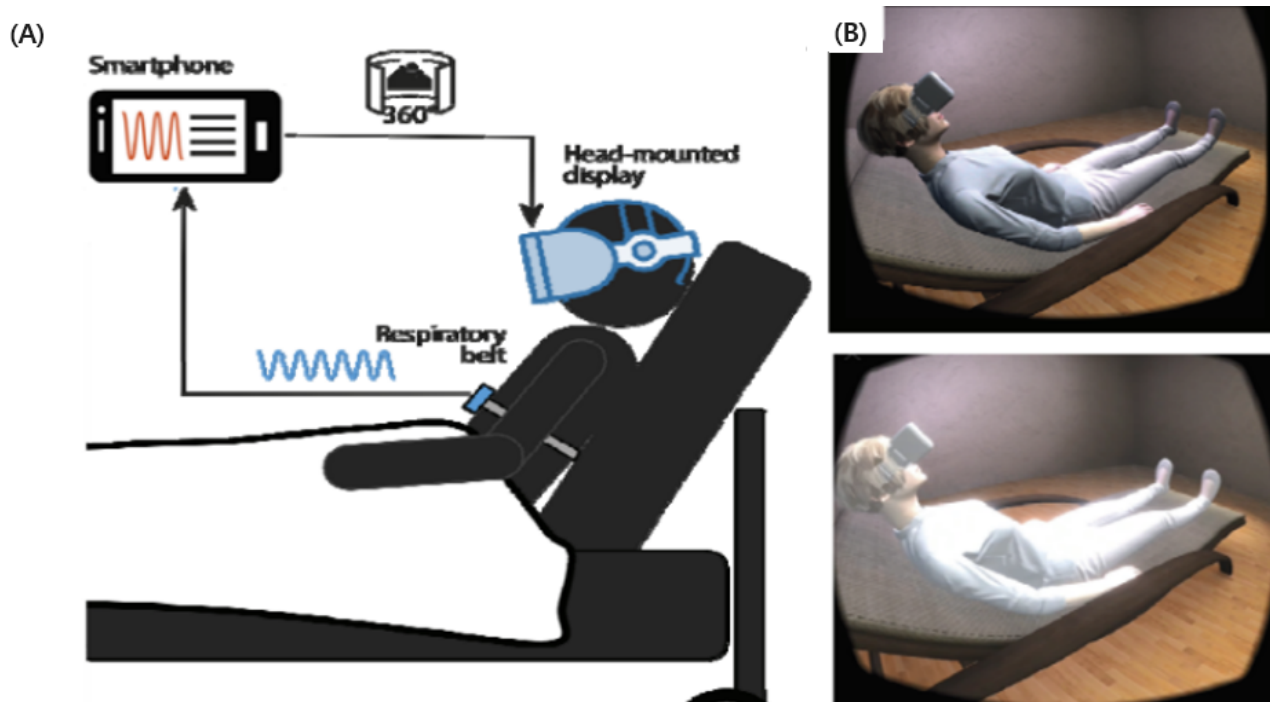


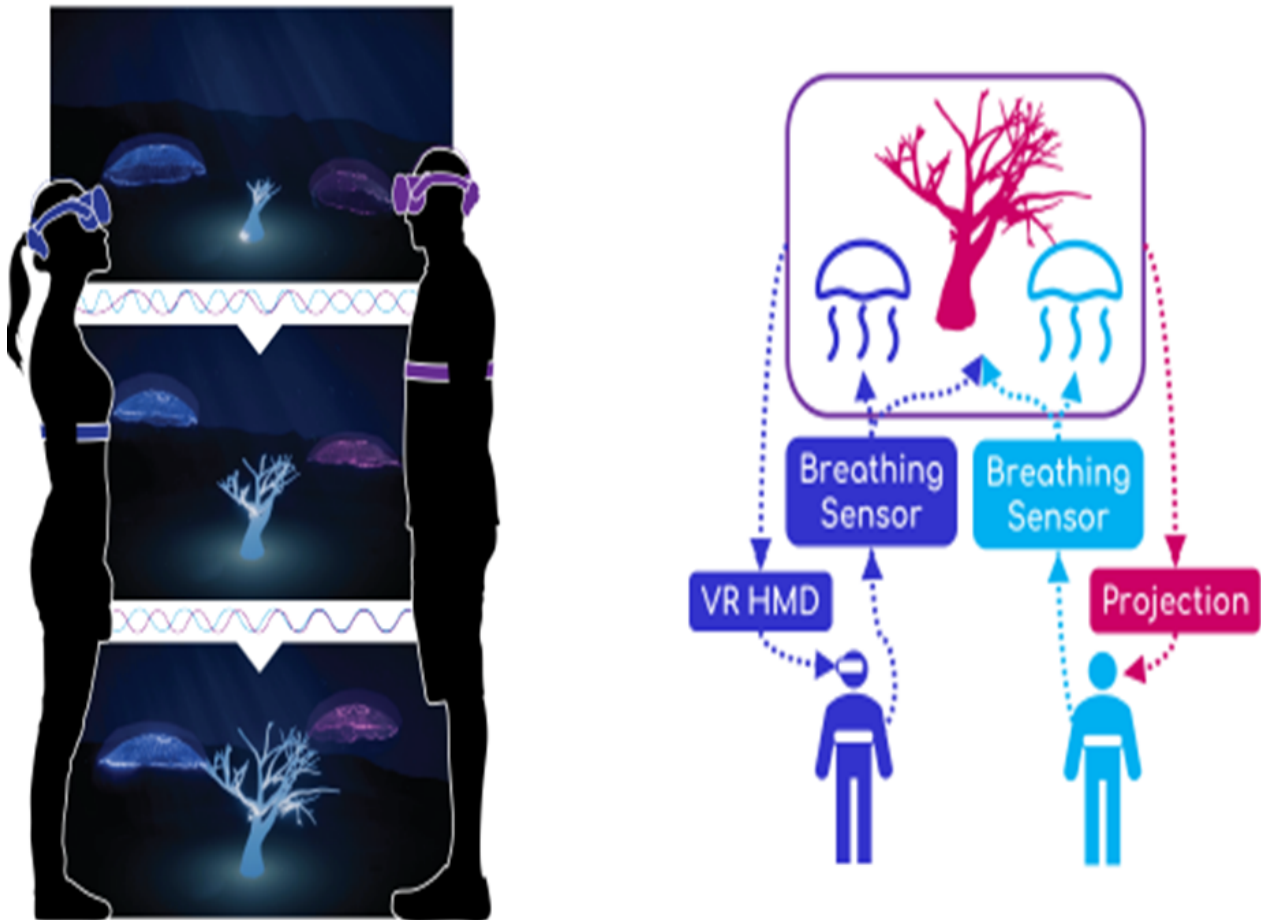
Figure 9. The virtual reality system developed for alleviating dyspnea. (A) Scheme showing the real posture of the patient and the biosignal devices. (B) Representation of the virtual body and how the body's luminosity changes according to the patient's chest movements.



A particularly interesting study used multi-user VR to simultaneously immerse two or more participants into an underwater world with jellyfish and a growing glass sponge (Figure 10) [33]. The aim was to synchronize the breathing between the participants, and enhance the breathing awareness, breathing pace, and relation between the participants. In this

environment, each participant's breath was represented by a jellyfish, which moved and glowed in such a way as to provide clear breathing feedback. As the participants synchronized their breathing, the glass sponge was structured to begin to grow and emit light.

Figure 10. The multi-user virtual reality JeL system. (A) Two jellyfish agents and a growing glass sponge. The jellyfish respond directly to each user's breathing, while the sponge reflects the synchronization of their breath. HDM: head-mounted display; VR: virtual reality.



Interestingly, 2 of the reviewed studies used existing predeveloped systems for pulmonary rehabilitation [42,43]. Rutkowski et al [42] used the virtual therapeutic garden game, released by the European Association of Psychotherapy (Figure 11). Initially, the garden appears grey (untidy and unkept), and the watering pot is on its side. Diaphragmatic exercises with

resistance, prolonged exhalation exercises, and chest percussion activate the watering pot to water the garden. With each rehabilitation session and the correct conduct of fitness exercises, the garden becomes increasingly colorful and alive, symbolizing the process of gaining health through the rehabilitation sessions.

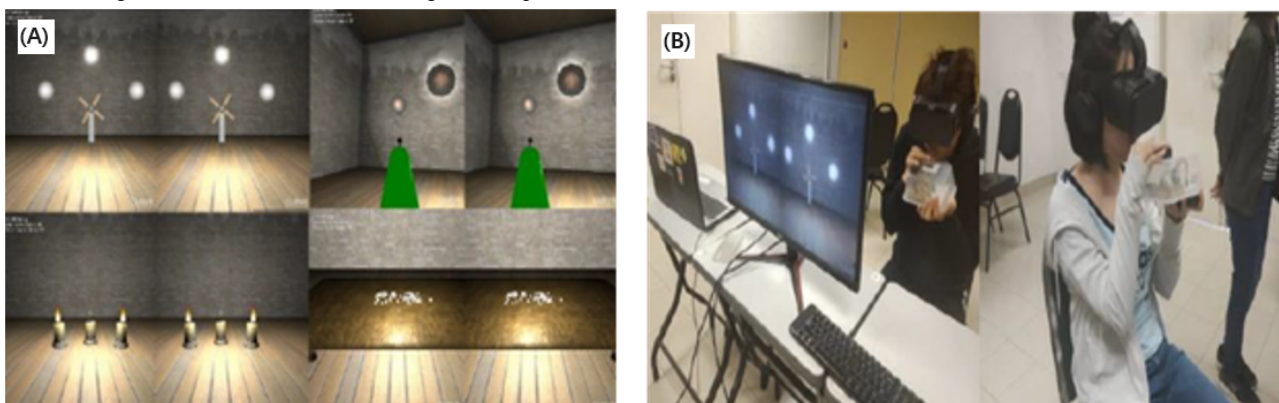
Figure 11. The virtual therapeutic garden game. (A) Initial stage of the game in grayscale. (B) Final stage of the game with the garden full of color.



Bubble Tower [43] investigated the development of mapping breathing techniques in VR gameplay mechanics (Figure 12). The whole platform offered a set of 8 mini-games, where Bubble Tower was designed to train the participant in the fundamentals of breathing techniques. The mini-games teach the participant

basic breathing skills like long and strong breathing, and breathing strength control. These mini-games include stages where the participant is required to pop the bubble with a strong breath, blow candles in a room with a long breath, build up the momentum for a windmill to spin fast with a long breath, etc.

Figure 12. The games in Bubble Tower. (A) Four games are presented. (B) Game users.



An interesting study presented a VE based on the escape room game philosophy (Figure 13) [48]. In the escape room scenario, the participant used different breathing pattern interactions to answer a sequence of tasks to escape from the room. The room had all the objects that the participant needed to escape. During the training, the participant interacted with different individual objects. The first task was to blow out candles on a cake, and

then, the participant had to blow bullets through a blow tube toward a target. The third task included the movement of ships based on breathing force. The participant continued with inflating balloons and sorting them by resistance. After that, the participant had to reveal numbers on a mirror with the breath. The last task involved shooting with a toy gun by holding the breath.

Figure 13. The virtual environment based on the escape room game philosophy. The large image shows the play area of all objects. The other images show some tasks from the game.



Discussion

Principal Findings

Based on all the studies that were reviewed (29 studies had a positive label and 3 had a neutral label), it is suggested that VR can be an effective solution for pulmonary rehabilitation among patients with lung cancer, patients with COPD, patients with asthma, and individuals and children who are dealing with mental health-related disorders such as anxiety. Overall, the results indicated that VR can enhance the functional outcomes of pulmonary rehabilitation, increase breathing body awareness, and improve relaxation techniques. In the COVID-19 crisis, evidence showed the need for VR technology adoption. VR pulmonary rehabilitation presents an opportunity for the safe and effective recovery of COVID-19 patients and survivors at home. This technology could be adopted on a large scale to further develop the well-being of individuals during pandemics like COVID-19 and could similarly advance autonomous medical care. In the reviewed studies, most of the VR systems included features of natural environments, like a beach, sky, and forest. Further, it is highly recommended for future studies to incorporate water elements (eg, bubbles) and undersea sceneries (eg, seabed, jellyfish, and sea plants) to enhance relaxation. Some systems involved the use of music and vibrant colors. As technology continues to advance and progress, it is expected that biofeedback in VR systems will have a vital role in the practice of breathing in both the medical setting and the real world. The reviewed studies proved the feasibility of implementing a VR system for pulmonary rehabilitation enhanced with biofeedback. Such a system can be a reliable solution to enhance participant training. An assortment of minimal-cost sensors and biofeedback frameworks can incorporate VR and provide exact and significant information from tasks in gamified biofeedback interventions for breathing. Regarding the adequacy of pulmonary rehabilitation, biofeedback VR innovations must bridge explicit obstacles like equipment assembly, participant population, experiment length, and breathing patterns. The boundless breathing direction in VR frameworks can cause issues in the legitimate decisions of breath-detection equipment. Accordingly, many specialists battle with equipment assembly, equipment incorporation, and its compatibility with VR systems. There have been hindrances

in adopting accepted procedures of biofeedback VR in various populations requiring breathing training for different purposes, including overcoming mental health issues and stress pressure, and achieving overall health benefits. The restricted length of examinations can prevent the assessment of the longer-term impacts of pulmonary rehabilitation.

Most of the studies (14/32) examined the effectiveness of breathing through VR based on physiological data [6-8,24,25,29,35,36,43-45,47-49]. Overall, the review suggests that VR is a reliable and feasible solution for pulmonary rehabilitation. Specifically, one of the reviewed studies [8] revealed that VR rehabilitation can be a reliable solution to treat pneumonia. Moreover, it was found that participants who performed pulmonary rehabilitation through VR felt more confident compared to those who performed the training with face-to-face supervision from health care professionals [25]. It was explained that embodied interactions through VR and biofeedback responses made the participants more aware of their inhalation and exhalation rhythm [28]. Additionally, the reviewed studies about pulmonary rehabilitation in COVID-19 patients reported significant improvements in tiredness, shortness and comfort of breath, and vital signs, such as HR, RR, blood pressure, and SpO₂ [48,49]. A study comparing patients with COPD undergoing VR pulmonary rehabilitation and those not undergoing this rehabilitation found that VR rehabilitation was associated with high stress release and a sharp reduction in depressive episodes [41]. The positive impact of VR on the enhancement of rehabilitation with different breathing patterns in emotional well-being has been documented by several studies (13/32), with most of these studies being focused on anxiety and stress monitoring [5,8,10,27,28,31,33,34,36,37,39-41,43,49]. The level of anxiety of participants was found to decrease within few minutes after using VR with biofeedback for controlling breathing. In particular, a study comparing induced anxiety between participants who used VR and those who did not use VR reported a reduction in the level of anxiety in those who used VR [39]. In addition, a study documented that apart from the positive effect VR has on anxiety, it can also increase concentration and positively motivate participants [54]. In particular, it was found that participants who performed pulmonary rehabilitation via VR were less reluctant to

participate in the training activities. Anxiety levels have also been studied in young populations [39] and COVID-19 patients [49]. VR was suggested to be an effective solution for children at risk for anxiety disorders [39] and was reported to be effective at improving anxiety and increasing the feeling of well-being in patients with COVID-19 [49].

A study reported that participants were able to perform paced breathing techniques without distraction [27]. It suggested the use of vibrant, rich, and multi-dimensional VEs to deliver an effective and enjoyable VR experience. Another study mentioned that water manifestation is a key element to decrease anxiety. More specifically, it was reported that having water features can enhance stress management techniques and significantly expand HRV based on paced breathing [27,54]. Two studies suggested that participants were able to more accurately control the pace of their breathing on adding

biofeedback [28,30]. Zafar et al [30] noticed that participants who were exposed to biofeedback systems were able to control their breathing more precisely as opposed to the traditional type of training. Correspondingly, participants of VR biofeedback systems scored higher in their subsequent stress test compared with the pretest. Furthermore, a study that examined the effectiveness of respiratory biofeedback during VR meditation by measuring EEG and ECG signals in a respiratory biofeedback state, control feedback stress state, and control no feedback state, proved that VR meditation is effective for relaxation and breathing exercises. The study findings suggest that if VR is used for meditation, no biofeedback equipment is needed to reduce arousal, providing a more affordable and less intrusive option to apply VR to relaxation exercises [28]. In summary, biofeedback is recommended for the effective deployment of VR systems for pulmonary rehabilitation. The feasibility and findings of the studies are presented in [Table 6](#).

Table 6. Virtual reality breathing studies: feasibility and findings.

Study	Feasibility	Findings	Label
Abushakra et al [7], 2014	VR ^a breathing therapy in real time	85% accuracy	Positive
Betka et al [49], 2022	VR respiratory rehabilitation for COVID-19 patients	Improvement in breathing comfort and enhancement of dyspnea recover.	Positive
Blum et al [25], 2019	VR breath gaming for stress monitoring	Increase in relaxation self-efficacy and reduction in mind wandering.	Positive
Blum et al [10], 2020	VR for breathing exercise	Satisfactory user experience, breath awareness, and greater focus on slow diaphragmatic breathing.	Positive
Brammer et al [41], 2021	VR for breathing-based stress training for police officers	Illustrated the feasibility of stress exposure biofeedback with examples of training in police officers.	Positive
Charoensook et al [31], 2019	VR system for physical fitness improvement	Significant difference in the average heart rate between traditional systems and the VR system.	Neutral
van Delden et al [5], 2020	VR for lung function tracking in children with asthma	100% of the estimated volume goal (full exhalation).	Positive
Feinberg et al [47], 2022	VR for breathing training through meditation	Quantitative and qualitative indicators showed an increase in meditation ability after completing the sessions.	Positive
Heng et al [43], 2020	VR for pulmonary rehabilitation	Minor technical issue with the sensor device.	Neutral
Hu et al [35], 2021	VR for pulmonary rehabilitation in children	Increase in motivation among children and improvement in their adherence to breathing exercises.	Positive
Gummidela et al [45], 2022	VR for relaxation training	Nongame interventions were better at promoting moment relaxation. Game-based interventions were more successful at promoting deep breathing during stressful tasks.	Positive
Jung et al [27], 2020	VR for COPD ^b rehabilitation	Improvements in the physical ability and psychological well-being of participants.	Positive
Kluge et al [36], 2021	VR for stress management in defense force groups	VR-based apps can develop stress management skills in a workplace setting.	Positive
Ladakis et al [37], 2021	VR for stress reduction in a work environment	VR can be a simple and useful tool for the immediate decrease of stress in various real-life environments.	Positive
Mevlevioğlu et al [38], 2021	VR for height exposure (acrophobia)	A correlation between arousal and virtual height showed that the developed VR experience is capable of producing the wanted effect.	Positive
Michela et al [44], 2022	VR for stress management in police officers	Improvement in breathing control, with a positive effect on breathing-induced low-frequency HRV ^c .	Positive
Patibanda et al [34], 2017	VR for breath gaming	Relaxation of mood among participants.	Positive
Prpa et al [26], 2018	VR for breathing awareness	Awareness of breathing while playing on the VR system.	Positive
Quintero et al [32], 2019	VR for slow-paced breathing exercises to support mental health	Higher relaxation level of participants during a no biofeedback VR scenario.	Neutral
Rockstroh et al [39], 2021	VR for fostering diaphragmatic breathing	VR-based breathing training increased perceived breath awareness, improved diaphragmatic breathing, increased relaxation, decreased perceived stress, and reduced symptoms of burnout.	Positive
Rodrigues et al [50], 2022	VR for controlling dyspnea and pain symptoms in hospitalized patients with COVID-19	Tiredness, shortness of breath, and anxiety decreased, and the feeling of well-being increased.	Positive

Study	Feasibility	Findings	Label
van Rooij et al [40], 2016	VR for breathing therapy to reduce anxiety in children	Decrease in self-reported anxiety.	Positive
Rutkowski et al [42], 2021	VR for pulmonary rehabilitation	Reduction in stress and emotional tension between prerehabilitation and postrehabilitation.	Positive
Shih et al [24], 2019	VR for breath gaming to strengthen cardiac functioning	75.5% accuracy in breathing phase detection.	Positive
Soyka et al [28], 2016	VR for home breathing therapy for stress	Improvement in stress monitoring techniques and increase in HRV.	Positive
Desnoyers-Stewart et al [33], 2019	VR for breath gaming to mediate physiological synchrony for social connection	Positive outcomes suggest that the system is functional.	Positive
Tabor et al [8], 2020	VR for respiratory pneumonia rehabilitation	The system makes use of state-of-the-art breath-sensing techniques without specialized sensing hardware.	Positive
Tao et al [46], 2020	VR for playing a music instrument with breath	The latency perception threshold is higher for inexperienced participants than experienced participants.	Positive
Tatzgern et al [48], 2022	VR for interacting with different scenarios with breathing patterns	The system can enhance the training experience and improve breathing awareness.	Positive
Tinga et al [29], 2018	VR for breath gaming for meditation	Reduction in anxiety and stress.	Positive
Tu et al [6], 2020	VR for home breath gaming	Errors lower than 0.61 s and 15 ms, and improvement in training effectiveness and experience.	Positive
Zafar et al [30], 2018	Video biofeedback system to teach breathing control	Biofeedback led to a better attentional-cognitive performance and helped participants to learn breathing control.	Positive

^aVR: virtual reality.

^bCOPD: chronic obstructive pulmonary disease.

^cHRV: heart rate variability.

Limitations and Future Work

Even though the effectiveness of VR for pulmonary rehabilitation is well documented, several limitations have been reported in the reviewed studies. First, some of the reviewed studies measured the relaxing effect of VR through the use of psychophysiological responses, such as HR, and self-reported questionnaires. However, some of the studies suggested the need for additional instruments that explicitly assess different aspects of affect and mood [10,41]. For example, a study suggested the collection of 2 different biosignals (PPG and ECG) for HR accuracy [10]. Moreover, the study mentioned that a participant's respiration has limited validation and recommended the use of an additional belt sensor [10]. It was suggested to measure stress levels using not only traditional reports, such as self-reports and the Stroop task, but also cortisol levels [41]. Future studies should consider triangulating the physiological data with interviews and other qualitative data to provide a holistic assessment of the impact of biofeedback systems [29,44]. Future studies can also investigate the factors that can enhance VR pulmonary rehabilitation to support existing relaxation and destress techniques, and this should be compared to traditional practices [27].

Second, the reviewed studies highlighted the limit of breathing guidance in VR systems, which can provoke complications and barriers in the correct choice of breathing sensing hardware

[45,47]. As a result, many researchers struggled with aspects of the hardware apparatus, like the weight of the hardware on the user's head in addition to the VR HMD [47], as well as with hardware integration and its compatibility with VR systems [45]. In addition, most hardware equipment involved high-end solutions, and the cost for the equipment in most of the studies was between €300 and €200 (US \$322 and US \$1289, respectively) [5,6,10,27,29-33,36-39,45]. Three studies [34,46,47] developed their own affordable equipment, for which the cost was approximately €70 (US \$75). Future studies should provide clear guidelines for the effective apparatus as well as the cost of the system. As mentioned previously [66], moving to low-cost and accessible solutions will decrease the need for technical support. This suggests that participants will be able to have their own personalized devices, which could lead to an increased quality of life.

It was further suggested for future studies to build systems that include machine learning algorithms to empower participant rehabilitation. These kinds of systems can offer the advantage of higher relaxation levels. For this, it is recommended for model algorithms to automatically classify breathing states, compared with other sensors, and analyze different visual cues in VEs. Moreover, it was stated that machine learning methods should adapt logic modules to provide automatic adaptations in VEs [31]. It is worth mentioning that Fast Fourier Transformation implementation presents a limitation compared with other

methods of low-frequency detection, although it is fully functional. For future studies, it is therefore suggested to implement a wavelet transform method, which can provide higher resolution at low frequencies without requiring a larger window size [33].

To improve the systems even further, future studies should examine the effectiveness of biofeedback compared with proper control conditions in different groups of participants under different types of circumstances to determine exactly when and why biofeedback might not be preferable. For example, the effects of biofeedback in children, as examined in the study by van Rooij et al [40], could differ from the effects of biofeedback in adults, as examined by Tinga et al [29]. In the study by Tinga et al [29], the reduction in arousal (on all outcome measures combined and HR specifically) was the largest in the control feedback placebo condition, indicating that respiratory biofeedback had no additional value in reducing arousal and was even less effective than the control feedback placebo. The above finding indicates no preference for respiratory biofeedback compared with control feedback placebo in lowering pain levels in participants with chronic back pain.

Third, a study suggested the extension of VR exposure time, since it was found that this might allow participants to develop their own strategies for producing respiration patterns [31]. Expectedly, most studies suggested that a large sample is required to verify the trend of average HRV and other bioindicators [30,43], as well as to address difficulties in VR design [8,45]. An enhanced sample size could have a positive impact on VR design since a wider set of participants can express their interests [48,49]. Finally, it has been suggested for future studies to extend experiments to multi-session investigations to examine the longer-term effects of pulmonary rehabilitation among participants [25,30,33,49].

Conclusion

The future directions of biofeedback VR technologies hold huge potential for significant advancements in the pulmonary field, ushering in a new era of personalized and adaptive experiences, enhanced sensor technologies, integration with artificial intelligence and machine learning, gamification and immersive exercises with integration into telehealth, and remote monitoring.

One of the most exciting prospects of VR is the ability to deliver personalized and adaptive experiences through biofeedback VR technologies. VR applications can dynamically tailor experiences to patients based on their specific needs. Real-time integration of user responses and physiological data enables

these applications to optimize the effectiveness of biofeedback interventions, ensuring that patients receive the most relevant and impactful feedback. Advancements in sensor technologies are another crucial area of development. Wearable sensors, such as biometric devices, provide real-time data on BR, HR, skin conductance, muscle tension, etc. Continued improvements in sensor miniaturization, wireless connectivity, and comfort will enhance the usability and reliability of biofeedback VR technologies, making them more accessible and user friendly.

The integration of artificial intelligence and machine learning presents exciting possibilities for biofeedback VR technologies. These algorithms can analyze massive amounts of biofeedback data, identify patterns, and provide personalized recommendations for stress reduction, relaxation breathing techniques, or breath performance enhancement. Machine learning can also help in monitoring progress, evaluating outcomes, and optimizing the effectiveness of biofeedback interventions. The cooperation between artificial intelligence, machine learning, and biofeedback VR technologies has the potential to unlock new levels of personalized and evidence-based interventions. Gamification and immersive experiences play crucial roles in engaging users and maximizing the benefits of biofeedback VR technologies. By incorporating game elements and designing interactive VEs, biofeedback VR applications can provide engaging and motivating experiences.

The reviewed studies showed that VR technology can be applied in various areas in the health field, such as stress management, anxiety disorders, pain management, phobia treatment, and rehabilitation. It is necessary to establish evidence-based practices and guidelines for the use of biofeedback VR technologies in health care through collaboration among researchers, health care professionals, and developers. The integration of biofeedback VR technologies in clinical settings will revolutionize the way doctors and researchers approach treatment, improving accessibility, reducing health care costs, and enhancing patient engagement and outcomes.

In the future, innovations in biofeedback VR technologies may also include developments in neurofeedback and brain-computer interfaces with the brain activity of patients. As technology continues to grow and VR progress is investigated, these future directions are poised to shape the field, leading to transformative applications and advancements in wellness, health care, education, etc. The continued exploration and integration of VR technologies and biofeedback technologies have the potential to revolutionize how we understand and enhance human performance, well-being, and quality of life in the future.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.

[[DOCX File, 31 KB - rehab_v10i1e47114_app1.docx](#)]

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Abbreviations

- COPD:** chronic obstructive pulmonary disease
- ECG:** electrocardiography
- EEG:** electroencephalography
- GAD-7:** Generalized Anxiety Disorder-7
- HADS:** Hospital Anxiety and Depression Scale
- HMD:** head-mounted display
- HR:** heart rate
- HRV:** heart rate variability
- IMI:** Intrinsic Motivation Inventory
- PPG:** photoplethysmography
- PSS:** Perceived Stress Scale
- RR:** respiratory rate
- SMS:** State Mindfulness Scale
- STAI:** State-Trait Anxiety Inventory
- VAS:** visual analog scale
- VE:** virtual environment

VR: virtual reality

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Review

Available Assistive Technology Outcome Measures: Systematic Review

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Abstract

Background: The World Health Organization claimed that measuring outcomes is necessary to understand the benefits of assistive technology (AT) and create evidence-based policies and systems to ensure universal access to it. In clinical practice, there is an increasing need for standardized methods to track AT interventions using outcome assessments.

Objective: This review provides an overview of the available outcome measures that can be used at the follow-up stage of any AT intervention and integrated into daily clinical or service practice.

Methods: We systematically searched for original manuscripts regarding available and used AT outcome measures by searching for titles and abstracts in the PubMed, Scopus, and Web of Science databases up to March 2023.

Results: We analyzed 955 articles, of which 50 (5.2%) were included in the review. Within these, 53 instruments have been mentioned and used to provide an AT outcome assessment. The most widely used tool is the Quebec User Evaluation of Satisfaction with Assistive Technology, followed by the Psychosocial Impact of Assistive Technology Scale. Moreover, the identified measures addressed 8 AT outcome domains: functional efficacy, satisfaction, psychosocial impact, caregiver burden, quality of life, participation, confidence, and usability. The AT category *Assistive products for activities and participation relating to personal mobility and transportation* was the most involved in the reviewed articles.

Conclusions: Among the 53 cited instruments, only 17 (32%) scales were designed to evaluate specifically assistive devices. Moreover, 64% (34/53) of the instruments were only mentioned once to denote poor uniformity and concordance in the instruments to be used, limiting the possibility of comparing the results of studies. This work could represent a good guide for promoting the use of validated AT outcome measures in clinical practice that can be helpful to AT assessment teams in their everyday activities and the improvement of clinical practice.

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KEYWORDS

assistive technology; AT; AT assessment; AT outcome measures; rehabilitation

Introduction

Background

The World Health Organization (WHO) has defined assistive technologies (ATs) as the fourth pillar of global health, along with drugs, vaccines, and medical devices [1]. Specifically, assistive products (APs) must be considered necessary to maintain or improve a person's functioning. Indeed, it is well known that AT has the potential to sustain people living with

limitations owing to age, disease, or disability in maintaining or improving their functioning and independence with a positive impact on mobility, social interaction, and the quality of life of patients and those around them [1,2]. In 2021, over 1 billion people globally needed ≥ 1 AT, a number that is expected to double by 2050 [1]. Despite the overt need for ATs, the evidence on the real ability of APs to reduce the impact of disease or disability in the user's life is still poor; reliable data on the need for AT and its outcomes are limited [3]. The AT outcome has

been indicated by the WHO as among the 5 top priorities in AT research [4]. However, only few countries in the WHO European Region have comprehensive monitoring mechanisms to evaluate the AT need and the impact on disease in the patient's life [5]. The need for evidence-based strategies in this field is also mentioned in the global report on AT published by the United Nations International Children's Emergency Fund and WHO in 2022 "Measuring outcomes and impact is necessary to understand the benefits of AT and create evidence-based policies and systems to ensure universal access to it" [1]. It is well known that the quality of the assessment has a wide impact on the user's experience with an AT, in addition to the quality of their interactions with the AT [6]. Stemming from the seminal work of Fuhrer et al [7], who defined the outcome in the context of AT provision as a "systematic investigation aimed at identifying the changes that are produced by AT in the lives of users and their environment," research more recently has started to emphasize the distinction between the outcomes and impact of AT. Specifically, the Global Alliance of Assistive Technology Organizations refers to outcomes as finite and measurable changes that occur in response to an intervention such as AT [8]. AT outcome assessment usually focuses on the short-term effect of an AT intervention (ie, provision of AT and its implementation in the user's life and context). Evidence from outcome research shows that AT enables people of all ages with any type of disability to overcome their functional difficulties, supporting them in achieving an important life [1]. On the other side, impact refers to broader changes that occur within the community as a result of outcomes [8]. As such, the impact is generally considered rather challenging to define and measure compared with the outcomes. This review focuses on assessing the outcome of providing an AT. In clinical practice, there is a growing need for standardized methods to track individual AT interventions by means of outcome assessment [9]. The use of internationally validated AT outcome measures can be helpful to AT assessment teams in their everyday activities and informs the improvement of clinical practice. Furthermore, different stakeholders are involved in the AT service delivery process (service manager, clinic director, different therapists, social workers, psychologists, rehabilitation engineers, funding agencies, AT users, and caregivers), and they see AT outcomes from different perspectives and might be interested in different aspects of AT outcomes [10].

As recently observed, measuring AT service delivery outcomes may be instrumental for any AT system to document evidence at individual, service, and system levels [2]. At the individual level, it allows AT and professionals to monitor their interventions and routinely perform corrective actions when necessary. At the service level, it facilitates the assessment and monitoring of the overall functioning of a specific service delivery process over time, as well as assuring the continuous involvement of all stakeholders. At the system level, outcome assessment allows the identification of differences in service delivery practices, processes, programs, and policies, thus providing policy makers with a reliable evidence base upon which the consequences (eg, factors) associated with these differences can be identified and addressed.

In the AT service delivery process, the most appropriate time to implement outcome measurement is at the follow-up, after a reasonable time of use of the APs by the users in their real living environment [11] to be able, if necessary, to implement corrective or improvement actions. Indeed, over the years, several studies have focused on the high rate of abandonment of received ATs owing to changes in health conditions [12] or failure of ATs to meet patients' or closest relatives' needs and expectations [6]. An AT solution brings about a disruption in the "system composed of the person, his or her environment and occupation" [13]. The system needs time to absorb the disruption and evolve toward a new balanced situation; the outcome is positive when this new situation is perceived by the person and by his or her primary network as beneficial to their life [14]. A variety of actors and factors are involved in this system, some of them being predictable and others unpredictable; thus, the actual outcomes can be detected only when the disruption transient has expired: outcome measurement should be carried out not *in the clinic* but *in the real environment* and not *here and now* but *there and tomorrow* [15].

A recent scoping review has been conducted to chart the landscape and development of AT evaluation tools across disparate fields [16]. In light of the increasing need for standardized methods to track individual AT interventions, we focused on clinical practice, particularly AT outcome measures within the rehabilitation path. In this context, a systematic review of the literature published in the last 2 decades has been undertaken to provide an overview of available outcome measures that can be used at the follow-up stage of any AT intervention and integrated into the daily clinical or service practice.

Objectives

This systematic review aims to answer the following research questions:

1. What AT intervention outcomes do the available instruments allow for evaluating?
2. To which categories of AT have the available measures been applied?

This review might be considered relevant for AT practitioners and researchers as, to our knowledge, no published systematic investigation of the extant literature has been recently performed to provide a comprehensive examination of available and used AT outcome measures.

Methods

This systematic review was conducted using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and a flow diagram [17]. The protocol for this review was registered in the PROSPERO (registration number CRD 42022338395).

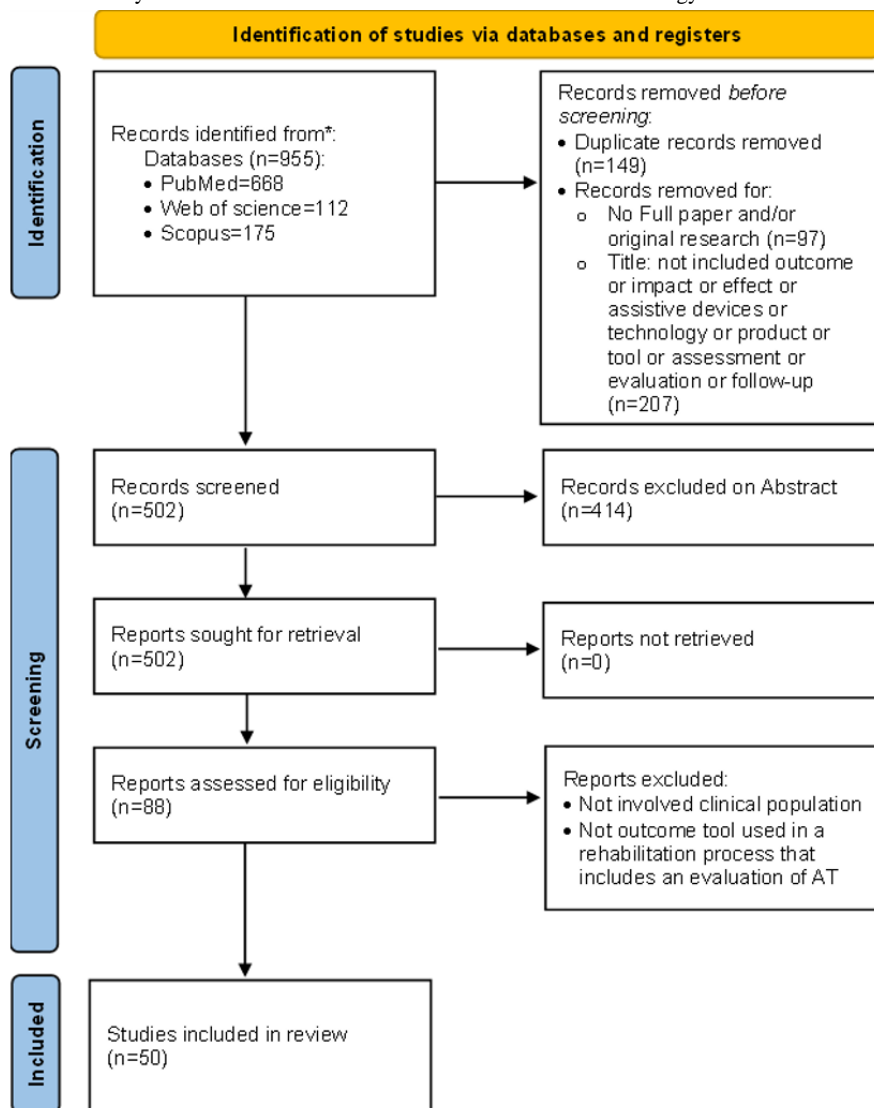
Eligibility Criteria

Studies were included if they fulfilled the following inclusion criteria: (1) original studies, (2) involving AT outcome or impact assessment, (3) published since 2002, and (4) published in the English language. As defined by the WHO, AT is an umbrella

term that covers the systems and services related to the delivery of APs and services, including hearing aids, wheelchairs, communication aids, spectacles, prostheses, pill organizers, and memory aids [1]. For a comprehensive review, we included all the APs. The exclusion criteria were non–full-text papers (ie, books, chapters of the books, qualitative studies, letters, comments, dissemination, and published abstracts without text), published in a non-English language, and involved a sample aged ≤18 years. The overall procedure of the study and the number of selected articles are shown in Figure 1. After

searching the electronic databases, 955 articles were collected. After removing duplicates and outliers (n=149), the remaining articles were used in the next phase. In the first screening phase, 304 articles were excluded based on the titles (n=207) and exclusion criteria (n=97). A second screening phase was conducted in which 414 articles were excluded by the abstract. A full-text review was conducted (n=88), and 38 (43%) papers were excluded based on the inclusion criteria. Finally, 50 articles were selected for the qualitative synthesis.

Figure 1. Overall procedure of the study and the number of selected articles. AT: assistive technology.



Information Sources for the Study Selection

Articles were searched in the PubMed, Web of Science, and Scopus electronic databases from 2002 to March 2023 (last 20 y). These databases appear adequate to cover the broad spectrum of topics in the target area [18]. Bibliographies identified articles, and a manual search of relevant journals for additional references was conducted. We used the search query string ((*assistive technology intervention*) AND ((*outcome measure**) OR (*impact measure**))) AND (*adult**) (the asterisk indicates that the search term was not limited to that word).

Selection and Data Collection Process

Eligibility screening was blindly and independently conducted by 2 researchers on the Rayyan platform [19]. Interreviewer disagreements were resolved by discussion to reach a consensus or by a third reviewer when the agreement was not reached. After selecting the studies, data collection focused on the demographic and clinical characteristics of patients, AT (including the category of assistive devices [ADs]), and AT outcome measures.

Results

Overview

In the last decade (2013-2022), the studies on outcome measures assessment have almost tripled compared with those in the previous decade (2002-2012). Indeed, 14 studies were conducted between 2002 and 2012 and 36 studies were conducted between 2013 and 2022. Moreover, in the last 2 years, there has been a substantial increase in studies in this area ([Multimedia Appendix 1](#)). The 50 papers included in this review can offer an overview of AT outcome or impact measures to try to answer our research question: “What AT outcome measures are currently available and used?”

To date, 53 instruments have been mentioned and used to provide an AT outcome measure assessment ([Multimedia Appendix 2 \[20-66\]](#)). In addition, 3 ad hoc questionnaires and an ad hoc interview were used.

The most widely used tool was the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0; 12/50, 24%), followed by the Psychosocial Impact of Assistive Technology Scale (9/50, 18%), Wheelchair Skills Test Questionnaire (WST-Q; 8/50, 16%), Wheelchair Use Confidence Scale for power wheelchair users (WheelCon-P; 6/50, 12%), and Caregiver Assistive Technology Outcome Measure (CATOM; 5/50, 10%). Another 3 tools have been mentioned in 4 papers, that is, Wheelchair Outcome Measure (WhOM), Canadian Occupational Performance Measure (COPM), and Spinal Cord Injury (SCI)–Functional Index (FI) or AT. Five tools were described in 3 papers, followed by 6 instruments used 2 times. The remaining 34 instruments were mentioned once.

The instruments differ with regard to the intervention outcomes domains considered and the category or type of AT to which they were applied. To create a reasoned and organized analysis of the available outcome measures for AT assessment, we have structured the *Results* section into paragraphs, starting with 2 questions.

What Intervention Outcomes Do the Available Instruments Allow for Evaluating?

The review of articles showed that 8 domains were evaluated by the available and used instruments. The most evaluated intervention outcome is “Functional Efficacy,” investigated in 72% (36/50) of the papers. The second most analyzed domain is satisfaction (28/50, 56%), followed by psychosocial impact (12/50, 24%), caregiver burden (6/50, 12%), quality of life (9/50, 18%), participation (8/50, 16%), confidence (6/50, 12%), and usability (3/50, 6%).

Functional Efficacy

Overview

AT can contribute to the achievement of enhanced functioning from an International Classification of Functioning perspective. Efficacy can be assessed by evaluating a variety of variables. Of the 50 reviewed studies, 36 (72%) have investigated this domain. Overall, 26 scales were used to evaluate the functional efficacy. Of these, 6 (23%) instruments were specifically

designed and developed for evaluating APs. The most commonly used questionnaire is the WST-Q, which appears to be an outcome measure in 9 studies.

Wheelchair Skills Test Questionnaire

The WST-Q is a standardized evaluation method developed and used to self-evaluate manual or powered wheelchair skills and safety [67]. In addition to assessing capacity (as in Wheelchair Skills Test; WST), the WST-Q assesses confidence and performance (what wheelchair users do and how they do it). In the reviewed articles, it was administered to patients and their informal caregivers [20,21]. With regard to patients, the studies showed that it is an effective way to evaluate variation in 32 power mobility skills (eg, the capability of putting on brakes, propelling a straight distance, and performing a reaching task from their wheelchair) in all power mobility AP users [22]. For example, studies used the WST-Q to evaluate the functional efficacy in patients with autosomal recessive spastic ataxia [23], multiple sclerosis, and SCI [24].

Furthermore, 22% (2/9) of the studies also reported the WST as an instrument to confirm the WST-Q results [25,26]. However, a study showed that the WST can be considered a reliable, valid, and useful tool for evaluating safety and performance domains in several clinical populations who need manual wheelchairs, specifically amputations, stroke, musculoskeletal disorders, SCI, and neuromuscular disorders [27].

SCI-FI or AT Tool

The SCI-FI or AT banks allow for assessing an individual’s ability to use new APs and how the ability to execute day-to-day functional activities (with AT) changes over time [28]. It focuses on the ability to perform activities, as usual, using APs, specifically basic mobility (eg, changing or maintaining body positions and transfers), self-care (eg, eating and dressing), fine motor (eg, manipulating and moving objects), ambulation, and wheelchair mobility. Four studies involving large samples (from 269 patients to 1237 patients) of patients with SCI used SCI-FI or AT to assess mobility ADs outcome such as wheelchairs [29,30]. Studies converge in supporting that SCI-FI or AT is an optimal solution to evaluate functioning with AT in 4 domains: basic mobility, self-care, fine motor function, and ambulation [31].

Life-Space Assessment

Overall, 3 studies used this self-report measure to quantify “how far and how often they have mobilized with or without assistance” during the last 4 weeks. In detail, this tool investigates power mobility in 5 “Life-Space Levels” (bedroom or sleeping area, external area of the residence, neighborhood, and inside and outside the city). The studies involved patients who required several mobility APs, including mobility service dogs and manual and powered wheelchairs. The reviewed articles showed that this tool can be administered to patients with diseases of the nervous system and sense organs, such as autosomal recessive spastic ataxia [23] or multiple sclerosis [24] and traumatic damage to the spinal cord [26].

Three questionnaires were cited in 2 studies for each to evaluate the functional efficacy of APs in terms of “functional

independence,” “functional mobility,” and “functional communication.”

Functional Independence Measure

The Functional Independence Measure (FIM) assesses the degree of assistance required by patients to perform motor (eg, eating, grooming, bathing, and dressing) and cognitive (eg, comprehension and expression) activities of daily living [68]. In the reviewed papers, the tool was used to assess the patient's level of disability as well as a change in patient status consequent to the AT intervention. The FIM has been used to evaluate changes in patients with several motor disabilities, including deficits because of traumatic SCI [29]. The reviewed studies showed that the FIM can be used to evaluate the functional efficacy of 2 main categories of ADs: products for controlling, carrying, moving, and handling objects and devices (ie, smart environment) and products for mobility (ie, wheelchairs) [29,32].

In their study, Tyner et al [29] adopted a modified version of FIM, the *Self-Report Functional Measure*, an alternative brief self-report instrument developed to measure 13 different motor functions affecting basic activities of daily living in wheelchair users with SCI.

Functional Mobility Assessment

The Functional Mobility Assessment (FMA) was adapted from the *Functional Everyday with a Wheelchair* (FEW) questionnaire, which included all items relevant to individuals who use mobility devices, that is, wheelchairs, scooters, canes, crutches, or walkers that allow them to perform functional tasks independently, safely, and efficiently as possible [33]. It measures the perceived functional independence of individuals in several tasks, such as “carrying out daily routine” or “personal care tasks.” The 2 reviewed studies applied the FMA as a functional performance efficacy measure applied to mobility APs (eg, wheelchairs, scooters, canes, crutches, and walkers).

FEW is a brief, structured self-report outcome measurement questionnaire used to evaluate the functioning in wheelchair users [69]. Only 1 reviewed study has used this tool to evaluate the performance in the actually lived environment of users who need manual and power mobility devices [34].

Functional Assessment of Communication Skills for Adults

The Functional Assessment of Communication Skills for Adults (FACS-A) is a 43-item scale that measures functional communication in daily living activities (eg, understanding television and radio, responding in an emergency, and using a calendar) [70]. In detail, it focuses on 4 domains: social communication; communication of basic needs; reading, writing, and number concepts; and daily planning. In their study, Vincent et al [35] used only items of the first 2 domains that might be affected by using APs with hearing persons. Specifically, FACS-A was used to evaluate changes in communication in hearing persons using “Le communicateur Oralys on pocket PC,” a software that translates sign language into oral French. In another study, FACS-A was adopted to evaluate functional communication in patients with cerebral palsy using augmentative and alternative communication [36].

Further Functional Efficacy Scales

The other 17 instruments were cited by only 1 article each. Among them, only 2 instruments have been developed for evaluating the AT intervention: the (1) *Wheelchair User's Shoulder Pain Index* (WUSPI) [71] and *Individually Prioritised Problem Assessment* (IPPA) [72,73]. WUSPI was used in a study involving adults with traumatic SCI, which showed the validity of WUSPI as a self-report measure to evaluate the effect of mobility service dogs on shoulder pain in wheelchair users during functional activities (eg, transfers, wheelchair mobility, self-care, and general activities) [26].

The other tools have not been specifically designed and developed for AT interventions. They allow for evaluating several aspects of functional efficacy and have been used according to the prescribed APs. For example, activities that can be performed using ADs can be broken down into several tasks, and assessing *difficulty in carrying them out* can be an efficacy indicator. In the literature, 3 instruments evaluating this aspect have been found: the (2) IPPA, the (3) COPM [74], and (4) *Assessment of Life Habits* (LIFE-H) [75]. IPPA is a validated tool that evaluates the perceived effectiveness of an AT intervention. Mortenson et al [37] showed that IPPA can be successfully used with different AT categories and clinical populations. Specifically, in the reviewed article, IPPA was used to evaluate the ability of AT interventions involving APs for personal mobility and domestic activities to improve older AT users' activity performance. COPM is a client-centered outcome measure for patients to identify and prioritize everyday issues that restrict their participation in everyday life. LIFE-H is a self-report measure to capture the self-rated level of accomplishment for everyday activities of people with disabilities, collecting information on all life habits that people carry out in their environments (home, workplace or school, and neighborhood). One study involved in this review showed that LIFE-H can be used in patients with autosomal recessive spastic ataxia and users of manual and powered wheelchairs [38]. Overall, 6 instruments described in 2 articles were available and were used to evaluate functional efficacy in *cognitive abilities*. A study has focused on changes in many cognitive domains (eg, orientation, memory, attention, and language) of older adults with or without dementia that uses an electric calendar to compensate for time orientation and memory [39]. The authors investigated changes in cognitive functioning using 2 screening tests: (5) *Mini-Mental Examination State* [76] and (6) *Neurobehavioral Cognitive Status Examination* [77]. Moreover, they investigated whether the chosen AP could impact the behaviors in daily living, measured by the short version of the (7) *Dementia Behavior Disturbance Scale*, a validated tool for behavioral and psychological symptoms in people with dementia [78]. Other studies have focused on specific cognitive domains, particularly language. The (8) *Communicative Effectiveness Index modified* was used by Londral et al [40] to measure the efficiency of assistive communication devices in supporting speech dysfunction in patients with amyotrophic lateral sclerosis. Another study evaluated the impact of assistive communication products in the language domain, focusing on receptive language skills, reading comprehension, and functional communication [36].

In detail, they evaluated patients with cerebral palsy using the (9) *Gray Silent Reading Test* for reading comprehension ability [79]; the (10) *Test of Auditory Comprehension of Language, revised* for comprehension of semantics, morphology, and syntax; and the (11) *Peabody Picture Vocabulary Test, revised* [80] for receptive (hearing) vocabulary.

Overall, 4 studies have focused on *functional autonomy/independence* related to AT interventions. First, Mortenson et al [41] assessed mobility independence and performance in activities of daily living in patients who needed mobility APs using 3 subscales of the (12) *Functional Autonomy Measurement System* [81]. The (13) *Barthel Index for Activities of Daily Living* was another tool used to measure functional independence in activities of daily living [82]. In the reviewed study, this instrument allowed for investigating changes in functional independence in performing everyday activities (eg, bathing, grooming, dressing, chair transfer, and mobility) in patients with autosomal recessive spastic ataxia who use manual and powered wheelchairs [38]. Similarly, the (14) *Spinal Cord Independence Measure III* has been used to evaluate any changes in performing activities of daily living and mobility in patients with SCI using manual and powered wheelchairs [42]. Finally, the (15) *Occupational Therapy Functional Assessment Compilation (OTFAC)* tool [43], which was initially designed as a comprehensive functional assessment tool for occupational therapists, can also be used to isolate the impact of an AT intervention on a person's functional performance. The reviewed article showed the feasibility of OTFAC as a tool for evaluating changes in functional autonomy in several clinical conditions using mobility APs such as wheelchairs and seating systems [43].

Finally, 2 studies have investigated functional changes in *basic and instrumental daily life activities* in 2 clinical populations (ie, dementia and amyotrophic lateral sclerosis). First, the (16) *Bristol Activity of Daily Living Scale (BADLS)* [83], which focuses on independence in performing 20 activities, was developed specifically to be used with patients affected by dementia. The reviewed study used the BADLS to evaluate whether AT interventions extend the time that people with dementia can continue to live independently at home [44]. In addition, the (17) *Amyotrophic Lateral Sclerosis Functional Rating Scale* is another valid scale to evaluate the patients' functioning in performing activities of daily living, making use of the prescribed assistive communication devices [40].

Satisfaction

Overview

In the standard "ISO 9241-11:2018 Ergonomics of human-system interaction—Part 11: Usability," the definition of satisfaction can also be found: "extent to which the user's physical, cognitive and emotional responses that result from the use of a system, product or service meet the user's needs and expectations."

The high abandonment rates of the AT are associated with the device's poor performance, which does not meet the environmental needs and does not consider the user's opinion [22]. The effective use of evidence-based strategies is

particularly necessary because the level of availability of AT, especially wheelchairs, is low and can be abandoned if inappropriate for the user. Wheelchair users often have problems such as, for example, discomfort and poor posture. Therefore, it is essential to investigate user satisfaction by involving users in a collaborative target identification process [45]. However, there are only a few wheelchair-specific measures. Overall, 18 articles focused on evaluating patients' satisfaction with using the prescribed AT devices. A total of 5 instruments were used.

QUEST 2.0 Tool

QUEST 2.0 allows for evaluating the individuals' satisfaction with the AT equipment they are using [84]. The reviewed articles showed that QUEST 2.0 is the most used questionnaire in AT outcome assessment. Papers appear heterogeneous in terms of AT categories and clinical populations. First, QUEST 2.0 can be successfully administered directly to patients to obtain the opinion of those using the APs. In more detail, QUEST 2.0 has been administered to many clinical conditions, including SCI [26], neuromuscular or musculoskeletal disorders (eg, rheumatoid arthritis) [46], and diseases of the nervous system and sense organs (eg, low vision) [35,47]. With regard to the evaluated ADs, QUEST 2.0 was used to evaluate user satisfaction in using 4 different categories of ADs: mobility [26], communication and information management [47,48], domestic activities [46,49], and controlling devices [32].

AT Device Predisposition Assessment

Assistive Technology Device Predisposition Assessment (ATD-PA) is one of the most well-known instruments for evaluating the overall user experience with AT. Only 1 study used the questionnaire ATD-PA (device form) to evaluate consumers' subjective satisfaction [50]. This study did not provide detailed information on the ATs or populations that may use it. Therefore, this tool is a stable, valid, and reliable instrument for evaluating products and services, and is potentially usable for all patients who need ATs.

LIFE-H Tool

The LIFE-H is a self-report measure of the perceived level of accomplishment for everyday activities of people with disabilities that includes a scale evaluating the individual's satisfaction regarding the accomplishment of life habits [75]. Moreover, 3 of the reviewed articles showed that this tool can be administered to patients with disabilities affected by diseases of the nervous system and sense organs, such as autosomal recessive spastic ataxia [38]. The studies applied the LIFE-H to 3 main categories of ATs, specifically mobility [37,38], communication and information management [35], and domestic activities [37].

WhOM Tool

WhOM is the second most commonly used patient-centered measure for evaluating satisfaction with the performance of self-identified activities. Unlike QUEST 2.0 and ATD-PA, it is a specific instrument for wheelchair and seating systems intervention [85]. The reviewed articles showed that this instrument has been used only in patients with 2 broad clinical categories: suspected or confirmed neurodegenerative

conditions, such as autosomal recessive spastic ataxia [38], and traumatic damage to the spinal cord [51,52].

Wheelchair Satisfaction Questionnaire

The Wheelchair Satisfaction Questionnaire (WSQ) is designed to provide data on wheelchair users' satisfaction with their AP at a given moment [53]. The only study mentioning this questionnaire supported its potential to give wheelchair users a quantifiable voice on wheelchair function [53]. It is well known that providing data from wheelchair users to wheelchair manufacturers and providers leads to a better design and provision.

Psychosocial Impact

The psychosocial impact can be seen as the impact on AT users' psychosocial well-being, including subjective perceptions of the changes that occur when they adopt AT [54]. To date, 12 reviewed articles have investigated this domain using 4 instruments.

Psychosocial Impact of ADs Scale

The Psychosocial Impact of Assistive Devices Scale (PIADS) scale was developed for evaluating AT devices, asking patients how their life has been affected by using the AT equipment [86]. It is the most used scale for evaluating psychosocial impact; indeed, 9 articles used this instrument, showing that this tool has been administered to several clinical conditions and AT products. First, studies showed that PIADS has been used for a broad spectrum of clinical conditions in need of APs: diseases of the nervous system (eg, spastic cerebral palsy) and sense organs (eg, low vision) [47,54,55], severe motor disabilities [32], and traumatic damage to the spinal cord [26]. With regard to APs, PIADS can be applied to 4 main categories of ADs: mobility (eg, wheelchairs and seating systems) [26,54], communication and information management [47,55], domestic activities [56], and controlling devices [32,57].

Further Psychosocial Impact Scales

Each of the other 3 instruments was cited by only one article to evaluate specific psychosocial impact components from the patient's perspective: self-esteem, personal well-being, and self-determination. These instruments have been used with specific categories of patients. For example, the *Rosenberg Self-Esteem Scale* has been used to explore the differences between manual and power wheelchair users regarding self-esteem in persons with SCI [42]. The *Arc's Self-Determination Scale* allowed for investigating autonomy, self-regulation, psychological empowerment, and self-realization in young patients with cerebral palsy using argumentative and alternative communication APs for at least 15 years [36]. Finally, *Personal Wellbeing Index* ensures well-being assessment in community-dwelling people (aged >65 y) who use APs to achieve individual goals for safety and security at home [58].

Caregiver Burden

Care activities can directly and indirectly impact caregivers' health and life [20]. AT can reduce users' dependence on human care, especially assistance from informal caregivers (ie, friends, family, and partners). In fact, it has been shown that the use of

AT can decrease the caregivers' physical and psychological burden (eg, stress and anxiety) [37]. However, AT may not completely eliminate responsibility and stress. Although ATs increase caregivers' sense of freedom and independence, some ADs may require their support. Therefore, it is essential to study caregivers' burden associated with AT [20].

Overall, 6 articles have focused on evaluating the impact of AT interventions on the burden experienced by informal caregivers. In detail, 2 instruments were used.

CATOM Tool

In total, 5 reviewed studies involved caregivers of APs users to investigate their burden through the CATOM questionnaire. CATOM is a tool that can provide a comprehensive evaluation of the burden experienced by informal caregivers, especially psychological burden [59]. Most papers (4/5, 80%) addressed caregivers of patients with motor disabilities who needed APs for activities related to personal mobility, above all powered wheelchairs [20,21]. However, one study showed that CATOM can be used to assess caregiver burden involving a wider range of clinical conditions [37]. Only one research group adopted CATOM in the assessment of caregivers of users of products for domestic activities and participation in domestic life [24].

Zarit Burden Interview

Zarit Burden Interview (ZBI) is a caregiver self-report measure used to evaluate the burden in supporting people needing ATs [87]. To date, 1 study has used this tool to evaluate the burden of caregivers of people with dementia using APs for performing domestic activities [44].

Quality of Life

Overview

The WHO defines quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It has a multidimensional nature and can be influenced by several factors and events that occur in a person's life. To date, 8 reviewed articles have investigated this domain using 6 instruments.

Short Form Health Survey

Overall, 3 studies adopted the 36-item Short Form Health Survey (SF-36) to investigate patient-perceived quality of life in participants using APs [88]. SF-36 allows for evaluating 8 domains of quality of life that could be influenced by the prescribed APs: physical functioning, energy or vitality, bodily pain, general health perceptions, limitations owing to physical and emotional problems, social role functioning, and mental health or emotional well-being. The reviewed article is heterogeneous in terms of APs and the clinical population. The APs belong to the mobility category, including wheelchairs and compressive short-sleeve jackets. As clinical populations, these studies involved patients with hereditary pathologies of the connective tissue, specifically Ehlers-Danlos syndrome [60] or SCI [26].

Further Quality of Life Scales

Each of the other 5 instruments was cited by only 1 article to evaluate the quality of life of patients with several clinical conditions and their caregivers. For example, (1) the *EuroQoL-5D-5L* is an instrument that evaluates the participant's perception of quality of life, investigating 5 dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. One study involving 495 patients with dementia used this tool to evaluate the quality of life in patients with ADs for domestic activities and participation in domestic life and their caregivers [44]. A study by Londral et al [40] described and used 2 questionnaires on quality of life to evaluate the impact of early support with assistive communication devices in patients with amyotrophic lateral sclerosis and their caregivers. First, (2) the *McGill Quality of Life Questionnaire* is used as a self-reported multidimensional tool to investigate patients' and their caregivers' overall quality of life, including physical well-being, psychological symptoms, existential well-being, and support. The other scale, (3) *World Health Organization Quality of Life (WHOQOL) brief version* [89], is administered only to caregivers to deepen the quality of life in 4 domains: physical and psychological health and well-being, social relations, and environment. This questionnaire has also been used with wheelchair users to investigate how the provision of wheelchairs affects their quality of life domains compared with wait-listed controls [22]. Another tool used with patients who needed assistive communication devices is the (4) *Quality-of-Life Profile for People with Physical and Sensory Disabilities (QOLP)* [90]. QOLP allows for collecting the perspective and experience (eg, thoughts, feelings, beliefs, attitudes, and resources) of people with disability, particularly young men who have used the assistive communication system for at least 15 years [36]. Finally, the (5) *Assessment Quality of Life* [91] was used to evaluate 8 dimensions of quality of life (ie, independent living, pain, senses, coping, mental health, happiness, relationships, and self-worth) in community-dwelling people (aged >65 y) who use APs for domestic activities and participation in domestic life [58].

Participation

Overview

For many people with disabilities, access to ATs has been identified as a facilitator of the full enjoyment of human rights and participation in society and employment [22]. Overall, 7 articles have focused on evaluating the impact of AT interventions on the participation domain. In detail, 5 instruments were used. However, only 2 instruments have been created to evaluate participation using AT, specifically mobility APs: the Nordic Mobility-Related Participation Outcome Evaluation of Assistive Device Intervention (NOMO) [61] and the Assistive Technology Outcomes Profile for Mobility (ATOP-M) [92].

NOMO Tool

The NOMO instrument evaluates the effectiveness of mobility devices in assessing mobility-related participation [61]. To date, only 1 study has used NOMO as an AT outcome measure involving patients with different self-reported impairments who

received a powered mobility device (powered wheelchair and scooter) [61].

ATOP-M Tool

The ATOP-M is a self-report measure of the impact of mobility devices on the level of activity and participation of the user [92]. Mortenson et al [59,62] conducted 2 studies involving a wide user base (>100 patients for the study) in which they proposed the ATOP-M as a valid instrument to evaluate the impact of power wheelchairs on the level of participation.

Late Life Disability Index

The Late Life Disability Index (LLDI) measures participation frequency and perceived limitation in 16 life tasks [93]. It has been frequently used as an outcome measure in geriatric research. The 3 articles that involve this scale converge in the evaluated APs, that is, powered wheelchairs. On the contrary, the studies disagree on the target. Indeed, 2 studies focused on patients. One study involving 115 end users underlined that the original scale might not be applicable to all power wheelchair users [62]. A following study by Mortenson et al [24] supported the use of LLDI in wheelchair users with multiple sclerosis and SCI. Finally, in the last study, the authors showed that LLDI can be successfully administered to caregivers, collecting the patients' limitations from the caregivers' point of view [20].

Craig Handicap Assessment and Reporting Technique

The Craig Handicap Assessment and Reporting Technique (CHART) scale assesses the degree of social and community participation [94]. It is designed as an interview tool, administered face-to-face or via telephone. Two reviewed studies proposed CHART as a tool for evaluating social participation related to manual and powered wheelchairs [22]. In addition, Hastings et al [42] used this interview with patients with tetraplegia caused by SCI.

Confidence

The trust of AT users that products work properly is subjective but also depends on device reliability.

To date, only 1 questionnaire has been implemented and used to evaluate this outcome. In detail, 6 reviewed studies have focused on the evaluation of confidence using the *WheelCon-P*, a self-report questionnaire that measures confidence with manual or power wheelchair use [95]. This tool has been administered to wheelchair users affected by several clinical conditions, particularly neurodegenerative conditions, such as autosomal recessive spastic ataxia (2 studies [23,38]), multiple sclerosis, and traumatic damage to the spinal cord [59].

User Experience: Usability and Acceptability

Overview

Usability is defined in the standard "ISO 9241-11:2018 Ergonomics of human-system interaction—Part 11: Usability" as "relevant when designing or evaluating interactions with a system, product or service." Moreover, usability is "relevant to the use by people with the widest range of capabilities," and it is defined 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.” “Acceptability” can be considered a higher level concept compared with usability and serves as a trade-off among all factors affecting the adoption of new technologies [96].

Furthermore, 3 articles focused on the user experience evaluation involving questionnaires assessing the usability and acceptability of the prescribed ADs. Specifically, 3 instruments were used.

System Usability Scale

The System Usability Scale (SUS) is a valid, reliable, and short questionnaire used to evaluate the overall usability of a wide range of technological devices [97]. However, only one study used SUS to evaluate ADs [32]. This study involved patients with severe motor disabilities who required a smart environment controlled by infrared oculography.

AT Outcome Measure

One study introduced the Assistive Technology Outcome Measure (ATOM) as a practical clinical tool that assesses AT usability and service in a short, easy-to-administer manner. This study showed the capability of ATOM to be administered to several clinical populations experienced in using a specific device. However, to date, it has only been used to evaluate the usability of APs for activities and participation related to personal mobility and transportation, specifically wheelchairs and seating systems [43].

Service User Technology Questionnaire

One study introduced the self-report questionnaire Service User Technology Questionnaire (SUTAQ) to evaluate the acceptability of ADs and identify the characteristics of people who were likely to reject technological health services [44]. The study involving 495 patients showed that SUTAQ can be easily administered to patients with dementia, which could have cognitive limitations [44]. In this context, the AT outcome measure has been used to evaluate the acceptability of ADs for domestic activities and participation in domestic life, which play an important role in increasing the quality of life of patients with neurodegenerative diseases and their caregivers.

Further Domains

It is well known that AT interventions can reduce the burden and psychological distress in the families of patients who need APs [44]. Among the behavioral symptoms that could affect the well-being and quality of life of caregivers, anxiety and depression symptoms were investigated. Gathercole and Howard [44] investigated psychological distress in caregivers of patients with dementia who needed APs for performing domestic activities. In detail, the caregivers underwent an evaluation with the *State-Trait Anxiety Inventory-6 items* [98] for anxiety symptoms and the screening tool *Centre for Epidemiologic Studies Depression Scale Revised* for depressive symptoms [99]. In another study, Rushton et al [20] evaluated the anxiety and depression symptoms of informal caregivers of powered wheelchair users using a single self-assessment scale, *Hospital Anxiety and Depression Scale*.

To Which Categories of AT Have the Available Tools Been Applied?

Overview

The ISO 9999:2016 standard classification has been used to define the AT categories. The studies involved in this review describe tools applied to 4 AT categories ([Multimedia Appendix 3](#)).

The category *APs for activities and participation relating to personal mobility and transportation* (ISO class 12) was the most involved in the reviewed article, being studied in 32 papers (32/50, 64%). The other 3 categories, *APs for communication and information management* (ISO class 22; 8/50, 16%), *APs for domestic activities and participation in domestic life* (ISO class 15; 6/50, 12%), and *APs for controlling, carrying, moving, and handling objects and devices* (ISO class 24; 2/50, 4%) were involved in fewer studies.

12 APs for Activities and Participation Relating to Personal Mobility and Transportation

Products are intended to support or replace a person’s capacity to move indoors and outdoors (ie, walking), transfer from one place to another, or use personal or public transportation.

Overall, 32 articles underlined the importance of APs for mobility and introduced several tools that could be used as AT outcome measures. This heterogeneous category involves manual and powered wheelchairs (the most used AP, cited in 28/32, 88% of papers), scooters, canes, crutches, or walkers. The 29 tools used in the reviewed articles allowed for assessing 7 domains, including functional efficacy (14/29, 48%), participation (5/29, 17%), satisfaction (4/29, 14%), psychosocial impact (2/29, 7%), quality of life (2/29, 7%), usability (1/29, 3%), and confidence (1/29, 3%). The functional efficacy was assessed by all papers involving APs for mobility using 14 tools. Of these instruments, 7 instruments are specifically designed and developed for evaluating APs (ie, WST-Q, WST, SCI-FI or AT, FEW, FMA, WUSPI, and IPPA), of which 5 (71%) are for mobility (WST-Q, WST, FEW, FMA, and WUSPI). The most commonly used questionnaire is the WST-Q, a standardized evaluation method developed and used to self-evaluate manual or powered wheelchair capacity, confidence, and performance in 32 power mobility skills [23,59]. The WST-Q is an effective outcome measure for evaluating functional efficacy in all wheelchair users [22,59], including patients with neurodegenerative and traumatic conditions [20,21,23,25,38,59,62]. In addition, 3 studies reported the WST as a reliable tool for evaluating the mobility capacity of manual wheelchair users [25-27]. Other tools allowed for evaluating specific subdomains of functional efficacy. First, 6 studies focused on changes in patients’ functional independence in performing activities of daily living [29]. In detail, 1 study used FIM and its modified version Self-Report Functional Measure to deepen changes in the patient’s level of disability in carrying out everyday motor tasks [29], whereas 3 studies adopted the FEW and its adapted version FMA to evaluate performance in personal care and daily routine tasks. Unlike the FEW, which is designed only for wheelchairs [34], the FMA includes items relevant to individuals who use any mobility devices, such as

wheelchairs, scooters, canes, crutches, or walkers [22,33]. Other valuable tools cited to evaluate the outcome of an AT intervention with manual and powered wheelchairs on a person's functional performance in performing everyday activities and mobility are the OTFAC [43], Barthel Index [38], and Spinal Cord Independence Measure 3 [42]. Three studies have used Life-Space Assessment to quantify power mobility during the last 4 weeks involving patients who need mobility APs, including mobility service dogs [26] and manual and powered wheelchairs [38,59]. With regard to tools for assessing difficulty in carrying out everyday tasks, the articles proposed the questionnaire COPM [26,34], the Life-H [38], and a scale designed for evaluating AT intervention, IPPA [37]. Finally, 3 studies used SCI-FI or AT to assess mobility ADs outcome in patients with SCI [28,29], focusing on 4 domains: basic mobility, self-care, fine motor function, and ambulation [31]. Moreover, WUSPI was used in a study involving this clinical category as a self-report outcome measure to evaluate the effect of mobility service dogs on shoulder pain in wheelchair users during functional activities [37]. Regarding satisfaction, 4 tools were used to evaluate this aspect in patients needing APs for mobility. Among the 11 articles investigating satisfaction, most (n=5, 45%) have used QUEST 2.0 [26,34,60,63,64], followed by WhOM (n=4, 36%) [38,45,51,52], WSQ (n=1, 9%) [53], and Life-H (n=1, 9%) [37]. Unlike QUEST 2.0 and Life-H, WhOM and WSQ are instruments designed for wheelchairs and seating systems intervention. With regard to the participation domain, changes in the degree of social participation (including perceived limitations) related to manual and powered wheelchairs were assessed in 7 articles by using 4 different tools: CHART [22,42], NOMO 1.0 [61], LLDI, and ATOP-M [59,62]. Among them, 2 instruments, NOMO and ATOP-M, have been created to evaluate participation changes related to assistive mobility [61,92]. Moreover, LLDI was successfully administered to caregivers, collecting the patients' limitations from the caregivers' point of view [20]. Furthermore, 1 study investigated the usability of wheelchairs and seating systems using the short tool ATOM [43]. WheelCon-P is the only questionnaire implemented and used for evaluating the confidence domain [62] and is designed for being administered to manual and powered wheelchair users. To date, 6 studies converged in supporting that it is usable with many neurodegenerative and traumatic clinical conditions [23,25,38,59,62,65]. The psychosocial impact was assessed by 5 articles using PIADS [26,34,43,54] and Rosenberg Self-Esteem Scale [42], whereas changes in quality of life because of APs (ie, wheelchairs, mobility service dogs, and compressive short-sleeve jackets) were evaluated in 4 articles through SF-36 [22,26,60,64] and in a single article by WHOQOL brief version [22]. Finally, 4 reviewed studies have involved caregivers of APs for mobility users to investigate their perceived psychological burden through the CATOM questionnaire [20,37,41]. Moreover, Rushton et al [20] deepened the anxiety and depression symptoms of informal caregivers of powered wheelchair users using the self-assessment Hospital Anxiety and Depression Scale.

15 APs for Domestic Activities and Participation in Domestic Life

Products are intended to support or replace a person's capacity to carry out domestic and everyday actions and tasks, including preparing or eating food and household cleaning.

Overall, 7 reviewed articles were concerned with APs for domestic activities, such as plastic cap wrenches, key turners, and AP for writing. To date, the 12 used tools allowed for assessing 5 domains, functional efficacy (3/12, 25%), satisfaction (2/12, 17%), psychosocial impact (2/12, 17%), quality of life (2/12, 17%), caregiver burden (2/12, 17%), and usability (1/12, 8%). In detail, 3 articles assessed satisfaction using QUEST 2.0 [46,49] and Life-H [37]. Only 1 article evaluated the usability of APs regarding the acceptability of ADs [44]. The psychosocial impact was assessed using PIADS [56] and Personal Wellbeing Index [58], whereas the quality of life was evaluated in 2 articles using Assessment Quality of Life [58] and EuroQol-5 [44]. Moreover, 3 articles investigated the functional efficacy domain, focusing on changes in primary and instrumental activities of daily living using BADLS [44], IPPA [37], and COPM [58]. Finally, CATOM and ZBI were used in assessing the burden of caregivers of people with a wide range of clinical conditions (including dementia) who use APs for performing domestic activities [37,44]. Moreover, Gathercole and Howard [44] investigated the psychological distress in caregivers of patients with dementia using State-Trait Anxiety Inventory for anxiety symptoms and Centre for Epidemiologic Studies Depression Scale Revised for depressive symptoms.

22 APs for Communication and Information Management

Products are intended to support or replace a person's capacity to receive, send, produce, and process information differently, including communicating through language, signs, and symbols; receiving; generating messages; carrying on conversations; and using communication devices.

Overall, 8 articles focused on this category, including several APs, such as pillbox, head-mounted visual AT, augmentative and alternative communication systems, speech synthesizers, and electric calendars. The 15 tools used in the reviewed articles allowed for assessing 5 domains, functional efficacy (n=9, 60%), quality of life (n=3, 20%), psychosocial impact (n=2, 13%), and satisfaction (n=1, 7%). In detail, the 4 articles evaluating satisfaction have used QUEST 2.0 [35,47,48,66]. The psychosocial impact was assessed by 3 articles using PIADS [47,55] and Arc's Self-Determination Scale [36], whereas the quality of life was evaluated in 2 articles through McGill Quality of Life Questionnaire, WHOQOL brief version [40], and Quality of Life Profile [36]. Finally, the functional efficacy of APs has been investigated by 4 articles in terms of (1) functional changes in primary and instrumental activities of daily life with Amyotrophic Lateral Sclerosis Functional Rating Scale [40] and Life-H [35]; (2) global cognitive abilities with Neurobehavioral Cognitive Status Examination, Dementia Behavior Disturbance Scale, and Mini-Mental Examination State [39]; (3) language domain—FACS-A [35,36] and Communicative Effectiveness Index modified [40] for functional communication; Gray Silent Reading Test for reading

comprehension ability; Test of Auditory Comprehension of Language, revised for comprehension of semantics, morphology, and syntax; and Peabody Picture Vocabulary Test, revised for receptive (hearing) vocabulary [36]. To date, no studies have evaluated the usability and confidence involving patients needing APs for communication and information management or the burden of their caregiver.

24 APs for Controlling, Carrying, Moving, and Handling Objects and Devices

Products are intended to facilitate a person's task performance require the movement or manipulation of an object. Two articles focused on this category, including smart environment [32] and environmental control APs (ie, electronic aids for daily living) [57]. The 5 tools used allowed for assessing 4 domains, functional efficacy (2/5, 40%), satisfaction (1/5, 20%), usability (1/5, 20%), and psychosocial impact (1/5, 20%). Sime and Bissoli [32] evaluated the satisfaction and usability of patients with motor difficulties in using smart environments by QUEST 2.0 and SUS, respectively [32]. Moreover, the authors assessed the functional efficacy using FIM and COPM to identify changes in patients' level of disability and everyday issues owing to AT intervention. Finally, both reviewed articles used PIADS to evaluate psychosocial impact.

Further Interesting Insights

Finally, this paragraph focuses on 4 other elements—original purpose of the tools, cross-sectional outcome measures, study participants and administration time, and modality of the instruments.

Original Purpose of the Tools

Among the reviewed tools, 17 scales were designed to evaluate the ADs, including the QUEST 2.0, ATD-PA, WhOM, WSQ, ATOM, WheelCon-P, PIADS, IPPA, WST, SCI-FI or AT, FEW, FMA, WST-Q, WUSPI, NOMO 1.0, ATOP-M, and CATOM. These tools allowed the assessment of 7 domains, satisfaction (4/17, 24%), usability (1/17, 6%), confidence (1/17, 6%), psychosocial impact (1/17, 6%), functional efficacy (7/17, 41%), participation (2/17, 12%), and caregiver burden (1/17, 6%).

Cross-Sectional Outcome Measures

Approximately half (23/50, 46%) of the reviewed studies described outcome measures applied to several APs in a single category. In contrast, only 2 studies used the same instruments for assessing AT products of multiple AT categories (ie, mobility and domestic activities). Interestingly, these studies involved only the caregivers of AT users (eg, CATOM or IPPA).

Participants

Overall, 74% (39/53) of the studies involved small samples of ≤ 100 patients or caregivers, of which 18% (7/39) involved ≤ 10 patients (2 case studies). Most studies (44/50, 88%) involved patients with different clinical conditions; 4 articles recruited caregivers, and the other 2 included both categories. Most studies did not report the specific pathological conditions of the sample, including "AT users." Among the reported clinical conditions, most studies involved patients with SCI ($n=8$), followed by neuromuscular or musculoskeletal disorders and diseases of the nervous system and sense organs (eg,

amyotrophic lateral sclerosis, dementia, stroke, multiple sclerosis, low vision, and autosomal recessive spastic ataxia).

Administration Time and Modality of the Instruments

Most instruments were self-report questionnaires completed by the participants involved in the study. Only 8 studies reported objective outcome measure instruments administered by clinicians. Of these, 4 (50%) also reported self-reported measures. With regard to administration time, only 6 studies reported this information.

Discussion

Overview

This review was designed to provide an overview of AT outcome measures to try to answer a wide research question: "What AT outcome measures are currently available and used for evaluating individual AT interventions?" It is well known that >1 billion people globally need ≥ 1 AT, a number that is expected to double by 2050 [1]. Measuring outcomes is necessary to understand the benefits of AT and create evidence-based policies and systems to improve universal access to it [1]. This review aims to provide a critical synthesis of the available and used instruments for AT outcome assessment.

The 50 reviewed articles have shown a wide increase (almost tripled compared with the previous decade) of the studies on outcome measure assessment in the last 10 years. This sudden increase in studies in this area could depend on the numerous initiatives carried out by the WHO and the Global Alliance of Assistive Technology Organizations [1,8].

To date, 53 instruments have been used to assess the outcomes of AT interventions. Despite the many reviewed tools, only 17 scales (approximately 30%) were designed to evaluate specifically the ADs, such as QUEST 2.0, ATD-PA, WhOM, WSQ, ATOM, WheelCon-P, PIADS, IPPA, WST, SCI-FI or AT, FEW, FMA, WST-Q, WUSPI, NOMO 1.0, ATOP-M, and CATOM. Among them, most are specifically designed and developed for manual and powered wheelchairs. It could depend on the fact that mobility APs are the second most used AT category, after glasses, 150 million people in the world need mobility APs, of which 75 million need wheelchairs [1]. The remaining instruments were primarily intended to measure the outcomes of individual intervention programs, which may or may not include APs. Interestingly, 34 instruments were only mentioned once to denote poor uniformity and concordance in the instruments to be used, limiting the possibility of comparing the results of the studies.

Points of Reflection on Available Tools According to AT Outcome Domains

The identified measures addressed 8 AT outcome domains: functional efficacy, satisfaction, psychosocial impact, caregiver burden, quality of life, participation, confidence, and usability. Functional efficacy is the most evaluated intervention outcome being consistent with the primary goal of AT interventions to achieve an enhancement in everyday functioning. Moreover, 26 scales were used to obtain outcome data within this domain, of which 6 (23%) instruments were specifically designed and

developed for evaluating APs. The most commonly used questionnaire is the WST-Q [67]. The type of constructs potentially evaluated with these tools is widely heterogeneous. First, they allow for measuring changes in functional independence in basic (eg, eating and dressing) and instrumental (eg, house cleaning and hobbies) daily living activities [29,37,44]. Moreover, a wide number of tools focus on improvement in ambulation and wheelchair mobility, including changing or maintaining body positions and transfers [23,26]. Finally, changes in the language domain—receptive language skills, reading comprehension, and functional communication (eg, understanding television and radio)—were investigated [36,40].

Despite the importance of functional efficacy, it is well known that the positive impact of APs goes far beyond functional efficacy by positively affecting the well-being, quality of life, participation, and the inclusion of individual users—families [1,2]. In this context, several articles have shown that numerous AT outcome assessment measures allow for evaluating the impact of AT intervention's on psychosocial impact, quality of life, and caregiver burden. The psychosocial impact was investigated using 4 instruments that analyzed subjective perceptions of changes in competence, adaptability, self-esteem, and self-determination. The most commonly used questionnaire is PIADS [47], which is used with a broad spectrum of neurological and traumatic clinical conditions [47,54,55]. The quality of life of APs users has been investigated using 6 different tools that provide information on the status and any changes in physical functioning, energy or vitality, bodily pain, general health, social role functioning, and mental health or emotional well-being. Moreover, the reviewed articles showed that other tools, such as CATOM and ZBI, can be used to evaluate the quality of life of caregivers, focusing on their psychological burden [40]. Evaluating this aspect appears to be a priority as care activities can, directly and indirectly, affect caregivers' health and life [20], and assistive solutions can hopefully lower the caregiver burden.

In addition to quality of life, some studies have focused on participation in society [22]. To this end, 5 instruments were used to investigate the frequency and perceived limitation of participation in several everyday tasks [61], such as visiting friends and family in their homes, participating in active recreation, going to restaurants, and shopping for groceries. The International Classification of Functioning supported the importance of participation as a critical part of psychosocial well-being [100,101]. However, only a few articles (8/50, 16%) have focused on this domain. Further studies should be conducted to elucidate this component.

Despite the need for AT and its potential role in improving patients functioning and quality of life, over the years, several studies have focused on the high rate of abandonment of the received AP owing to the poor performance of the device, which does not meet the environmental needs and does not consider the opinion of the user [6,22]. In this context, evaluating satisfaction with using APs appears to be a priority because giving users a quantifiable voice in APs functioning could lead to better design and provision and increased use [53]. The review showed that 5 tools were available and used, and 56% (28/50)

of the articles focused on the satisfaction domain. Similarly, evaluating the user experience of patients in using APs in terms of technological usability and acceptability appears important. However, only 3 articles and 3 tools (SUS, ATOM, and SUTAQ) have focused on this domain. It is important to keep in mind that data on needs, barriers to access, and users' experience with APs are equally crucial to guide the design of appropriate systems to meet reported needs [1].

Points of Reflection on Available Tools According to AT Category

The review showed that approximately half of the reviewed studies described outcome measures applied to several APs, but in a single category. In contrast, only 2 studies used the same instruments for assessing AT products of multiple AT categories (ie, mobility and domestic activities). Interestingly, these studies involved only the caregivers of AT users. Moreover, the number of studies and tools used for each category of APs was not homogeneous. In detail, the most evaluated category is APs for activities and participation relating to personal mobility and transportation. The 29 used tools allow for assessing all 8 AT outcome domains. It is important because among 1 billion people needing APs, approximately 150 million need mobility aids, of which 75 million need wheelchairs and 35 prostheses or orthoses. In contrast, few tools are used as outcome measures for an intervention involving APs for controlling, carrying, moving, and handling objects and devices [32]. With regard to APs for domestic activities and communication, few studies have been conducted, but the available and used tools have evaluated several domains, such as functional efficacy, satisfaction, psychosocial impact, quality of life, and caregiver burden. Further studies are needed to investigate these domains.

Further Interesting Insights

Another interesting point of reflection is that 74% (39/53) of the studies involved small samples of ≤ 100 patients or caregivers, of which 18% (7/39) involved ≤ 10 patients (with 2 case studies). Most studies (44/50, 88%) involved patients with different clinical conditions; 4 articles recruited caregivers and the other 2 included both categories. Most studies did not report the specific pathological conditions of the sample involving "AT users." Indeed, a global report on AT supported that the sample of those who need AT is widely heterogeneous, including people with communicable and noncommunicable, mental health, neurodegenerative (eg, amyotrophic lateral sclerosis, dementia, stroke, multiple sclerosis, low vision, and autosomal recessive spastic ataxia), or traumatic conditions (eg, SCI) [1].

Finally, an open point is the administration time and modality of the instruments as most instruments are self-report questionnaires filled in by the participants, and the administration time is almost never reported.

Implications for Clinical Practice

To our knowledge, this is the first systematic review to investigate the available outcome measures for evaluating individual AT interventions. Owing to the growing need for standardized methods to track individual AT interventions [9], this work could represent a good guide for promoting the use

of validated AT outcome measures in clinical practice that can be helpful to AT assessment teams in their everyday activities and the improvement of clinical practice.

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Authors' Contributions

FB and CS conceptualized the study and finalized the methodology. FB, LD, and CS did the formal analysis and were involved in data curation. FB and CS prepared the original draft and reviewed and edited the draft. RMC supervised the study. All the authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Graphical representation of the trend in the number of publications on outcome measure assessment over time.

[DOCX File, 25 KB - [rehab_v10i1e51124_app1.docx](#)]

Multimedia Appendix 2

Information (evaluated domain, assistive technology [AT] category, description, and scoring) on available instruments was used to provide an AT outcome measure assessment.

[DOCX File, 48 KB - [rehab_v10i1e51124_app2.docx](#)]

Multimedia Appendix 3

Evaluable domains for each category of assistive technology with the available tools.

[DOCX File, 23 KB - [rehab_v10i1e51124_app3.docx](#)]

Multimedia Appendix 4

PRISMA Checklist.

[PDF File (Adobe PDF File), 66 KB - [rehab_v10i1e51124_app4.pdf](#)]

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Abbreviations

AD: assistive device
AP: assistive product
AT: assistive technology
ATD-PA: Assistive Technology Device Predisposition Assessment
ATOM: Assistive Technology Outcome Measure
ATOP-M: Assistive Technology Outcomes Profile for Mobility
BADLS: Bristol Activity of Daily Living Scale
CATOM: Caregiver Assistive Technology Outcome Measure
CHART: Craig Handicap Assessment and Reporting Technique
COPM: Canadian Occupational Performance Measure
FACS-A: Functional Assessment of Communication Skills for Adults
FEW: Functional Everyday with a Wheelchair
FI: Functional Index
FIM: Functional Independence Measure
FMA: Functional Mobility Assessment
IPPA: Individually Prioritised Problem Assessment
LIFE-H: Assessment of Life Habits
LLDI: Late Life Disability Index
NOMO: Nordic Mobility-Related Participation Outcome Evaluation of Assistive Device Intervention
OTFAC: Occupational Therapy Functional Assessment Compilation
PIADS: Psychosocial Impact of Assistive Devices Scale
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QOLP: Quality-of-Life Profile for People with Physical and Sensory Disabilities
QUEST 2.0: Quebec User Evaluation of Satisfaction with Assistive Technology
SCI: Spinal Cord Injury
SF-36: 36-item Short Form Health Survey
SUS: System Usability Scale
SUTAQ: Service User Technology Questionnaire
WheelCon-P: Wheelchair Use Confidence Scale for power wheelchair users
WHO: World Health Organization
WhOM: Wheelchair Outcome Measure
WHOQOL: World Health Organization Quality of Life
WSQ: Wheelchair Satisfaction Questionnaire
WST: Wheelchair Skills Test
WST-Q: Wheelchair Skills Test Questionnaire
WUSPI: Wheelchair User's Shoulder Pain Index
ZBI: Zarit Burden Interview

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Original Paper

Blended Care in Patients With Knee and Hip Osteoarthritis in Physical Therapy: Delphi Study on Needs and Preconditions

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Abstract

Background: Osteoarthritis is a major public health concern. Despite existing evidence-based treatment options, the health care situation remains unsatisfactory. Digital care options, especially when combined with in-person sessions, seem to be promising.

Objective: The aim of this study was to investigate the needs, preconditions, barriers, and facilitators of blended physical therapy for osteoarthritis.

Methods: This Delphi study consisted of interviews, an online questionnaire, and focus groups. Participants were physical therapists, patients with hip and/or knee osteoarthritis with or without experience in digital care, and stakeholders of the health care system. In the first phase, interviews were conducted with patients and physical therapists. The interview guide was based on the Consolidated Framework For Implementation Research. The interviews focused on experiences with digital and blended care. Furthermore, needs, facilitators, and barriers were discussed. In the second phase, an online questionnaire and focus groups served the process to confirm the needs and collect preconditions. The online questionnaire contained statements drawn by the results of the interviews. Patients and physical therapists were invited to complete the questionnaire and participate in one of the three focus groups including (1) patients; (2) physical therapists; and (3) a patient, a physical therapist, and stakeholders from the health care system. The focus groups were used to determine concordance with the results of the interviews and the online questionnaire.

Results: Nine physical therapists, seven patients, and six stakeholders confirmed that an increase of acceptance of the digital care part by physical therapists and patients is crucial. One of the most frequently mentioned facilitators was conducting regular in-person sessions. Physical therapists and patients concluded that blended physical therapy must be tailored to the patients' needs. Participants of the last focus group stated that the reimbursement of blended physical therapy needs to be clarified.

Conclusions: Most importantly, it is necessary to strengthen the acceptance of patients and physical therapists toward digital care. Overall, for development and usage purposes, it is crucial to take the needs and preconditions into account.

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KEYWORDS

telerehabilitation; osteoarthritis; physical therapy; knee; hip; blended; preconditions; Delphi; focus group; user need

Introduction

Osteoarthritis (OA) is a major public health problem with a high prevalence worldwide, which will further increase in the coming years due to the aging population, rising obesity rate, and people being physically inactive [1]. In particular, the burden of OA on the health care system is expected to grow exponentially [1]. While effective treatment is available, conservative treatment options (especially physical training and education) are still underutilized [2]. Therefore, it is crucial to find effective and efficient treatment strategies to face this challenge.

To facilitate the access to primary care and to reduce health-related costs, digital health care is a promising approach. In particular, when considering the course of the COVID-19 pandemic, the potential of digital health care has been demonstrated, confirming that it is not simply a trend [3]. A general definition of digital health care is the application of information and communication technologies across a broad range of activities performed in health care [4]. Innovations in digital health care enable appropriate and efficient care and offer a range of effective digital health interventions for various somatic problems [5]. Such approaches provide high accessibility at any time and place, may attract people who do not make use of traditional physical therapy services, and are easily scalable [6]. However, the challenge of digital health care is the adherence to the treatment and the missing patient-provider relationship [7]. Linking the advantages of online and offline guidance and treatment yields positive outcomes, since this approach combines the best of two worlds. Integrating in-person and digital health care is referred to as “blended care.” [8]. On the one hand, blended care overcomes the barriers of using solely digital health care, such as low adherence rates to the treatment [7,9,10]. On the other hand, blended care includes the benefit of personal attention of a health

care professional. If the digital health focuses on patient empowerment, blended care potentially increases and facilitates a patient’s self-management and ultimately decreases costs [9,11,12]. In the Netherlands, a blended physical therapy intervention called *e-Exercise* has already proven its potential for people with hip or knee OA [13]. This *e-Exercise* intervention revealed the same effectiveness with less physical therapy sessions compared to traditional physical therapy [13].

However, it is important to note that blended care is not suitable in all cases, potentially because of variations in the preferences and motivation of patients, severity of illness, comorbidities, level of education, and digital and health literacy [14,15]. In addition, blended care has to meet the needs of the physical therapists. Thus, to optimize the usage of blended care approaches in an outpatient setting, it is important to involve both patients and physical therapists as well as other relevant stakeholders to take their needs and preconditions into account [16].

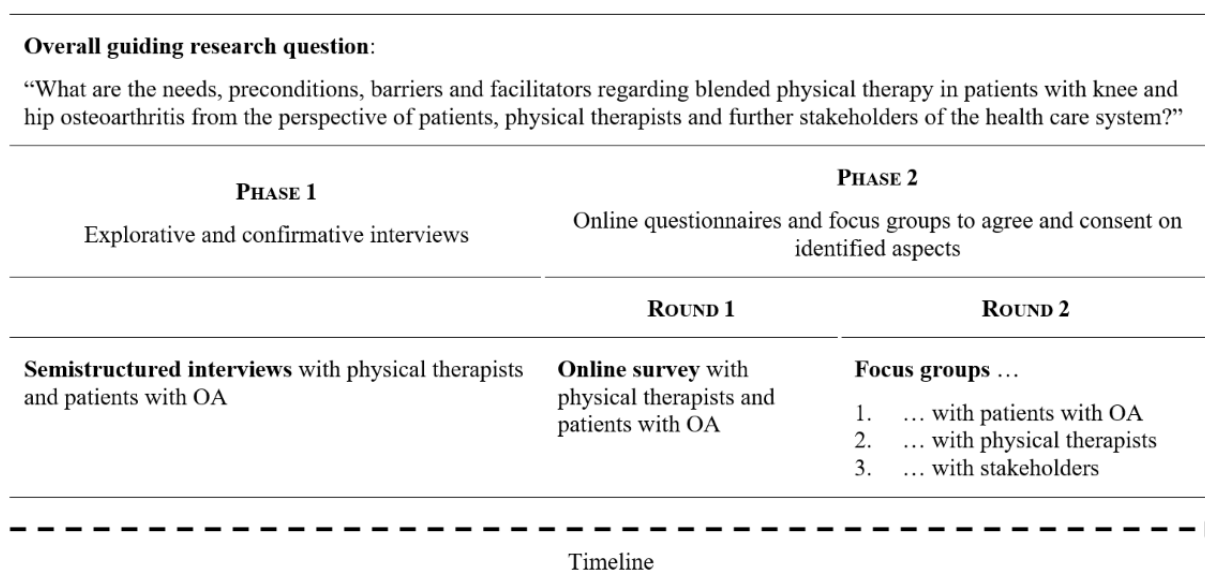
Therefore, the objective of this study was to obtain insight on the needs, preconditions, barriers, and facilitators regarding blended physical therapy in patients with knee and hip OA from the perspective of patients, physical therapists, and other stakeholders of the health care system.

Methods

Design

A Delphi method was used [17] aiming to obtain insight into the needs, preconditions, facilitators, and barriers with respect to the content, sequence, and ratio of blended physical therapy. Established methodological criteria for reporting Delphi studies were followed to ensure quality [18]. The study design is shown in Figure 1.

Figure 1. Study method flow chart. OA: osteoarthritis.



Ethics Considerations

This study was conducted in accordance with the Declaration of Helsinki [19]. The ethics committee of the University of Applied Health Sciences Bochum approved the study (201116_Grüneberg, 04.01.2021). All participants gave written informed consent before data collection began.

Participants

Physical Therapists

We recruited physical therapists using the database of clinical cooperation partners of the University of Applied Health Sciences (Bochum) and through personal networks. To be eligible, physical therapists needed to be registered physical therapists (have a degree in physical therapy) and work in an outpatient physical therapy setting. Furthermore, they needed to have at least 5 years of experience in treating patients with hip or knee OA, give informed consent, be able to understand and speak German, have access to the internet, and own a digital device (eg, tablet, smartphone, or laptop).

Patients

Participating physical therapists were asked to contact eligible patients with OA and sent them an information letter regarding the study. Furthermore, patients were recruited through personal networks (eg, via patient associations). Inclusion criteria for the patients were medically diagnosed idiopathic OA of the knee or the hip and signed informed consent. Further criteria were to be able to understand and speak German, have received at least one prescription for physical therapy regarding their OA-related symptoms, own a digital device (eg, tablet, smartphone, or laptop), and have internet access.

The aim was to recruit both physical therapists and patients who already had experience with digital health care in any context, as well as physical therapists and patients who did not have this experience. Participants were recruited until saturation was reached, which was when no new information would be identified from the last two interviews [20]. Theoretical sampling was used [21].

Stakeholders of the Health Care System

To obtain a broad distribution of participants, we aimed to recruit a member of a patient association, an owner of a physiotherapeutic practice, a physician, a politician in the field of health care, a person of a health insurance company, a representative of a company developing digital devices, and a member of a physical therapy association. We recruited these stakeholders through patient associations, assisted by a German physical therapy association and through personal networks. To be eligible, participants needed to have at least 5 years of professional experience in their field, internet access, own a digital device (eg, tablet, smartphone, or laptop), give signed informed consent, and have sufficient skills in German.

The inclusion and exclusion criteria were screened via telephone before study participation for all participants.

Procedure

The Delphi process consisted of two phases; phase 1 included explorative and confirmative interviews and phase 2 included

an online questionnaire and focus groups to agree and consent on identified aspects, which was separated in two rounds (Figure 1).

Phase 1 was an explorative phase with the aim to capture different perspectives. Both patients and physical therapists filled out questionnaires regarding demographic data (age, gender, educational level, and experience with digital/blended care) and their (digital) health literacy assessed by the European Health Literacy Survey Questionnaire (HLS-EU-Q16) and the eHealth Literacy Scale (eHEALS) [22,23]. Further, they were asked to participate in individual semistructured interviews via telephone. Two slightly different questionnaires were used for patients and physical therapists, respectively. Topics for the interviews were developed on the basis of the Consolidated Framework For Implementation Research (CFIR) (see the interview guides for patients and physical therapists in [Multimedia Appendix 1](#)) [24]. The CFIR consists of the following five domains: (1) characteristics of the individuals involved, (2) innovation characteristics, (3) inner setting, (4) outer setting, and (5) the process of implementation [24]. The process of implementation was not questioned, since there was no specific intervention to implement at that point. Each participant was asked about their experiences with digital health care, and the possible facilitators and barriers they experienced or would expect from digital and blended care in the four domains of the CFIR. In between, a short video [25] was presented during each interview, which showed an example of blended care (combination of in-person physical therapy, video conference, and app) and gave a definition of blended care to create a common understanding. Blended care was defined as an approach in which digital health care is integrated into regular physical therapy.

The aim of phase 2, consisting of two rounds, was to agree and consent on needs, barriers, facilitators, and preconditions for blended care in physical therapy. The same group of physical therapists and patients was invited to fill out an (anonymous) online questionnaire via a secured online platform (SoSci Survey) in round one. Two researchers (AA and FW) translated the results of the interviews in phase 1 into statements; the participants had to agree or to disagree on these statements measured on a 4-point Likert scale from “I completely disagree” (1) to “I completely agree” (4). For instance, if the majority of the participants in the interviews stated that they would like to be taught physical exercises in person, the corresponding statement would be “I prefer the instruction of physical exercises within in-person sessions.” The online questionnaire was quantitatively evaluated and the results were used for round two of this phase. At the beginning of the second round, the results from the questionnaire were briefly presented and the aim of the focus group was explained. The focus groups were conducted via Zoom, version 5.13.5 (12053). Online pin boards (Padlets) were used to present the findings from the online questionnaire and to create a good overview for the participants of the focus groups. The content was structured to individual, innovation, inner setting, and outer setting domains. The focus groups were moderated by one researcher to guide the group through the different topics and come up with specific preconditions for further development and usage of blended

care concepts. Three focus groups (patients, physical therapists, and stakeholders) were conducted to agree and consent on results of the online questionnaire (Figure 1). In addition, the aim was to examine what essential preconditions are necessary to make blended physical therapy feasible in an outpatient practice.

Data Analysis

Phase 1

Two researchers (AA and FW) transcribed verbatim and coded the transcripts of the interviews. Data analysis of the interviews was performed based on the framework approach [26]. Using explorative data analysis for each main topic from the interview scheme, citations were extracted and arranged into themes and subthemes. Subsequently, these themes were discussed between the researchers (AA, FW) until consensus was reached; the complete list of themes and subthemes is presented in Multimedia Appendix 2. Finally, all codes of each theme of every participant were displayed in a table [27]. Next, one researcher (FW) examined the raw data again to ensure the robustness of the analytical process and to confirm that all data were indeed reflected in the coding. Transcription, coding, organization, and analysis were performed using MAXQDA Plus 2020, Windows version 20.3.0.

Phase 2

Data from round one were exported from the secure online platform into an Excel sheet. Demographics, data from the (digital) health literacy questionnaires, as well as data from the online questionnaire were analyzed descriptively with SPSS (IBM SPSS Statistics 25). Results were analyzed by quantifying

scores on each item from the questionnaire and calculating percentages of patients and physical therapists who chose a certain answer on the items.

In round two, focus groups were recorded in writing protocols. Data were categorized into the corresponding themes or subthemes of the interviews according to the CFIR domains. Categorization was discussed between two researchers (CG and FW) until consensus was reached. Data were screened regarding repetitions and each theme and corresponding subthemes were summarized.

Results

Participants

Nine physical therapists and seven patients participated in the interviews and the online questionnaire. Five of the physical therapists and four of the patients took part in the focus groups, respectively, and the third focus group consisted of six stakeholders and one physical therapist of the first phase. For physical therapists of phase 1, saturation was reached after nine interviews. The characteristics of physical therapists are shown in Table 1.

Concerning the patients in phase 1, saturation was achieved after seven interviews. Table 2 displays the characteristics of patients. One physical therapist with experience in digital health joined the other stakeholders in the last focus group. The politician in the field of health care was not able to participate in the focus group.

Table 1. Characteristics of physical therapists (N=9).

Characteristics	Value
Age (years), mean (SD)	33.0 (6.5)
Sex, n (%)	
Male	4 (44)
Female	5 (55)
Clinical experience (years), mean (SD)	9.4 (6.2)
Clinical experience in treating patients with OA ^a (years), mean (SD)	9.4 (6.2)
Level of education, n (%)	
Masters, diploma, state examination (university [of applied sciences]); EQF ^b Level 7	2 (22)
Bachelors (university or university of applied sciences); EQF Level 6	6 (67)
State examination/completion of a vocational training; EQF Level 5	1 (11)
Prior experience in online therapy, n (%)	4 (44)
Working hours/week, mean (SD)	32.0 (12.5)
General health literacy (HLS-EU-Q16^c), n (%)	
Adequate	4 (44)
Problematic	4 (44)
Inadequate	1 (11)
Digital health literacy (G-eHEALS ^d), mean (SD)	32 (7)

^aOA: osteoarthritis.

^bEQF: European Qualifications Framework.

^cHLS-EU-Q16: the European Health Literacy Survey Questionnaire (0=low/no health literacy to 16=high health literacy).

^dG-eHEALS: German eHealth Literacy Scale (0-40; higher score indicates better digital health literacy).

Table 2. Characteristics of patients (N=7).

Characteristics	Value
Age (years), mean (SD)	59.9 (10.8)
Sex, n (%)	
Male	4 (57)
Female	3 (43)
Osteoarthritis, n (%)	
Hip osteoarthritis	3 (43)
Knee osteoarthritis	1 (14)
Both	3 (43)
Time since diagnosis (years), mean (SD)	
Hip osteoarthritis	9.8 (8.3)
Knee osteoarthritis	7.0 (3.8)
Degree of self-reported limitations due to osteoarthritis, n (%)	
Fair	2 (29)
Mild	5 (71)
Duration of physical therapy due to osteoarthritis-related symptoms (years), mean (SD)	3.6 (6.0)
Level of education, n (%)	
High	5 (71)
Low	2 (29)
Prior experience in online therapy, n (%)	3 (43)
Adequate general health literacy (HLS-EU-Q16 ^a), n (%)	7 (100)
Digital health literacy (G-eHEALS ^b), mean (SD)	32.6 (4.4)

^aHLS-EU-Q16: European Health Literacy Survey Questionnaire (0=low/no health literacy to 16=high health literacy).

^bG-eHEALS: German eHealth Literacy Scale (0-40; higher score indicates better digital health literacy).

Textbox 1 summarizes the needs and preconditions of the patients, physical therapists, and the stakeholders regarding blended care, which are the final results of the two phases. The

data of the two phases were combined and structured according to the domains of the CFIR.

Textbox 1. Consensus of the needs and preconditions regarding blended physical therapy from the perspective of patients with osteoarthritis, physical therapists, and stakeholders.

Personal factors (individual)

- Change of the role of physical therapists and gaining new competences
(Necessity of changing the role of physical therapists, patient and physical therapist being equal partners, new competences are necessary)
- Attitudes and acceptance (changing attitudes and increasing the acceptance for digital health)
(Necessity to change attitudes toward and acceptance for digital health)

Intervention-related factors (innovation)

- Digital content and feature
(Educational components, information exchange, and exercise program as digital content; important to include motivational strategies in the app such as reminders)
- Usability and operability
(Easy and intuitive app, necessity of user-friendliness, patient-friendly language, flexibility in decision-making, wide accessibility of the app, feedback through data)
- Blended care concept (individualization, ratio, and allocation)
(Individualization is necessary, integration of evidence-based information, regular in-person sessions, 60:40 ratio of online and in-person sessions, flexibility of online or in-person mode)

Organizational factors (inner setting)

- Practice setting (eg, working conditions, personnel structures, hardware)
(Change of rooms, necessity of hardware, WLAN, software, positive influence on the working conditions, change of personnel structures, change of time schedules, necessity of interoperability of different programs)
- Change of (interprofessional) cooperation/communication
(Facilitation of interprofessional communication by online environment)

System-related factors (outer setting)

- Necessity to change efficiency (eg, time and costs)
(Time to prepare, efficiency of time, increase in costs, who will pay?)
- Necessity of clear structural conditions (eg, rules regarding data protection and security)
(Clear description of concept is necessary, prescription or integration in disease management program is necessary; legal basis; necessity of clear rules and legal aspects regarding data protection; data protection guidelines; implementation of advanced training/ skills)
- Clear rules and roles before an implementation
(Development process of digital devices; responsibility for implementation process [stakeholders])

Personal Factors (Individual)

Change of the Role of Physical Therapists and Gaining New Competences

A changing role of physical therapists was a central precondition for blended care, which received consensus of physical therapists and stakeholders. Different facets of changes have been mentioned; however, the main adjustment was seen in the patient-provider relationship. According to physical therapists, both should be on an equal level with the physical therapist being in a guiding role. There was a full consensus of the physical therapists that blended care has an essential impact to facilitate a patient's self-management and individual responsibility.

Patients also considered a healthy relationship with and trust in the physical therapist as a crucial precondition for blended care.

In contrast to the perspective of physical therapists, passive interventions (and therefore in-person contact) were still one of the most important aspects of physical therapy for patients. Patients were afraid of having less in-person sessions in favor of more digital sessions.

Patients and physical therapists considered adequate communication skills of both groups and a moderate level of health literacy of patients as necessary. From the perspective of physical therapists, a core competence within blended care was the need to be familiar with the technology used. All physical therapists and stakeholders concluded that decision-making is a further competence required if the approach is to be useful and feasible for every patient. As a precondition for using digital health in physical therapy, they mentioned an adequate training of new competences for the physical therapists and gaining positive experiences with digital care for both patients and physical therapists.

Attitudes and Acceptance

All participants mentioned the COVID-19 pandemic as a facilitator for blended care, especially increasing the acceptance of digital care. Most of the physical therapists were open regarding digital care. Patients needed and wanted to learn how to handle digital tools in advance. The acceptance of blended care of patients varied; however, in general, they recognized the convenience to exercise anytime and place and incorporating the therapy into their daily lives. Further preconditions to

increase the acceptance of patients were the confidence in the physical therapist and sufficient time to learn and practice.

Intervention-Related Factors (Innovation)

Digital Content and Features

The vast majority of all participants considered educational components, information exchange, and an exercise program as content that can be carried out digitally. The results of the online questionnaire regarding the preferred mode of delivery are shown in [Table 3](#).

Table 3. Preferred mode of the therapy component (online, in-person, or online and/or in-person) from the perspective of physical therapists and patients (N=16).

Therapy components	Patients (n=6)	Physical therapists (n=9)
First therapy session/getting to know	In-person (n=6)	In-person (n=5)
Information/education session	In-person (n=5)	Online and/or in-person (n=5)
Consultation	Online and/or in-person (n=4)	Online and/or in-person (n=7)
Screening process/diagnostic process	In-person (n=4)	Face-to-face (n=6)
Instruction of exercises	In-person (n=4)	Online and/or in-person (n=5)
Functional integration of movement into activities of daily living	In-person (n=4)	Online and/or in-person (n=8)
Evaluation/last therapy session	In-person (n=6)	Online and/or in-person (n=9)

All physical therapists agreed on the importance to integrate motivational strategies in the technology, such as with activity trackers and reminders ([Table 4](#)).

Physical therapists perceived the digital program within blended care as a guiding tool, whereas patients saw digital components only as a supplement to regular in-person sessions. The results of the online questionnaire including specific software features and content are presented in [Table 4](#).

Table 4. Preferred content and features of the digital program within a blended physical therapy approach from the patients' and physical therapists' perspectives.

Content and features	Patients (n=7), n (%)	Physical therapists (n=9), n (%)
Content of the digital program		
Exercise/training plans that include PA ^a and exercises	7 (100)	9 (100)
Therapy/treatment plans that include goal-appropriate exercises and treatment	7 (100)	9 (100)
Examination/warning of red flags regarding the treatment of patients with OA ^b	6 (86)	9 (100)
Test/MI ^c instructions performed by the patient on their own or by the physical therapist with the patient (eg, 6MWT ^d , TUG ^e)	4 (57)	7 (78)
Communication/exchange with physicians or other professions	4 (57)	5 (56)
Information on relevant topics for patients with OA	3 (43)	9 (100)
Patient-reported outcome measures (eg, KOOS ^f , HOOS ^g)	3 (43)	8 (89)
Features of the digital program		
Chat for communication between physical therapists and patients	6 (86)	7 (78)
Documentation system for the physical therapist	5 (71)	7 (78)
Agenda with future physical therapy appointments	5 (71)	3 (33)
Video chat	4 (57)	9 (100)
Diary of patients to collect PA and exercises	4 (57)	8 (89)
Collecting/capturing of data of the course of therapy of the patient	4 (57)	7 (78)
Reminder messages of appointments	3 (43)	9 (100)
Reminder messages of PA	2 (29)	8 (89)

^aPA: physical activity.

^bOA: osteoarthritis.

^cMI: measurement instrument.

^d6MWT: 6-minute walking test.

^eTUG: timed "up & go" test.

^fKOOS: Knee Injury and Osteoarthritis Outcome Score.

^gHOOS: Hip Disability and Osteoarthritis Outcome Score.

Usability and Operability

Patients and physical therapists had the same opinion regarding the importance of technology being user-friendly. From their perspective, digital tools should be easy and intuitive to use.

Blended Care Concept

All participants agreed that blended care must be tailored to the patients' individual needs. Participants considered in the online questionnaire an average ratio of 60/40 digital/in-person sessions as optimal (Table 5). Physical therapists and patients considered that a first in-person session is crucial, and that the longer the treatment process, the less in-person sessions are necessary.

Stakeholders stated that the needs of the patient, access to devices, state of condition and confidence in physical therapy, motivation of the patient, as well as a high level of patients' self-management are factors that influence the decision on the most appropriate therapy mode.

An academic education and several years of professional experience as a physical therapist were mentioned as preconditions, since this supports the decision on the therapy mode from the perspective of the stakeholders.

The stakeholders emphasized the value of "taking the physical therapist home," which would increase the sustainability of therapy in their point of view.

Table 5. Preferred ratio of online and in-person therapy of patients with osteoarthritis.

Online/in-person ratio	Patients (n=7)	Physical therapists (n=9)
0%/100%	1	0
10%/90%	0	0
20%/80%	1	0
30%/70%	1	0
40%/60%	1	0
50%/50%	1	2
60%/40%	1	3
70%/30%	1	4
80%/20%	0	0
90%/10%	0	0
100%/0%	0	0

Organizational Factors (Inner Setting)

Practice Setting

Patients and physical therapists considered a separate room only for digital care (eg, video conference) as necessary to be undisturbed, maintain privacy of the patient, and having all equipment ready to use.

Physical therapists considered a change of practice structures as necessary. Proper time planning is important (eg, to prepare digital sessions). The stated preconditions regarding a practice setting for the usage of blended care are summarized in Table S1 of [Multimedia Appendix 3](#).

A precondition for blended care was that every user has access to digital devices and a stable internet connection. Physical therapists preferred tablets or laptops as hardware. Patients considered missing equipment and technical requirements as a barrier for blended care. They preferred a large screen on their digital devices. The stakeholders stated the importance of the interoperability of different systems, especially with already existing systems.

Change of (Interprofessional) Cooperation/Communication

The interviewed physical therapists expected a facilitation and simplification of the interprofessional communication and cooperation within blended care. For instance, data should be collected and stored in a more structured way and the treating physician would have the option to access the status or progress of the patient; in that way, the communication between the physical therapist and physician will be based on results and data. Further, the transfer of a patient to another physical therapist can be easily achieved.

System-Related Factors (Outer Setting)

Necessity to Change Efficiency

Stakeholders concluded that time is an advantage but also a disadvantage. For instance, blended care could save time when filling out questionnaires in advance; however, there is more time needed for preparation. All participants were in accordance

that the financial reimbursement for blended care needed to be clarified (eg, time for preparation and for the digital care part, costs for licenses and systems). Stakeholders determined that health insurance companies needed to cover the costs for in-person and digital care. Therefore, the single blended care intervention needed to be specified and described well.

Necessity of Clear Structural Conditions

Structural preconditions mentioned included legal requirements, proof of effectiveness, data protection, and security. Stakeholders suggested certifications for each type of technology, which meet data protection guidelines. Additionally, physical therapists suggested educating patients regarding data protection and security.

An (advanced) training for physical therapists should particularly focus on digital communication, data protection issues, and evidence-based digital care. Patients should particularly be educated regarding the handling of technology.

Clear Rules and Roles Before Implementation

Stakeholders concluded that important steps before an implementation of blended care are its communication and promotion, dealing with resistance, training of physical therapists as specialists, and well-prepared introduction of technologies.

Structural facilitators were seen in the COVID-19 pandemic and if patients were provided with digital devices. The competitive market, missing transparency, privacy issues, and different understandings of blended care were considered as structural barriers. All facilitators and barriers regarding blended physical therapy are listed in Figure S1 of [Multimedia Appendix 3](#).

Discussion

This study investigated different perspectives of patients, physical therapists, and stakeholders on blended physical therapy of patients with OA.

Overall, patients and physical therapists are skeptical about blended physical therapy, which can be seen in the results of

both groups. For instance, there was low patient acceptance of the digital care part; patients and physical therapists expressed the importance of in-person care and the integration of in-person treatment at the beginning and the end of each therapy session. They were afraid that the digital care part could replace the in-person sessions with their therapist, which are crucial for them. Thus, blended physical therapy is currently unknown for both patients and physical therapists. Since it will fit into future care models, it is still crucial to acquaint patients and physical therapists with blended physical therapy. Therefore, it is important to listen carefully to the preconditions, facilitators, and barriers raised by both the patients and physical therapists.

The most commonly stated facilitators of blended physical therapy according to all participants were the individualization of blended physical therapy, the user-friendliness of the technology, the COVID-19 pandemic, access to digital devices, and a stable internet connection. Barriers of blended physical therapy included technical skills of patients and physical therapists, costs, as well as society's lack of knowledge and information regarding blended physical therapy interventions.

One major finding was that the acceptance of the digital care part within blended physical therapy is still quite low in patients, whereas physical therapists are more open to using this technology. Interestingly, the Dutch *e-Exercise* project revealed a reverse trend in this regard, in which patients were more enthusiastic and physical therapists more critical [9]. This is quite remarkable, since it is most likely due to the fact that the patients had experiences with a specific blended intervention, which clearly influenced their opinion and attitude toward blended physical therapy. Therefore, it seems crucial to gain positive experiences with blended physical therapy [28]. In contrast, physical therapists had mixed experiences with *e-Exercise*, since the workload increased and it was more time-consuming, especially at the beginning [29]. Patients, who did not have any experience with digital care, were more skeptical and expected more barriers to its use. A further personal precondition that was raised was the learning of new competences. Patients, as well as physical therapists, seem to be open and willing to learn new competences, which can possibly increase the acceptance and change their attitudes regarding blended physical therapy [30,31]. This has also been mentioned in previous studies as a key facilitator for the uptake and acceptance of digital care [30,31].

An intervention-related precondition is to have a first and last in-person physical therapy session. This aspect was crucial for physical therapists, since they have difficulties imagining performing a thorough first assessment or evaluation digitally [28,32].

A further intervention-related precondition is the individualization of care. A key finding was that there is no "one-size-fits-all" solution, but rather there is a necessity to tailor blended physical therapy to the specific needs of each patient. This is mentioned as a main advantage of blended physical therapy, since it is beyond the borders of traditional care to provide, for instance, immediate and automated feedback specifically tailored to the patient [11,28,30]. While they still have the opportunity to see their patient in person, they will

also have more time for other interactions such as in-depth conversations and personal attention. In general, physical therapists need to have the possibility to act flexibly and to have the competence to decide whether or not a patient is suitable for blended care. The Dutch *Blended Physiotherapy Checklist* already supports and guides physical therapists in their clinical reasoning process while setting up a personalized blended physical therapy intervention [14].

Important preconditions regarding organizational factors are the interoperability of different types of software. In particular, the physical therapists need to use different systems (eg, administration, training programs), which is a deterrent to use without data transfer between the systems [33]. Therefore, information technology companies have the responsibility to develop interfaces between systems to enable interoperability. A change of facilities is also necessary to create sufficient privacy and a safe space for the physical therapist and the patient (eg, while having a video conference) [28,34].

The main system-related precondition is the reimbursement of blended physical therapy, which is also an issue in different countries [15,34-36]. Even though the COVID-19 pandemic enabled reimbursement of telehealth services, there is still no permanent solution [35]. Since there is still a lack of a payment solution, it is recommended to conduct pilot studies to investigate the usability and effectiveness of specific blended physical therapy approaches keeping the mentioned preconditions, facilitators, and barriers identified in this study in mind. Furthermore, it is important to obtain a clear picture of data protection and safety issues. Stakeholders consented to have certificates for software, which help to obtain an overview as a user and rates technologies regarding their value, which is already in place in some countries [15,34]. Independent, public institutions might generate these guidelines, certificates, and overviews for users. A further important system-related precondition raised was the development of an advanced training program for digital competences, which can be integrated in the curriculum of undergraduate and postgraduate physical therapist training programs. Therefore, it is necessary to create a framework of digital competences [37].

An important strength of this study is the investigation of blended physical therapy and not solely digital care. Simultaneously, it is challenging to investigate these two concepts separately, since they are very connected and participants had difficulties in distinguishing between them. Therefore, parts of the results relate to digital care in general and not solely to blended physical therapy. A further strength is the inclusion of both the patient and the physical therapist perspectives, which is complemented by a final discussion of stakeholders. Additionally, the recruitment of two different groups of patients and physical therapists (with and without experience in digital health) contributed to a holistic picture. Limitations of our study are that our findings cannot be generalized to every type of blended physical therapy, since they may differ. In particular, showing the video with an example of blended care to the participants affected the results. It could be possible that needs, barriers, facilitators, and preconditions would vary if a completely different blended care concept would be introduced. Furthermore, two researchers

held the interviews, which might have influenced the flow of the interviews in different ways. To prevent this, a topic guide was used, which supported covering the main topics.

Although both patients and physical therapists were not too enthusiastic about blended physical therapy, consensus on the needs and preconditions of blended physical therapy serves as

a principal foundation for relevant caregivers, stakeholders, and researchers. Needs, preconditions, facilitators, and barriers have been indicated in four domains. The findings underline the importance of developing blended physical therapy interventions with a whole group of different stakeholders, which is crucial to facilitate the use and implementation of blended physical therapy at a later stage.

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Data Availability

Data are available on reasonable request. Data are in the form of digital voice recording of interviews, which were also transcribed verbatim into Word files. Data of the online questionnaire and demographics are available as Excel files. Data of the focus groups are available in form of written protocols as Word files. These data are stored in a password-secured research drive, which is only accessible to author FW. Voice recordings contain identifiable data, which will not be available on request to maintain anonymity of the participants. The other files with deidentified participant data may be made available on reasonable request.

Authors' Contributions

Concept/idea/research design: FW, CK, CG, CV; Writing: FW, CK, AA, CG, CV; Data collection: FW, AA; Data analysis: FW, AA, CG; Project management: FW, CG; Providing facilities/equipment: CG; Providing institutional liaisons: CG; Consultation (including review of manuscript before submitting): FW, CK, AA, CG, CV.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Semistructured interview guides for the interviews with (1) patients and (2) physical therapists.

[\[PDF File \(Adobe PDF File\), 649 KB - rehab_v10i1e43813_app1.pdf\]](#)

Multimedia Appendix 2

List of themes and subthemes of the data analysis of the interviews.

[\[PDF File \(Adobe PDF File\), 391 KB - rehab_v10i1e43813_app2.pdf\]](#)

Multimedia Appendix 3

Table S1 and Figure S1.

[\[PDF File \(Adobe PDF File\), 507 KB - rehab_v10i1e43813_app3.pdf\]](#)

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Abbreviations

CFIR: Consolidated Framework For Implementation Research
eHEALS: eHealth Literacy Scale
HLS-EU-Q16: European Health Literacy Survey Questionnaire
OA: osteoarthritis

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Original Paper

Movement Component Analysis of Reaching Strategies in Individuals With Stroke: Preliminary Study

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Abstract

Background: Upper limb motor paresis is a major symptom of stroke, which limits activities of daily living and compromises the quality of life. Kinematic analysis offers an in-depth and objective means to evaluate poststroke upper limb paresis, with anticipation for its effective application in clinical settings.

Objective: This study aims to compare the movement strategies of patients with hemiparesis due to stroke and healthy individuals in forward reach and hand-to-mouth reach, using a simple methodology designed to quantify the contribution of various movement components to the reaching action.

Methods: A 3D motion analysis was conducted, using a simplified marker set (placed at the mandible, the seventh cervical vertebra, acromion, lateral epicondyle of the humerus, metacarpophalangeal [MP] joint of the index finger, and greater trochanter of the femur). For the forward reach task, we measured the distance the index finger's MP joint traveled from its starting position to the forward target location on the anterior-posterior axis. For the hand-to-mouth reach task, the shortening of the vertical distance between the index finger MP joint and the position of the chin at the start of the measurement was measured. For both measurements, the contributions of relevant upper limb and trunk movements were calculated.

Results: A total of 20 healthy individuals and 10 patients with stroke participated in this study. In the forward reach task, the contribution of shoulder or elbow flexion was significantly smaller in participants with stroke than in healthy participants (mean 52.5%, SD 24.5% vs mean 85.2%, SD 4.5%; $P < .001$), whereas the contribution of trunk flexion was significantly larger in stroke participants than in healthy participants (mean 34.0%, SD 28.5% vs mean 3.0%, SD 2.8%; $P < .001$). In the hand-to-mouth reach task, the contribution of shoulder or elbow flexion was significantly smaller in participants with stroke than in healthy participants (mean 71.8%, SD 23.7% vs mean 90.7%, SD 11.8%; $P = .009$), whereas shoulder girdle elevation and shoulder abduction were significantly larger in participants with stroke than in healthy participants (mean 10.5%, SD 5.7% vs mean 6.5%, SD 3.0%; $P = .02$ and mean 16.5%, SD 18.7% vs mean 3.0%, SD 10.4%; $P = .02$, respectively).

Conclusions: Compared with healthy participants, participants with stroke achieved a significantly greater distance via trunk flexion in the forward reach task and shoulder abduction and shoulder girdle elevation in the hand-to-mouth reach task, both of these differences are regarded as compensatory movements. Understanding the characteristics of individual motor strategies, such as dependence on compensatory movements, may contribute to tailored goal setting in stroke rehabilitation.

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KEYWORDS

stroke; upper limb paresis; compensatory movements; three-dimensional motion analysis; reaching movement; rehabilitation; motion analysis; reaching; 3D; three dimensional; motion capture; motion; movement; limb; extremity; extremities; mobility; hemiparesis; paralysis; compensate; compensatory

Introduction

Upper limb motor paresis due to a stroke may impose limitations on patients' activities of daily living and quality of life [1-3]; the improvement of these conditions is an important goal of stroke rehabilitation. Therefore, periodic, accurate assessment of upper limb movement function during the course of treatment is fundamental to ensure effective upper limb retraining.

In rehabilitation settings, upper limb function is commonly assessed using several clinical measures, such as the Fugl-Meyer Assessment (FMA) scale, which assesses basic motor function [4], and the Action Research Arm Test, which assesses the basic functional capacity of the upper limb [5]. Previous studies have demonstrated the reliability and validity of these scales [6-8] and their clinical utility. However, clinical scales are based on clinician observation; thus, the risk of bias cannot be completely eliminated. In fact, the previously reported minimum detectable changes for these scales are large. Lin et al [9] reported that, according to interrater reliability, the minimum detectable changes of the FMA and Action Research Arm Test are 12.9 (20% of the total score) and 13.1 (23% of the total score), respectively. Such findings indicate that these clinical scales may have limited sensitivity to slight differences. In addition, these scales are used by summing the scores on the performance of various movements; therefore, they cannot be used to analyze a single movement in detail.

To address these issues, several studies have developed objective methods using measurement devices [10,11]. These efforts include movement tests with 3D motion analysis and robotic measurements, which have shown that various aspects of human upper limb motion can be quantified using these technologies [12-15]. Central to these analyses is the study of hand movements, as the hand serves as the primary end effector of the upper limb. What individuals can achieve with their upper limbs is determined by these hand displacements and their manipulation abilities.

Moreover, a better comprehension of altered body mechanics serves to guide clinical reasoning, develop evidence-based interventions, and monitor patients' progress through follow-up [16]. In this regard, quantifying the underlying joint movement mechanisms that contribute to these upper limb movement patterns is essential for achieving better rehabilitation outcomes. Previous studies have shed light on the advantages and practicality of kinematic analysis for different reaching actions and real-world activities of daily living movements [17-22].

One of the major concerns in such kinematic analysis is the evaluation of compensatory joint movements. These movements serve as strategies to counteract the limitations posed by paresis to enhance the patient's functional abilities. For those with severe paresis, reaching movements might be challenging. In such cases, interventions aim to boost compensatory actions, such as trunk flexion and shoulder abduction, to aid the

movement [23,24]. However, these compensatory maneuvers usually consume more energy, making them less optimal than natural movements [25]. Conversely, in milder paresis, the intervention focuses on minimizing such compensatory motions to enhance movement efficiency [26,27]. In essence, although compensatory motions are essential when paresis is present, they should not be excessively relied upon when possible. Kinematic analysis offers a method to precisely quantify these movements. Clinically relevant activities, such as reaching and drinking movements, have been a focal point for kinematic studies. For example, Alt Murphy et al [17] highlighted the primary kinematic characteristics in patients with stroke during reaching and drinking movements. These features encompass compensatory actions, such as trunk tilt and shoulder abduction, as well as parameters, such as movement velocity and smoothness [17]. Aprile et al [28] reported the contribution of compensatory head motions while bringing a glass to one's mouth. Since compensatory movements play a role in actions, such as reaching and drinking, it is crucial to assess their actual contribution. Quantifying this allows us to gain a deeper understanding of the functional movement challenges in patients with motor impairments, potentially streamlining the rehabilitation process by addressing core issues.

Drawing from these insights, we have devised a new analytical method to assess the impact of various movement components, including compensatory movements, on reaching actions. This approach quantifies and visualizes the contribution of each component during the reaching process. In designing our study, we prioritized clinical relevance, using a simplified methodology with a limited set of markers. Our goal in this study was to use this method to contrast the reaching strategies of patients with stroke against those of healthy individuals. We hypothesized that patients with stroke would exhibit a greater dependence on compensatory movements in reaching tasks compared to healthy individuals.

Methods

Participants

The participants were patients with hemiparesis due to stroke who underwent rehabilitation at Fujita Health University Hospital. The inclusion criteria were as follows: (1) existence of hemiparesis due to stroke with upper limb motor dysfunction, (2) ability to understand movement instructions, and (3) ability to maintain a sitting position for at least 30 minutes. The exclusion criterion was a history of neuromuscular or musculoskeletal diseases that could interfere with reaching movements of the upper limb.

In this study, healthy adults were included as the control group. Those with a history of neuromuscular or musculoskeletal diseases that might interfere with upper extremity reaching movements were excluded.

Ethical Considerations

This study was approved by the institutional review board of Fujita Health University (HM21-006). Informed consent was obtained from all participants.

Data Collection

A total of 2 upper limb reaching movements were measured in participants with stroke and healthy participants. While the 2 upper limb reaching movements in all healthy participants were measured using their dominant right hand, it was measured in patients with stroke using their affected side, irrespective of whether it was the dominant or nondominant side.

A 3D motion analysis was conducted using KinemaTracer (Kissei Comtec Corporation), which comprises a computer that records and analyzes data and 6 charge-coupled device cameras

installed around the participant (Figure 1). Measurements were made at a sampling frequency of 60 Hz. The 6 cameras were calibrated using control objects to minimize errors. The size of the control object was 120×60×50 cm. The average absolute error of the device was 1.5-2.4 mm on the left-right axis, 0.5-1.7 mm on the front-back axis, and 1.6-1.7 mm on the vertical axis, and is often used for motion analysis of the upper and lower limbs of participants with hemiplegia [29-31]. To develop a clinically feasible method to quantify the compensatory strategy, a simplified marker set was used. Colored markers with a diameter of 30 mm were affixed to the participants at 10 locations, namely, the mandible, the spinous process of the seventh cervical vertebra, the acromion, the lateral epicondyle of the humerus, the metacarpophalangeal (MP) joint of the index finger, and the greater trochanter (Figure 2).

Figure 1. The setting of the 3D motion analysis system. The setup involves a computer responsible for data recording and analysis and 6 charge-coupled device cameras positioned around the participant.

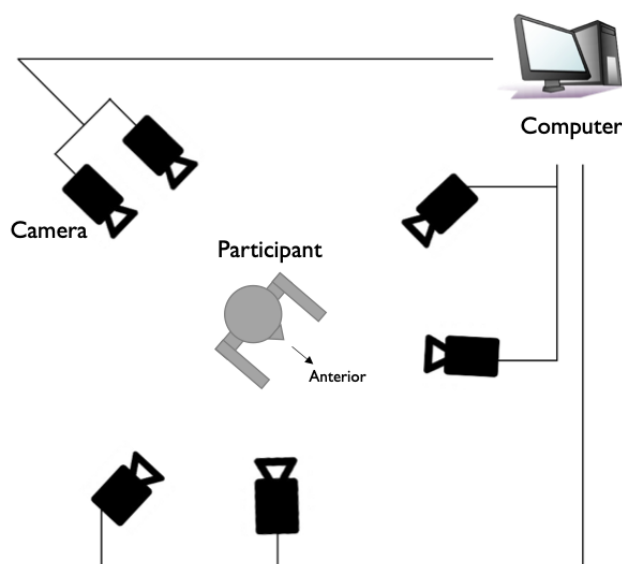
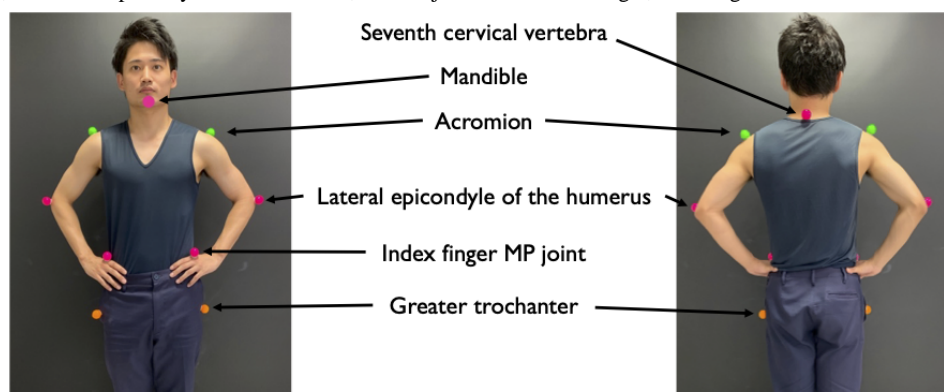


Figure 2. Marker locations. The markers were positioned at the following anatomical points: the mandible, the seventh cervical vertebra's spinous process, the acromion, the lateral epicondyle of the humerus, the MP joint of the index finger, and the greater trochanter. MP: metacarpophalangeal.



During the measurements, the participants sat on a chair. During both the forward reaching and the hand-to-mouth reaching sessions, the participant's hand was placed on a starting table set at a level of elbow and a distance of one-third of the upper limb length from the acromion in the upright trunk position. In both sessions, participants were instructed to carry an object that was 5.0 cm in diameter, 8.0 cm in length, and 50 g in weight

at a comfortable speed. In the forward reaching session, participants were instructed to perform a reaching motion from the starting position to a platform placed at the maximum reaching position with the arm fully extended in an upright trunk position. In the hand-to-mouth reaching session, participants were instructed to bring their hands to their mouths from the

starting position. All table heights were aligned with the forearm at 0° shoulder flexion and 90° elbow flexion.

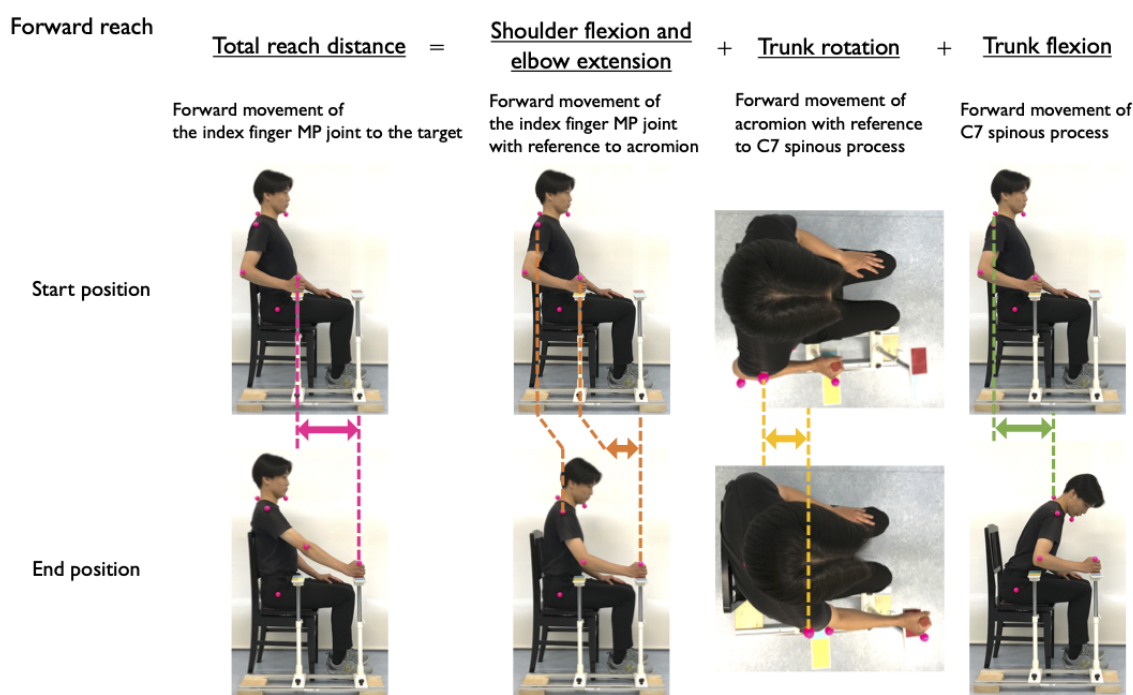
In addition, we collected clinical findings: age, sex, and upper extremity length. Patients with stroke collected disease, postonset period, paralytic side, FMA total score of the upper extremity, and total score of shoulder, elbow, and forearm excluding reflexes.

Data Analysis

The measured kinematic variables contained the 3D displacements (X-, Y-, and Z-axes) of the 10 markers. The X-, Y-, and Z-axes represent the lateral, forward or backward, and vertical directions, respectively.

For the forward reach task, the forward distance traveled by the finger MP joint from the starting position to the forward target location on the Y-axis was measured. Subsequently, the contributions of (1) shoulder flexion and elbow extension, (2) trunk rotation, and (3) trunk flexion toward the forward direction were calculated. The contribution of each movement was calculated as the forward movement of (1) the index finger MP joint with reference to the acromion, (2) the acromion with reference to the spinous process of the seventh cervical vertebra, and (3) the spinous process of the seventh cervical vertebra (Figure 3).

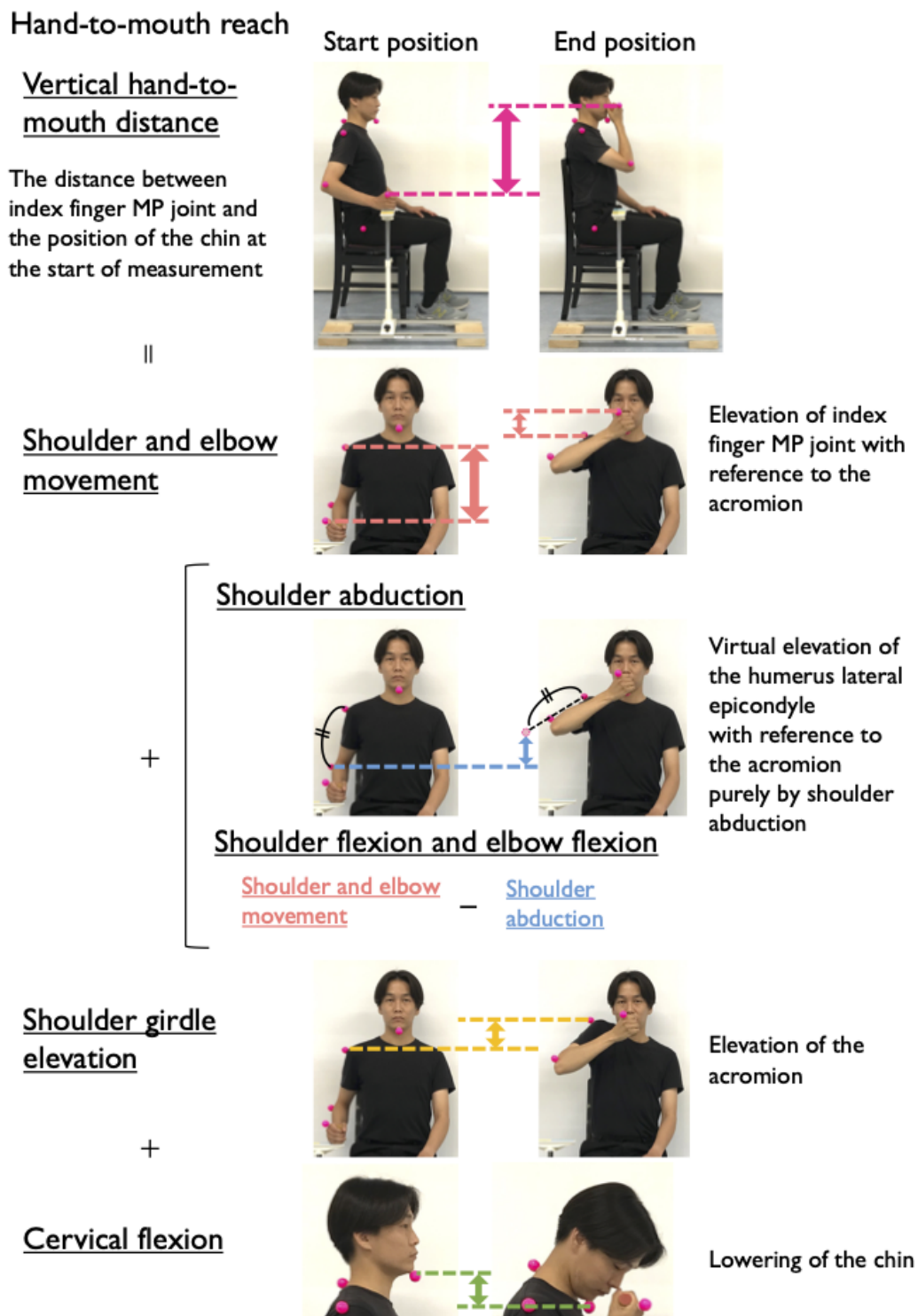
Figure 3. Components of the forward reach: shoulder flexion or elbow extension, trunk rotation, and trunk flexion. The distance in the forward-backward direction of each movement was calculated. MP: metacarpophalangeal.



For the hand-to-mouth reach task, the shortening of the vertical distance between the index finger MP joint and the position of the chin at the start of the measurement was measured. The contributions of (4) shoulder flexion and elbow flexion, (5) shoulder abduction, (6) shoulder girdle elevation, and (7) cervical flexion were calculated. The contributions of movements (4) and (5) were calculated in the following order: the sum of movements (4) and (5) (elevation of the hand through shoulder and elbow flexion) was calculated by the vertical displacement of the index MP joint with reference to the acromion, and movement (5) was calculated as the vertical

elevation of the humeral epicondyle through shoulder abduction assuming the humeral epicondyle-acromion length did not change during abduction. The contributions of movements (6) and (7) were calculated as the vertical elevation of the acromion and the vertical drop of the chin, respectively (Figure 4). The displacement of each marker between the start and end positions in forward and hand-to-mouth reach tasks was calibrated by the position of the greater trochanter. The contribution of all components was calculated as a percentage of the total reach distance, which was determined by the arm length as mentioned above.

Figure 4. Components of hand-to-mouth reach: shoulder flexion or elbow flexion, shoulder abduction, shoulder girdle elevation, and cervical flexion. The distance in the vertical direction of each movement was calculated. MP: metacarpophalangeal.



Statistical Analysis

We performed a Student *t* test to compare each measure between participants with hemiplegia due to stroke and healthy controls to determine the characteristic movements of goal achievement in upper limb reaching movements for participants with hemiplegia due to stroke. All statistical analyses were performed

using Statistical Package for Social Science (SPSS, version 28.0.1.0; IBM Corp), and the significance level was set at $P < .05$.

Results

A total of 20 healthy individuals and 10 patients with stroke participated in this study. The demographic characteristics of the participants are presented in Table 1. The average age of

healthy participants was 26.5 (SD 4.9) years, whereas that of participants with stroke was 70.7 (SD 13.8) years. Among the participants with stroke, 4 had intracerebral hemorrhage, and 6 had cerebral infarction. The average total score of the FMA was 52.1 (SD 10.7), and the subtotal of the components of the

shoulder, elbow, and forearm, excluding reflex scores, was 23.9 (SD 5.3). All patients with stroke had left hemiparesis and thus were measured using their nondominant left hand, while all healthy individuals were measured using their dominant right hand.

Table 1. Demographic data of the participants.

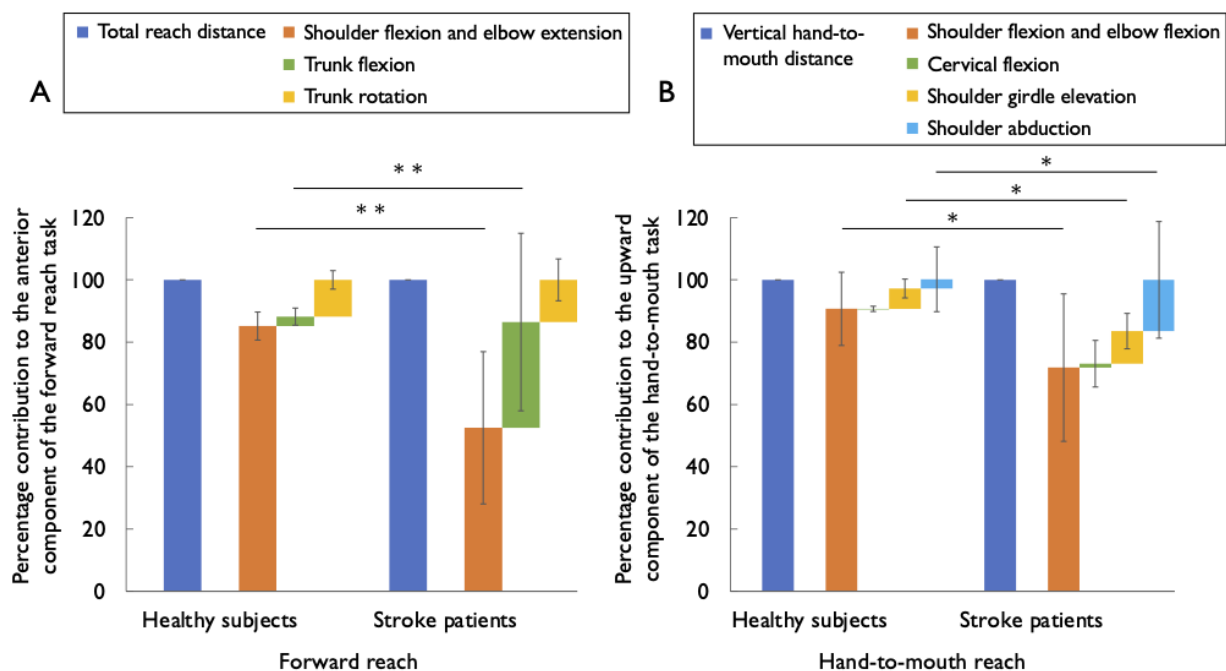
	Healthy participants (N=20)	Stroke participants (N=10)
Age in years, mean (SD)	26.5 (4.9)	70.7 (13.8)
Sex, n (%)		
Male	9 (45)	5 (50)
Female	11 (55)	5 (50)
Dominant hand, n (%)		
Right	19 (95)	10 (100)
Left	1 (5)	0
Upper extremity length (cm), mean (SD)	71.7 (3.9)	69.4 (5.1)
Diagnosis, n (%)		
Intracerebral hemorrhage	— ^a	4 (40)
Cerebral infarction	—	6 (60)
Time after stroke (days), mean (SD)	—	76.6 (43.6)
Affected side, n (%)		
Right	—	0
Left	—	10 (100)
Fugl-Meyer Assessment (total score of upper extremity), mean (SD)	—	52.1 (10.7)
Fugl-Meyer Assessment (total score of shoulder, elbow, and forearm excluding reflexes), mean (SD)	—	23.9 (5.3)

^aNot available.

The measurement results for the forward reach task and hand-to-mouth reach task are shown in [Figure 5](#). All patients

could reach the target in both the forward and hand-to-mouth reaching movements.

Figure 5. Quantification of dependence on compensatory movements. (A) Total reach distance in forward reaches on the Y-axis (blue) and its components in healthy participants and participants with stroke. Components: Shoulder flexion or elbow extension (orange), trunk flexion (green), and trunk rotation (yellow). (B) Vertical hand-to-mouth distance on the Z-axis (blue) and its components in healthy participants and participants with stroke. Components: Shoulder flexion or elbow extension (orange), cervical flexion (green), shoulder girdle elevation (yellow), and shoulder abduction (light blue). * $P < .05$, ** $P < .01$.



A comparison of the components of the forward reach revealed significant differences in the contribution of shoulder, elbow, and trunk flexion components between participants with stroke and healthy participants. The percentage contribution of shoulder and elbow flexion to the anterior component of the forward reach task was significantly smaller in participants with stroke than in healthy participants (mean 52.5%, SD 24.5% vs mean 85.2%, SD 4.5%; $P < .001$), whereas the percentage contribution of trunk flexion was significantly larger in stroke participants than in healthy participants (mean 34.0%, SD 28.5% vs mean 3.0%, SD 2.8%; $P < .001$). The percentage contribution of trunk rotation was not significantly different between participants with stroke and healthy participants (mean 13.6%, SD 6.7% vs mean 11.8%, SD 3.0%; $P = .35$).

A comparison of the components of the hand-to-mouth reach revealed significant differences in the contribution of shoulder and elbow flexion, shoulder girdle elevation, and shoulder abduction components between participants with stroke and healthy participants. The percentage contribution of shoulder and elbow flexion to the upward component of the hand-to-mouth task was significantly smaller in participants with stroke than in healthy participants (mean 71.8%, SD 23.7% vs mean 90.7%, SD 11.8%; $P = .009$), whereas the percentage contribution of shoulder girdle elevation and shoulder abduction were significantly larger in participants with stroke than in healthy participants (mean 10.5%, SD 5.7% vs mean 6.5%, SD 3.0%; $P = .02$ and mean 16.5%, SD 18.7% vs mean 3.0%, SD 10.4%; $P = .02$, respectively). The percentage contribution of cervical flexion was not significantly different between participants with stroke and healthy participants (mean 1.3%, SD 7.5% vs mean -0.2%, SD 0.9%; $P = .42$).

Discussion

Principal Findings

In this study, we attempted to analyze the reaching movement strategy in participants with stroke and healthy participants by quantifying the contribution of each movement component to forward and hand-to-mouth reaching. This study successfully identified that the movements that contributed to reaching differed between these populations. The contribution of shoulder flexion and elbow extension, which is the main component in the forward reach of healthy participants, was small in participants with stroke, whereas trunk flexion was significantly larger in participants with stroke than in healthy participants. In the hand-to-mouth reach, the contribution of shoulder and elbow flexion was smaller in participants with stroke than in healthy participants, whereas the contribution of upward elevation movements from shoulder abduction and shoulder girdle elevation was larger in participants with stroke than in healthy participants.

The difference in the movement strategies shown in this study may be attributed to movement abnormalities due to motor paresis of shoulder and elbow flexion and extension. In the participants with hemiparesis, the motor ability is retained in half of the body, and proximal muscles are relatively well restored during the course of recovery, possibly because of the bilateral innervation by the central nervous system [32]. Therefore, the impaired movement in the paretic side is often compensated by the nonparetic limb or proximal muscles with less severe paresis [33]. This analysis demonstrated that the contribution of a “normal” strategy in reaching, as quantified by the percentage contribution of shoulder flexion and elbow extension to the anterior component of the forward reach task,

and the percentage contribution of shoulder and elbow flexion to the upward component of the hand-to-mouth task, was significantly reduced in reaching in participants with hemiparesis compared with healthy participants. These strategies, dominant in healthy participants, were replaced by compensatory joint movements not observed in the healthy participants: trunk flexion in the forward reach task and shoulder abduction and shoulder girdle elevation in the hand-to-mouth task. The findings of this study align with those of previous studies that highlight the role of compensatory trunk and shoulder movements [17,34,35]. Notably, Alt Murphy et al [17] demonstrated the relative contribution of such compensatory actions to reaching and drinking tasks. Building on this, our study delves deeper, quantitatively illustrating the contribution of each component to the functional objectives of reaching tasks.

Clinical Implications

Recognizing the interrelationship of joint displacement and quantifying the degree of dependence, as in this pilot study, may be useful for clinical monitoring and goal setting of motor skills. In this study, participants with mild-to-moderate hemiparesis due to stroke were able to reach their primary target in reaching movement; however, they relied on compensatory movements to achieve this goal. Compensatory movements are generally considered inefficient compared to normal-like reaching movements, and reducing such compensatory movements seems to be an important goal of rehabilitation interventions in patients with this level of paresis. The quantification and visualization of the actual contribution of such compensatory movement should help clinical decision-making in planning interventions. Furthermore, the visualization of the degree of dependence on compensatory movements may be more useful when combined with the indexing of skill goal achievements—in this case, the reach distance—to measure the effectiveness of interventions. When analyzing the effects of interventions or assistive devices, examining the motor skills essential for achieving goals, such as forward reach task and hand-to-mouth task, along with the reliance on compensatory movements, can offer a deeper insight into how an intervention might impact patient activity.

Limitations

This study had several limitations. First, the measurement did not include the speed of each reaching performance. Considering that the speed of movement tasks affects other aspects of performance, this may have influenced the results of this study.

A more detailed analysis in the future with additional performance indices, such as speed, smoothness, and accuracy, could improve the understanding of the reaching ability of patients with motor paresis. Furthermore, the limited number of markers in this study prioritizes clinical application and ease of implementation. However, this constraint poses challenges in analyzing additional parameters like joint angles. Balancing this focus on contribution data with clinical feasibility requires further deliberation on the need for more detailed information. Second, the sample size was limited, and there was a significant variation in the index values. All patients had left hemiparesis, which meant measurements were performed using their nondominant hands. In contrast, the dominant right hand was used for the healthy participants. Robertson et al [36] pointed out that there might be performance differences between left and right paresis, which could further influence the study outcomes. The cumulative impact of these biases might affect the results. It is also worth noting that the control group comprised young adults, which could restrict the accuracy of gauging the impact of hemiparesis in this study. Despite this limitation, we believe our results retain their significance by effectively visualizing the unique motor strategies that patients with stroke use during reaching actions, emphasizing the crucial role of compensatory movements. Future studies, ideally with larger sample sizes and age- and side-matched controls, will certainly further refine our understanding of motor impairments in reaching. Despite the acknowledged limitations, this study provides meaningful contributions by introducing a simplified method to quantify and visualize joint motion strategies for reaching movements, thereby potentially facilitating the clinical application of upper limb motion analysis.

Conclusions

In this study, our goal was to assess the contributions of various joint movements to reaching actions and to distinguish between patients with stroke and healthy participants. Our analysis successfully highlighted a distinctive motor strategy in patients with stroke: the typical contributions of shoulder and elbow joint movements seen in healthy individuals were diminished, whereas the contribution of other joints, often deemed compensatory movements, was elevated in patients with stroke. The detailed evaluation of reaching ability this study offers, considering both actual reaching proficiency and reliance on compensatory movements, provides a valuable foundation for setting pertinent and effective rehabilitation goals.

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Data Availability

The data collected and analyzed during the study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization and original draft preparation were undertaken by HO and MM. The methodology was developed by HO, MM, ES, and YO. The software was managed by HO, YI, and SM. Formal analysis, investigation, and data curation were conducted by HO, YI, SM, and SY. Review and editing were carried out by HO, MM, YK, and YO. Supervision was provided by YK, ES, and YO. Project administration was overseen by MM and YO. All authors have read and agreed to the published version of the paper.

Conflicts of Interest

None declared.

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Abbreviations

FMA: Fugl-Meyer Assessment

MP: metacarpophalangeal

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Original Paper

Outcomes of Implementing a Webinar-Based Strategy to Improve Spinal Cord Injury Knowledge and Community Building: Convergent Mixed Methods Study

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Abstract

Background: COVID-19 disrupted services received by persons with spinal cord injury (SCI) worldwide. The International Disability Alliance declared the need for a disability-inclusive response to the COVID-19 crisis, as decreased access to health care services for individuals living with varying levels of function was unacceptable. As a result, an SCI community in Canada created a novel webinar-based strategy aimed at improving access to self-management information for people living with SCI and other stakeholders. However, although telehealth practices have previously been used effectively in SCI management and rehabilitation, little to no scholarship has investigated the outcomes of implementing a webinar-based telehealth strategy in this population.

Objective: This study aims to understand the outcomes of implementing the webinar series. Specifically, the authors aimed to determine the reach of the series; understand its impact on social connectedness, perceptions of disability, and overall quality of interactions among persons with SCI, their families, service providers, and the public at large; and explore the long-term sustainability of the initiative.

Methods: The authors implemented a community-based participatory strategy to define a convergent mixed methods design to triangulate qualitative and quantitative data collected simultaneously. Quantitative methods included pop-up questions administered during the live webinars, surveys administered following webinars, and an analysis of YouTube analytics. Qualitative methods included semistructured interviews with persons with SCI and health care providers who attended at least one webinar. The results were integrated, following methods adapted from Creswell and Clark.

Results: A total of 234 individuals attended at least 1 of the 6 webinars that took place during the 6-month study period. In total, 13.2% (31/234) of the participants completed the postwebinar survey, and 23% (7/31) participated in the semistructured

interviews. The reach of the webinar series was mainly to persons with SCI, followed by health professionals, with most of them living in urban areas. The topics *sexuality* and *research* were the most viewed on YouTube. The knowledge disseminated during the webinars was mainly perceived as valid and useful, related to the fact that the presentation format involved people with lived experience and clinical experts. The webinars did not necessarily help build a new extended community of people involved in SCI but helped strengthen the existing community of people with SCI in Alberta. The webinar positively influenced the perceptions of *normality* and *disability* regarding people with SCI. The webinar format was perceived as highly usable and accessible.

Conclusions: The webinar series was associated with improved participant knowledge of what is possible to achieve after an SCI and their perceptions of disability. The long-term implementation of this initiative is feasible, but further considerations to increase its reach to rural areas and ensure the integration of diverse individuals should be taken.

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KEYWORDS

spinal cord injury; telehealth; webinars; mixed methods; implementation

Introduction

Background

COVID-19 disrupted services received by persons with spinal cord injury (SCI) worldwide [1]. The International Disability Alliance declared the need for a disability-inclusive response to the COVID-19 crisis, as decreased access to health care services for individuals living with varying levels of function, including those with SCI, was unacceptable [2]. As a result, the SCI community in Alberta, Canada, created a novel telehealth, webinar-based strategy aimed at improving access to self-management information for people living with SCI and other stakeholders: the “Alberta Spinal Cord Injury Community of Interactive Learning Series” (AB-SCILS). For the purposes of this study, the authors defined *telehealth* in a broader sense than the typical definition. Specifically, the authors defined *telehealth* based on the *New England Journal of Medicine* definition of *telehealth* as applied to education and patient engagement: technology used to provide health care education and allow patients to take more control of their well-being by empowering self-management and fostering spaces of emotional support [3].

Telehealth practices have previously been used in SCI management and rehabilitation and found to be effective. A systematic review (N=25) found that virtual reality-based technologies for SCI rehabilitation enhanced motor function, aerobic function, balance, and psychological aspects related to SCI while also reducing pain [3]. The authors also noted that virtual reality-based technologies were highly motivating and engaging environments for rehabilitation [4]. A pretest-posttest study of the effectiveness of a home-based telerehabilitation (ie, web-based delivery of rehabilitation) program on reducing shoulder pain and improving shoulder function (N=16) in people with SCI found that pain was reduced, whereas function was improved [5]. Telehealth modalities have also been found to be favored for the self-management of persons with SCI as they mitigate the transportation and mobility barriers of in-person appointments [6]. A recent community-engaged pilot study evaluated the usability and effectiveness of a telehealth self-management intervention for persons with SCI (N=10) [6]. The pilot included the creation and viewing of instructional videos [7]. Participants were satisfied with the initiative and found the videos motivating and relatable owing to those in the

videos being people with lived experience and to the videos being acceptable lengths [7].

Previous research finding that webinars can substantially improve the self-management of people living with chronic conditions (such as cancer [8]) and are effective in promoting adult learning [9] was used as the justification to develop the AB-SCILS. However, little to no scholarship has investigated the outcomes of implementing a webinar-based telehealth strategy among individuals with SCI. With a forced shift to telehealth because of the onset of the pandemic and its continued use in the present day, research into the outcomes of implementing a strategy such as the AB-SCILS is warranted.

Organizational Context

The AB-SCILS was developed by a group of stakeholders, representing (1) the provincial health care system (ie, Alberta Health Services); (2) Spinal Cord Injury Alberta, the main community organization supporting persons with SCI in the province; and (3) Praxis, a Canadian-based not-for-profit organization that leads global collaboration in SCI research, innovation, and care. The AB-SCILS was developed in response to the need for a disability-inclusive response to the COVID-19 pandemic for individuals living with SCI. The webinars were co-designed by persons with SCI (ie, lived experience experts) and clinical experts so that both firsthand and clinical perspectives were shared during each webinar. All webinars were recorded and posted on a dedicated YouTube channel and are open to the public.

Through consultation with an advisory panel of community partners living with SCI (discussed in the following sections), the authors anticipated that the AB-SCILS would increase the audience’s knowledge of SCI, thus affecting their perceptions of SCI-related disability, as well as improve the ability of persons with SCI to self-manage by building a sense of community, thus ameliorating the isolating effects of the COVID-19 pandemic.

Research Aims

This study aimed to understand the outcomes of implementing the AB-SCILS. Specifically, the authors aimed to (1) determine the reach of the AB-SCILS to the various members of the SCI community in Alberta (ie, persons with SCI; their families; service providers; and the broader community, including rural

communities where support is limited); (2) understand the impact of the initiative on social connectedness, perceptions of disability, and overall quality of interactions among persons with SCI, their families, service providers, and the public at large; and (3) explore the long-term sustainability of the AB-SCILS.

Methods

Overview

This was a mixed methods study, and the methods are described in detail in a published study protocol [10]. Methods included pop-up questions administered during live webinars, surveys, semistructured interviews, and analysis of YouTube analytics. In summary, pop-up questions and YouTube analytics were used to describe the population attending the webinars as well as those who accessed them via YouTube after the live sessions, thereby providing information on the initiative’s reach. Surveys and semistructured interviews were used to understand the impact of the AB-SCILS on community building and perceptions of disability. The authors aimed to understand both the reach and impact to provide insights on the sustainability of the initiative. If the AB-SCILS reached the intended audience and had the desired impact, the authors perceived that it should be sustainable.

Study Co-design

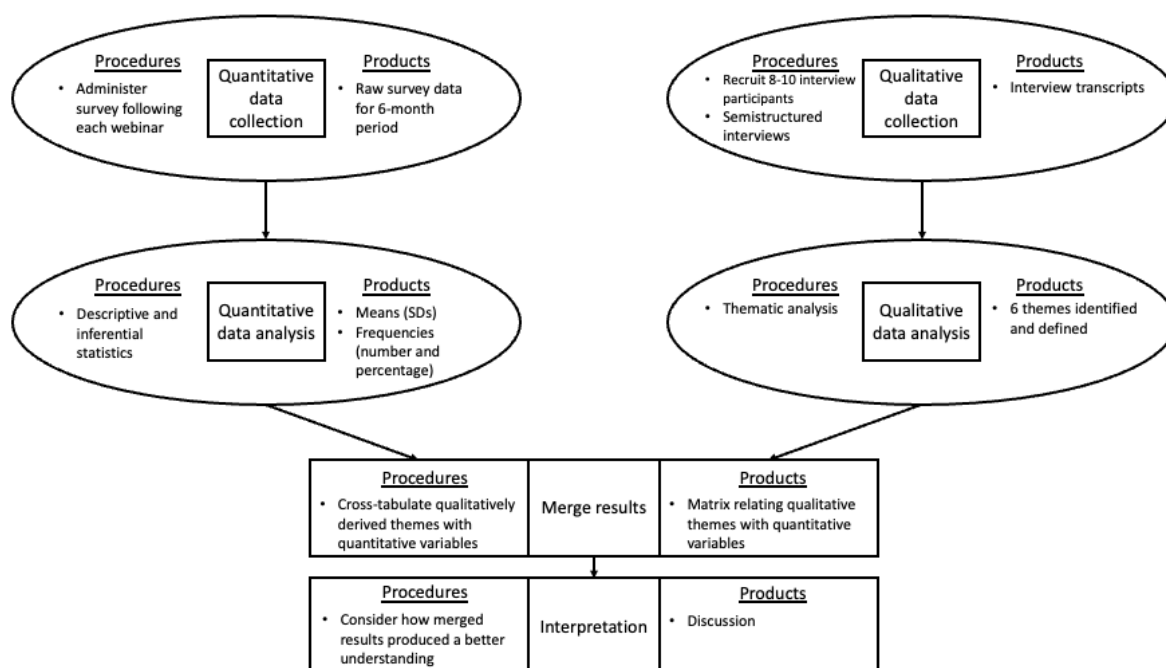
The authors used a community-based participatory strategy to define a convergent mixed methods design [11]. At the beginning of the evaluation process, the authors established an advisory panel of 3 individuals with SCI to understand how they thought the AB-SCILS should be evaluated. At the end of the initial meeting, the authors inquired into these individuals’ preferred level of participation in the study using the

International Association for Public Participation 2 Spectrum of Public Participation [12] to ground the discussion. The advisory panel chose to be *involved*, thus working directly with the research team throughout the process to ensure that their concerns with and visions for the AB-SCILS were understood and considered. As a result, the authors hosted bimonthly discussions with the panel to garner feedback on the ongoing analysis and preliminary findings, including suggestions on how results should be interpreted.

The authors used a convergent mixed methods design [11] to triangulate qualitative and quantitative data collected simultaneously. The findings from each data source were subsequently compared to obtain a more complete understanding of the AB-SCILS’ impact (Figure 1). A convergent mixed methods design brings together the strengths and weaknesses of both qualitative and quantitative methods [11]. This design is oriented toward real-world practice, with a focus on the importance of the research question being investigated rather than on the methodologies used [11]. Qualitative methods included semistructured interviews with persons with SCI and health care providers who attended at least one of the AB-SCILS webinars. Quantitative methods included surveys administered following AB-SCILS webinars and an analysis of YouTube analytics.

The authors used Sandelowski’s framework [13] for qualitative description to inform the qualitative component of the study. In qualitative description, a researcher does not deliberately choose to describe an event in terms of a specific framework or system but rather presents the facts of the study in layman’s terms [13]. Qualitative description studies often draw their results from naturalistic inquiry or the study of something in its natural state [13].

Figure 1. Flowchart depicting procedures and products in convergent mixed methods design (adapted from Creswell and Clark [11]).



Study Population

Overview

In consultation with the advisory panel, the authors determined that the AB-SCILS should not be solely targeted toward people with SCI. To build a broader SCI community, it was determined that the AB-SCILS should target persons with SCI (including patients who were hospitalized) and their families, health care professionals that are a part of their care journey (eg, general practitioners, nurses, rehabilitation providers [physiotherapists and occupational therapists], social workers, and psychiatrists), and members of the broader community (eg, teachers and city designers). Therefore, the population of interest included all individuals who attended the AB-SCILS between November 2020 and April 2021.

Inclusion and Exclusion Criteria

Participants had to be aged ≥ 18 years and have attended at least one AB-SCILS webinar. They also had to be able to read and understand English on their own or have support (ie, language translation) from their family or friends. There were no exclusion criteria applied in this study.

Recruitment and Sampling

The authors sought a convenience sample of approximately 30% of all AB-SCILS attendees for the pop-up questions and follow-up surveys. The link to the follow-up survey was sent to all webinar attendees via email. All attendees had to provide an email address when registering for each webinar. Attendees were welcome to fill out the surveys more than once during the 6-month evaluation period and were encouraged to do so by having their names be entered into a draw for a tablet at the end of the project.

The authors aimed to recruit approximately 8 to 10 AB-SCILS attendees to participate in the interviews. Individuals were asked whether they consented to be contacted for a follow-up interview after completing the survey. If attendees consented to be contacted, their contact information was shared with the study coordinator. The study coordinator then contacted these attendees to go through the informed consent process and arrange a date and time for the phone interview.

Data Collection

To understand the reach of the AB-SCILS, the authors sought descriptive statistics of those attending the webinars within the study period as well as those who accessed the webinars on YouTube following the live sessions. All individuals who attended the webinars live had the chance to complete a series of pop-up questions during each webinar. Pop-up questions were administered during each webinar held within the study period. Questions included (1) type of participant (ie, person with SCI, family member of someone with SCI, health care provider, researcher, program manager, student, or other); (2) whether attendees were from Edmonton, Calgary, elsewhere in Alberta, or outside Alberta; (3) attendance record (ie, first webinar, attended 1-3 webinars, attended 4-6 webinars, or attended >6 webinars); and (4) whether they had accessed past webinars on YouTube. To understand the reach following the live session, aggregate YouTube analytics data were accessed through the AB-SCILS YouTube account. YouTube data included total views, number of unique viewers, shares, comments added, and watch time (hours) per webinar.

To measure the impact and sustainability of the AB-SCILS, the authors completed follow-up surveys and semistructured interviews. Follow-up surveys were sent following each webinar to every attendee. Survey responses were captured using REDCap (Research Electronic Data Capture; Vanderbilt University) [14]. The survey package was codeveloped with the advisory panel and included questions about telehealth usability as well as the ability of the AB-SCILS to foster social connectedness and change perceptions of disability. Questions related to social connectedness and telehealth usability were adapted from the Sense of Virtual Community questionnaire [15] and the Telehealth Usability Questionnaire [16], respectively. Questions regarding challenging perceptions of living with a disability were written in consultation with the advisory panel. A more detailed explanation of each survey can be found in [Textbox 1](#), and all the questions can be found in the *Results* section. The survey package also included demographic questions (eg, age, sex, educational background, and occupational status).

Textbox 1. Alberta Spinal Cord Injury Community of Interactive Learning Series (AB-SCILS) evaluation survey details and scoring instructions.

Sense of Virtual Community questionnaire (SOVC)

- The authors adapted the SOVC questionnaire by Abfalter et al [15], which has 15 items and is measured on a Likert scale from 0 to 3, with 0 indicating “not at all” and 3 indicating “completely.” The scale measures facets of membership in a web-based community, influence on the community, integration and fulfillment of needs, and shared emotional connection among members [15].

Telehealth Usability Questionnaire (TUQ)

- The TUQ-10 measures the following domains: usefulness, ease of use and learnability, interface quality, reliability, and satisfaction and future use [16]. Each domain is measured on a Likert scale from 1 to 5, with 1 indicating “strongly disagree” and 5 indicating “strongly agree” [16].

Challenging perceptions of disability questionnaire

- The challenging perceptions questionnaire contained 11 questions. In total, 5 questions were measured on a 5-point Likert scale ranging from “strongly disagree” to “strongly agree” and analyzed perceived levels of knowledge before and after each webinar, as well as perceptions of whether individuals with lived experience of spinal cord injury (SCI) could lead normal, meaningful, and independent lives. The remaining 6 questions were measured on a 7-point Likert scale ranging from “always” to “never” and analyzed feelings people had when interacting with people with lived experience of SCI (eg, sadness, happiness, anger, anxiety, calmness, and feeling sorry).

The interviews were conducted by an experienced interviewer trained in qualitative methods. The semistructured interviews were 1:1 and remote (conducted by phone). The interview guide was informed by the advisory panel. The interviews asked about webinar experiences, perceived successes and challenges of the webinars themselves, takeaways of the webinars (ie, whether their views on SCI were challenged and how so), and the ability of the AB-SCILS to build a broader SCI community. The interviews also asked about social inclusion, quality of life, and perceptions of living with a disability. Probing questions were used to elicit greater description as necessary. The interviews were recorded using a digital audio recorder and were confidentially transcribed verbatim.

Data Analysis

Quantitative Analysis

Pop-up and YouTube analytics data were analyzed using Microsoft Excel (Microsoft Corp). The authors calculated the means and SDs of any interval data and the frequencies (number and percentage) of any categorical data. Survey data were analyzed cross-sectionally and longitudinally using SPSS (IBM Corp) and Stata (StataCorp) [17,18], and 2 members of the team completed the analyses separately.

Qualitative Analysis

Thematic analysis was completed on all interview transcripts using a specialized software for qualitative data management (Dedoose; SocioCultural Research Consultants) [19]. Thematic analysis involved reading through the transcripts and grouping similar ideas together as codes. Codes were then grouped together into overarching themes. A member of the research team (KB) coded all the transcripts. To ensure accuracy of coding, 2 other members of the research team (RM and AL-S) coded a portion of the transcripts. In total, 3 research team members (KB, RM, and AL-S) met to discuss codes and themes and develop a common analytical coding framework. The transcripts were then reread to ensure that they were coded appropriately based on the agreed-upon analytical coding framework.

The 3 members involved in the analysis were a Master's of Public Health student with no previous experience conducting research with the SCI community (KB), a social worker with SCI lived experience and a long trajectory supporting people with SCI in the community (RM), and an academic physiatrist with clinical experience in SCI and a doctorate in rehabilitation sciences (AL-S). These members continuously reflected on their assumptions while analyzing the data, and the 3 agreed on the importance of challenging preconceived notions of *normality* (ie, what it meant to lead a *normal* life as someone with SCI), as these often result in unfair service access for people with disabilities. Rigor was promoted through an audit trail of decisions for accountability, open-ended questions to prioritize participant voices, the use of a thick description of the context in which the AB-SCILS operates, collaborative coding for discussion of subjectivity and openness in analysis, and reflexive journaling and discussion [20].

Integrated Analysis

To triangulate findings from the quantitative and qualitative data arms [11], the authors began with each of the key themes generated from the qualitative analyses. A key statement was then written that embodied what each theme was about. The authors then discussed which questions from the follow-up survey addressed the factors discussed in each theme. Next, specific assumptions were tested based on each relevant follow-up survey question using ordinal directions expressed by frequency of level of agreement, coded dichotomously. If assumptions were confirmed, meaning that $\geq 80\%$ of the responses were in whatever ordinal direction was expected (ie, $\geq 80\%$ agreement or disagreement), the authors completed no further assumption testing. If assumptions were not confirmed, inferential tests were conducted to explore the effects of potential predictive variables (type of participant, sex, and educational level) and their association with responses of agreement or disagreement. Specifically, the authors estimated odds ratios (ORs) through simple logistic regression modeling considering a Cronbach α value of .05 as significant.

Ethics Approval, Informed Consent, and Participant Reimbursement

The University of Alberta Health Research Ethics Board approved this study (Pro00102178). All participants provided informed consent before taking part in the study. All study data were deidentified, and a pseudonym was assigned to participant contributions where appropriate. All participants who completed the survey were entered into a draw for a tablet computer (value of CAD \$200 [US \$148.06]). Those who participated in an interview received a CAD \$20 (US \$14.81) gift card.

Results

AB-SCILS Reach

There were 234 individuals who attended at least 1 of the 6 webinars that occurred during the 6-month study period (ie, November 2020 to April 2021). Not all attendees answered the pop-up questions, leading to variations in the number of total responses for each question. The results from the pop-up questions (Table 1) revealed that most webinar participants were persons with SCI (66/147, 44.9%) or health care providers (41/147, 27.9%), had attended >6 webinars (42/117, 35.9%), and were from either the Edmonton (68/140, 48.6%) or Calgary (50/140, 35.7%) areas. There was an almost even split between whether participants had viewed a webinar on YouTube (58/117, 49.6%) or not (59/117, 50.4%) following the live session.

YouTube analytics results are presented in Table 2. The webinar with the most YouTube views was "Episode 15—Sexuality After SCI" (299/771, 38.7%). This webinar also had the highest number of unique viewers (212/594, 35.7%) and shares (6/22, 27%) and the longest watch time (22.1 hours) during the study period. "Episode 16—SCI Research and Experimental Technologies" received the most comments (4/9, 44%) on YouTube during the study period.

Table 1. Understanding during-webinar reach via pop-up questions.

Variable	Participants, n (%)
Type of participant, (n=147)	
Person with lived experience	66 (44.9)
Family member or caregiver	6 (4.1)
Health care provider	41 (27.9)
Researcher	7 (4.8)
Program manager	13 (8.8)
Student	4 (2.7)
Other	10 (6.8)
Place of residence, (n=140)	
Edmonton	68 (48.6)
Calgary	50 (35.7)
Elsewhere in Alberta	20 (14.3)
Outside Alberta	2 (1.4)
Webinar attendance, (n=117)	
First webinar	31 (26.5)
Attended 1-3 webinars	20 (17.1)
Attended 4-6 webinars	24 (20.5)
Attended >6 webinars	42 (35.9)
Accessed webinars on YouTube, (n=117)	
Yes	58 (49.6)
No	59 (50.4)

Table 2. Understanding postwebinar reach via YouTube analytics.

	Total views, (n=772), n (%)	Unique viewers, (n=594), n (%)	Shares, (n=22), n (%)	Comments, (n=9), n (%)	Watch time, hours
Episode 12—A Conversation With Synaptic Neuro Rehabilitation and Reyu Recovery Centre	71 (9.2)	53 (8.9)	5 (22.7)	0 (0)	4.2
Episode 13—Activity Based Lifestyle: Ways of Staying Fit in Your Community	105 (13.6)	26 (4.4)	2 (9.1)	2 (22.2)	15.5
Episode 14—Mental Health: Depression and Coping Skills	89 (11.5)	61 (10.3)	4 (18.2)	2 (22.2)	4.4
Episode 15—Sexuality After SCI ^a	299 (38.7)	212 (35.7)	6 (27.3)	1 (11.1)	22.1
Episode 16—SCI Research and Experimental Technologies	45 (5.8)	64 (10.8)	3 (13.6)	4 (44.4)	3.7
Episode 17—Returning to Your Rural Community	163 (21.1)	178 (30)	2 (9.1)	0 (0)	17.5
Value, mean (SD)	128.7 (92.4)	99 (76.3)	3.7 (1.6)	1.5 (1.5)	11.2 (8.1)

^aSCI: spinal cord injury.

AB-SCILS Impact and Sustainability

Overview

There were 31 unique webinar attendees who completed the survey. Survey sample demographics are shown in [Table 3](#). Most respondents were female (21/31, 68%), persons with SCI (19/31, 61%), legally married (and not separated; 16/31, 52%), White (26/31, 84%), had a bachelor's degree (10/31, 32%), and worked 1 to 39 hours per week (14/31, 45%). A total of 19% (6/31) of the attendees completed the survey on more than one

occasion. Their longitudinal data were analyzed but not reported because of the small sample size. Survey questions (with associated question numbers), which survey each question was adapted from, and the survey results are shown in [Multimedia Appendix 1](#).

A total of 3% (7/234) of the webinar attendees participated in the interviews. Of these 7 attendees, 5 (71%) were persons with SCI and 2 (29%) were health care providers involved in SCI care. Six key themes were generated during the thematic

analysis: (1) legitimacy of knowledge, (2) applying knowledge, (3) building community, (4) challenging normality, (5) meeting community needs, and (6) webinar platform usability. The authors constructed key statements directly from each theme (Table 4).

Table 3. Follow-up survey demographics (n=31).

Variable	Values
Age (years), mean (SD)	45 (12.8)
Sex, n (%)	
Male	10 (32)
Female	21 (68)
Type of participant, n (%)	
Person with lived experience	19 (61)
Family member	3 (10)
Health care provider	6 (19)
Student	1 (3)
Manager	1 (3)
Other	1 (3)
Marital status, n (%)	
Single	6 (19)
Legally married (not separated)	16 (52)
Common law	6 (19)
Separated	1 (3)
Never legally married	0 (0)
Divorced	1 (3)
Prefer not to disclose	1 (3)
Race or ethnicity, n (%)	
Ethnic minority	4 (13)
White	26 (84)
Prefer not to disclose	1 (3)
Educational level, n (%)	
High school diploma or equivalent	2 (6)
Some postsecondary education, no degree	6 (19)
Apprenticeship	6 (19)
Associate degree	3 (10)
Bachelor's degree	10 (32)
Graduate degree	4 (13)
Employment status, n (%)	
Not employed and not looking	6 (19)
Unable to work	1 (3)
Retired	2 (6)
Working 1-39 hours per week	14 (45)
Working ≥40 hours per week	4 (13)
Prefer not to disclose	4 (13)

Table 4. Themes identified from the interviews with corresponding constructed key statements and exemplary quotes.

Theme and key statement	Exemplary quote
Legitimacy of knowledge	
The integration of clinical and lived experience perspectives created legitimate, accessible, and approachable new knowledge.	“I guess now I’m at the point where the equal like peer and provider information is great and working together to see that it’s the two worlds working together, the two fields working together... to give a total picture is great.” [Female; person with lived experience of SCI ^a]
Applying knowledge	
The AB-SCILS ^b provided knowledge that people can apply as well as a space for people with lived experience of SCI and health care providers to apply and disseminate knowledge (ie, double knowledge translation).	“In my personal life I have a brother who is going through a process of transferring to a wheelchair so it’s also good for my personal life to know and like learn about how to help him as well as I work with families and some of these families have kids with or part of the family has physical disabilities so I definitely think that it’s worthwhile and useful.” [Female; provider]
Building community	
Community was built through connections around common knowledge and empowerment of the pre-existing SCI community.	“...there was a new injury there as well and she was a very shy gal and uh she didn’t say too much but she did take my number and accept that I could contact her after the meeting so that’s a very big positive coming from your meeting. That’s probably the biggest positive gold star that you could have is a new injury that was shy and kind of isolated to be able to come forward and accept new information and more contact. That’s probably the brightest star in your whole webinar right there. Is giving someone the opportunity to hope for something better.” [Male; provider and person with lived experience of SCI]
The AB-SCILS needs to ensure that people feel like they are part of a safe space so that they can express their views and perspectives in the community.	“I felt like it was very nice to have a discussion with different people who either live with spinal cord injury or work with spinal cord injury...but...like I said did feel like it was little bit anti[workplace]. So that didn’t make me feel like I was part of that community.” [Female; provider]
The AB-SCILS also needs to ensure that it does not exclude people by not considering the diversity and format of the webinars.	“With little kids...it makes it harder for me to get out and join those things like unless it’s okay for me to bring the kids along kind of thing...I like the zoom, I really like the zoom...for the information the online format is great...it would be a little bit more accessible for me to do online.” [Female; person with lived experience of SCI]
Challenging normality	
The idea of what a “normal” life with SCI looked like was challenged through reconstruction and coconstruction of <i>normality</i> by people with lived experience of SCI and other attendees.	“...it’s a cultural shift or societal shift to...look at a person with a spinal cord injury, see their struggles and their setbacks but not look down on them in a way. Like to empathize instead of sympathize.” [Female; person with lived experience of SCI]
Meeting community needs	
The purpose of the AB-SCILS was not clear to every attendee, which meant that it did not always meet the needs of all community members.	“...what exactly is the purpose of the...SCILS...like is it mainly for education?” [Female; provider]
Webinar platform usability	
Connectivity, professionalism, and knowledge shared from both people with lived experience of SCI and clinicians equated to attendees viewing the webinar as usable.	“...I appreciate all of it honestly. I love that there’s the professionals there giving some of the...well-researched information because that’s always very helpful to check in with that stuff...and then having the peers speaking and hearing their experiences, very valuable, and then I think there was a break out room...for that one and that was great too because then we all got to speak about our personal experiences and connect so I appreciate all of those aspects.” [Female; person with lived experience of SCI]

^aSCI: spinal cord injury.

^bAB-SCILS: Alberta Spinal Cord Injury Community of Interactive Learning Series.

Mixed Integrated Findings

The following is a description of the integrated results organized by the categories constructed through the mixed analysis ([Multimedia Appendix 2](#)).

Category 1: Knowledge Disseminated During the Webinars and Its Applicability

The knowledge disseminated through the 6 webinars evaluated was perceived as valid and effective in increasing knowledge about the topics presented, which demonstrated that the

pedagogical approach taken in the webinar was effective in increasing knowledge in the audience. Most survey participants (28/31, 90%) agreed that they trusted the people delivering the content and the people attending and organizing the webinar (ie, quantitative results), which aligns with the “Legitimacy of Knowledge” theme (ie, qualitative results). In addition, about half (15/31, 48%) of the survey participants reported not knowing much about the topic presented before attending, and most (26/31, 83%) agreed that their knowledge about the topic

increased after participating in the webinar (ie, quantitative results).

The applicability of the knowledge disseminated during the 6 webinars evaluated was perceived as high because of its dissemination format, which included a combination of clinical and lived experience experts. The theme identified as “Applying Knowledge” demonstrated that the AB-SCILS provided a space for people with lived experience and people with professional expertise to converge and present information that was both factual and practical for daily life (ie, qualitative results). In addition, most survey participants (27/31, 87%) perceived that their needs, priorities, and goals were reflected in the webinar’s content (ie, quantitative results).

Category 2: AB-SCILS Impact on Community Building and Social Connectedness

The AB-SCILS did not have a strong impact on community building between people with lived experience, family members, service providers, and the public at large. However, the webinars did contribute to strengthening preexisting community connections among persons with SCI. The theme “Building Community” demonstrated that persons with SCI perceived the webinars as a platform to connect and strengthen relationships with peers (ie, qualitative results). However, narratives from participants without lived experience did not express a sense of community building with other participants when attending the webinars (ie, qualitative results). This finding aligns with the survey results, which demonstrated that, even though participants perceived webinar members as highly trustworthy, as good leaders, and as caring, they did not feel that they could talk to other participants about their problems (ie, quantitative results). In addition, survey participants did not agree with being known by other webinar participants, enjoying being with other webinar participants, or the importance of fitting in within the webinar community (ie, quantitative results). Interestingly, the authors found a significant association between reported gender and enjoying the company of other webinar participants. Men were 4.99 times ($P=.04$) more likely to report being with other members of AB-SCILS and enjoying their company in comparison with women (ie, quantitative results).

The theme “Meeting Community Needs” indicated that the purpose of the AB-SCILS as a community-building effort was not clear to all participants, and consequently, some participants’ narratives expressed that their expectations and needs were not always met when attending the webinars (ie, qualitative results). The survey findings confirmed that participants did not unanimously agree that they had important needs met when participating in the AB-SCILS (ie, quantitative results). Furthermore, subgroup inferential analyses showed that most of the participants who self-identified as health care providers (5/6, 83%) disagreed with having important needs met after participating in the webinars (OR 0.011; $P=.06$; ie, quantitative results).

Category 3: AB-SCILS Impact on SCI Perceptions of Normality and Disability

The webinar had an impact on the perception of whether persons with SCI can lead meaningful, “normal” lives. The theme “Challenging Normality” showed that participants were able to

reconstruct the idea of what a “normal life” for a person with SCI looks like after attending the webinars (ie, qualitative results). This theme stemmed directly from the fact that the webinar content was cocreated with persons with SCI, which provided firsthand experience to participants of how successful and “normal” a person with SCI’s life could be. Survey responses supported these results, showing that most participants agreed with the statement that people with SCI can lead meaningful (31/31, 100%), normal (28/31, 90%), and independent (30/31, 97%) lives (ie, quantitative results). Interestingly, when it came to exploring emotions related to SCI perception, not all participants demonstrated positive or neutral feelings when exposed to people with SCI. Many participants disagreed with feeling *sorry* (19/31, 61%) or *sad* (18/31, 59%) when they saw a person with SCI (ie, quantitative results). Similarly, many participants agreed with feeling *happy* (13/31, 41%) or *calm* (25/31, 81%) when encountering people with SCI (ie, quantitative results). A subgroup inferential analysis showed that having a postsecondary education was associated with higher odds of feeling “happy” or “calm” when seeing a person with SCI in comparison with participants without a postsecondary education (OR 12.6; $P=.03$ and OR 11; $P=.01$, respectively; ie, quantitative results).

Category 4: AB-SCILS Usability

The webinar platform was perceived as highly usable and accessible. The theme “Webinar Platform Usability” suggested that the webinar platform, including its live and recorded sessions, was perceived as highly useful as it enhanced connectivity among persons with SCI in an accessible, electronic environment (ie, qualitative results). It was also perceived that the webinar usability was enhanced by the professionalism of the presenters as well as the way the content was presented, which always included peer and professional knowledge integrated in a practical way (ie, qualitative results). In addition, survey results demonstrated that the webinar platform was highly accessible, simple to use, and easy to learn, and most participants (26/31, 83%) felt that they could use it productively in a timely manner (ie, quantitative results).

Discussion

Principal Findings

This study showed that the reach of the AB-SCILS webinar was mainly to persons with SCI, followed by health professionals, with most of them living in urban areas. The topics *sexuality* and *research* were the most viewed afterward on YouTube. The knowledge disseminated during the webinars was mainly perceived as valid and useful, mainly because of its presentation format involving people with lived experience and clinical experts. The AB-SCILS did not necessarily help build a new extended community of people involved in SCI but helped strengthen the existing community of people with SCI in Alberta. The webinar influenced the perceptions of *normality* and *disability* regarding people with SCI, showing that, after attending the AB-SCILS, people agreed more with the fact that having an SCI does not preclude individuals from leading meaningful lives. Finally, the results demonstrated that the

webinar format is highly usable and accessible, implying that AB-SCILS sustainability in the long term is feasible.

Most participants in the webinar were persons with SCI or health care providers (107/147, 72.8%) from either the Edmonton or Calgary area (118/140, 84.3%). This lack of rural participation may have been because it was anecdotally more challenging to get information about the AB-SCILS out to rural areas. There are often fewer individuals with SCI living rurally as well. There may also be some challenges related to limited access to technology. A study conducted in 2014 found that rural-dwelling Canadians had lower levels of internet access, with a lower number having a desktop, laptop, or mobile device with internet access at home compared with those living in urban areas [21]. The impact of this lack of internet access in rural Canada may have been amplified during the COVID-19 pandemic, with society transitioning to mainly web-based modes of communication [22]. Consequently, exploring access to web-based technology in rural areas of Alberta will be essential to improve the reach of webinar initiatives such as the AB-SCILS.

Although there was good participation in the live webinars, with >200 attendees during the study period, there were also a substantial number of views on YouTube after the live sessions. This suggests that the timing of the webinars may be a determinant of whether some participants can attend the live sessions, speaking to the importance of having the webinars available for later views. Chiswell et al [8] evaluated a suite of webinars in terms of overall experience, viewer satisfaction, self-reported changes in knowledge, and confidence to discuss webinar topics. The authors found that the main reason why individuals did not attend the live webinar was due to prior commitments, the time of day at which the webinar was scheduled, or preference to listen to the webinar at a later time [8]. Consequently, it is important to record webinars such as the AB-SCILS to improve their reach and accessibility. Recording webinars and making them available on the web will allow people to view them even if they are unable to attend live or if they want to watch the session again to reinforce their knowledge.

The webinars posted on the YouTube channel that were evaluated in this study also varied in terms of number of views, comments, shares, and watch time. The webinar with the most views and shares and the longest watch time was “Episode 15—Sexuality After SCI.” Attendees may have viewed, shared, and watched this episode the most because of perceived importance or curiosity about the topic. Previous research investigating the characteristics that drive virality, or sharing, of web-based advertisements found that information-focused content is less likely to be shared unless the information is novel or interesting in nature [23]. Furthermore, content evoking discrete positive emotions such as inspiration, warmth, amusement, and excitement was found to be more likely to be shared [23]. Although these findings were not studied in the context of webinars, it can be purported that “Episode 15—Sexuality After SCI” may have been viewed, shared, and watched more than the other AB-SCILS episodes because of viewer interest and lack of previous knowledge about the topic. This episode may have also evoked positive emotions in

viewers, adding to its likelihood of being shared via social media. It will be important to further investigate the types of emotions evoked by the different content included in the AB-SCILS webinars.

The AB-SCILS worked by disseminating knowledge that was perceived as trustworthy in a format that allowed attendees to know more about the topics presented after the webinar. Previous research has demonstrated that webinars are an effective modality to improve the knowledge of viewers [24–26]. A meta-analysis (N=12 articles) found that participants developed more knowledge and skills during longer webinars compared with shorter webinars [24]. Furthermore, the authors noted differences in participant knowledge gains resulting from what webinar platform was used (ie, Cisco Webex was associated with greater knowledge gains compared with Adobe Connect [24]), which suggests that the webinar platform used may affect the perceived quality of the information being shared. Interestingly, repeating the same topic in multiple webinars did not result in greater knowledge gains compared with sharing the topic in only one webinar [24]. This suggests that, in the AB-SCILS, topics should likely only be presented once unless there is novel information to share.

The knowledge disseminated in the AB-SCILS was applicable to the needs, goals, and priorities of persons with SCI and helped increase awareness that it is possible to lead a meaningful life after SCI. However, some attendees (13/31, 42%) did not agree with being able to discuss their own problems with the webinar community, suggesting that there may be factors hindering the sharing and applicability of the knowledge presented in the webinars. A qualitative study demonstrated that having peer coaches positively affects the self-management of people with SCI [27]. In addition, a scoping review on peer-led interventions for people with SCI demonstrated that the positive effect of having peers guiding and presenting information on self-management is effective, mostly in a one-to-one format [28]. Consequently, this study’s findings may suggest that, even though the knowledge disseminated in the AB-SCILS was highly applicable (because of the participation of persons with SCI) and respected (because of the participation of clinical experts), the lack of a one-on-one space to make this knowledge more personalized hindered the potential of translating the disseminated knowledge into meaningful life changes. In other words, it is fair to say that the format of the AB-SCILS helped people change their perceptions of what is possible related to living with SCI, but its format did not allow individuals to effectively channel these new perceptions into concrete actions to improve the lives of people with SCI.

This study’s results suggest that the AB-SCILS community was built through connections regarding common knowledge and empowerment of a preexisting SCI community in the province. However, the authors identified that the AB-SCILS needs to ensure that people feel like they are part of a safe space so that they can express their views and perspectives in a community that goes beyond people with SCI and includes family members, care providers, and the public at large, ensuring that it includes people by considering the diversity and format of the webinars. Considering the web-based community-building framework followed that of Abfalter et al [15], this study’s findings suggest

that the AB-SCILS could be further improved by enhancing its strategies to promote a sense of membership among all people involved in the lives of persons with SCI as well as integrating all possible members with the common goal of fulfilling individuals' needs by building and sharing emotional connections.

It is important to reflect on the finding that the purpose of the AB-SCILS was not clear to all attendees, suggesting that some individuals did not have their needs met by participating in the webinars. In a published article presenting 12 tips to create an effective and impactful webinar, Topor and Budson [29] suggested conducting a needs assessment with the webinar organizer and participants to learn what each group hopes to obtain from the webinar. This allows the webinar to be tailored to the needs of all stakeholders. AB-SCILS attendees may have felt that they did not have their needs met during the webinar because of learning with individuals who were outside of their usual "communities" (eg, persons with SCI vs health care providers). An article investigating whether and how the demographics of peers could influence engagement and knowledge retention suggests that social engagement matters in web-based courses [30]. Specifically, the authors found that individuals affiliated with age-similar others in a web-based course had a higher probability of course completion [30]. Consequently, the AB-SCILS could be further improved by integrating a strategy that allows for continuous consultation with community members to define the needs and priorities to build future webinars in this initiative, as well as considering a more central role of SCI peers in the delivery of AB-SCILS strategies.

The AB-SCILS had an impact on the cognitive perception of whether persons with SCI can lead meaningful, *normal* lives as the webinar content was cocreated with persons with lived experience. However, the authors also found an association between educational level and feeling *happy* or *calm* when interacting with persons with SCI as those with a postsecondary education reported these feelings more compared with those without a postsecondary education. A literature review (N=48 articles) analyzing the acceptance of employees with disabilities at work found that individuals with lower levels of education favored the segregation of individuals with disabilities [31]. Similarly, those with higher knowledge and previous experience interacting with persons with lived experience of disability had more favorable attitudes toward them. This underlines the importance of understanding more about the association between level of education and perceptions of disability as this could help tailor educational strategies to foster better community integration for people with SCI.

This study revealed that the AB-SCILS webinar platform was viewed as simple to use and easy to learn and allowed attendees to become productive quickly. A study suggested that there is no difference in the quality or acquisition of knowledge between web-based and traditional methods of learning such as self-reading, lectures, or face-to-face interaction [32]. This study's results support this finding, reassuring that the webinar format has teaching qualities equivalent to those of other traditional methods. Therefore, implementing webinar formats

to generate effective learning spaces for people with SCI and all others involved in their lives is a feasible strategy.

Finally, in terms of sustainability, it is assumed that the webinars are sustainable as they were perceived as highly usable and accessible. Furthermore, the webinars are financially sustainable as the creation of the AB-SCILS was independent from this study's grant funding; all those who contributed to the AB-SCILS did so without receiving any additional monetary compensation (the grant funded this study). However, with changing provincial COVID-19 public health mandates, AB-SCILS contributors have had to return to their prepandemic employment demands, resulting in little to no time available to invest in the AB-SCILS. As such, the AB-SCILS has currently been put on hold, with the plan to evolve the webinars to fit within the changing climate and continue to be responsive to the needs of the community. It is essential to note that this current challenge is not because the demand for the AB-SCILS decreased. Demand has remained consistent, as evidenced by the continued viewing of past webinars on YouTube and offshoots of AB-SCILS forming through community members. Instead, this challenge has resulted from organizational changes not considered during the creation of the AB-SCILS and, therefore, presents a key learning opportunity in relation to sustainability: for the AB-SCILS to be sustainable in the long term, more organizational support and dedicated personnel are required.

Limitations

This mixed methods study has some limitations. First, the authors did not validate or test the psychometric properties of the challenging normality survey that they created. However, this survey was developed in consultation with persons with SCI, and therefore, it was considered valid to explore this phenomenon. Second, the authors did not differentiate between time since injury in individuals with SCI and health providers' years of experience working with SCI. This limited the authors' ability to understand how the webinar affected people at different stages in relation to the phenomenon of SCI. Measuring time since injury and years of experience could have helped the authors further tailor the content and dissemination strategy of the AB-SCILS. Third, there was a low response rate to the survey (31/234, 13.2%). Most notably, there was a low number of health care providers who completed the surveys and, subsequently, a low number of health care providers who participated in the interviews. However, the low representation of health care providers in comparison with individuals living with SCI was expected and representative of the population who attended the AB-SCILS. Fourth, the population who participated in this study mostly identified as female. Although we do not have pop-up question data on gender, thus limiting our ability to know if this was representative of the population attending the AB-SCILS, research shows that most individuals in Canada with traumatic [33] and nontraumatic SCI [34] are male. The low representation of health care providers and male participants with SCI limited the generalizability of the survey results and the representability of this group in the interviews' narratives. More participation from health care providers and male individuals with SCI could have provided further breadth

and depth of information about the overall impact and feasibility of the AB-SCILS.

Conclusions

The AB-SCILS, a webinar-based strategy to promote community building in SCI through the creation of a safe learning space guided by peers and clinical experts, improved participants'

knowledge of what is possible to achieve after an SCI, positively affecting their perceptions of disability. The long-term implementation of this initiative is feasible, but further considerations to increase its reach to rural and underserved areas and ensure the integration of diverse individuals, including family members and care providers, should be taken.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

KB and AL-S were responsible for data collection, data analysis, manuscript writing, and final edits. RM was involved in promoting data collection and ongoing data analysis. BL, BN, and KM were patient partners who assisted in conceptualizing the project and provided ongoing feedback during the analysis. All other coauthors were involved in providing input on the manuscript, approved the submitted version, and agreed to be personally accountable for their own contributions and ensure that questions on the work are appropriately investigated and resolved.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Alberta Spinal Cord Injury Community of Interactive Learning Series survey questions, corresponding surveys, and survey results (n=31).

[[DOCX File, 25 KB - rehab_v10i1e46575_app1.docx](#)]

Multimedia Appendix 2

Integrated results generated through mixed methods analysis.

[[DOCX File, 18 KB - rehab_v10i1e46575_app2.docx](#)]

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Abbreviations

AB-SCILS: Alberta Spinal Cord Injury Community of Interactive Learning Series

OR: odds ratio

REDCap: Research Electronic Data Capture

SCI: spinal cord injury

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Original Paper

Effects of Real-Time Pressure Map Feedback on Confidence in Pressure Management in Wheelchair Users With Spinal Cord Injury: Pilot Intervention Study

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Abstract

Background: Wheelchair users with a spinal cord injury (SCI) are at a high risk for developing pressure injuries (PIs). Performing weight shifts is a primary method of pressure management for PI prevention; however, individuals with SCI may lack confidence in their abilities to perform adequate pressure relief due to their lack of sensation. Real-time seat interface pressure mapping feedback may provide partial substitution for sensory feedback such that an individual's confidence is improved.

Objective: We aim to examine how confidence for pressure management by wheelchair users with SCI was impacted by providing access to real-time, on-demand seat interface pressure mapping feedback.

Methods: Adults with SCI (N=23) completed self-efficacy questions addressing confidence around 4 factors related to performing weight shifts in this longitudinal, repeated-measures study. We evaluated the impact of providing standard PI prevention education and access to live pressure map feedback on confidence levels for performing weight shifts.

Results: Access to live pressure map feedback while learning how to perform weight shifts resulted in significantly higher confidence about moving far enough to relieve pressure at high-risk areas. Confidence for adhering to the recommended weight shift frequency and duration was not significantly impacted by in-clinic education or use of pressure map feedback. Confidence that performing weight shifts reduces PI risk increased most following education, with slight additional increase when pressure map feedback was added.

Conclusions: Access to live pressure mapping feedback improves confidence about performing weight shifts that relieve pressure when provided in the clinical setting and demonstrates potential for the same in the home. This preliminary exploration of a smartphone-based pressure mapping intervention highlights the value of access to continuous pressure mapping feedback to improve awareness and confidence for managing pressure.

Trial Registration: ClinicalTrials.gov NCT03987243; <https://clinicaltrials.gov/study/NCT03987243>

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KEYWORDS

spinal cord injury; wheelchair; pressure injury prevention; self-efficacy; pressure mapping; pressure; mapping; map; interface; spine; spinal cord; feedback; real time; mobile phone

Introduction

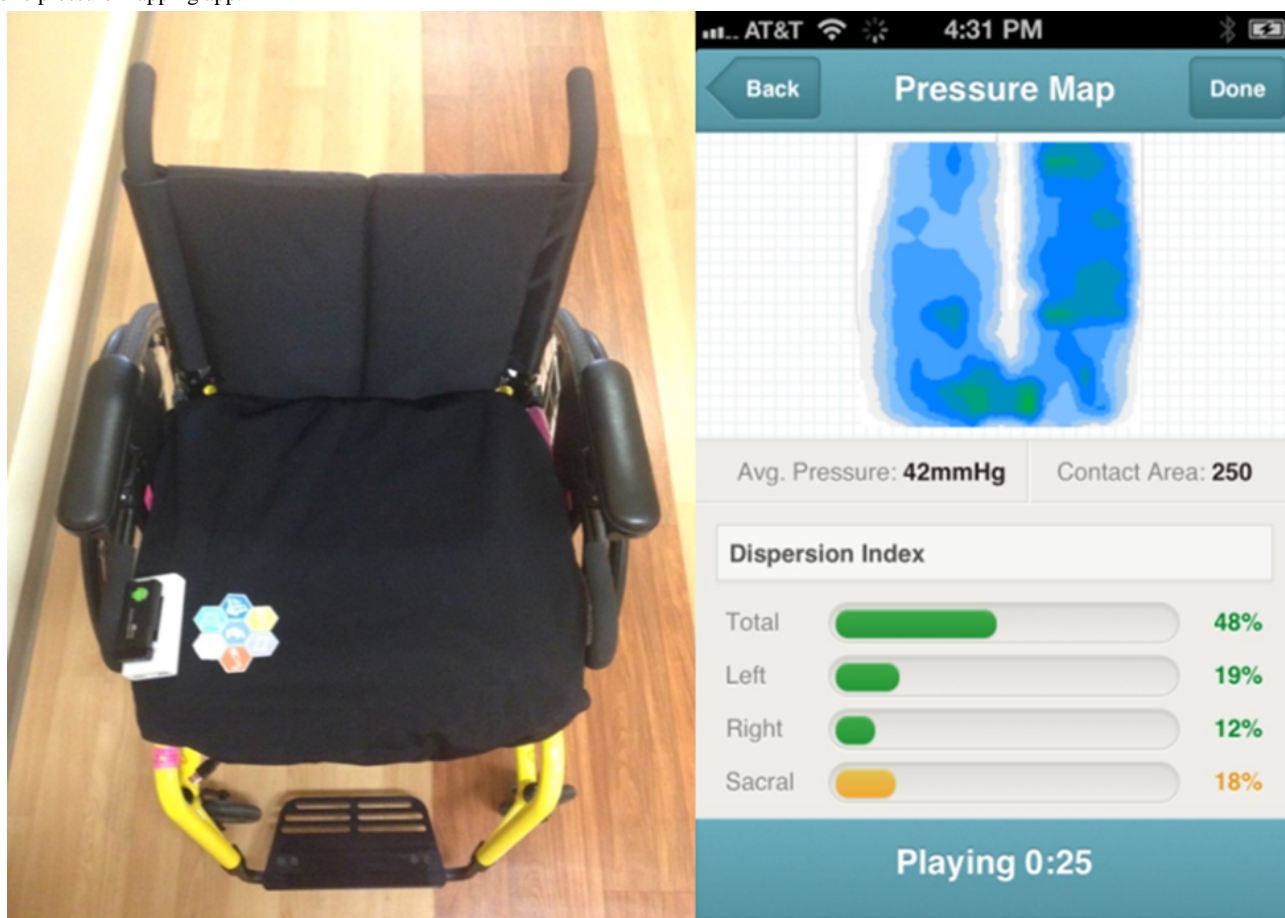
Wheelchair users with a spinal cord injury (SCI) are at a high risk for developing pressure injuries (PIs) [1]. Heightened risk is due to motor and sensory impairments that require prolonged periods of sitting coupled with difficulty sensing pressure on the skin. PI risk for those with SCI is persistent across the life span and significantly impacts quality of life and occupational engagement when present because healing requires bedrest and time away from routine activities [2]. Individuals with SCI must learn effective self-management strategies to mitigate their risk for developing PIs [3].

During initial rehabilitation, patient education for PI prevention emphasizes techniques to redistribute pressure away from bony areas of the pelvis, where most PI occur in the SCI population [4,5]. Therapists teach new wheelchair users how to perform effective weight shifts using written materials and demonstration of techniques. Further, therapists use seat interface pressure mapping (IPM) as an effective way to visualize how pressure is distributed and to guide wheelchair positioning [6,7].

However, evidence suggests that prevention knowledge and pressure management behaviors gained during inpatient rehabilitation decay over time [8], and wheelchair users with SCI complete far fewer weight shifts than recommended and that movements are inconsistent and sporadic from day to day [9,10].

We posit that 1 factor to target for improving pressure management behaviors is a person’s own confidence in their ability to perform effective weight shifts [11]. Further, we hypothesize that a key aspect for improving confidence in pressure management behavior is the access to feedback about seating pressures while in a wheelchair. The natural sensory feedback is missing in individuals with SCI, so they require an alternative feedback system that can improve confidence and lead to action taken on proper pressure management. Thus, we are interested in developing and testing interventions that can improve confidence. In response to this, we have developed a mobile pressure mapping app (mPMAP) [12-14] that provides real-time pressure map display on a smartphone screen via wireless connection to the commercially available 4-way stretch BodiTrac pressure mat (Vista Medical, Inc; Figure 1).

Figure 1. (Left) BodiTrac pressure map and wireless mPMAP hardware on top of seat cushion, (right) web-based mobile app (mPMAP). mPMAP: mobile pressure mapping app.



The purpose of this study was to assess how confidence scores related to pressure management change when individuals with SCI receive (1) pressure management education alone (in-clinic), (2) education with on-demand IPM feedback (in-clinic), and (3) home use of on-demand IPM feedback (for a trial period). We tested this by surveying user's confidence about 3 specific aspects of managing pressure and the strength of their belief that weight shifts can prevent PI. We hypothesized that use of on-demand seat IPM system would result in increased confidence across pressure management factors (PI prevention, weight shift effectiveness, weight shift frequency, and weight shift duration).

Methods

Ethical Considerations

Manual and power wheelchair users with complete SCI who were able to perform weight shifts or use power tilt independently participated in this study. Participants were recruited through convenience sampling from an SCI outpatient rehabilitation program and wheelchair seating clinic at a large Midwestern medical system, after the institutional review board's approval (16-007531). Participants provided informed consent prior to data collection, and all data reported are deidentified. Participants were compensated with US \$100 for completing this study. Data collection occurred between October 2016 and August 2017. Inclusion criteria required participants to use a wheelchair for a minimum of 6 hours per day, independence in performing weight shifts by leaning or by using power seat functions, and ability to independently use a smartphone. Exclusion criteria prohibited participation if there was an active PI on the pelvic region.

Study Design

This longitudinal, within-subject, repeated measures design was conducted over a 1-month period. Participants participated in an in-clinic study visit followed by in-home data collection for 1 month.

Interventions

We provided standard education for PI prevention that focused on weight shifts to redistribute pressure. We used videos produced by the Rehabilitation Research and Training Center on SCI that depict individuals with SCI performing the tasks [15] and printed patient education materials with drawings depicting the weight shifts [16,17]. We used IPM to provide visual feedback during the in-clinic visit (Vista Medical, Inc) and a mobile app version (mPMAP; Figure 1) for participant access to visual feedback during the in-home phase.

Outcome Measure: Self-Efficacy (SE) Scale to Assess Confidence

We measured level of confidence for performing weight shifts using a 4-item self-efficacy (SE) survey developed for this study using the principles outlined in the "Guide for constructing self-efficacy scales" [18]. Content validity was confirmed through expert clinician review by occupational therapy and physical therapy staff on an SCI rehabilitation team. The SE questions were each rated from 1 (lowest confidence) to 100

(highest confidence) by the participants. The first SE question (Q1) targeted an individual's outcome belief that completing weight shifts prevents PIs. The remaining questions assessed judgment of their current capability to complete weight shift maneuvers based on 3 criteria: (Q2) effectiveness (moving far enough to improve pressure distribution), (Q3) consistency (completing weight shifts every half hour), and (Q4) duration (holding weight shifts for 2 minute).

In-Clinic Visit

A preintervention baseline SE measure was obtained with the 4-item SE survey. Next, to ensure a consistent level of education about how to redistribute pressure through leaning or use of power tilt, we provided structured education for performing weight shift maneuvers for PI prevention. Participants practiced completing the weight shift maneuvers with feedback from this study team's seating and mobility expert. For full forward and side leans, participants were asked to move as far as possible in each direction and for partial forward and side leans, they leaned far enough to rest elbows on lap or on armrests or tires, similar to the approach used in earlier studies [19]. *The structured weight shift maneuver protocol was completed as follows:* (1) full forward lean, (2) full right-side lean, (3) full left-side lean, (4) partial forward lean, (5) partial right-side lean, and (6) partial left-side lean. Weight shift maneuvers were determined completed for full leans when the participant moved safely as far as they could in the intended direction which included holding on to foot plates for forward lean or the tire for the side leans. For the partial lean, participants were instructed to lean half as far as their full lean. The lean approach described was used because each individual had variable levels of control and ability to lean; hence the maneuvers and pressure offload goals were customized for each user. For power tilt users, full weight shift required tilting back as far as the chair allowed (45-55 degrees) and to 30 degrees for partial tilt [20]. After providing education, a second administration of the SE items was completed.

Next, we introduced use of IPM feedback using a clinical system with computer display visible to the participants. Real-time pressure distribution feedback was shown to the participants as they completed a series of weight shift movements. Participants were instructed to observe the changes in pressure distribution on the screen while they practiced weight shifts. After exposure to IPM feedback, participants answered the SE survey a third time.

In-Home Use of mPMAP

At the conclusion of the in-clinic visit, each participant was provided with an iPhone with a 30-day prepaid data plan and an mPMAP system to use at home. Participants were instructed that the testing period was 30 days and that they would alternate across weeks in which they would or would not use the system (an ABAB design). This study's period began with a 1-week period of using the system, followed by 1 week not using the system, followed by a second and final week using the system, followed by a final week of this study not using the system. All participants demonstrated an ability to access and use mPMAP independently through teach-back observation. Daily activity logs, with assigned days for accessing the mPMAP feedback

highlighted, were provided to each participant to record days of mPMAP use and comments on usability of the system. Participants were contacted within 2 days of starting the home use period to repeat the SE survey for reliability testing of the items and then again during each of the alternating periods of mPMAP use and without mPMAP use during the in-home data collection period. In total, participants completed the SE survey 5 times during the at home period.

Data Analysis

Statistical analyses were carried out using SPSS statistical software (version 24.0; IBM Corp) for Windows [21]. Because the data were skewed, Wilcoxon signed rank test was the most appropriate statistical test [22]. We calculated effect size (r) with the recommended method for nonparametric repeated measures, [23], and interpreted the effect size of r using Cohen guidelines: large effect size=0.5, medium=0.3, and small effect size=0.1 [23]. We made 3 within-person, pairwise planned comparisons for each SE item confidence score: (1) baseline

measure versus posteducation, (2) posteducation versus posteducation IPM feedback, and (3) with mPMAP use at home versus without use of mPMAP at home. Because these were planned comparisons, we did not apply an adjustment for multiple comparisons.

Results

Participant Characteristics

There were no statistically significant characteristic differences between those who completed the in-clinic (N=23) and in-home (N=16) data collection periods (Table 1). The sample was heterogeneous with representation across injury level, wheelchair and cushion types, PI experience, time since injury, and age. The sex distribution at the in-clinic visit was 78.3% (n=18) male and 21.7% (n=5) female, and in the home phase, the distribution shifted to 68.8% (n=11) male and 31.3% (n=5) female as 7 men did not complete the in-home data collection.

Table 1. Participant characteristics.

Variables	In-clinic visit (n=23)	In-home phase (n=16)
Gender, n (%)		
Male	18 (78.3)	11 (68.8)
Female	5 (21.7)	5 (31.3)
SCI^a level, n (%)		
Cervical	10 (43.5)	6 (37.5)
Thoracic	12 (52.2)	9 (56.3)
Lumbar	1 (4.3)	1 (6.3)
Wheelchair, n (%)		
Manual	14 (60.9)	10 (62.5)
Power with tilt	8 (34.8)	5 (31.3)
Power without tilt	1 (4.3)	1 (6.3)
Seat cushion, n (%)		
Offloading, noncustom	6 (26.1)	5 (31.3)
Immersion	16 (69.6)	11 (68.8)
Alternating air (powered)	1 (6.3)	0 (0)
Pressure injury history, n (%)		
Pelvic pressure injury	11 (47.8)	9 (56.3)
Surgical repair	10 (43.5)	7 (43.8)
Onset time (years), n (%)		
0-5	7 (30.4)	3 (18.8)
6-15	4 (17.4)	3 (18.8)
16 or older	12 (52.2)	10 (62.5)
Age (years), mean (SD), median (IQR)	42.17 (13.16), 39 (21-65)	42.5 (12.38), 40 (27-63)
Years since onset, mean (SD), median (IQR)	15.74 (11.77), 18 (1-43)	18.13 (11.40), 20 (2-43)

^aSCI: spinal cord injury.

PI Prevention

Confidence that performing weight shifts prevents PI increased significantly from baseline (mean 85.2, SD 23.7) to after standard education was provided (mean 90.2, SD 14.2; $P=.02$),

with a large effect size ($r=-0.503$). Score increased further (mean 94.3, SD 9.9) after introduction of IPM feedback in clinic and remained above mean score of 93.8 (SD 9.9) for the 1-month at-home phase of this study (Tables 2 and 3), but this increase was not statistically significant, and the effect size was small.

Table 2. Mean self-efficacy scores across time for 4-items in response to: “I believe I am able to...”

Time	Prevent pressure injury using weight shifts		Move far enough to relieve pressure	
	Mean (SD)	95% CI	Mean (SD)	95% CI
Baseline ^a	85.2 (23.7)	75.0-95.5	79.8 (25.8)	68.6-90.9
Posteducation ^a	90.2 (14.2)	84.1-96.3	85.7 (17.7)	78.0-93.3
Education + map ^a	94.3 (9.9)	90.1-98.6	97.0 (5.6)	94.5-99.4
Test-retest ^b	94.5 (10.1)	89.6-99.4	97.6 (4.2)	95.6-99.7
mPMAP ^c 1 ^d	93.8 (9.9)	88.7-98.9	95.3 (8.9)	90.7-99.9
No mPMAP 1 ^e	93.8 (9.4)	88.7-98.8	91.9 (11.8)	85.6-98.2
mPMAP 2 ^f	96.2 (7.7)	91.5-100.8	97.3 (6.0)	93.7-100.9
No mPMAP 2 ^g	95.9 (7.4)	91.0-100.9	95.0 (8.7)	89.2-100.8

^an=23.

^bn=19.

^cmPMAP: mobile pressure mapping app.

^dn=17.

^en=16.

^fn=13.

^gn=11.

Table 3. Mean self-efficacy scores across time for 4-items in response to: “I believe I am able to...”

Time	Perform weight shifts every 30 minutes		Hold weight shifts for duration of 2 minutes	
	Mean (SD)	95% CI	Mean (SD)	95% CI
Baseline ^a	82.3 (28.8)	69.9-94.8	88.9 (25.0)	78.1-99.7
Posteducation ^a	89.8 (20.1)	81.1-98.5	92.4 (16.5)	85.3-99.5
Education + map ^a	91.5 (16.9)	84.2-98.8	92.0 (16.7)	84.7-99.2
Test-retest ^b	94.7 (10.2)	89.8-99.7	94.2 (10.2)	89.3-99.1
mPMAP ^c 1 ^d	95.0 (10.5)	89.6-100.4	95.9 (9.2)	91.1-100.6
No mPMAP 1 ^e	89.7 (15.6)	81.3-98.0	93.4 (9.8)	88.2-98.7
mPMAP 2 ^f	95.4 (9.7)	89.5-101.2	92.3 (13.6)	84.1-100.5
No mPMAP 2 ^g	91.8 (12.5)	83.4-100.2	91.4 (14.2)	81.9-100.9

^an=23.

^bn=19.

^cmPMAP: mobile pressure mapping app.

^dn=17.

^en=16.

^fn=13.

^gn=11.

Weight Shift Effectiveness

Confidence for knowing one has moved far enough to effectively redistribute pressure during a weight shift had the lowest mean score out of the 4 questions at baseline (mean 79.8, SD 25.8) with slight increase after standard education was delivered (mean 85.7, SD 17.7; Tables 2 and 3). However, after given access to IPM feedback, the mean confidence score increased

significantly (mean 97.0, SD 5.6; $P=.002$), with a large effect size ($r=-0.642$; Table 4). This was the largest effect size observed across questions and comparisons. Additionally, during at-home IPM access, the mean confidence score was significantly higher (mean 95.3, SD 8.9) than period of time without IPM access (mean 91.9, SD 11.8), $P=.02$, again, with a large effect size ($r=-0.566$; Table 4).

Table 4. Wilcoxon signed rank tests for self-efficacy scores.

I believe I am able to:	Baseline versus posteducation (N=23)			Posteducation versus education + IPM ^a feedback (N=23)			mPMAP ^b use versus no mPMAP use at home ^c (N=16)		
	Z ^d	P value	r ^e	Z	P value	r	Z	P value	r
Prevent pressure injuries by performing weight shifts at regular intervals when I am in my wheelchair.	2.41	.02 ^f	0.503	1.414	.16	0.295	0.213	.83	0.053
Move far enough during weight shifts to relieve pressure at my high-risk areas.	0.088	.38	0.018	3.077	.002 ^f	0.642	2.264	.02 ^f	0.566
Consistently perform weight shifts at least every half hour during the day.	1.826	.07	0.381	0.736	.46	0.153	1.59	.11	0.398
Hold my weight shifts for two full minutes as recommended for at least half of my weight shifts.	0	>.99	0	0.378	.71	0.079	1.361	.17	0.34

^aIPM: interface pressure map.

^bmPMAP: mobile pressure mapping app.

^cThe first week of mPMAP use was compared with first week of non-mPMAP use at home.

^dZ: Wilcoxon signed rank test statistic.

^er: effect size (Z/\sqrt{N} ; Cohen).

^f $P<.05$.

Weight Shift Frequency and Duration

Confidence for performing weight shifts at the recommended frequency of every 30 minutes and holding for duration of 2 minutes did not change significantly from baseline measure to following standard education, between standard education and access to IPM feedback, or with access to IPM feedback at home (Tables 2-4).

Discussion

Primary Findings

These results provide evidence that access to IPM feedback improves confidence around pressure management by wheelchair users with SCI, and specifically around awareness of how to move to redistribute pressure effectively. Each of the 4 questions (PI prevention, weight shift effectiveness, weight shift frequency, and weight shift duration) were grounded in SE theory and each addressed a specific aspect of pressure management.

PI Prevention

The first question focused on the outcome expectation that one is able to prevent PIs by performing weight shifts. We predicted that IPM feedback would increase confidence more than standard education; however, the most significant increase occurred immediately after we provided standard patient education. Confidence remained higher than baseline after IPM

was introduced and while IPM was used at home. Further, because this study had just a 1-month in-home period, we do not yet know if ongoing access to IPM would reduce the knowledge decay observed in other studies [8] that occurs in the first year after education is provided to those newly injured. Other studies have provided evidence that education provided to individuals with SCI about PI prevention improves SE or knowledge, but they have not specifically addressed confidence around performance of weight shifts as we have demonstrated in this study.

Weight Shift Effectiveness

We observed the strongest impact of IPM feedback on the second survey item which queries confidence in knowing how far to move to effectively redistribute pressure. Because lack of sensation is a major PI risk factor in the SCI population, we could expect that awareness of pressure would improve with a surrogate visual feedback mechanism provided by sensors that measure pressure directly between the person and their seat cushion. By increasing awareness of pressure using IPM, the participants in our study reported significantly improved confidence about their ability to manage pressure through movement. Confidence decreased when the IPM feedback was removed during the in-home phase of this study, signaling that perhaps access to IPM feedback may need to be continuous or on-demand as a long-term compensatory strategy. While seat IPM has been criticized for limited effectiveness in predicting those at risk when used as an assessment from 1 clinical

assessment [24], it does not negate the potential value of IPM for prevention when used as real-time feedback provided directly to the end user [25].

Weight Shift Frequency and Duration

In total, 2 of the SE questions targeted the timing of weight shifts, and they appeared unaffected by introduction of IPM feedback which may be due to the lack of reminders or alarms in the system. Wheelchair users with SCI have been shown to not move as frequently as guidelines suggest, which could explain the lower confidence scores around these 2 specific items. If the questions were worded differently, to suggest confidence in adhering to their personal goals for frequency and duration of performing weight shifts, the response may have been different. Since concluding data collection in this study which used the initial prototype on-demand pressure mapping system, we have made new developments that include features desired by veterans who have SCI [26]. The updated system includes user-controlled settings for reminders and alerts which may prove to be more effective for improving confidence for these aspects of weight shift performance.

Future Research

Future research should explore the impact of IPM combined with reminders to perform weight shifts and alerts to high pressure on weight shift confidence and also subsequent impact on pressure management including weight shift behaviors when using the compensatory strategies. The simple 4-item scale used in this study that specifically addresses weight shift performance factors could be useful in clinical practice to determine where the wheelchair user feels least confident and then interventions could focus on that specific aspect of weight shifts when

discussing self-management strategies. Additionally, the current method of placing a pressure mat on top of a wheelchair cushion has known negative effects including sliding, challenges with postural stability, and moisture-wicking; hence, future research will explore alternative methods to capture pressure data with sensors that can overcome the issues related to placing a mat in the interface between the user and the cushion.

Limitations

Due to lack of access to participant level app interaction, we do not know how often the participants accessed the pressure map feedback in the home. Further, we did not incorporate self-reported use of the system into our analysis. The weight shift protocol performed used a qualitative approach to guide participants. Our sample size was less than 25, and heterogeneous which reduced our ability to consider covariates such as level of injury or prior experience with PI into the results. The results of this study serve to test whether visual on-demand pressure map feedback increases confidence toward pressure management; however, the results do not provide evidence toward the translation of high confidence into increased adherence to improved pressure management strategies.

Conclusions

Our results provide evidence that on-demand pressure map feedback, when used to guide weight shifts, has a positive impact on wheelchair user's confidence in performing effective weight shifts to reduce pressure. Additional exploration could consider how confidence levels respond to technologies that more specifically target weight shift timing. Clinical efficacy studies are recommended to explore how these technologies impact PI incidence over time.

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Data Availability

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

Conflicts of Interest

Authors TLVD and MMBM are inventors of the mPMAP used as an intervention in this study.

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Abbreviations

IPM: interface pressure mapping

mPMAP: mobile pressure mapping app

PI: pressure injury
SCI: spinal cord injury
SE: self-efficacy

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Original Paper

Clinicians' Experiences of Implementing a Telerehabilitation Toolkit During the COVID-19 Pandemic: Qualitative Descriptive Study

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Abstract

Background: Although the COVID-19 pandemic resulted in a rapid implementation and scale-up of telehealth for patients in need of rehabilitation, an overall slower scaling up to telerehabilitation has been documented.

Objective: The purpose of this study was to understand experiences of implementing telerehabilitation during the COVID-19 pandemic as well as using the Toronto Rehab Telerehab Toolkit from the perspective of rehabilitation professionals across Canada and internationally.

Methods: The study adopted a qualitative descriptive approach that consisted of telephone- or videoconference-supported interviews and focus groups. Participants included rehabilitation providers as well as health care leaders who had used the Toronto Rehab Telerehab Toolkit. Each participant took part in a semi-structured interview or focus group, lasting approximately 30-40 minutes. Thematic analysis was used to understand the barriers and enablers of providing telerehabilitation and implementing the Toronto Rehab Telerehab Toolkit. Three members of the research team independently analyzed a set of the same transcripts and met after each set to discuss their analysis.

Results: A total of 22 participants participated, and 7 interviews and 4 focus groups were included. The data of participants were collected from both Canadian (Alberta, New Brunswick, and Ontario) and international sites (Australia, Greece, and South Korea). A total of 11 sites were represented, 5 of which focused on neurological rehabilitation. Participants included health care providers (ie, physicians, occupational therapists, physical therapists, speech language pathologists, and social workers), managers and system leaders, as well as research and education professionals. Overall, 4 themes were identified including (1) implementation considerations for telerehabilitation, encompassing 2 subthemes of “infrastructure, equipment, and space” and “leadership and organizational support”; (2) innovations developed as a result of telerehabilitation; (3) the toolkit as a catalyst for implementing telerehabilitation; and (4) recommendations for improving the toolkit.

Conclusions: Findings from this qualitative study confirm some of the previously identified experiences with implementing telerehabilitation, but from the perspective of Canadian and international rehabilitation providers and leaders. These findings include the importance of adequate infrastructure, equipment, and space; the key role of organizational or leadership support in adopting telerehabilitation; and availing resources to implement it. Importantly, participants in our study described the toolkit as

an important resource to broker networking opportunities and highlighted the need to pivot to telerehabilitation, especially early in the pandemic. Findings from this study will be used to improve the next iteration of the toolkit (Toolkit 2.0) to promote safe, accessible, and effective telerehabilitation to those patients in need in the future.

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KEYWORDS

telerehabilitation; implementation; toolkit; COVID-19; qualitative; clinician

Introduction

Rehabilitation aims to enhance and restore functional ability, independence, and quality of life for those with physical, cognitive, and communication impairments or disabilities. Access to rehabilitation can be especially challenging for individuals with disabilities in rural communities as well as those who are less able to attend in-person therapy due to distance, transportation, financial resources, and mobility challenges [1-3]. Ongoing rehabilitation often requires therapy over many sessions, which can be challenging for maintaining continuity of care when travel to appointments is required [4]. Ensuring equitable access to rehabilitation services by identifying, targeting, and removing barriers faced by underserved and vulnerable populations has been recognized as a key component of a comprehensive rehabilitation system [5].

Telerehabilitation has been increasingly used as a means to address these challenges (ie, reducing the burden of travel time and related fatigue, improving access to care, and continuity of care) [6]. During the COVID-19 pandemic, telerehabilitation has been critical to providing ongoing care for those people living with impairments or disabilities [4]. Telerehabilitation is a branch of telemedicine that uses telecommunication technologies to deliver rehabilitation services synchronously or asynchronously to patients at a distance [7]. Specifically, telerehabilitation encompasses diagnosing, evaluating, and managing health care for persons with physical, cognitive, or social impairment and disability [7]. Telerehabilitation has been shown to be both feasible and effective in chronic heart failure and coronary artery disease [8], stroke [9], multiple sclerosis [10], and spinal cord injuries [11].

Although the COVID-19 pandemic resulted in a rapid implementation and scale-up of telehealth [12,13], for patients in need of rehabilitation, an overall slower scaling up to telerehabilitation has been documented [9]. This has brought to the forefront a need for rehabilitation researchers and clinicians to better understand how to deliver effective telerehabilitation services in ways that are safe to patients.

To address these challenges, our team developed the Toronto Rehab Telerehab Toolkit. The telerehabilitation implementation team at Toronto Rehab included practice leaders, program service managers, a researcher, and a physician, who were engaged throughout all phases of program development, implementation, and evaluation. The toolkit was then developed through consultation and co-development with health care providers, leaders, patients, and caregivers, with the aim of continuously evolving through user feedback and experience

as a telerehabilitation community. The goal of this toolkit was to provide a guiding framework to improve access to rehabilitation through telerehabilitation and to share our knowledge, insights, and lessons learned from the early phases of the pandemic. The toolkit contains resources and processes around 4 implementation domains: getting started, preparing patients and carers, implementing virtual rehab, and evaluation and monitoring [14]. Thus, the purpose of this study was to understand experiences of implementing telerehabilitation during the COVID-19 pandemic as well as using the Toronto Rehab Telerehab Toolkit from the perspective of rehabilitation professionals across Canada and internationally.

Methods

Study Design

This study adopted a qualitative descriptive approach that consisted of telephone- or web-based (ie, Microsoft Teams) interviews and focus groups. Previous research has demonstrated the viability of other videoconferencing platforms (ie, Zoom) for qualitative data collection because of its ease of use, cost-effectiveness, data management options, and security features [15]. A qualitative descriptive design is a well-accepted approach for studying topics about which little is known and providing practical solutions that are relevant to policy makers and health care practitioners [16,17]. Telephone- or web-based interviews and focus groups were selected because of the geographic dispersion of the study participants. We followed the Consolidated Criteria for Reporting Qualitative Research checklist [18] for the reporting of the study. This checklist promotes the reporting of the important components of a qualitative study, including the research team, methods, context, results, and interpretations.

Recruitment

Participants included rehabilitation providers (eg, physicians, occupational therapists, and physical therapists) as well as health care leaders who had provided telerehabilitation and implemented the Toronto Rehab Telerehab Toolkit. Participants were contacted by email about their willingness to participate in the interview and focus group if they first consented to being contacted for this purpose when they requested a copy of the toolkit. Purposive sampling (ie, maximum variation) [19] was used to ensure diversity in geography, type of rehabilitation center, and rehabilitation population. Participants were recruited between January and August 2021. Recruitment ceased when a discussion and review of the responses revealed that saturation had been achieved [20].

Data Collection

Each participant took part in a semistructured telephone- or web-based interview or focus group, lasting approximately 30-40 minutes. Members of the research team (SM and AA) conducted the interviews and focus groups. The interview and focus group guide consisted of semistructured, open-ended questions and was pilot-tested with 1 leader and 1 provider, and it was refined in response to feedback. Probes or recursive questioning were used to explore issues in greater depth and to verify understanding of the information being collected [19]. The probes were revised and refined as data collection progressed to establish saturation [19,21]. The complete list of questions is included in [Multimedia Appendix 1](#). No repeat focus groups or interviews were conducted; all were digitally recorded. The recordings were transcribed verbatim for data analysis by a professional transcriptionist. These transcripts were not returned to participants for comments or corrections. Field notes were made during or after the interviews and focus groups.

Data Analysis

Thematic analysis as described by Braun and Clark [22] was used to understand the barriers and enablers of providing telerehabilitation and implementing the Toronto Rehab Telerehab Toolkit. Three members of the research team (SM, AA, and MM) independently coded a set of the same transcripts and met after each set to discuss their codes. During these meetings, codes were discussed, and discrepancies were resolved until agreement of the coded transcripts was reached. After the first meeting, an initial codebook was established and applied to the new set of transcripts. The codebook was revised as themes were identified. SM is a scientist and has a PhD in Health Services Research as well as expertise in knowledge translation.

She has approximately 14 years of experience conducting qualitative research. AA is a physiotherapist with expertise in implementation science, patient experience, and neurological rehabilitation. She has 16 years of experience with qualitative methods and methodologies, including conducting interviews and focus groups. MM is a physiatrist (ie, MD) with expertise in stroke, brain injury, and rehabilitation research. Disagreements or discrepancies around codes, themes, and subthemes were resolved by a group discussion and reference to the original transcripts. The themes were not shared with participants due to feasibility considerations.

Ethical Considerations

This project was reviewed by the Quality Improvement Review Committee of University Health Network. The nature of the project was deemed as quality assurance or quality improvement, as defined in Tri-Council Policy Statement V.2, and the project was provided with a Research Ethics Board exemption.

Results

Description of Participants

A total of 22 participants participated, and 7 interviews and 4 focus groups were included. The data of participants from both Canadian (Alberta, New Brunswick, and Ontario) and international sites (Australia, Greece, and South Korea) were collected ([Table 1](#)). A total of 11 sites were represented ([Table 2](#)), 5 of which focused on neurological rehabilitation. Participants included health care providers (ie, physicians, occupational therapists, physical therapists, speech language pathologists, and social workers), managers and system leaders, as well as research and education professionals. There were no refusals to participate or dropouts.

Table 1. Description of participants by profession.

Participants by profession	Values, n (%)
Providers (occupational therapists, physical therapists, speech language pathologists, and social workers)	7 (31.8)
Physicians	3 (13.6)
Managers and leaders	6 (27.3)
System leaders	2 (9.1)
People with lived experiences	1 (4.5)
Research and education	3 (13.6)

Table 2. Description of type of rehab.

Type of rehab	Values, n (%)
Neurological	5 (45.5)
Cardiac	2 (18.2)
General	2 (18.2)
Private practice (neurological focus)	1 (9.1)
Long-term care	1 (9.1)

Overview of Themes

Overall, 4 themes were identified including (1) implementation considerations for telerehabilitation, encompassing 2 subthemes of “infrastructure, equipment, and space” and “leadership and organizational support”; (2) innovations developed as a result of telerehabilitation; (3) the toolkit as a catalyst for implementing telerehabilitation; and (4) recommendations for improving the toolkit. The implementation considerations subthemes could be considered barriers or facilitators to implementing telerehabilitation depending on their presence or absence. Some representative quotations were identified and selected from the transcripts to illustrate the themes.

Implementation Considerations for Telerehabilitation

Within the theme of implementation considerations, presence of adequate infrastructure, equipment, and space was described as a facilitator to implementing telerehabilitation. Participants emphasized the importance of extra computers; training for platforms, such as Zoom and Skype, to conduct virtual care; and technological support at their organizations. Some participant perspectives are as follows:

And it took them [providers] a while to figure that out. And I have to say that our teams were amazingly innovative and really reached out with as many people as possible to try and flex these programs like Zoom and Skype to the max. When they were using [virtual] breakout rooms, I have to say they are pretty resilient in trying to figure that out. So, it worked for some teams. [Site 1]

Well, we actually now are spending probably our first, like, our first class session is just basically, an introduction to Zoom. Some patients don't even have an email, so if they have an email, we can get them set up with an email, we tell them that's all you need,...an email link. But that first session is usually a challenge. [Site 2]

The prioritization of space for telerehabilitation was also seen as a facilitator to care, as the following quote represents:

They [providers] feel that the clinic room has enough space to be able to do that, but they need the equipment to be able to outfit it. So, we've put forward that we would like five multipurpose clinic rooms that will allow either in-person or virtual. [Site 1]

Conversely, participants also described a lack of infrastructure, equipment, and space as barriers to implementing telerehabilitation. Specifically, participants described patients' own lack of equipment or internet access as barriers to telerehabilitation and the difficulties of finding dedicated and appropriate space for virtual care. Below are some quotes illustrating this theme:

Some patients don't have a blood pressure machine, some patients just can't do it, some patients don't have the ability to figure out the Six-Minute Walk [Test]. There's a really nice...app, but if you don't have a cell phone,...It's hard for patients. [Site 2]

Not all of our patients have internet access, not all of our patients have devices, they don't have computer access, they just don't, and some of our patients aren't in the city setting, it's remote. [Site 2]

Leadership and organizational support was another subtheme of implementation considerations for telerehabilitation. Participants described its presence and absence as both a facilitator and barrier to implementing telerehabilitation, such as the following quotes:

So, our facility ramped up the access to equipment, expanded the use of our personal devices to be able to support virtual. [Site1]

Imagine that we have to find ourselves the personal computer or the camera to do these things. Sometimes, [clinician name] and I, we brought, ourselves, our own personal laptops to do this. We even had to persuade the [names a leadership role] of the hospital to allow us to do that. [Site 3]

Innovations Developed as a Result of Telerehabilitation

Participants also described innovations that resulted from implementing telerehabilitation during the pandemic. Some of these included interprofessional assessments (eg, performed by both an occupational therapist and a physical therapist), which were described as especially helpful for complex patients. Another site described the development of a virtual hospital. Finally, another participant described their site's heightened use of home pulse oximetry as a result of implementing telerehabilitation as one way for patients to track their outcomes at home.

Toolkit as a Catalyst for Implementing Telerehabilitation

Participants often described the toolkit as a device in and of itself to reach out to other clinicians about telerehabilitation (ie, establishing a community of practice), such as the following perspective: “I think it's a great engagement tool for planning when talking with clinicians” (Site 5). Participants also indicated that the toolkit was helpful to demonstrate the importance of telerehabilitation to their organizations, especially during the early stages of the pandemic. For example, at the onset of the pandemic, one site showed the toolkit to their leadership team and indicated “...look at what they are doing at Toronto Rehab. They are innovating next door. We need to do this” (Site 6). Participants at this same site indicated that the toolkit also provided them with credibility to continue rehabilitation during this early stage and view rehabilitation as an essential service.

Recommendations for the Toolkit

Lastly, participants also offered specific recommendations for improving the toolkit. These included adding practical content, such as diagrams, videos, tips of the week, and patient stories. Participants also suggested including specific information on how to conduct virtual assessments, how to address liability, and prompting sites to tailor the content of the toolkit to their own contextual needs.

Discussion

The purpose of this qualitative descriptive study was to understand experiences of implementing telerehabilitation during the COVID-19 pandemic as well as using the Toronto Rehab Telerehab Toolkit from the perspective of rehabilitation professionals across Canada and internationally.

Overall, 4 themes were identified including implementation considerations for telerehabilitation; innovations developed as a result of telerehabilitation; the toolkit as a catalyst for implementing telerehabilitation; and recommendations for improving the toolkit.

We identified 2 key implementation subthemes [23] for telerehabilitation, which were described as both barriers and facilitators. One subtheme was infrastructure, equipment, and space. This barrier has been previously reported on by both Negrini and colleagues [24] and Jafni [23], whereby limited technical resources, a dearth of devices, and slow internet bandwidth on the part of patients were identified as key barriers to telerehabilitation. Barriers with respect to infrastructure and equipment can be exacerbated by the potentially high levels of physical, emotional, and cognitive efforts needed to be engaged in telerehabilitation [22]. Indeed, participants in our study described some of the difficulties that older or more complex patients experience while participating in telerehabilitation and the critical and multidimensional roles that caregivers play in assisting in meaningful participation. Similarly, low expertise in using specific hardware or software on the part of health care providers has been previously identified as a barrier to telerehabilitation implementation [21]. In our study, participants indicated that a lack of technical expertise could be mitigated by dedicated IT support for the specific purpose of telerehabilitation and the necessary organizational leadership. Kreider and colleagues [4] also noted the crucial role of administrative support from rehabilitation management in terms extra and quiet rooms as well as computers and accessories needed to ensure patients' privacy during telerehabilitation sessions.

The critical role of organizational and leadership support was also reported in the study by Kreider and colleagues [4]. For example, in studying providers' shift to telerehabilitation at the US Veterans Health Administration during COVID-19, Kreider and colleagues [4] identified a "willingness to give telerehabilitation a chance" as a "key ingredient" to implementing telerehabilitation. The authors noted that across a variety of levels (ie, patient, provider, or leadership), this willingness, in addition to making adjustments and persisting with the use of available technologies, was essential to successfully transitioning to telerehabilitation services during the pandemic. Specifically, the authors described the importance of administrative support by medical leadership and rehabilitation managers to lead these efforts. In our study, some participants noted that the existence of the toolkit acted as a catalyst for implementing telerehabilitation in that it provided credence to characterizing rehabilitation as an essential service and implementing telerehabilitation, particularly early in the pandemic.

Participants in our study also described how innovations have been accelerated because of the use of telerehabilitation. The COVID-19 pandemic heightened the imperative for clinicians and researchers to better understand the practicalities of delivering telerehabilitation services in ways that are both safe and effective. The need for practical guidance in implementing telerehabilitation is indeed exemplified by the breadth of this practical guidance available through web-based sources [25-29]. As a result, we developed the Toronto Rehab Telerehab Toolkit, which provided this consolidated practical guidance, and as identified by our participants, brokered networking opportunities with other clinicians (locally, provincially, and nationally), leading to the establishment of a community of practice in some cases. Some study participants also described the increased use of remote technologies that were available because of telerehabilitation, including pulse oximetry. A systematic review of the effectiveness and safety of pulse oximetry in remote monitoring of patients with COVID-19 has supported its safety and usefulness for identifying the risk of deterioration and the need for advanced care [30].

Finally, participants provided a number of recommendations to improve the next version of the toolkit. These included very practical additions such as "tips of the week" for providers and using patient stories to share learnings and accelerate change. Participants also suggested including specific information on how to conduct virtual assessments and how to address concerns about potential liability. Similarly, Kreider and colleagues [4] described that providers had to change their approaches when conducting clinical assessments via telerehabilitation, including initially being challenged to find creative and innovative solutions to address the move from in-person, hands-on clinical assessment methods and measurement tools. Some participants detailed how they mitigated these challenges by shifting the assessment to a more functional focus with diligent clinical observation. Kreider and colleagues [4] also highlighted issues of patient safety with telerehabilitation and the critical role that family members played in ensuring safety during these remote sessions. The authors have used their own findings to develop a list of strategies and supports for telerehabilitation sessions during the chart review and scheduling, setting up or preparation, assessment and intervention planning, and during the session, as well as administrative supports. The specific, identified recommendations in this study will be incorporated into the next version of our toolkit.

We acknowledge some limitations in our study. We likely had a selection bias in terms of the participants who were interviewed in our study. Participants who had more positive experiences with telerehabilitation and the toolkit were more likely to participate. Similarly, only providers and health care leaders who had implemented the Toronto Rehab Telerehab Toolkit participated. Furthermore, none of the study participants were from rural rehabilitation sites. It is likely that providers at these sites would have had different experiences with telerehabilitation and the toolkit compared to clinicians from urban centers. At the same time, our study had a number of strengths in terms of demonstrating multiple aspects of trustworthiness including peer debriefing (credibility); a description of the study sample, although more detailed

information about our participants could have been obtained (transferability); independent review of the data to arrive at codes and themes (dependability); and decision trails between data and interpretation (confirmability) [31].

Findings from this qualitative study confirm some of the previously identified experiences with implementing telerehabilitation but from the perspective of Canadian and international rehabilitation providers and managers. These findings include 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 it. Importantly, participants in our study described the toolkit as an important resource to broker networking opportunities and highlight the need to pivot to telerehabilitation, especially early in the pandemic. Specific recommendations gleaned from this study will be used to improve the next iteration of the toolkit (Toolkit 2.0) to promote safe, accessible, and effective telerehabilitation to those patients in need into the future.

Acknowledgments

We would like to thank the rehabilitation providers and managers who participated in this study. The Toronto Rehab Telerehab Toolkit can be accessed at telerehabtoolkit.ca [32] and we acknowledge and thank all of our partners who contributed to it. All authors contributed to the work and provided final approval of the version submitted for publication and agree to be accountable for all aspects of the work as presented. No funding was received for this study.

Data Availability

The data sets generated or analyzed during this study are not publicly available, as this was not outlined in the quality improvement application, but they are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of questions.

[[PDF File \(Adobe PDF File\), 169 KB - rehab_v10i1e44591_app1.pdf](#)]

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Original Paper

Efficacy and Safety of Home-Based Cardiac Telemonitoring Rehabilitation in Patients After Transcatheter Aortic Valve Implantation: Single-Center Usability and Feasibility Study

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Abstract

Background: No consensus exists on the efficacy of home-based cardiac rehabilitation (CR) in patients who have undergone transcatheter aortic valve implantation (TAVI). Additionally, there are no reports on home-based cardiac telemonitoring rehabilitation (HBTR) in patients after TAVI.

Objective: We aimed to investigate the efficacy of HBTR in patients who have undergone TAVI.

Methods: This single-center preliminary study introduced HBTR to patients after TAVI, and the efficacy outcomes of the rehabilitation method were compared to that of a historical control cohort. The historical control cohort (control group) consisted of 6 consecutive patients who underwent ordinary outpatient CR after TAVI from February 2016 to March 2020. Patients who participated in the HBTR program were only recruited after the TAVI procedure and before discharge between April 2021 and May 2022. In the first 2 weeks after TAVI, patients underwent outpatient CR and were trained using telemonitoring rehabilitation systems. Thereafter, patients underwent HBTR twice a week for 12 weeks. The control group performed standard outpatient CR at least once a week for 12 to 16 weeks. Efficacy was assessed using peak oxygen uptake (VO_2) prior to and after CR.

Results: Eleven patients were included in the HBTR group. All patients underwent 24 HBTR sessions during the 12-week training period, and no adverse events were observed. The control group participants performed 19 (SD 7) sessions during the training period, and no adverse events were observed. Participants in the HBTR and control groups had a mean age of 80.4 (SD 6.0) years and 79.0 (SD 3.9) years, respectively. In the HBTR group, preintervention and postintervention peak VO_2 values were 12.0 (SD 1.7) mL/min/kg and 14.3 (SD 2.7) mL/min/kg ($P=.03$), respectively. The peak VO_2 changes in the HBTR and control groups were 2.4 (SD 1.4) mL/min/kg and 1.3 (SD 5.0) mL/min/kg ($P=.64$), respectively.

Conclusions: Home-based CR using a telemonitoring system is a safe outpatient rehabilitation method. Its efficacy is not inferior to that of standard CR in patients who have undergone TAVI.

Trial Registration: Japan Registry of Clinical Trials jRCTs032200122; <https://jrct.niph.go.jp/latest-detail/jRCTs032200122>

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KEYWORDS

transcatheter aortic valve implantation; telerehabilitation; cardiac rehabilitation; remote; telemonitoring

Introduction

Transcatheter aortic valve implantation (TAVI) was developed as a new catheter-based treatment for severe aortic valve stenosis. TAVI is a less invasive treatment; however, since majority of the patients who undergo TAVI are geriatric, reports have suggested that approximately half of all patients with intermediate risk who undergo TAVI are at risk of death or disability due to stroke within 5 years [1]. These adverse events after TAVI are associated with preoperative and perioperative physical dysfunction [2,3]. Postoperative cardiac rehabilitation (CR) is therefore crucial. Studies have indicated that post-TAVI CR improves exercise tolerance and reduces mortality [4,5]. However, the percentage of cardiac patients participating in outpatient CR is less than 10% in Japan, which poses a serious problem [6,7]. The low availability of practical and social support is likely related to the low participation rates [8,9]. Additionally, the lower number of patients undergoing TAVI owing to older age and a decline in their physical condition may have contributed to the low percentage of participation. Indeed, only 6 (2%) patients participated in outpatient CR at St. Marianna University Hospital among 390 patients who underwent TAVI.

In light of these considerations, home-based cardiac telemonitoring rehabilitation (HBTR) is considered a practical method for increasing participation in outpatient rehabilitation. HBTR is considered effective as a commute-less rehabilitation, and with this approach, the participation rate can possibly be increased. Some studies have reported HBTR in patients after

TAVI [10-13]. One of these studies revealed the safety of HBTR in patients who have undergone TAVI [10]; however, no consensus has been reached regarding its efficacy, and all these studies were only performed using mobile apps or wearable devices. Therefore, the effectiveness of HBTR, and the safety and feasibility of HBTR in patients who have undergone TAVI remain unknown.

This study hypothesizes that HBTR is a feasible, safe, and effective approach to perform telemonitoring with appropriate support in patients who have undergone TAVI, and aims to investigate the efficacy of HBTR in patients who have undergone TAVI.

Methods

Study Design and Participants

This was a single-center preliminary study that introduced an HBTR program to patients after TAVI, with a historical control cohort. From April 2021 to May 2022, patients who underwent TAVI for aortic valve stenosis at St. Marianna University Hospital were recruited to participate in an HBTR program (HBTR group) in this study. Patients who participated in the HBTR program were only recruited after undergoing the TAVI procedure and before discharge according to the inclusion and exclusion criteria (Textbox 1).

The historical control cohort (control group) consisted of all 6 patients who underwent standard outpatient CR at the same institution out of 390 patients who underwent TAVI between February 2016 and March 2020.

Textbox 1. Inclusion and exclusion criteria.**Inclusion criteria**

1. Underwent transcatheter aortic valve implantation (TAVI) and started cardiac rehabilitation (CR) during hospitalization.
2. Provided written informed consent.
3. Aged over 20 years.
4. Can be accompanied by an attendant when remote CR is performed.

Exclusion criteria

1. New York Heart Association (NYHA) class 4.
2. Cerebral infarction after TAVI.
3. Myocardial infarction within 1 month of treatment.
4. Unknown or untreated syncope or cardiac arrest.
5. History of operation for implantable cardioverter defibrillator/cardiac resynchronization therapy-defibrillator, or cardiopulmonary arrest within the last 6 months.
6. Unstable angina pectoris.
7. Severe adverse events during hospitalized CR.
8. Severe renal dysfunction (estimate glomerular filtration rate <15 mL/min/1.73 m²).
9. Severe liver dysfunction.
10. Difficulty understanding the system of remote CR.
11. No internet connection at home.
12. Already participated in other clinical trials.
13. Cannot understand the contents of this trial due to dementia or other psychiatric diseases.
14. Participation deemed inappropriate by the research director.

TAVI Procedure

Indications for TAVI were determined based on current recommendations [14]. An interdisciplinary heart team, including cardiothoracic surgeons, anesthesiologists, interventional cardiologists, and echocardiography cardiologists, selected the valve type and decided upon other procedural strategies. TAVI was performed in a hybrid operating room under general anesthesia. As part of general care, all patients underwent standardized inpatient CR after TAVI.

Ethics Approval

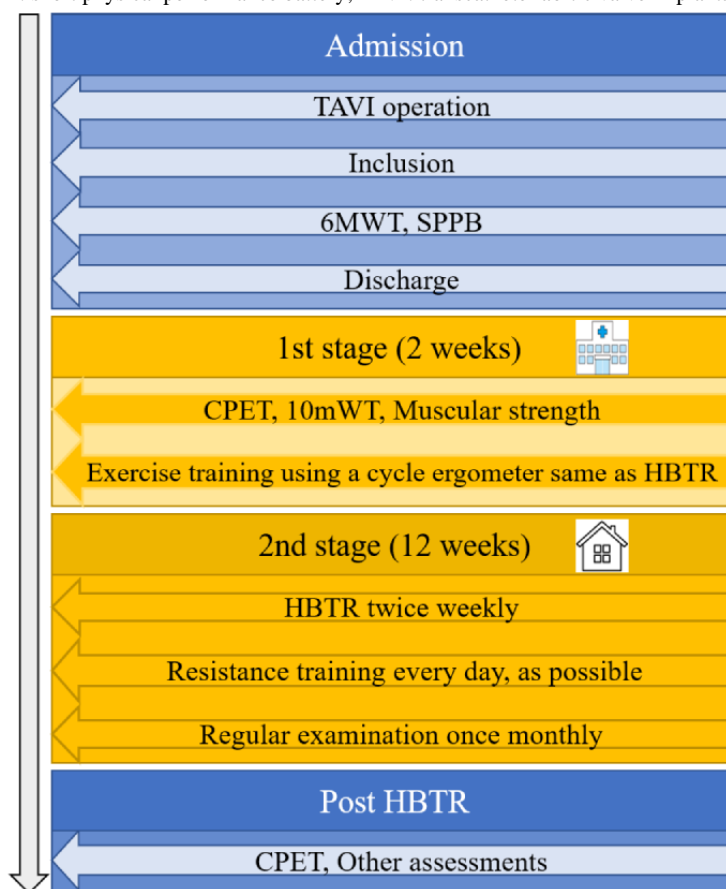
Written informed consent for publication of their details was obtained from the study participants. This study was performed in accordance with the ethical principles of the Declaration of Helsinki. This study was also approved by the Clinical Research Ethics Committee of St. Marianna University School of Medicine (study protocol number: SMU0124), and the study was registered with the Japan Registry of Clinical Trials (JRCTs032200122) on September 14, 2020. Additionally, an

independent data safety monitoring board reviewed the patient data.

Cardiopulmonary Exercise Test

For the preintervention and postintervention physical assessments, symptom-limited cardiopulmonary exercise tests (CPETs) were performed to determine peak oxygen uptake (VO₂), anaerobic threshold (AT), and carbon dioxide production efficiency derived from the linear relationship between minute ventilation (VE) and carbon dioxide output (VCO₂) (VE vs VCO₂ slope) using a cycle ergometer (SE-8; Mitsubishi Electric Engineering Co, Ltd) and a breath-by-breath gas analyzer (Inter Reha Co, Ltd). The exercise protocol for the cycle ergometer involved a 0-W warm-up and 10-W/min ramping. The preinterventional CPET was performed when starting the first stage of the rehabilitation program, and the postinterventional CPET was performed within 2 weeks after the final session of HBTR (Figure 1). In the control group, the preinterventional CPET was performed within 2 weeks after discharge and the postinterventional CPET was performed within 2 weeks after the final session of outpatient rehabilitation.

Figure 1. Timeline of the intervention in the HBTR group. Patients were recruited and included after the TAVI procedure. In the first stage, for 2 weeks, the CPET, 10mWT, and muscular strength were simultaneously assessed. After these assessments, the participants practiced with the cycle ergometer and telemonitoring system, which were the same as those in HBTR, in the hospital. In the second 12-week stage, the participants performed HBTR twice weekly. At the end of the second 12-week stage, the CPET, 6MWT, SPPB, 10mWT, and muscular strength were assessed within 2 weeks after the last HBTR session. 6MWT: 6-minute walk test; 10mWT: 10-m walk test; CPET: cardiopulmonary exercise test; HBTR: home-based cardiac telemonitoring rehabilitation; SPPB: short physical performance battery; TAVI: transcatheter aortic valve implantation.



Physical Assessment

The 6-minute walk test (6MWT) and short physical performance battery (SPPB), which is composed of a composite of 4-meter walking velocity, time taken to rise from a seated position 5 times, and standing balance, were performed immediately before discharge and within 2 weeks after the last session of HBTR. The 10-meter walk test (10mWT) and muscular strength were examined on the same day as the CPET. The 10mWT was performed in 2 different ways. Initially, the participant walked at a comfortable speed, and the second time, the participant walked as quickly as possible. This test assessed the participant's gait speed (m/s). Muscular strength was assessed by measuring hand grip strength (HGS) and quadriceps isometric strength (QIS). The HGS was measured using a grip meter (JAMAR; Bissell Healthcare Co). The QIS was measured using a digital handheld dynamometer (μ -Tas; ANIMA). The HGS and QIS values were defined as the average values of the left and right limbs. In the control group, the SPPB and 10mWT were performed just before discharge from the hospital and within 2 weeks after the final session of outpatient rehabilitation. Muscular strength was measured on the same day as the CPET. However, the 6MWT was not performed in the control group.

Intervention

The intervention participants underwent a 14-week hybrid CR program consisting of 2 stages in the HBTR group. In the 2 weeks of the first stage, a baseline clinical examination was performed, and patients were educated as part of a comprehensive program. The participants also practiced on a cycle ergometer (ai-ex; Konami Sports & Life Co, Ltd). Simultaneously, they were familiarized with the telemonitoring system (Heart-Line; Nipro Co, Ltd), which was the same as that used in HBTR. The participants were trained to become accustomed to these technologies at least twice during the first stage. After the first stage, a cycle ergometer and a tablet PC (iPad; Apple Co, Ltd) were delivered by a mechanical supervisor within 2 weeks. During this period, participants performed standard outpatient rehabilitation 1 to 2 times a week.

In the second 12-week stage, participants in the HBTR group performed HBTR twice weekly. These participants performed aerobic training using the cycle ergometer. The target intensity was based on the AT from the CPET at the start of the second stage. Before starting the exercise, medical staff had video calls with participants. The medical staff assessed the participants' physical state, and the participants began the exercise thereafter. The video call was maintained throughout the exercise session, and the medical staff checked the electrocardiogram (ECG) via the internet. The exercise duration was initially at 15 minutes

and was gradually increased to 30 minutes within the first 2 weeks. The exercise load was arranged according to the participant’s perceived exertion (ie, a score of 11-13 on the Borg scale).

Additionally, participants were instructed to perform 3 sets of 10 repetitions of resistance training (standing calf raises and sit-to-stand exercises) every day. The medical staff checked whether the participants were able to perform the resistance training every day during every video call.

In contrast, the control group performed standard outpatient CR once to twice a week for 12 to 16 weeks after TAVI. CR consisted of aerobic exercise using a cycle ergometer and treadmill ergometer, and mild-to-moderate resistance training. The intensity of aerobic exercise was based on the AT from the CPET at the start of outpatient CR. The exercise time was half an hour to 1 hour per session. In addition to the usual outpatient CR, the control group participants were also instructed to perform 3 sets of 10 repetitions of resistance training (standing calf raises and sit-to-stand exercises) every day.

During the rehabilitation term, patients in both groups were examined in the hospital once a month.

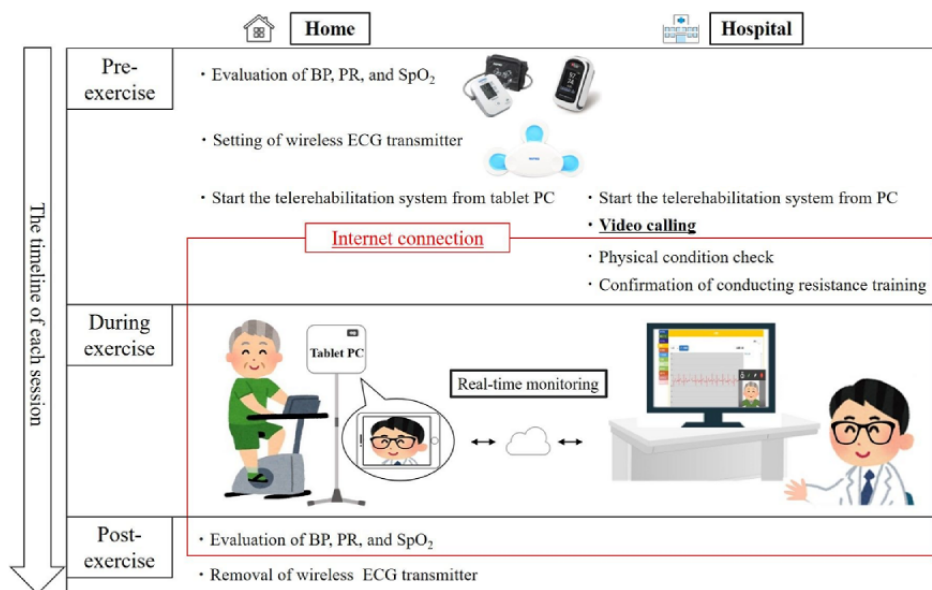
Telemonitoring Rehabilitation Equipment and Management

For the exercise training, all participants used the same type of cycle ergometer. Before and after each exercise session, each

participant measured their blood pressure, pulse rate, and percutaneous oxygen saturation (SpO₂) using a blood pressure manometer (NBP-1BLE; Nipro Co, Ltd) and a pulse oximeter (MightySat; Nipro Co, Ltd) (Figure 2). Before starting each aerobic exercise session, the participants put on a wireless ECG transmitter (Cocolon; Nipro Co, Ltd) and opened the telemonitoring app from the tablet PC. To simplify this task, the tablet setup only allowed the patients to use the telemonitoring app. At the start of the aerobic exercise session, video calling was performed by rehabilitation medical staff at the hospital using a telemonitoring app system. During exercise training, video and ECG monitoring were continued using the telemonitoring app system. This monitoring system was encrypted using a secure socket layer.

In this study, all participants were required to be accompanied by an attendant at each exercise session in anticipation of adverse events. During the first 2 to 4 exercise sessions, the mechanical supervisor assisted with the operation of each piece of equipment. At the time of each exercise session, if the participant could not connect to the telemonitoring app system, the session was moved to another day, and the medical staff or mechanical supervisor assisted with the connection until the next session.

Figure 2. HBTR session timeline. Before each exercise session, the participants’ BP, PR, and SpO₂ were evaluated. Soon after, a wireless ECG transmitter was placed on the left precordial side of the chest, and a telerehabilitation app on a tablet PC was initiated. Thereafter, all participants waited for video calls from the medical staff. The medical staff started video calling after launching the telerehabilitation app. During the video call, the medical staff evaluated the participants’ physical conditions and confirmed the implementation status of resistance training. Subsequently, the participants began the exercise. During the exercise, the medical staff continued to check the participants and monitor their ECG data. After the exercise, the participants re-evaluated their BP, PR, and SpO₂. The video call was ended after the medical staff confirmed these parameters. The participants then removed their wireless ECG transmitters. BP: blood pressure; ECG: electrocardiogram; PR: pulse rate; SpO₂: percutaneous oxygen saturation.



Other Measurements

We examined patient baseline characteristics and the Society of Thoracic Surgeons (STS) risk scores for predicting the risk of mortality [15,16]; used the Mini Nutritional Assessment-Short Form (MNA-SF) for assessing preoperative nutritional status

[17]; and assessed procedural outcomes, duration of postoperative hospitalization, laboratory data, and medication. Laboratory data were assessed just before discharge from the hospital and on the same day as the postinterventional assessment. Medication was assessed at the time of discharge.

The Katz index was used to assess and record basic activities of daily living and functional status, which were evaluated at discharge from the hospital [18]. Information concerning the success of the implanted device was obtained from the Valve Academic Research Consortium-2 criteria [19]. Early safety was evaluated 30 days post-TAVI by assessing the procedural outcomes of all-cause death, stroke (disabling and nondisabling), life-threatening bleeding, acute kidney injury (risk, injury, failure, loss, and end-stage kidney disease [stage 2 or 3, or renal replacement therapy]), coronary artery obstruction requiring intervention, major vascular complications, and pacemaker implantation after TAVI. The duration of postoperative hospitalization was defined as the time from operation to discharge. Laboratory data were evaluated at the first session of the first stage, and medication was evaluated at discharge.

Endpoint

The primary endpoint was the change in peak VO₂ between the initial and final CPET. The secondary endpoints were the changes in AT, 6MWT, grip strength, and isometric knee extension force. Additionally, during the 12-week rehabilitation, the safety of HBTR was evaluated by assessing adverse events during exercise training.

Statistical Analysis

Baseline characteristics, physical assessments, and CPET data between preintervention and postintervention were compared in the HBTR group. Additionally, changes in preintervention and postintervention values were compared between the HBTR and control groups.

Continuous variables have been expressed as mean (SD), and categorical variables have been expressed as numbers and percentages. The normality of distribution for continuous

variables was evaluated using the Shapiro-Wilk test. The Mann-Whitney *U* test was used to analyze quantitative variables, and the Fisher exact test was used for qualitative variables. Statistical significance was set at a 2-sided *P*-value <.05. All analyses were performed using JMP Pro version 15 (SAS Institute).

Results

Patient Characteristics

In the HBTR group, 176 patients underwent TAVI. Of these, 164 patients met the exclusion criteria or failed to meet the inclusion criteria. Of the 12 patients who met the inclusion criteria, 11 patients completed the first 2-week stage; 1 patient did not undergo HBTR due to worsening heart failure before starting stage 1 CR (Figure 3).

In the control group, all 6 patients met all the inclusion criteria except criterion number 4 and they did not meet criteria numbers 1 to 10 and 12 to 14 of the exclusion criteria (Textbox 1). The control group participants performed 19 (SD 7) sessions during the training period.

With regard to the second 12-week stage, there were 8 occasions where the exercise session was prolonged because of internet connection errors; however, all 11 patients underwent 24 HBTR sessions. Patient demographics and clinical characteristics at baseline are shown in Table 1. The mean patient age was 80.4 (SD 6.0) years and 79.0 (SD 3.9) years in the HBTR and control groups, respectively. Three participants out of 11 in the HBTR group and 3 out of 6 in the control group had an MNA-SF score of less than 12 points. There were no significant differences in patient characteristics between the HBTR and control groups.

Figure 3. Study flowchart of the HBTR group. CR: cardiac rehabilitation; CRT-D: cardiac resynchronization therapy-defibrillator; HBTR: home-based cardiac telemonitoring rehabilitation; ICD: implantable cardioverter defibrillator; TAVI: transcatheter aortic valve implantation.

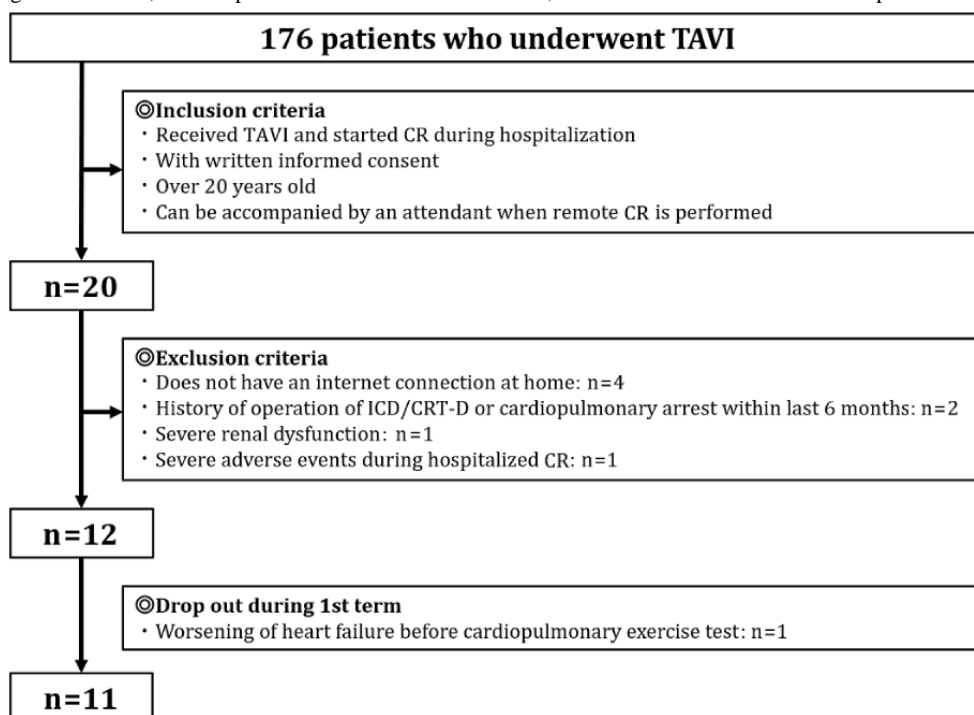


Table 1. Baseline patient characteristics.

Characteristic	HBTR ^a group (n=11)	Control group (n=6)	P value ^b
Age (years), mean (SD)	80.4 (6.0)	79.0 (3.9)	.34
Male gender, n (%)	6 (55)	3 (50)	.87
BMI (kg/m ²), mean (SD)	26.1 (4.6)	23.7 (3.1)	.21
NYHA^c, n (%)			.49
I	9 (82)	4 (67)	
II	2 (18)	2 (33)	
III	0 (0)	0 (0)	
Duration of postoperative hospitalization, mean (SD)	6.2 (1.7)	7.7 (2.1)	.17
Hypertension, n (%)	10 (91)	5 (6)	.65
Dyslipidemia, n (%)	9 (82)	6 (100)	.09
Diabetes mellitus, n (%)	6 (55)	2 (33)	.40
COPD ^d , n (%)	2 (19)	2 (33)	.49
Previous pacemaker implantation, n (%)	1 (9)	1 (17)	.65
Atrial fibrillation, n (%)	5 (45)	1 (17)	.22
Previous cerebral infarction, n (%)	2 (19)	0 (0)	.17
Previous PCI ^e or CABG ^f , n (%)	1 (9)	1 (17)	.22
Peripheral artery disease, n (%)	1 (9)	2 (33)	.07
Prior open cardiac surgery, n (%)	1 (9)	1 (17)	.65
Preoperative STS ^g score (mortality), mean (SD)	3.6 (1.7)	4.1 (1.9)	.56
Katz index, mean (SD)	6.0 (0.0)	6.0 (0.0)	>.99
MNA-SF ^h , mean (SD)	11.5 (0.8)	12.7 (1.2)	.32
Hemoglobin level (g/dL), mean (SD)	11.2 (1.3)	12.4 (1.2)	.35
Albumin level (g/dL), mean (SD)	4.0 (0.3)	4.1 (0.2)	.69
eGFR ⁱ (mL/min/1.73 m ²), mean (SD)	53.2 (19.3)	51.4 (10.5)	.81
NT-proBNP ^j (pg/mL), mean (SD)	852.5 (710.2)	500.0 (282.3)	.17
LVEF ^k (%), mean (SD)	60.9 (4.2)	66.3 (5.1)	.05
Aortic valve area (cm ²), mean (SD)	1.63 (0.26)	1.51 (0.47)	.57
Mean pressure gradient (mmHg), mean (SD)	10.1 (3.1)	13.2 (2.6)	.08
Transfemoral approach, n (%)	11 (100)	6 (100)	>.99
Device success, n (%)	10 (91)	6 (100)	.34
Early safety at 30 days, n (%)	10 (91)	6 (100)	.34
Medication, n (%)			
β-blocker	4 (36)	4 (67)	.56
ACE-I ^l /ARB ^m	8 (73)	4 (67)	.82
Calcium channel blocker	5 (45)	4 (67)	.44
Loop diuretics	4 (36)	1 (17)	.40
Aspirin/clopidogrel	5 (45)	5 (83)	.12
Warfarin	1 (9)	0 (0)	.34
Direct oral anticoagulants	5 (45)	1 (17)	.23
Statins	9 (82)	6 (100)	.17

^aHBTR: home-based cardiac telemonitoring rehabilitation.

^bThe Mann-Whitney *U* test was used to analyze quantitative variables, and the Fisher exact test was used for qualitative variables.

^cNYHA: New York Heart Association.

^dCOPD: chronic obstructive pulmonary disease.

^ePCI: percutaneous coronary intervention.

^fCABG: coronary artery bypass grafting.

^gSTS: Society of Thoracic Surgeons.

^hMNA-SF: Mini Nutritional Assessment-Short Form.

ⁱeGFR: estimated glomerular filtration rate.

^jNT-proBNP: N-terminal pro-B natriuretic peptide.

^kLVEF: left ventricular ejection fraction.

^lACE-I: angiotensin-converting enzyme inhibitor.

^mARB: angiotensin-receptor blocker.

Efficacy of Cardiac Telerehabilitation

The preintervention and postintervention physical assessment outcomes in the HBTR group showed that the postinterventional peak VO₂ and 6MWT values were significantly greater than the preinterventional values (mean 14.3, SD 2.7 mL/min/kg vs

mean 12.0, SD 1.7 mL/min/kg; $P=.03$; and mean 345.0, SD 109.7 m vs mean 267.0, SD 72.0 m; $P=.04$, respectively; [Table 2](#)). Regarding other parameters, there were no significant changes between the preintervention and postintervention assessments.

Table 2. Changes in physical assessment outcomes in the study groups.

Characteristic	HBTR ^a group, mean (SD)			Control group, mean (SD)			<i>P</i> value ^b for peri-interventional difference in the HBTR group	<i>P</i> value ^b for change between the 2 groups
	Baseline	After intervention	Change	Baseline	After intervention	Change		
Peak VO ₂ ^c (mL/min/kg)	12.0 (1.7)	14.3 (2.7)	2.4 (1.4)	13.2 (1.6)	14.5 (5.2)	1.3 (5.0)	.03	.64
6-minute walk test (m)	267.0 (72.0)	345.0 (109.7)	78.0 (83.5)	N/A ^d	N/A	N/A	.04	N/A
AT ^e (mL/min/kg)	8.7 (1.3)	9.6 (1.4)	0.9 (1.1)	9.2 (1.4)	9.9 (1.4)	0.6 (1.9)	.15	.61
VE ^f vs VCO ₂ ^g slope	33.0 (6.4)	30.4 (4.2)	-2.6 (4.5)	32.5 (6.9)	28.8 (8.2)	-3.7 (4.0)	.48	.63
Peak work rate (watt)	54.3 (11.7)	62.7 (13.5)	8.5 (7.1)	60.0 (12.2)	64.2 (10.6)	4.2 (13.1)	.87	.48
Peak RER ^h	1.17 (0.13)	1.16 (0.11)	0.01 (0.14)	1.11 (0.11)	1.17 (0.07)	0.06 (0.15)	.33	.35
Hand grip strength (kg)	20.0 (7.5)	20.7 (7.1)	0.7 (2.2)	23.9 (3.2)	25.7 (5.3)	1.8 (2.6)	.82	.34
Quadriceps isometric strength (kg)	24.7 (7.8)	26.0 (7.0)	1.3 (3.5)	23.6 (5.0)	25.7 (7.2)	2.1 (3.0)	.69	.35
SPPBⁱ (points)	10.4 (12.2)	11.1 (1.6)	0.7 (1.4)	11.6 (0.5)	11.7 (0.5)	0.2 (0.4)	.31	.25
Balance	3.8 (0.4)	3.9 (0.3)	0.1 (0.3)	4.0 (0.0)	4.0 (0.0)	0.0 (0.0)	.56	.34
Gait speed	3.3 (0.8)	3.7 (0.6)	0.5 (0.8)	4.0 (0.0)	4.0 (0.0)	0.0 (0.0)	.15	.10
Chair stand	3.3 (1.1)	3.5 (1.2)	0.2 (0.8)	3.5 (0.5)	3.7 (0.5)	0.2 (0.4)	.72	.96
10-meter walk speed (m/s)								
Comfortable	0.9 (0.2)	1.0 (0.2)	0.1 (0.2)	1.1 (0.1)	1.1 (0.1)	0.0 (0.2)	.32	.32
Fastest	1.2 (0.3)	1.3 (0.3)	0.1 (0.2)	1.4 (0.2)	1.4 (0.1)	0.0 (0.1)	.51	.43

^aHBTR: home-based cardiac telemonitoring rehabilitation.

^bThe Mann-Whitney *U* test was used to analyze quantitative variables.

^cVO₂: oxygen uptake.

^dN/A: not applicable.

^eAT: anaerobic threshold.

^fVE: minute ventilation.

^gVCO₂: carbon dioxide output.

^hRER: respiratory exchange ratio.

ⁱSPPB: short physical performance battery.

Change Values in the HBTR and Control Groups

The comparison of change values between the HBTR and control groups is shown in Table 2. The peak VO₂ change values were 2.4 (SD 1.4) mL/min/kg and 1.3 (SD 5.0) mL/min/kg in the HBTR and control groups, respectively (*P*=.64). There were no significant differences in any of the variables between the 2 groups.

Safety

No adverse events were observed in the HBTR and control groups.

Discussion

Principal Findings

This study investigated the efficacy and safety of an HBTR program involving the use of a cycle ergometer in patients after TAVI, with a historical cohort. In this study, all patients in the HBTR group completed all exercise sessions twice a week, and no adverse events were reported. HBTR was significantly effective in improving exercise tolerance after TAVI. Additionally, the efficacy of HBTR was comparable to that of standard outpatient CR.

Effectiveness of CR for Patients After TAVI

In this study, our analysis showed similar changes in exercise tolerance, assessed by peak VO₂, between the HBTR and control

groups. In the HBTR group, although the peak VO_2 and 6MWT values significantly improved, no significant difference in the change in muscle strength was observed. A previous study suggested that cardiac telerehabilitation improves lower muscle strength [20]. In contrast, our study participants were older than those in the previous study, and the previous study did not include patients who underwent TAVI, but instead included those with heart failure. Furthermore, the exercise frequency in our study was lower than that reported in the previous study [20]. These factors may have affected our results as aging is one of the main factors affecting skeletal muscle loss [21].

Another previous study that included patients who underwent TAVI showed that standard CR improves exercise tolerance, as assessed by the 6MWT [22]. Compared to the aforementioned study, the exercise frequency in this study was lower and our program duration was longer, yet we observed a similar effect (12 weeks of exercise did improve exercise tolerance).

Telemonitoring Rehabilitation for Patients After TAVI

The low ratio of outpatient CR participants in Japan is related to low practical and social support [8,9]. One reason for this is associated with physical function; a decline in the physical function of a patient requires more support to visit a hospital. Most of the patients who underwent TAVI were geriatric, and our previous study showed that about two-thirds of patients who underwent TAVI were categorized as having physical prefrailty or frailty [23]. Therefore, patients who undergo TAVI are more likely to encounter difficulties in visiting a hospital unassisted. Thus, HBTR may be a solution for these types of patients.

Adapting HBTR for general use and preventing internet connection errors are the most important areas of this mode of rehabilitation. Internet connection errors usually occur due to slow connection speed or operation errors. With regard to connection, connecting to the telerehabilitation system entailed the use of video calling and also ECG monitoring. Therefore, to reduce the internet load, we did not conduct digital monitoring of blood pressure, pulse rate, and SpO_2 . With respect to operation errors, the average age of the participants in this study was 80 years, and low information technology literacy was assumed. Therefore, to reduce the risk of failing to complete the program, the presence of an attendant was required. We

were able to finally complete full sessions of HBTR because of the attendants assisting the participants.

Clinical and Research Scope of the Study in the Future

The HBTR program in this study mainly involved exercise therapy and patient education. We did not provide nutritional or dietary support. To achieve comprehensive CR, nutritional or dietary support is important in addition to exercise therapy and patient education. Low food intake is one of the main reasons for frailty, and steeper declines in food intake have been reported among even older adults [24]. Because of this, malnutrition is a prognostic factor in patients undergoing TAVI [23]. Therefore, we should have provided more nutritional or dietary support to the participants.

Future studies should include programs of exercise therapy combined with nutritional or dietary support for patients who are undergoing TAVI in larger and more diverse cohorts.

Limitations

This study has several limitations. First, this was a single-center nonrandomized study with a small number of patients; thus, the possibility of type 1 error in the results of this study cannot be denied, and the generalizability of our findings is limited. Second, there may have been selection bias as the inclusion criteria of this study were limited by the needs of the participants to be supported by an attendant and to have an internet network; thus, patients with social and environmental vulnerabilities may have been excluded. Third, there may have been some information bias. In this study, daily activity could not be evaluated; we could therefore not exclude the possibility that daily activity affected the results. In addition, in the HBTR sessions, we could not monitor the cycle ergometer. Therefore, we could not confirm whether the patients had adjusted the device to the correct intensity.

Conclusions

Our study results demonstrate that HBTR is effective in improving exercise tolerance and can be safely performed in patients who have undergone TAVI. However, this study had a small sample size; therefore, a further investigation is required to establish an optimal assessment of HBTR in this group of patients.

Acknowledgments

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Data Availability

The deidentified participant data will not be shared.

Authors' Contributions

All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by KA and SD. The first draft of the manuscript was written by KA, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

MI is a clinical proctor of Edwards Lifesciences. SK is a training proctor of Abbott Medical Japan. The other authors have no conflicts of interest to declare.

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Abbreviations

- 6MWT:** 6-minute walk test
10mWT: 10-meter walk test
AT: anaerobic threshold
CPET: cardiopulmonary exercise test
CR: cardiac rehabilitation
ECG: electrocardiogram
HBTR: home-based cardiac telemonitoring rehabilitation
HGS: hand grip strength
MNA-SF: Mini Nutritional Assessment-Short Form
QIS: quadriceps isometric strength
SpO₂: percutaneous oxygen saturation
SPPB: short physical performance battery
TAVI: transcatheter aortic valve implantation
VCO₂: carbon dioxide output
VE: minute ventilation
VO₂: oxygen uptake

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Original Paper

Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study

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Abstract

Background: Aging is closely associated with an increased prevalence of musculoskeletal conditions. Digital musculoskeletal care interventions emerged to deliver timely and proper rehabilitation; however, older adults frequently face specific barriers and concerns with digital care programs (DCPs).

Objective: This study aims to investigate whether known barriers and concerns of older adults impacted their participation in or engagement with a DCP or the observed clinical outcomes in comparison with younger individuals.

Methods: We conducted a secondary analysis of a single-arm investigation assessing the recovery of patients with musculoskeletal conditions following a DCP for up to 12 weeks. Patients were categorized according to age: ≤ 44 years old (young adults), 45-64 years old (middle-aged adults), and ≥ 65 years old (older adults). DCP access and engagement were evaluated by assessing starting proportions, completion rates, ability to perform exercises autonomously, assistance requests, communication with their physical therapist, and program satisfaction. Clinical outcomes included change between baseline and program end for pain (including response rate to a minimal clinically important difference of 30%), analgesic usage, mental health, work productivity, and non-work-related activity impairment.

Results: Of 16,229 patients, 12,082 started the program: 38.3% (n=4629) were young adults, 55.7% (n=6726) were middle-aged adults, and 6% (n=727) were older adults. Older patients were more likely to start the intervention and to complete the program compared to young adults (odds ratio [OR] 1.72, 95% CI 1.45-2.06; $P < .001$ and OR 2.40, 95% CI 1.97-2.92; $P < .001$, respectively) and middle-aged adults (OR 1.22, 95% CI 1.03-1.45; $P = .03$ and OR 1.38, 95% CI 1.14-1.68; $P = .001$, respectively). Whereas older patients requested more technical assistance and exhibited a slower learning curve in exercise performance, their engagement was higher, as reflected by higher adherence to both exercise and education pieces. Older patients interacted more with the physical therapist (mean 12.6, SD 18.4 vs mean 10.7, SD 14.7 of young adults) and showed higher satisfaction scores (mean 8.7, SD 1.9). Significant improvements were observed in all clinical outcomes and were similar between groups, including pain response rates (young adults: 949/1516, 62.6%; middle-aged adults: 1848/2834, 65.2%; and older adults: 241/387, 62.3%; $P = .17$).

Conclusions: Older adults showed high adherence, engagement, and satisfaction with the DCP, which were greater than in their younger counterparts, together with significant clinical improvements in all studied outcomes. This suggests DCPs can successfully address and overcome some of the barriers surrounding the participation and adequacy of digital models in the older adult population.

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KEYWORDS

aged; digital therapy; eHealth; musculoskeletal conditions; older adults; pain; physical therapy; telehealth; telerehabilitation

Introduction

The US population over 65 years of age is forecast to double in the coming decades, from 49.2 million in 2016 to 94.7 million people in 2060, depicting aging as a major driver of changes in US health care systems [1]. Aging is associated with an increased likelihood of developing musculoskeletal conditions [2-5], with around 40% to 60% of older adults reporting persistent musculoskeletal pain [6]. Older adults contribute to 35.2% of the US \$381 billion annual spending in this domain [7]. Musculoskeletal disorders elevate the risk of developing comorbidities [8] and increase the odds of mortality [9] in older adults as a result of decreased physical activity, which increases falls and frailty, poor mental health, sleep disturbances, and overall impaired quality of life [2,3,10-13].

Current guidelines advocate for exercise-based physical therapy as the mainstay intervention in musculoskeletal care [14-16]. Telerehabilitation emerged to address barriers associated with conventional physical therapy, thereby improving access to care by mitigating provider shortages, travel and time constraints, and obviating concerns about infection during the COVID-19 pandemic [17]. Despite a general acceptance of telerehabilitation, older adults face specific barriers and concerns associated with digital programs [18,19]. These are related to accessing and being comfortable technology, internet accessibility, perception of a lack of personal connection in digital care, and perceived insufficient effectiveness of remote interventions. Thus, it is particularly important to frame the development of interventions acknowledging generational needs. Helping older adults become more tech-savvy has been shown to improve their health and overall quality of life, as it improves access to information and to community while promoting self-efficacy in daily life [20]. Moreover, the internet usage gap between those who are older than 65 years and younger individuals has narrowed in the past decade [1], providing an opportunity to leverage digital health as a scalable solution that will benefit older adults. Herein, we describe a patient-centered multimodal digital care program (DCP) combining exercise with education and cognitive behavioral therapy (CBT) that has been validated for several acute and chronic musculoskeletal conditions [21-25]. This program was designed to maximize adherence, acknowledging each participant's unique needs. This study aimed to investigate whether the known barriers and concerns of older patients impacted their participation in or engagement with a DCP, or the observed clinical outcomes, in comparison with younger individuals. This secondary analysis hypothesizes that regardless of age, all patients will experience

comparable levels of engagement and significant improvements in all clinical outcomes.

Methods

Study Design

This is a secondary analysis of a single-arm investigation into clinical and engagement-related outcomes of patients with musculoskeletal conditions following a DCP delivered between June 18, 2020, and August 3, 2022.

Study Population

Inclusion criteria were US adult (≥ 18 years of age) beneficiaries of employer health plans with the presence of musculoskeletal pain either in the ankle, elbow, hip, knee, low back, neck, shoulder, wrist, or hand, and duration of pain of >12 weeks. Eligible individuals were invited to apply to Sword Health's DCP (Draper, Utah) through a dedicated enrollment website. Exclusion criteria include health conditions incompatible with at least 20 minutes of light to moderate exercise, ongoing cancer treatment, and the presence of signs or symptoms indicative of serious pathology (eg, rapid progressive motor weakness or sensory alterations, or bowel or bladder dysfunction). All participants provided informed consent. Participants who skipped exercise sessions for 28 consecutive days were considered dropouts.

Intervention

The intervention consisted of exercise, education, and CBT administered for up to 12 weeks, depending on each patient's condition. During onboarding, patients selected a certified doctor of physical therapy (DPT) according to their preferences, who was responsible for tailoring and monitoring the program according to the patient's goals. Each patient received a Food and Drug Administration-listed class II medical device that included a tablet with a mobile app (already installed and ready to use), which displayed exercises and provided real-time video and audio biofeedback on exercise execution through either the use of motion trackers or the tablet's camera. It was recommended that patients perform 3 sessions per week. Exercise data were stored in a cloud-based portal that enabled asynchronous and remote monitoring by the DPT. Condition-specific education and CBT were made available through written articles, audio content, and interactive modules focused on health literacy, pain self-management skills, and mental health [14-16].

The DCP was designed to minimize barriers for those less comfortable with technology and to build trust and commitment from the start. This included an on-call onboarding assistant

who was available to help fill out the onboarding form and answer any questions regarding the program's journey. Onboarding assistance was also provided through the enrollment web chat room. Tablet app design followed best practices for acknowledging older adults' use [26] (eg, white spaces between content, allowing to adjust font size and audio volume). The time between exercises could be adjusted to age-appropriate rhythms. Continuous technical support was available to troubleshoot any issues across the intervention (either related to tablet, sensors, or connectivity). A set-up booklet was provided to guide tablet initiation and Wi-Fi connection. A Wi-Fi hotspot was provided to those lacking an internet

connection. A personal connection with the DPT was fostered through the onboarding video call and a built-in secure chat on a smartphone app. This allowed for rapport development between DPTs (frequent outreach to provide motivation and feedback on evolution) and patients (who could share ongoing questions and concerns).

Outcomes

Assessment surveys collected at baseline, 4, 8, and 12 weeks were used to analyze mean changes in clinical outcomes between baseline and program end. Engagement data were collected from the cloud-based portal. [Table 1](#) describes the studied outcomes.

Table 1. Description of the assessed outcomes.

Outcome measure	Outcome description
Engagement	
Assistance requests	Amount of support requests during enrollment, onboarding, app installment, member account set-up, and participation
Exercise performance	Corresponds to the sum of correct movements divided by the sum of total movements (independently if correct or incorrect) for each session
Sessions per week	Mean number of sessions performed per week
Total time on sessions	Total time spent exercising during the intervention
Total articles read	Number of articles read during the intervention
Total messages sent by the member	Number of text messages sent by the patient to the DPT ^a
Satisfaction	Evaluated through the question: "On a scale from 0 to 10, how likely is it that you would recommend this intervention to a friend or neighbor?"
Clinical	
Numerical Pain Rating Scale	"Please rate your average pain over the past 7 days from 0 (no pain at all) to 10 (worst pain imaginable)." A 30% or greater decrease was considered to represent a "Minimal clinically important difference (MCID)" [27]
Mental health	Anxiety was assessed by the GAD-7 ^b (range 0-21) [28], and depression was assessed by the PHQ-9 ^c (range 0-27) [29], in which higher scores denote worse outcomes
WPAI ^d	Collected within employed population to assess overall work impairment (WPAI overall), presenteeism (WPAI work), absenteeism (WPAI time), and activities impairment (WPAI activity) [30], with higher scores denoting poorer outcomes
Analgesics intake	Consumption of analgesics (either over-the-counter or prescribed) for the treated condition (binary response)

^aDPT: doctor of physical therapy.

^bGAD-7: Generalized Anxiety Disorder 7-item scale.

^cPHQ-9: Patient Health Questionnaire 9-item scale.

^dWPAI: Work Productivity and Activity Impairment Questionnaire.

Statistical Analysis

Participants were categorized into 3 age groups: ≤44 years old (young adults), 45-64 years old (middle-aged adults), and ≥65 years old (older adults). The threshold used to identify older adults is in accordance with age classifications established by the World Health Organization [31] and the US Census, while the threshold to differentiate young and middle-aged adults was based on previous reports from the Centers for Disease Control and Prevention [32,33]. Demographics and clinical outcomes at baseline and engagement metrics were compared between groups using a 1-way ANOVA with Bonferroni correction or

chi-square test. Distance to health care facilities was calculated using each patient's geo-coordinates cross-referenced with the geographic location of health care resources (filtered for clinics, doctors, hospitals, and rehabilitation units) [34,35].

A multiple-group latent growth curve analysis (mLGCA) following an intention-to-treat approach was used to assess clinical outcome changes at the program end as well as exercise performance across the program. LGCA is a structural equation model [36] that provides estimates of overall change based on individual trajectories using time as a continuous variable. Key advantages of LGCA include providing a measure of fitness and addressing missing data through full information maximum

likelihood [37]. mLGCA allows the creation of separate models for different groups, accounting for unbalanced group size while simultaneously permitting intergroup comparisons. An analysis focused on patients with minimally significant baseline impairment in the various domains was performed: ≥ 5 points for Generalized Anxiety Disorder 7-item scale (GAD-7) and Patient Health Questionnaire 9-item scale (PHQ-9) [28,29], and >0 for Work Productivity and Activity Impairment Questionnaire (WPAI; overall, work, time, and activity). A robust sandwich estimator was used for standard errors. Gender, BMI, race or ethnicity (White, non-White, and prefer not to specify), rurality (rural vs urban [38]), and symptomatic anatomical areas (upper limb, lower limb, and spine) were used as covariates for all the above-mentioned models.

An adjusted ordinal regression analysis was performed to longitudinally assess the latent distribution of analgesic consumption until the program ended within and between age groups. An adjusted odds ratio (OR) for being a program starter, being a completer, and reaching the minimum clinically important difference for pain was calculated using binary logistic regression.

Since education levels were considered a robust and consistent predictor of eHealth literacy [39], the impact of education levels (lower education: less than high school diploma, high school diploma, and some college vs higher education: bachelor's or graduate degree) on engagement outcomes was evaluated among older adults through mLGCA. All statistical analyses were conducted using commercially available software (SPSS v22; IBM Corp) and R (version 4.2.2, R Foundation for Statistical Computing). The level of significance was set at $P < .05$ for all 2-sided hypothesis tests.

Ethics Approval

The trial was prospectively approved (New England IRB number 120190313) and registered on ClinicalTrials.gov (NCT04092946) on September 17, 2019.

Results

Overview

From a total of 16,229 patients, 12,082 (74.4%) started the study, of which 4629 (38.3%) were young adults (≤ 44 years old), 6726 (55.7%) were middle-aged adults (45-64 years old), and 727 (6%) were older adults (≥ 65 years old; Figure 1 and Table 2).

The likelihood to start the intervention (ie, engaging with exercise sessions) was higher among older adults compared to young adults (OR 1.72, 95% CI 1.45-2.06; $P < .001$), and middle-aged adults (OR 1.22, 95% CI 1.03-1.45; $P = .03$). The proportion of those requesting assistance (in the scope of the enrollment, onboarding, app install, member account registration, and set-up questions) was higher for older adults (138/727, 19%) versus middle-aged adults (103/6726, 15.3%) and young adults (481/4629, 10.4%; $P < .001$), with similar assistance requests per person between groups (mean 1.2, SD 0.5 requests per person in middle-aged adults vs mean 1.1, SD 0.4 requests per person in young adults and mean 1.1, SD 0.4 requests per person for older adults; $P < .001$). The older adults group was also more likely to complete the program than the young (OR 2.40, 95% CI 1.97-2.92; $P < .001$) and middle-aged adults (OR 1.38, 95% CI 1.14-1.68; $P = .001$) groups.

Figure 1. Flowchart of the study stratified by age following the CONSORT (Consolidated Standards of Reporting Trials) guidelines. *Exclusions unrelated to the clinical condition.

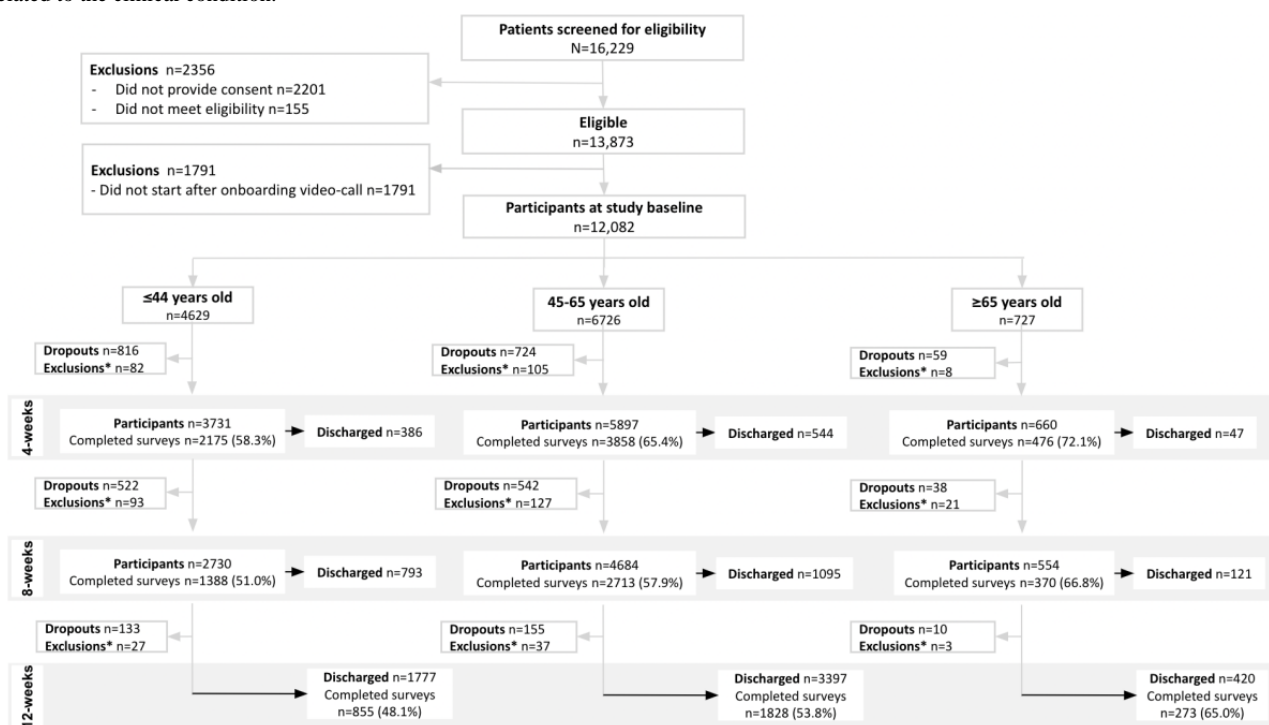


Table 2. Cohort demographic characteristics stratified by age groups. Missing values: BMI (n=23); geographic location (n=4); and distance to health facilities within 6 miles (n=25).

Characteristics	Age groups			P value
	Young adults (≤44 years old; n=4629)	Middle-aged adults (45-64 years old; n=6726)	Older adults (≥65 years old; n=727)	
Age (years), mean (SD)	35.9 (5.7)	54.5 (5.6)	67.3 (3.1)	<.001
Gender, n (%)				<.001
Woman	2587 (55.9)	4005 (59.5)	352 (48.4)	
Man	2011 (43.4)	2708 (40.3)	372 (51.2)	
Nonbinary	25 (0.5)	10 (0.1)	2 (0.3)	
Other	0 (0)	1 (0)	1 (0.1)	
Prefers not to answer	6 (0.1)	2 (0)	0 (0)	
BMI (kg/m ²), mean (SD)	28.4 (6.7)	29.7 (6.7)	29 (5.8)	<.001
BMI category (kg/m²), n (%)				<.001
Underweight (<18.5)	51 (1.1)	39 (0.6)	6 (0.8)	
Normal (18.5-25)	1576 (34)	1663 (24.7)	165 (22.7)	
Overweight (25-30)	1524 (32.9)	2266 (33.7)	296 (40.7)	
Obese (30-40)	1169 (25.3)	2199 (32.7)	224 (30.8)	
Morbidly obese (>40)	305 (6.6)	542 (8.1)	34 (4.7)	
Race and ethnicity, n (%)				<.001
Asian	460 (9.9)	458 (6.8)	32 (4.4)	
Black	343 (7.4)	559 (8.3)	35 (4.8)	
Hispanic	444 (9.6)	462 (6.9)	29 (4)	
Non-Hispanic White	2078 (44.9)	3384 (50.3)	391 (53.8)	
Other	139 (3)	108 (1.6)	1 (0.1)	
Not available or prefers not to specify	1165 (25.2)	1755 (26.1)	239 (32.9)	
Employment status, n (%)				<.001
Employed	4278 (92.4)	6139 (91.3)	577 (79.4)	
Not employed	233 (5)	426 (6.3)	138 (19)	
Not available or prefers not to answer	118 (2.5)	161 (2.4)	12 (1.7)	
Education level, n (%)				<.001
Less than high school diploma	25 (0.5)	46 (0.7)	5 (0.7)	
High school diploma	266 (5.7)	501 (7.4)	68 (9.4)	
Some college	835 (18)	1518 (22.6)	155 (21.3)	
Bachelor's degree	1694 (36.6)	2184 (32.5)	208 (28.6)	
Graduate degree	1040 (22.5)	1353 (20.1)	183 (25.2)	
Prefers not to answer or is not available	769 (16.6)	1124 (16.7)	108 (14.9)	
Geographic location, n (%)				<.001
Urban	4182 (90.4)	5918 (88)	631 (86.8)	
Rural	446 (9.6)	805 (12)	96 (13.2)	
Minimum distance to nearest health care facilities in miles				<.001
Median (IQR)	2.1 (3.5)	2.5 (4.2)	2.6 (4.1)	
Mean (SD)	4.2 (6.1)	4.9 (6.6)	5.1 (7)	
Number of health care facilities located within 6-mile radius of residence				<.001

Characteristics	Age groups			P value
	Young adults (≤ 44 years old; n=4629)	Middle-aged adults (45-64 years old; n=6726)	Older adults (≥ 65 years old; n=727)	
Median (IQR)	5.00 (14)	4.00 (8)	3.00 (8)	
Symptomatic anatomical area, n (%)				<.001
Ankle	229 (4.9)	263 (3.9)	20 (2.8)	
Elbow	91 (2)	175 (2.6)	7 (1)	
Hip	399 (8.6)	683 (10.2)	97 (13.3)	
Knee	599 (12.9)	1097 (16.3)	153 (21)	
Low back	1937 (41.8)	2359 (35.1)	269 (37)	
Neck	538 (11.6)	661 (9.8)	57 (7.8)	
Shoulder	666 (14.4)	1229 (18.3)	109 (15)	
Wrist or hand	170 (3.7)	259 (3.9)	15 (2.1)	

Baseline Characteristics

The older adults group was more balanced gender-wise compared to other age groups, which contained a greater proportion of women (Table 2). Young and middle-aged cohorts had lower BMI levels and included significantly more people of color than older adults (Table 2). Although the majority of older adults were employed (79.4%), the group also had the highest percentage of nonemployed participants (19% vs 6.3% and 5%; $P<.001$), which was primarily due to the high percentage of retirees (106/138). Young adults reported significantly higher education levels than middle-aged and older adults (Table 2). Older adults mainly resided in urban areas but also had the highest percentage (13.2%) of patients situated in rural areas compared to young (9.6%) and middle-aged adults (12%; $P<.001$). Older adults lived farther away from health care facilities, with fewer providers within a 6-mile radius compared to other groups (Table 2).

The most reported symptomatic anatomical areas across groups were the low back, knee, and shoulder (Table 2). Pain scores

were significantly higher in older (mean 4.83, SD 2.0) and middle-aged adults (mean 4.90, SD 2.0) compared to young adults (mean 4.48, SD 1.9; $P<.001$; Table 3). A commensurate trend was observed for analgesic consumption (34.3% of older adults vs 27.1% in middle-aged adults vs 16% in young adults; $P<.001$). Among those who reported at least mild anxiety or depression symptoms at baseline, older adults had lower levels of anxiety (mean 7.98, SD 3.6 vs mean 8.54, SD 3.9 in middle-aged adults and mean 9.2, SD 4.1 in young adults; $P<.001$), and depression (mean 8.12, SD 3.4 vs mean 9.07, SD 4.2 in middle-aged and mean 9.66, SD 4.5 in young adults; $P<.001$; Table 3). A significantly higher proportion of young adults (2429/4278, 56.8%) reported overall productivity impairment at baseline versus middle-aged (3217/6139, 52.4%) and older adults (281/577, 48.7%; $P<.001$; Table 3). However, similar average work productivity and activity impairment scores were observed between groups (Table 3). Presenteeism was particularly an issue for young adults (WPAI work: mean 29, SD 19; $P=.02$), while absenteeism was mainly reported by older adults still in the workforce compared to other age categories (WPAI time: mean 40, SD 40.6; $P=.002$; Table 3).

Table 3. Clinical characteristics at baseline stratified by age. For unfiltered cases, see Table S1 in [Multimedia Appendix 1](#).

Outcomes	Age group						P value
	Young adults (≤44 years old)		Middle-aged adults (45-64 years old)		Older adults (≥65 years old)		
	Patients, n	Mean (SD)	Patients, n	Mean (SD)	Patients, n	Mean (SD)	
Pain	4629	4.48 (1.9)	6726	4.90 (2.0)	727	4.83 (2.0)	<.001
GAD-7 ^a score of ≥5	1778	9.15 (4.1)	1815	8.54 (3.9)	133	7.98 (3.6)	<.001
PHQ-9 ^b score of ≥5	1292	9.66 (4.5)	1410	9.07 (4.2)	136	8.12 (3.4)	<.001
WPAI ^c -Overall score of >0	2429	31.4 (21.8)	3217	30.9 (22.0)	281	29.7 (23.5)	.42
WPAI-Work score of >0	2363	29 (19.0)	3090	28.4 (18.8)	260	25.7 (17.6)	.02
WPAI-Time score of >0	477	23.8 (28.0)	595	26 (30.5)	46	40 (40.6)	.002
WPAI-Activity score of >0	3532	35 (21.5)	5109	35.7 (22.5)	536	35.2 (22.3)	.31
Analgesic intake (binary), n (%)	741 (16)	N/A ^d	1821 (27.1)	N/A	249 (34.3)	N/A	<.001

^aGAD-7: Generalized Anxiety Disorder 7-item scale.

^bPHQ-9: Patient Health Questionnaire 9-item scale.

^cWPAI: Work Productivity and Activity Impairment Questionnaire.

^dN/A: not applicable.

Engagement Outcomes

Overview

Older adults completed significantly more sessions than the other groups (sessions per week: mean 3.1, SD 1.2 for older adults vs mean 2.4, SD 0.9 for young adults, and mean 2.7, SD 1.1 for middle-aged adults; $P<.001$). Older adults also dedicated more overall time to sessions (mean 698.5, SD 740.4 minutes) than young (mean 320.6, SD 354.7 minutes; $P<.001$) and middle-aged adults (mean 473.9, SD 524.6 minutes; $P<.001$).

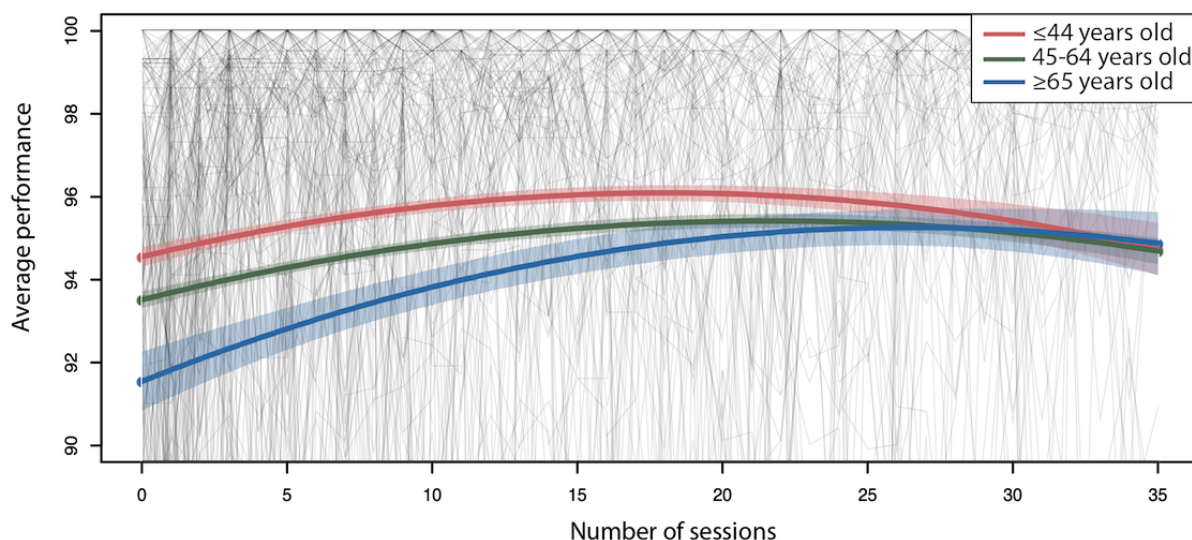
Regarding the learning curve for correctly performing the proposed exercises, all groups attained high exercise performance (>90%) at the intervention start, with older adults performing at significantly lower levels than the other cohorts (intercept: 91.5, 95% CI 90.8-92.2 vs 93.5, 95% CI 93.3-93.7 for middle-aged adults and 94.5, 95% CI 94.3-94.8 for young

adults; $P<.001$ for all combinations; [Figure 2A](#) and [Table S2](#) in [Multimedia Appendix 1](#) [40,41]). However, the difference between older and middle-aged exercise performance disappeared by session 20 ([Figure 2A](#) and [Tables S2](#) and [S3](#) in [Multimedia Appendix 1](#)). The leveling effect observed toward the intervention's end was not statistically significant between groups. Older adults read on average more pieces of education than other groups (mean 3.9, SD 6.7 vs mean 2.2, SD 4.3 young adults; $P<.001$ vs mean 3.3, SD 6.0 middle-aged adults; $P=.005$).

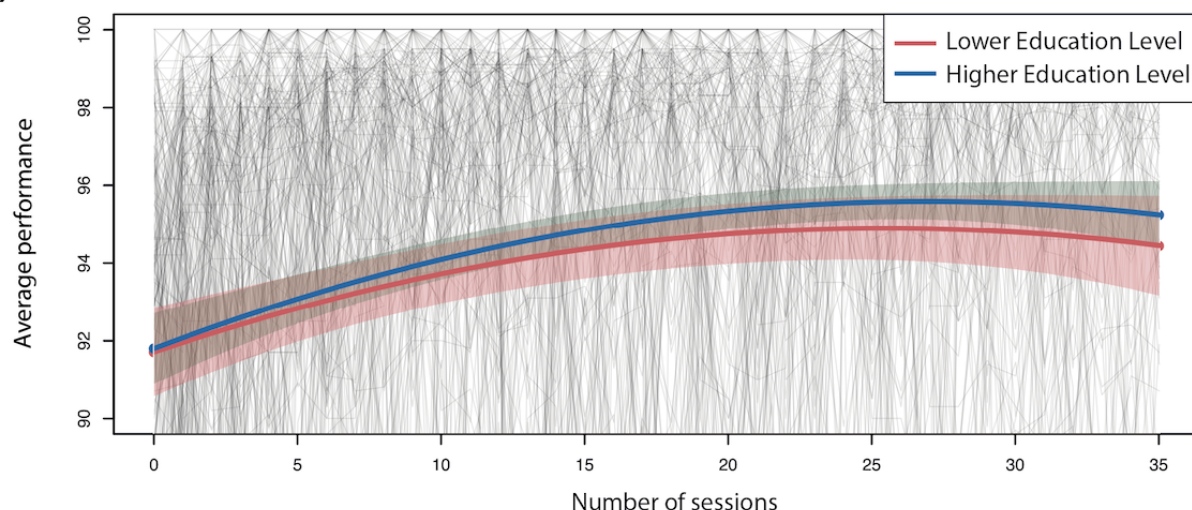
Both older adults (mean 12.6, SD 18.4) and middle-aged adults (mean 11.8, SD 16.7) sent significantly more text messages with the DPT than young adults (mean 10.7, SD 14.7; $P=.02$ and $P=.004$, respectively). Total satisfaction with the program was high, with older adults (mean 8.7, SD 1.9) and middle-aged adults (mean 8.8, SD 1.7) being significantly more satisfied with the program than younger patients (mean 8.5, SD 1.8; $P<.001$).

Figure 2. Engagement outcomes. (A) Average exercise performance trajectories broken down by age group. (B) Average performance for older adults stratified by education attainment. Shadowing indicates each trajectory's confidence interval, while individual trajectories are depicted with lighter gray lines.

(A)



(B)



Subgroup Analysis: Impact of Education Level on Older Adults' Engagement

Among older adults, those with lower education levels spent a similar amount of time on sessions (mean 640.5, SD 599.3 vs mean 649.3, SD 705.5; $P=.09$) and participated in a similar number of sessions per week (mean 3.0, SD 1.2 vs mean 3.1, SD 1.2; $P=.10$) as those with higher education levels. Similar numbers of educational resources were viewed (mean 3.5, SD 6.1 vs mean 3.7, SD 6.6; $P=.38$) and messages were sent to the DPT (mean 13.5, SD 20.1 vs mean 11.8, SD 16.5; $P=.32$) in

the older cohort regardless of education level. Exercise performance trajectories were not influenced by education level (Figure 2B and Table S4 in Multimedia Appendix 1). Overall satisfaction was similar between groups (mean 8.7, SD 1.8 for the lower education subgroup vs mean 8.9, SD 1.7 for the high education subgroup; $P=.25$).

Clinical Outcomes

Clinical outcomes are presented in Table 4. The mLGCA model's estimates and fitness are presented in Tables S5 and S6 in Multimedia Appendix 1, respectively, showing a good fit.

Table 4. Program end and estimated outcome mean change for each age category.

Outcome measure	Young adults (≤44 years old; n=4629), mean (95% CI)	Middle-aged adults (45-64 years old; n=6726), mean (95% CI)	Older adults (≥65 years old; n=727), mean (95% CI)
Pain			
Program end	1.90 (1.62 to 2.18)	2.09 (1.91 to 2.26)	2.53 (1.97 to 3.08)
Mean change	2.37 (2.08 to 2.66)	2.62 (2.43 to 2.80)	2.11 (1.53 to 2.69)
GAD-7^a score of ≥5			
Program end	3.82 (2.73 to 4.90)	3.99 (3.03 to 4.95)	4.90 (3.06 to 6.74)
Mean change	5.21 (4.15 to 6.28)	4.26 (3.32 to 5.22)	3.10 (0.98 to 5.22)
PHQ-9^b score of ≥5			
Program end	4.25 (2.74 to 5.76)	3.13 (2.16 to 4.10)	4.79 (2.47 to 7.11)
Mean change	4.97 (3.53 to 6.42)	4.94 (3.93 to 5.94)	2.10 (-0.70 to 4.90)
WPAI^c-Overall score of >0			
Program end	13.71 (9.52 to 17.90)	10.73 (7.83 to 13.62)	17.98 (7.15 to 28.81)
Mean change	16.01 (11.87 to 20.15)	18.29 (15.26 to 21.32)	7.12 (0 to 17.65)
WPAI-Work score of >0			
Program end	12.12 (8.33 to 15.90)	8.59 (6.22 to 10.96)	12.58 (5.89 to 19.26)
Mean change	14.70 (10.85 to 18.54)	17.82 (15.30 to 20.34)	9.77 (3.21 to 16.33)
WPAI-Time score of >0^d			
Program end	9.50 (5.7 to 13.28)	8.12 (5.24 to 11.00)	13.45 (2.93 to 24.00)
Mean change	14.13 (10.06 to 18.20)	17.84 (14.45 to 21.21)	23.88 (13.64 to 34.12)
WPAI-Activity score of >0			
Program end	11.25 (8.46 to 14.04)	12.27 (10.17 to 14.37)	12.20 (6.46 to 17.94)
Mean change	20.69 (17.66 to 23.73)	19.34 (17.11 to 21.57)	13.62 (7.03 to 20.20)

^aGAD-7: Generalized Anxiety Disorder 7-item scale.

^bPHQ-9: Patient Health Questionnaire 9-item scale.

^cWPAI: Work Productivity and Activity Impairment Questionnaire.

^dWPAI Time results were yielded from an unconditional model due to poor model fitness when adjusting for the covariates.

Pain

All age groups experienced significant reductions in pain by program end (Table 4), with no statistically significant differences between them (young adults: 2.37, 95% CI 2.08-2.66; middle-aged adults: 2.62, 95% CI 2.43-2.80; and older adults: 2.11, 95% CI 1.53-2.69; *P* values in Table S7 in Multimedia Appendix 1). Response rate did not differ across groups (young adults: 949/1516, 62.6%; middle-aged adults: 1848/2834, 65.2%; and older adults: 241/387, 62.3%; *P*=.17), when considering a 30% minimal clinically important difference for pain [27].

Analgesic Consumption

All groups reduced analgesic consumption by the program's end. Using intention-to-treat analysis, a lower probability of analgesic intake at the program's end was similar across groups (mean change in young adults group: -0.040; *P*<.001; middle-aged adults group: -0.056; *P*<.001; and older adults group: -0.091; *P*<.001; Table S8 and Figure S1 in Multimedia Appendix 1).

Mental Health

Despite different mental distress levels (GAD-7 and PHQ-9 scores of ≥5) at baseline (Table 3), all groups showed significant and similar improvements at the intervention's end (*P*<.001; Table 4, Table S7 in Multimedia Appendix 1). The observed end scores indicated the absence of relevant anxiety (young adults: 3.82, 95% CI 2.73-4.90; middle-aged adults: 3.99, 95% CI 3.03-4.95; and older adults: 4.90, 95% CI 3.06-6.74) [28], and depression symptoms at program end (young adults: OR 4.25, 95% CI 2.74-5.76; adults: OR 3.13, 95% CI 2.16-4.10; and older adults: OR 4.76, 95% CI 2.47-7.11) [29].

Productivity

Recovery in overall productivity was significant and similar between groups (mean changes for young adults 16.01, 95% CI 11.87-20.15; middle-aged adults 18.29, 95% CI 15.26-21.32; and older adults 7.12, 95% CI 0-17.65; Table 4 and *P* values in Table S7 in Multimedia Appendix 1). Older adults reported similar presenteeism recovery to young adults (9.77, 95% CI 3.21-16.33 vs 14.70, 95% CI 10.85-18.54, respectively; *P*=.20), but slightly lower than middle-aged adults (vs 17.81, 95% CI

15.30-20.34; $P=.02$; Table 4 and Table S7 in [Multimedia Appendix 1](#)). The older adults group reported a high improvement in absenteeism (23.88, 95% CI 13.64-34.12), which was not significantly different from the other groups (14.13, 95% CI 10.06-18.20, $P=.08$ in young adults and 17.84, 95% CI 14.45-21.21, $P=.27$ in middle-aged adults; Table S7 in [Multimedia Appendix 1](#)). All groups recovered from the impairment in non-work-related activities to the same extent (Table S7 in [Multimedia Appendix 1](#)).

Discussion

Main Findings

Older adults may face age-specific barriers and concerns when considering digital musculoskeletal care. This study aimed to investigate whether these barriers and concerns impacted their participation in or engagement with a DCP or the observed clinical outcomes in comparison with younger individuals. Here, among those who applied to the program, older adults were more likely to start the intervention. Although they requested more technical assistance and exhibited lower initial exercise performance, the performance gap shortened over time, disappearing after 20 sessions. Overall, engagement was higher among older adults. The adherence to exercise and education and the frequent communication with the DPT suggest older adults felt comfortable with the technology and were able to establish a therapeutic relationship. Engagement outcomes were not influenced by education level, which was used as a proxy for digital literacy. Significant and similar clinical improvements in pain (with similar response rate), mental health, analgesic consumption, and productivity were observed across age groups, reinforcing the relevance of the program regardless of age. Overall, this study supports the delivery of digital musculoskeletal care to older adults.

Comparison With Previous Research

Older adults account for 16% of the US population [42], whose distribution in terms of race and ethnicity [42], rurality [43], and employment [42] matches the older adult cohort herein described.

Comfort With Technology

Health equity considerations highlight the importance of developing interventions that specifically address the barriers and concerns felt by older patients. Evidence suggests that musculoskeletal digital programs are feasible in this population [44-47]. In this study, we observed higher adoption than previously reported for older adults [45,46], as well as a higher likelihood of starting the intervention than their younger counterparts, suggesting that the possible distrust phenomenon was overcome in this particular cohort.

Although a higher number of older adults asked for technical assistance, the mean requests per patient were similar across groups. At the intervention start, older adults had lower exercise performance than younger groups, despite starting at a high score. Importantly, older patients were able to learn and improve their performance, challenging the myth that older adults are less capable of using technology. This is further reinforced by the similar engagement metrics observed regardless of education

levels, although the older adult cohort reported a slightly higher proportion of those with higher education (bachelor's degree or higher) than the US population [42].

The tailored exercise program with continuous feedback and monitoring may have empowered patients to exercise [48,49], positively impacting their self-efficacy and motivation to adhere to the intervention, as previously suggested [50]. Older adults were more adherent than other age groups, as shown by the higher number of executed sessions, time dedicated to sessions, and completion rates, in accordance with previous literature [44]. However, older adults were on average located farther away from health care facilities, which bolsters the rationale for using a DCP, especially for those with limited mobility capabilities who rely on caregivers to commute to in-person clinics.

Musculoskeletal pain management guidelines recommend education during interventions [14-16], and digital interventions may play a crucial role in dissemination, given their tailored nature, and wide and convenient accessibility. High engagement in educational content was observed, particularly in older adults.

Establishment of a Therapeutic Relationship in Remote Care

Establishing a collaborative relationship between the patient and DPT is key to building rapport, ensuring patient adherence, and driving positive clinical outcomes [51,52]. The DCP ensured collaborative goal setting, development of achievable tasks during onboarding, and ongoing bidirectional communication [51,52]. These factors have been previously shown to be key elements in establishing a strong therapeutic alliance [51-53]. The higher number of messages sent by older adults to the DPT, and the higher satisfaction with the program highlight the importance of the DCP design to change the perception of lack of personal connection in digital care. These results are in line with studies reporting that technologically advanced solutions can achieve the same level of trust as traditional methods [54].

Clinical Outcomes

Significant and similar improvements in pain (including comparable response rates) were observed across age groups. Older adults have lower pain thresholds and lower tolerance than their younger counterparts [55], and have been shown to have lower recovery rates on some outcome measures than their younger peers [56]. The higher number of completed sessions by older adults may have contributed to this finding, as higher adherence is associated with better outcomes [57,58]. Despite a larger proportion of older adults reporting analgesic consumption at baseline, they were able to significantly reduce analgesic intake to the same extent as other age groups. This is particularly important in an era where medications are overprescribed and older adults are prone to side effects and drug-drug interactions [59-61].

Musculoskeletal pain is a major driver of productivity impairment [62,63]. At baseline, 79.4% of older adults were in the workforce, but about half reported productivity issues mainly driven by absenteeism [64,65]. Older patients reported similarly significant productivity and non-work-related activity improvements as younger patients at the program end. This

suggests that despite the obstacles to returning to work for this age group [66], the DCP was effective in reducing absenteeism. Non-work-related activity improvement is particularly important for older adults as it contributes to the maintenance of autonomy.

Collectively, these findings supported wider dissemination of DCPs in the older adult population. Although not all patients may be eligible for a digital program (eg, due to cognitive decline) [67], a significant proportion of this population could benefit from timely and continuous care to manage their chronic musculoskeletal conditions. Future research should aim to identify and better characterize those who can benefit the most from digital programs, and design and study ways to improve implementation. Mobilizing older adults toward the use of digital technology may empower patients to play an active role in care management, thereby decreasing condition-related mental distress and improving their overall quality of life.

Strengths and Limitations

The major strength of this study is the novelty of analyzing specific engagement metrics to deep dive into the older adults' interface with a DCP, which were not explored before. An additional strength is the wide range of clinical outcomes based on validated scales, which can enhance generalizability. This study provides the groundwork to further develop and refine telerehabilitation programs that ensure equitable and continuous care regardless of age.

The major limitation is the lack of a control group, for which the most obvious comparator would be a "waiting list." This may not be ethical considering the high accessibility this technology affords in a real-world context. Another alternative would be a control group that receives "usual care," which could provide valuable insight into the acceptance of digital interventions versus conventional care. Since the program enrolled beneficiaries of employers' health benefits, the current cohort may not be representative of the older adult population in the United States, for whom Medicare is the major insurance payer. Despite education levels being considered a proxy of digital literacy, other objective metrics might provide a better understanding of the impact of digital literacy on telerehabilitation. Finally, the lack of long-term follow-up precludes the evaluation of long-term benefits.

Conclusions

This study reports high adherence, engagement, and satisfaction with a digital musculoskeletal care program in an older adult population, which were greater than in younger counterparts. Older adults achieved statistically significant and clinically meaningful improvements in all studied outcomes (in pain, mental health, analgesics consumption, and productivity), suggesting that DCPs can successfully overcome some of the barriers surrounding participation in this population. This study showcases the importance of acknowledging generational needs when designing digital interventions in order to ensure equitable and continuous care regardless of age.

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

All authors made a significant contribution to the work reported as follows: FDC and FC were responsible for the study concept and design; MM acquired the data; RGM performed the statistical analysis; FC, ACA, DJ, MM, and SPC interpreted the data; ACA and FC were responsible for drafting the work; and VB was responsible for funding. Critical revision of the manuscript for important intellectual content was done by all authors. All authors were involved in the final approval of the version.

Conflicts of Interest

ACA, FC, DJ, MM, RGM, FDC, and VY are employees of Sword Health, the sponsor of this study. FDC, VY, and VB also hold equity in Sword Health, and VB is the chief executive officer of the same company. SPC is an independent clinical consultant who received an adviser honorarium from Sword Health.

Multimedia Appendix 1

Information regarding (1) baseline clinical characteristics for unfiltered cases, (2) model estimates and fitness from latent growth curve analysis (LGCA) following intent-to-treat analysis, (3) statistical differences in exercise performance between groups, (4) model estimates and fitness from LGCA stratified by education levels following intent-to-treat analysis, (5) model estimates from the conditional model, (6) model fitness from conditional LGCA, (7) statistical differences between groups in mean changes for clinical outcomes, (8) probability of analgesics consumptions, and (9) medication reduction trajectories per age category.

[[DOCX File, 1613 KB](#) - [rehab_v10i1e49673_app1.docx](#)]

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Abbreviations

CBT: cognitive behavioral therapy

DCP: digital care program

GAD-7: Generalized Anxiety Disorder 7-item scale

mLGCA: multiple-group latent growth curve analysis

OR: odds ratio

PHQ-9: Patient Health Questionnaire 9-item scale

WPAI: Work Productivity and Activity Impairment Questionnaire

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Original Paper

Identifying the Active Ingredients of a Computerized Speech and Language Therapy Intervention for Poststroke Aphasia: Multiple Methods Investigation Alongside a Randomized Controlled Trial

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Abstract

Background: Aphasia is a communication disorder affecting more than one-third of stroke survivors. Computerized Speech and Language Therapy (CSLT) is a complex intervention requiring computer software, speech and language therapists, volunteers, or therapy assistants, as well as self-managed practice from the person with aphasia. CSLT was found to improve word finding, a common symptom of aphasia, in a multicenter randomized controlled trial (Clinical and Cost Effectiveness of Computer Treatment for Aphasia Post Stroke [Big CACTUS]).

Objective: This study provides a detailed description of the CSLT intervention delivered in the Big CACTUS trial and identified the active ingredients of the intervention directly associated with improved word finding for people with aphasia.

Methods: We conducted a multiple methods study within the context of a randomized controlled trial. In study 1, qualitative interviews explored key informants' understanding of the CSLT intervention, how the components interacted, and how they could be measured. Qualitative data were transcribed verbatim and analyzed thematically. Qualitative findings informed the process measures collected as part of a process evaluation of the CSLT intervention delivered in the Big CACTUS trial. In study 2, quantitative analyses explored the relationship between intervention process measures (length of computer therapy access; therapists' knowledge of CSLT; degree of rationale for CSLT tailoring; and time spent using the software to practice cued confrontation naming, noncued naming, and using words in functional sentences) and change in word-finding ability over a 6-month intervention period.

Results: Qualitative interviews were conducted with 7 CSLT approach experts. Thematic analysis identified four overarching components of the CSLT approach: (1) the StepByStep software (version 5; Steps Consulting Ltd), (2) therapy setup: tailoring and personalizing, (3) regular independent practice, and (4) support and monitoring. Quantitative analyses included process and outcome data from 83 participants randomized to the intervention arm of the Big CACTUS trial. The process measures found to be directly associated with improved word-finding ability were therapists providing a thorough rationale for tailoring the computerized therapy exercises and the amount of time the person with aphasia spent using the computer software to practice using words in functional sentences.

Conclusions: The qualitative exploration of the CSLT approach provided a detailed description of the components, theories, and mechanisms underpinning the intervention and facilitated the identification of process measures to be collected in the Big CACTUS trial. Quantitative analysis furthered our understanding of which components of the intervention are associated with clinical improvement. To optimize the benefits of using the CSLT approach for word finding, therapists are advised to pay particular attention to the active ingredients of the intervention: tailoring the therapy exercises based on the individual's specific language difficulties and encouraging people with aphasia to practice the exercises focused on saying words in functional sentences.

Trial Registration: ISRCTN Registry ISRCTN68798818; <https://www.isrctn.com/ISRCTN68798818>

KEYWORDS

aphasia; stroke; computer therapy; tele-rehabilitation; speech and language therapy; word finding; qualitative; language; language therapy; speech therapy; aphasia therapy; speech; interview; self managed; computer aphasia; persistent aphasia; rehabilitation; machines; technology; computer; online; online health; ehealth; digital health

Introduction

Globally, an estimated 12.2 million cases of stroke occur each year [1]. Approximately one-third of stroke survivors experience aphasia, an acquired communication disorder, affecting the production and comprehension of verbal language and the ability to read or write [2]. Due to health care costs, limited speech and language therapy is provided to people with poststroke aphasia beyond the first few months [3].

Self-managed approaches have gained traction as health care providers try to meet the growing demand for their services [4]. Computerized Speech and Language Therapy (CSLT) provides an opportunity for people with aphasia to self-manage their own rehabilitation by practicing rehabilitation exercises in their own homes [5]. A review demonstrated that CSLT is effective compared to no therapy but acknowledged the need for more research to establish whether it is effective compared to face-to-face speech and language therapy [6].

The Clinical and Cost Effectiveness of Computer Treatment for Aphasia Post Stroke (Big CACTUS) trial evaluated the clinical effectiveness and cost-effectiveness of CSLT for people with poststroke aphasia in the long term compared to usual care or attention control. Full details of the trial have been reported elsewhere [5,7]. CSLT was found to improve word finding compared to usual care and attention control, although the clinical gains did not generalize to improvement in conversation. CSLT was found to enable greater amounts of practice than available with usual care (28 hours CSLT vs 3.8 hours usual speech and language therapy between baseline and 6 months), leading to improved ability to retrieve words of personal importance than with usual care (CSLT group improved word finding by 16.2% [$P<.0001$] more than those in the usual care group and 14.4% [$P<.0001$] more than those in the attention control group). Demonstrating that CSLT can be used to support sufficient amounts of therapy practice to enable effective retrieval of specific words, with speech and language therapists (SLTs) needing to provide additional support and activities to help people with aphasia use the words in everyday contexts [5,7].

CSLT is a complex rehabilitation intervention often requiring technology or software relevant to the impairment of people with aphasia, input and support from professionals or informal caregivers, as well as a commitment from people with aphasia to use the CSLT. The complexity of CSLT arises from its multiple components and actors that operate both independently and interdependently. This can make it difficult to identify the components or groups of interrelated components that are important mechanisms of change [8]. Intervention components may include the content of an intervention, features that promote adherence, or aspects of implementation [9]. The importance

of identifying the active ingredients (the essential and indispensable aspects) of interventions has been recognized in aphasia research [10] and beyond [11].

Furthermore, complex interventions are typically implemented within complex systems by individuals with their own competing views and objectives, which can often result in intervention adaptation at the point of implementation [12]. If we do not know which components of the CSLT approach are particularly associated with improved word retrieval and SLTs only implement certain components, but not those most closely associated with improvement, this may limit the potential benefits to people with aphasia [13]. By establishing which CSLT approach components are associated with improved word retrieval, we can provide additional information to SLTs considering using the approach in their practice to help them optimize the way in which they implement it [13].

A comprehensive understanding of complex interventions is also vital to enable better reporting of interventions. The introduction of the Template for Intervention Description and Replication (TIDieR) checklist and guide [14] has both encouraged researchers to provide more detail about their interventions but also acted as an evaluation tool to demonstrate how infrequently intervention details are reported. Intervention reporting has been found wanting in both aphasia [15] and telehealth research [16].

In this study, we aimed to provide a detailed description of the CSLT approach components delivered in the Big CACTUS study and identify those components most associated with change in word-finding ability for people with aphasia, by addressing the following 2 questions:

1. What are the components of the CSLT intervention delivered in the Big CACTUS trial?
2. Are any of the components directly associated with improvement in word finding?

Methods

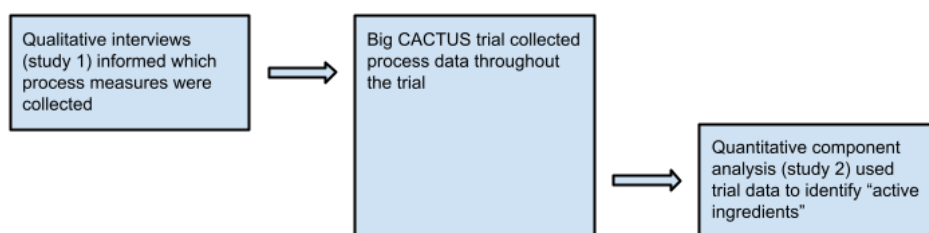
Overview

From October 2014 to August 2016, people with aphasia were recruited into a pragmatic, 3-arm, single-blind (outcome assessor), individually randomized controlled trial of CSLT [5,7]. The Big CACTUS trial was carried out in 21 SLT departments across the United Kingdom. Sites were recruited through national advertisements via relevant professional bodies. Participants were eligible if they had received a diagnosis of poststroke aphasia at least 4 months prior to randomization and were aged 18 years or older. Participants were excluded if they required treatment in a language other than English, were already using computer therapy to address their word-finding impairment, or had another premorbid speech and language

disorder caused by a neurological deficit other than stroke. Participants were randomized to 1 of 3 groups: computer aphasia therapy plus usual care (CSLT), attention or activity control (puzzle books and regular phone calls) plus usual care, or usual care alone. The CSLT intervention targeted the participant's word-finding impairment. The intervention consisted of self-managed aphasia therapy using the StepByStep software (version 5; Steps Consulting Ltd), which presents a series of word-finding exercises that can be tailored to the individual's abilities and allows practice items to be personalized.

We conducted a multiple methods study within the context of the Big CACTUS randomized controlled trial (see Figure 1). Study 1 comprised qualitative interviews exploring key informants' understanding of the CSLT intervention, how the components interacted, and how they could be measured. Qualitative findings informed the process measures collected as part of a process evaluation [17] of the CSLT intervention delivered in the Big CACTUS trial. Study 2 comprised quantitative analyses exploring the relationship between intervention process measures and changes in word-finding ability. The methods, analysis, and findings are reported in turn for each study.

Figure 1. Diagram illustrating the relationship between the qualitative and quantitative studies.



Data and Sample

Study 1: Qualitative Interviews

We conducted qualitative interviews with key informants in the early phase of the trial in order to describe the components being delivered in the CSLT approach to word-finding therapy and how the components were thought to interact. We identified the key informants using a nominated expert sampling strategy [18]. The aim was to include a variety of expert perspectives in the sample, including those of (1) the designers of the StepByStep software used in the CSLT approach, (2) therapists who use the CSLT approach regularly in clinical practice, (3) researchers who have evaluated the CSLT approach, (4) patients and caregivers who have helped to design and test the software, as well as (5) representatives of a charity delivering a CSLT service in West Yorkshire. We used a snowball sampling strategy, by asking all participants if they knew anyone with relevant expertise, to ensure experts not known to the authors were not overlooked.

Participants were contacted via email. Information sheets were provided and written consent was sought. The Consent Support Tool [19] was used to determine the optimum format to present information to people with aphasia. Interviews were conducted in person and over the phone at the convenience of the participant. We used an interview schedule to guide the semistructured interviews with questions about what participants perceived to be the components of the intervention, the theories underpinning the components, how the components interact, and how the components could be measured within the Big CACTUS trial. As well as providing a verbal response to the questions, participants were invited to write down the components, so they could refer back to them and arrange them to demonstrate relationships. Post-it notes were used as a visual aid during the interviews; using paper and pen for face-to-face

interviews and “Google Drawings” when the interview was conducted over the phone (shared on Google Drive so the interviewer could see it in real time). The interviews were recorded and transcribed verbatim.

Study 2: Quantitative Component Analysis

We used trial data from participants randomized to receive the CSLT intervention for which process and outcome data were available in order to identify which intervention components were directly associated with improved word finding. The dependent outcome variable was a change in word finding of 100 personally relevant, treated words assessed using a picture-naming test at baseline and 6 months. The maximum score was 2 points for each word (2=correct response; 1=correct response following repetition, self-correction, or delay of 5 seconds; and 0=incorrect). The pictures were presented in the assessment section of the StepByStep software.

Process variables relating to the delivery and receipt of the components of the CSLT intervention were informed by the findings from the qualitative interviews described below and measured as part of a process evaluation conducted alongside the trial to measure intervention fidelity. Consequently, the process measures included in the quantitative component analysis will be described in the results of the qualitative interviews.

Analysis

Study 1: Qualitative Analysis

We used a 6-stage process of thematic analysis involving familiarization, iterative development of an initial coding framework, identification of themes, reviewing themes, naming and defining themes, and writing up the findings [20]. Familiarization was achieved through transcribing and reading the interview transcripts. A deductive approach was adopted in

the early stage of analysis, meaning the questions from the interview schedule informed the higher-order themes. Subsequently, codes emerged from the data that allowed the exploration of different interpretations of the CSLT approach. Analysis of transcripts and visual data (eg, Post-it note diagrams) were managed in NVivo (version 10; QSR International). The process of reviewing and defining the themes and subthemes resulted in the key components being defined as themes and the development of a diagram depicting the components of the intervention and how they interact.

The initial process of familiarization, coding, and theme identification was conducted by MH, an experienced qualitative researcher. The process of reviewing and defining themes was conducted by all authors to increase the dependability of the findings. A reflective journal was kept during the interview and analysis process to enhance the credibility of the research.

Study 2: Quantitative Analysis

First, we examined whether individual process variables relating to the components of the intervention were associated with a change in word-finding ability using correlations, 2-tailed *t* tests, and ANOVAs for continuous, binary categorical, and categorical variables, respectively. These bivariate analyses determined the variables for inclusion in a multivariate model using a *P* value cut-off of $P < .05$. Second, we conducted multivariate linear regression analysis examining the association between those process measures identified in the bivariate analyses and change in word-finding ability. The model was adjusted for age and sex. We conducted collinearity checks, and 1 variable was removed where significant multicollinearity was identified. We regarded $P < .05$ as statistically significant. All statistical analysis was conducted using IBM SPSS Statistics for Windows (version 25; IBM Corp).

Ethical Considerations

Informed consent was obtained from all qualitative study participants, and this element of the study was approved by the Research Ethics Committee in the School of Health and Related

Research at the University of Sheffield (002436). For the quantitative component analysis, the following research ethics committees approvals included the secondary analysis of anonymized data without additional consent: Leeds West National Health Service Research Ethics Committee (13/YH/0377) and the Scottish A Research Ethics Committee (14/SS/0023). All data are anonymized. However, in the qualitative study, it may be possible for participants to be identified due to their roles in relation to the StepByStep software; this was highlighted to participants prior to their participation. Participants were not compensated for their time.

Results

Study 1: Findings From Qualitative Interviews

Participants

Of the 8 CSLT approach experts we invited to participate, 7 took part in 5 individual and 1 joint interview. We conducted 3 interviews face-to-face and 3 over the phone. In total, 4 participants were female. The median age of participants was 49 (range 32-56) years.

All participants used the CSLT approach frequently with use varying from daily to biweekly and the median length of CSLT approach use was 7 (range 2.5-15) years. All expert roles identified a priori were included in the sample (StepByStep software designers, therapists using the CSLT approach regularly, researchers involved in evaluating the CSLT approach, patients and caregivers who have used the CSLT approach and helped to test the StepByStep software, and volunteers supporting patients using the CSLT approach through a charity). In total, 5 participants had more than 1 role in relation to the CSLT approach, and participants' roles are illustrated after each quote using the italicized words above. The designers who have a financial stake in the StepByStep software declared a potential bias. Full details of participants' demographic information and relationship to the CSLT approach are presented in [Table 1](#).

Table 1. Study 1 participant demographic information and relationship to the CSLT^a approach.

Self-selected role in relation to the CSLT approach	Age	Sex	Final level of education	Ethnic group	Years working with CSLT approach	Frequency of CSLT approach use	Financial interest in software
Therapist, designer, and researcher	38	Female	Higher degree	White British	5	Weekly	No
Therapist and researcher	32	Female	Degree	White British	6	Weekly	No
People with aphasia	56	Male	Diploma or certificate in higher education	White British	7	Everyday	No
Caregiver and volunteer	54	Female	Diploma or certificate in higher education	White British	7	Biweekly	No
Volunteer	39	Male	Higher degree	White and Asian	2.5	Daily	No
Therapist, designer, and researcher	49	Female	Higher degree	White British	10	Daily	Yes
Designer	49	Male	Higher degree	White British	15	Biweekly	Yes

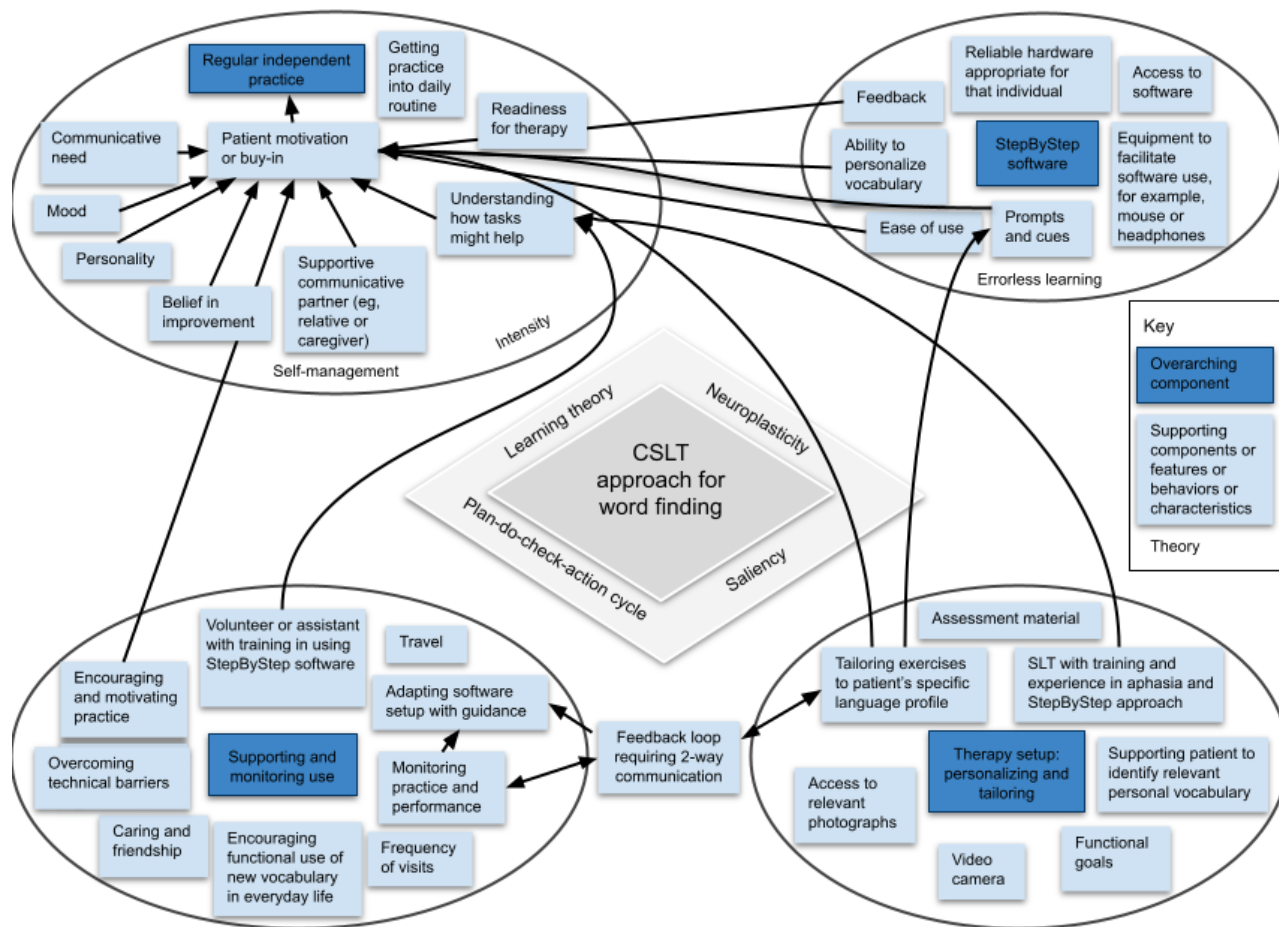
^aCSLT: Computerized Speech and Language Therapy.

Findings

We identified 4 themes describing the overarching components of the CSLT approach: (1) the StepByStep software, (2) therapy setup: personalizing and tailoring, (3) regular independent practice, and (4) supporting and monitoring use. The overarching

components are shown in [Figure 2](#) along with the supporting components, features, behaviors, characteristics, and theories that were perceived by participants to influence the delivery of this complex intervention; these will be described in turn below. A final theme related to measuring the components and processes of the CSLT approach.

Figure 2. Diagram illustrating the CSLT approach as described by CSLT approach experts. CSLT: Computerized Speech and Language Therapy; SLT: speech and language therapist.



The StepByStep Software

A volunteer described in lay terms their understanding of the StepByStep software:

StepByStep...is a conversion of genuine speech and language therapy exercises that were paper based and have been made into something that can be used on a computer. [Volunteer]

Dialogue concentrated on the availability of the software and features of the StepByStep software that motivated use, including perceived ease of use, the prompts and cues available, the feedback the software provides on practice time and performance, and the capacity to personalize vocabulary through selecting items of personal relevance. The importance of having appropriate and reliable hardware and additional equipment, such as a mouse or a microphone, to facilitate software use despite other disabilities, was recognized.

The key theory underpinning the StepByStep software itself is that of errorless learning [21]. The stepped approach starts with tasks that can be more easily achieved before moving on to more difficult exercises, however, this can be enhanced through SLT involvement in tailoring the software.

Although that errorless learning and that stepped approach is still built into the software, so to an extent it would do it on its own, but perhaps we can do it even more sensitively if there's a speech and language

therapist involved. [Therapist, researcher, and designer]

Therapy Setup: Tailoring and Personalizing

The type and level of difficulty of the exercises on the StepByStep software can be tailored to the patient's needs. Establishing the most appropriate level of difficulty was perceived to require "formal and informal assessment" of the individual's language impairment. Tailoring the exercises was perceived by most participants to increase the effectiveness of the therapy because it would "motivate practice and stimulate learning." Value was placed on the knowledge and skill of the person tailoring the therapy.

You would need a speech and language therapist with some experience in diagnosing and identifying somebody's level of impairment and then experience and knowledge in how to tailor the program. [Therapist and researcher]

An interaction was noted between tailoring the exercises and the monitoring and supporting use component because it is only through monitoring use that suboptimal tailoring can be identified and adjusted. Where tailoring and monitoring are performed by different people this creates an additional requirement for a "feedback loop" between the therapist and the volunteer or assistant.

While the software provides the facility to personalize the vocabulary, the addition of vocabulary relevant to the individual patient was described as part of the therapy setup process. Patient and caregiver participants felt that familiarity enabled the patient to recognize items more easily making the relearning process easier.

Because you couldn't tell what the picture was, whereas because it's a photograph you know exactly what it is and if it's your own kettle then it takes away some of the confusion because it's something you're familiar with. [Caregiver and volunteer]

Regular Independent Practice

As a self-managed intervention, participants perceived regular, repetitive, independent practice to be an essential component of the intervention to enable the desired outcome to be achieved. All of the participants recognized the importance of the patient being motivated or “buying-in” to the CSLT approach to ensure that regular independent practice occurs. Some participants discussed motivation in relation to the individuals’ personality or linked to other internal factors, such as mood or a need for greater communication.

This therapy is hard therapy and so if their communicative need isn't there then I find that they're not going to be as motivated and they're not going to do it as intensively as is required really. [Therapist, researcher, and designer]

Whereas others focused on how external factors related to the intervention can influence motivation, for example, the therapist and supporters were perceived to play a key role in ensuring the therapy was set up appropriately, explaining how the intervention works and the process of recovery as well as providing positive or negative reinforcement. The importance of practice being carried out regularly was discussed in relation to the theory of neuroplasticity [22].

I consider the brain to be a muscle and if you were training any other muscle then you'd have to do repeated exercise on that muscle and you'd have to increase, if we talk about weights for example if you were doing a bicep exercise you'd over time have to increase the difficulty by increasing the weight or the repetition to actually have an impact. [Volunteer]

Supporting and Monitoring Use

Supporting and monitoring the use of the software was the component with the widest variety of interpretations with some debate around who should be providing the support (assistant, volunteer, or therapist). However, irrespective of who was providing the support there was agreement around the activities required to support use and it was acknowledged that this depended on the needs of the individual patient. Activities included enabling the patient to use the software by helping to overcome technical barriers, building a supportive motivational professional relationship or friendship, monitoring practice and performance, adapting the software when required, and enabling opportunities to practice words targeted by the program in conversation in order to aid generalization.

It's really just giving encouragement and trying to stop there being problems so that the person who's using it hasn't got the problems to sort out really, being one step ahead. [Volunteer and caregiver]

Someone going along regularly and being someone that cares, I think that in itself, just someone that cares and forming a friendship. [Volunteer]

Views regarding the frequency with which support was required varied among participants, but there was agreement about the importance of providing support when needed by the patient and this was perceived to require more frequent visits initially with the frequency diminishing over time for most patients.

It is individualized, as a rule of thumb quite regularly for the first 4-6 weeks and then spread out to once a month. [Volunteer]

Measuring the Components and Processes of the CSLT Approach

Most participants referred back to their CSLT approach diagram when they described how they would measure the process of delivering the CSLT approach in the Big CACTUS trial. All participants recommended measuring the delivery of some aspect of each of the 4 overarching components. The 10 most frequently described aspects of the CSLT intervention that were perceived to need measuring were selected to be applied to the delivery of the CSLT approach within the Big CACTUS trial, see [Table 2](#).

Table 2. Aspects of the intervention participants most frequently described measuring in order to understand the process of delivering and receiving the CSLT^a approach in the Big CACTUS trial.

Overarching component	Ten aspects of the CLST approach to be measured in the Big CACTUS trial
StepByStep software	<ul style="list-style-type: none"> • How long was the software available to people with aphasia? • How easy is it to use the software?
Therapy setup (tailoring and personalizing)	<ul style="list-style-type: none"> • What sequence of steps are selected and why (eg, justification for tailoring)? • How skilled is the person assessing people with aphasia and setting up the software? • How are the steps adjusted or adapted in response to the performance of people with aphasia? • How much have the practice words been personalized?
Regular independent practice	<ul style="list-style-type: none"> • How much do people practice? • How motivated are the people with aphasia to practice? • What therapy exercises do people practice?
Supporting and monitoring use	<ul style="list-style-type: none"> • How good is the relationship between the supporter (volunteer or assistant) and the people with aphasia?

^aCSLT: Computerized Speech and Language Therapy.

The findings from the qualitative element of the study informed the process measures that were collected as part of the fidelity assessment of the Big CACTUS trial and therefore available for inclusion in the quantitative component analysis. The process measures were operationalized as follows:

First, measures related to the StepByStep software included duration of software availability recorded by the therapist (days) and a patient-reported measure of ease of use of the software (how easy is it to use the StepByStep computer therapy? Scored from 1 to 10; 1=very easy).

Second, measures of therapy setup (tailoring and personalizing) included duration of therapist time setting up and supporting the patient (minutes); therapist knowledge of the CSLT approach assessed by a quiz completed 5 months after randomization of their first participant (maximum score=15); completeness of therapists rationale for tailoring the therapy exercises as documented on a therapy planning form (0=partially complete; 1=rationale provided for every exercise); patient-reported measure of personalization of target words (are the words on the StepByStep computer therapy words you want to say? Scored on a 5-point scale from “All” to “None”; 1=all).

Third, regular independent practice measures included duration of therapy practice recorded electronically by the software within 6 months of randomization (minutes); the amount of time spent on the different types of therapy exercises available within the software (picture recognition, confrontation naming, using writing to cue naming, naming from a grid, and naming words in functional sentences) recorded electronically; patient-reported measure of motivation to carry out independent practice (how motivated are you to practice your StepByStep computer therapy exercises? Scored from 1 to 10; 1=very motivated). The “picture recognition” exercise is designed for familiarization with the target words or images. The “confrontation naming” exercise presents the patient with an image of the target word with cues. The “using writing to cue naming” exercise shows a word to spell or an anagram to unscramble in order to prompt retrieval of the word using the voice recognition function. The “naming from a grid” exercise requires the patient to name the items without cues using the

speech recognition function and then name the same items again from memory. The “using words in functional sentences” exercise asks a question and requires the patient to answer the question using the target word in a sentence.

Fourth, measures of supporting and monitoring use included duration of support and monitoring reported by the therapy assistant or volunteer (minutes); and the quality of the relationship between the therapy assistant or volunteer and the patient. The quality of the relationship was measured using the Working Alliance Inventory–Short Revised Therapist version (WAI-SRT), which was completed by the assistant or volunteer 4 months into the intervention period [23]. A composite score was used including questions relating to the therapeutic bond, as well as task and goal agreement.

Study 2: Results of Quantitative Component Analysis

Participants

Data from all participants randomized to the intervention arm of the Big CACTUS trial with baseline and 6-month word-finding assessments were included in the analysis (n=83). Due to death, investigator decision, and withdrawal of consent, 14 intervention arm participants did not complete the 6-month outcome measure. Of the 83 participants eligible for inclusion in the quantitative analysis, the mean age was 64.35 years and 57% (n=47) were male. Participant’s mean change in word finding over the 6-month intervention period was 32.84 (SD 30.51).

Bivariate Analysis

Process variables relevant to each of the 4 key components highlighted in the qualitative interviews will be described in turn along with their relationship to change in word-finding ability.

The StepByStep software was available to patients for 75.4% (median 138/183 days) of the maximum possible time, and its availability demonstrated a positive, statistically significant correlation with the change in word-finding ability ($r=0.353$; $n=83$; $P=.001$). The software was perceived to be moderately easy to use (median score 5 out of 10; 1=very easy); however,

the number of responses to this question was low, and it was not found to be correlated with change in word-finding ability ($r=0.245$; $n=30$; $P=.19$).

The median duration of therapist time spent on therapy setup and support was 7 hours 35 minutes; this was not found to be associated with a change in word-finding ability ($r=0.175$; $n=83$; $P=.11$). The median score on the quiz of the treating therapists' knowledge of the intervention was 10 out of 15; this was not correlated with a change in word-finding ability ($r=0.061$; $n=83$; $P=.581$). The rationale for tailoring documented on the therapy planning form was complete for 65% (54/83) of participants compared to having only been partially completed for the remaining participants; the provision of a thorough rationale for tailoring was found to be associated with a change in word-finding ability ($t_{80}=-2.139$; $n=82$; $P=.04$). Along with tailoring, the other aspect of the therapy setup was personalization. Participants perceived that most of the words (median 4 out of 5; 1=none) were of personal relevance; however, the number of responses to the question was low and no association was found ($r=0.138$; $n=32$; $P=.67$).

The median amount of independent practice carried out by the patients was 25 hours 57 minutes. A weak, positive statistically significant correlation was found between the total amount of practice and change in word-finding ability ($r=0.271$; $n=83$; $P=.01$). Furthermore, the amount of time spent on 2 of the individual therapy exercises was found to be associated with a change in word-finding ability, with a median of 5 hours 32 minutes spent on confrontation naming exercises ($r=0.241$; $n=79$; $P=.03$) and 1 hour 38 minutes spent on naming words in functional sentences ($r=0.313$; $n=79$; $P=.005$). In contrast, no statistically significant association was found between time spent on the remaining 3 exercises and change in word-finding ability, with a median of 1 hour 31 minutes spent on picture recognition or matching exercises ($r=-0.029$; $n=79$; $P=.80$), 9

hours 7 minutes spent on using writing to cue naming exercises ($r=0.103$; $n=79$; $P=.37$), and 1 hour 3 minutes spent on naming from a grid exercises ($r=0.215$; $n=79$; $P=.06$). Participants rated their motivation to carry out regular independent practice as a median of 4 out of 10 (1=very motivated); however, the number of responses was low, and no statistically significant association was found between patients' level of motivation and change in word-finding ability ($r=-0.029$; $n=30$; $P=.88$).

The median amount of support and monitoring provided by volunteers and therapy assistants was 4 hours 15 minutes; a weak, positive, and statistically significant correlation was found between the duration of support and monitoring and patients' change in word-finding ability ($r=0.286$; $n=75$; $P=.01$). The quality of the relationship between the volunteer or therapy assistant scored using the WAI-SRT scored a median of 4 out of 5; however, the number of responses was low, and no association was found between the WAI-SRT score and change in word-finding ability ($r=0.183$; $n=19$; $P=.45$).

Multivariate Analysis

We entered the process variables found to be associated with a change in word-finding ability into a multivariate linear regression model. Collinearity checks demonstrated that total practice time was highly correlated with time spent practicing 2 of the individual exercises (confrontation naming and naming words in functional sentences), so it was subsequently excluded from the model as the latter 2 variables conveyed more detail. After adjusting for age and sex, we found that providing a thorough rationale for tailoring the therapy exercises ($P=.04$) and time spent practicing naming words in functional sentences exercises ($P=.046$) were statistically significantly associated with change in word-finding ability (see Table 3). The adjusted R^2 was 0.216, indicating that 21.6% of the variance in change in word-finding ability could be accounted for by this multivariate linear regression model.

Table 3. Multivariate linear regression on change in word-finding ability^a.

Variable	Coefficient	P value
Duration of software availability (days)	0.141	.25
Completeness of therapist rationale for tailoring the therapy exercises (0=partial; 1=complete)	0.221	.046
Time spent practicing confrontation naming exercises (hours)	0.131	.24
Time spent practicing naming words in functional sentence exercises (hours)	0.236	.04
Duration of support and monitoring reported by the therapy assistant or volunteer (minutes)	0.173	.15
Age (1-year increments)	-0.146	.18
Sex (0=male, 1=female)	-0.1	.35

^aThe value of adjusted R^2 for this multivariate linear regression model is 0.216.

Discussion

Key Findings

Through qualitative interviews, 4 overarching components of the CSLT approach for word finding used in the Big CACTUS study were identified: (1) the StepByStep software, (2) therapy setup: tailoring and personalization, (3) regular independent practice, and (4) supporting and monitoring use. In addition to

identifying the overarching components of the intervention and providing a detailed description of the underpinning theories, mechanisms, and processes, participants also identified key processes of the CSLT approach that should be measured in the Big CACTUS trial. Through analysis of the association between process and outcome data, 2 "active ingredients" of the CSLT intervention were identified: therapists tailoring the therapy exercises based on the impairment of people with aphasia and

people with aphasia practicing naming words in functional sentences.

This study provides a comprehensive description of the CSLT approach from a variety of different perspectives. The complexity of the approach can be seen in the diagram depicting its overarching components and the objects, processes, behaviors, and theories that underpin the intervention. Howe [24] proposed that complexity can be a property both of an intervention and the context in which it is operationalized and that we can only truly understand that complexity by recognizing that knowledge generation comes from clinicians and implementers as much as it comes from intervention researchers. Thus, the importance of engaging with a variety of stakeholders to truly understand the complexity of a self-managed computer-based intervention, such as the CSLT approach, is highlighted.

The completion of this research also informed the Big CACTUS trial team's understanding of the CSLT approach and the completion of the TIDieR checklist for the Big CACTUS trial [5,7]. Improved intervention reporting of the CSLT approach has the potential to enable SLTs to deliver this computerized therapy as intended and thereby enable people with aphasia to achieve improved word finding as found in the Big CACTUS trial.

Secondary analysis of data from the Big CACTUS trial identified 2 "active ingredients" of the CSLT approach: therapists tailoring the therapy exercises and people with aphasia practicing using words in functional sentences. As therapists implement the CSLT approach with inevitable adaptations to the local context [12], it may be most beneficial to people with aphasia if they are mindful of the importance of these aspects of the intervention and seek to retain them when adapting the approach locally.

Tailoring the therapy exercises for the individual patient in the CSLT approach involved selecting prompts and cues (eg, semantic or phonological cues) most likely to help the patient based on their impairment. The tailoring of the type and difficulty of therapy exercises is supported by evidence of the effectiveness of model-oriented aphasia therapy, which tailors exercises based on the patient's symptoms [25]. SLTs have identified that tailoring computer software to the needs of individuals can be time-consuming [26]. It is therefore possible that therapists could be tempted not to tailor in order to offer people with aphasia computerized SLT exercises more time efficiently. However, it would appear to be worth the initial outlay of time as participants' word finding improved significantly more if a more thorough rationale for tailoring was provided.

The amount of time spent using the computer software to practice naming words in functional sentences was found to be significantly associated with improved word finding. Evidence from the neuroscience literature suggests that it is beneficial to practice the language in relevant action contexts (referred to as the behavioral relevance principle [27]), this could provide a possible explanation for why "naming words in functional sentences" (which sometimes included an action, eg, "Where do you go to do your shopping? We go to the supermarket")

was the only exercise associated with improved word finding. A wide variety of mobile apps for word finding are available on the market, and this finding suggests that being able to practice in sentences may be a key feature to look for in order to maximize improvement of word retrieval [28].

Complex interventions are not static and they do not operate within a vacuum [29]. The StepByStep software itself is constantly being refined and updated (Steps Consulting Ltd website). The findings of this study have resulted in updates to the StepByStep software that encourage people with aphasia to move through the exercises more quickly to increase the amount of time spent on the final exercise, naming words in functional sentences. In addition, a series of apps are in development by Steps Consulting Ltd, including a telehealth app that will allow SLTs to tailor therapy exercises remotely.

Those who have called for more research to investigate the mechanisms between intervention delivery and outcome suggest that one of the benefits of identifying causal components or active ingredients of the intervention is to enable the intervention to be adapted to the local context while remaining effective [11,13]. Therefore, if the components whose delivery is associated with improved outcomes are not delivered, one would not expect the desired outcome to be achieved. As such, the clinical recommendations to therapists implementing the StepByStep approach intervention in clinical practice would be to (1) have a thorough rationale for how the therapy is tailored to the individual people with aphasia and (2) encourage people with aphasia to focus on practicing therapy exercises requiring the production of words in functional sentences.

Limitations

An interview approach was selected for practical reasons due to participants' geographical diversity and limited availability and in order to facilitate the involvement of people with aphasia. Focus groups would have provided an opportunity to illuminate agreement and inconsistencies in participants' understanding of the key components of the CSLT approach [30]. It is possible that the nominated expert sampling strategy did not reach saturation for the qualitative interviews and that there were other StepByStep experts not known to the author or identified by the snowball sampling technique.

Process measures included the use of unvalidated tools to measure tailoring, therapist knowledge, motivation, ease of use, and personalization—a limitation widely acknowledged in fidelity research due, in part, to the need for measures to be tailored to specific interventions [31,32]. Furthermore, it was not possible to measure all processes directly, and consequently, proxy measures were used. For example, due to resource limitations, it was not possible to determine for each person with aphasia the extent to which the therapy program was tailored to the individual's impairment, and consequently, a proxy measure of providing a thorough rationale for tailoring a therapy planning form was used.

The use of bivariate analyses to determine factors for inclusion in a multivariate model increases the chance of a type I error, due to the model being overfitted. However, the method was used because it offers increased transparency compared to using

an automated regression function, such as Stepwise regression [33]. The multivariate model only accounted for 21.6% of the variation in word-finding ability, thus demonstrating that other factors are at play. Possible factors might include individual differences, such as lesion size [34]; wider contextual factors, such as social support; or other components of the intervention not measured within this study. Future research could develop a more comprehensive model to account for improvement in word finding incorporating individual differences, such as those described above, as well as aspects of intervention delivery.

Conclusions

The qualitative exploration of the CSLT approach provided a detailed description of the components, theories, and

mechanisms underpinning the intervention and facilitated the identification of appropriate process measures to be collected in the Big CACTUS trial. The quantitative component analysis furthered our understanding of which components of the intervention are associated with clinical improvement. In order to optimize the benefits of using the CSLT approach for word finding, therapists are advised to pay particular attention to the active ingredients of the intervention: tailoring the therapy exercises based on the individual's specific language difficulties and encouraging people with aphasia to practice using words in functional sentences.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on request.

Authors' Contributions

All authors contributed to the conception and design of the study. MH conducted the interviews, performed the qualitative and quantitative data analysis, and wrote the first draft of the paper. RP and CC contributed to the interpretation of the qualitative and quantitative findings and made substantial suggestions to the paper. All authors approved the final paper.

Conflicts of Interest

None declared.

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Abbreviations

Big CACTUS: Clinical and Cost Effectiveness of Computer Treatment for Aphasia Post Stroke

CSLT: Computerized Speech and Language Therapy

SLT: speech and language therapist

TIDieR: Template for Intervention Description and Replication

WAI-SRT: Working Alliance Inventory–Short Revised Therapist

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Original Paper

Effects of Virtual Reality Exercises on Chronic Low Back Pain: Quasi-Experimental Study

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Abstract

Background: Low back pain is a common health problem globally. Based on the duration of pain, it is classified as acute, subacute, or chronic low back pain. Different treatment strategies are available to reduce chronic low back pain. Virtual reality (VR) is a novel approach in back pain rehabilitation.

Objective: This study aimed to compare the effects of VR games on chronic low back pain.

Methods: This quasi-experimental study was conducted among 40 patients with chronic low back pain. The data were collected using a nonprobability, convenient sampling technique. Patients visiting the Department of Physiotherapy, Government Services Hospital, Lahore, Pakistan, were recruited and equally divided into 4 groups. Group A received the Reflex Ridge game; group B received the Body Ball game; group C combined the 2 games without back-strengthening exercises; and group D combined the 2 games with back-strengthening exercises. The participants received 8 treatment sessions, with 3 sessions/wk. The outcomes were pre- and posttest measurements of pain intensity, low back disability, and lumbar range of motion. The repeated measurement ANOVA was used for inter- and intragroup comparison, with significance at $P \leq .05$.

Results: The study comprised a sample of 40 patients with low back pain; 12 (40%) were female and 28 (60%) were male, with a mean age of 37.85 (SD 12.15) years. The pre- and posttest mean pain scores were 7.60 (SD 1.84) and 4.20 (SD 1.62) in group A, 6.60 (SD 1.776) and 5.90 (SD 1.73) in group B, 6.90 (SD 1.73) and 5.40 (SD 1.07) in group C, and 7.10 (SD 1.53) and 3.60 (SD 0.97) in group D, respectively. The mean pain score differences of group D (combining the Reflex Ridge and Body Ball games with back-strengthening exercises) compared to groups A, B, and C were $-.60$ ($P=.76$), -2.30 ($P<.001$), and -1.80 ($P=.03$), respectively. Regarding the range of motion, the forward lumbar flexion mean differences of group D compared to groups A, B, and C were 3.80 ($P=.21$), 4.80 ($P=.07$), and 7.40 ($P<.001$), respectively. Similarly, the right lateral lumbar flexion mean differences of group D compared to groups A, B, and C were 2.80 ($P=.04$), 5.20 ($P<.001$), and 4.80 ($P<.001$), respectively. The left lateral lumbar flexion mean differences of group D compared to groups A, B, and C were 2.80 ($P<.001$), 4.80 ($P=.02$), and 2.20 ($P<.001$), respectively, showing significant pre- and posttreatment effects.

Conclusions: VR exercises had statistically significant effects on improving pain, low back disability, and range of motion in all groups, but the combination of Reflex Ridge and Body Ball games with back-strengthening exercises had dominant effects compared to the other groups.

Trial Registration: Iranian Registry of Clinical Trial IRCT20200330046895N1; <https://en.irct.ir/trial/46916>

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KEYWORDS

low back pain, lumbar range of motion; pain; Oswestry disability index; virtual reality; exercise; back pain; lumbar; range of motion; virtual reality; VR; rehabilitation; gaming; serious game

Introduction

Low back pain (LBP) is a prevalent health concern that becomes more common as people age [1]. Based on the duration of pain, it is further classified into 3 categories: acute, subacute, or chronic LBP [2]. LBP affects people of all ages, from children to older adults, and can afflict people in high-, middle-, and low-income countries. People with physically demanding jobs, those with physical and mental illnesses, smokers, and people with obesity are more likely to have LBP [3]. From the third decade of life to 60 years of age, the frequency of chronic LBP rises linearly, with women being more affected [4]. Furthermore, the fear of pain is more strongly linked to impairment in people with chronic LBP than in people with acute LBP [5]. Patients avoid spinal flexion because of the fear of pain, especially lumbar flexion [6]. This kinesiophobia can be managed using virtual reality (VR) maneuvers including the neuromodulation of body perception, distraction, and graded exposure therapy. These 3 mechanisms are considered the theoretical basis of VR therapeutic effects [7].

To treat persistent LBP, various treatments, including nonpharmacological interventions, can be used. VR is a type of rehabilitation technology that allows users to engage in a computer-generated environment [8]. Recently, the development of portable and affordable motion tracking systems has broadened the use of VR in the management and rehabilitation of patients with musculoskeletal pain [9]. VR has 3 elements: interaction, immersion (sometimes nonimmersive), and imagination [10]. Through a head-mounted display that follows the movement of the participant's body, VR gives the sensation of being entirely encircled by a virtual world [11]. VR games have already been integrated into rehabilitation programs for patients with chronic pain [12]. Distraction is one of the suggested mechanisms that explains the effects of VR on pain [13]. In orthopedic rehabilitation, clinical trials have previously assessed VR effectiveness in individuals with different musculoskeletal disorders, including ankle sprain, anterior cruciate ligament injury, and frozen shoulder [14]. It also makes it possible to increase movement in patients with kinesiophobia due to chronic pain [15]. Among different treatment regimens, the use of isokinetic and VR exercises is considered to be effective [16]. The idea is to catch the attention of the user in such a way that the patient's mind focuses on the game while performing game tasks that are actually exercises for pain and rehabilitation [17]. With this approach, we are able to translate clinical guidelines into the VR environment to facilitate future implementation in the care pathway [18]. Virtual exercises are based on body movements including catching, squatting, bending, jumping, and a combination of these movements during the rehabilitation process [19]. The lack of adequate physical activity or sedentary lifestyle is one of the major problems [20]. The use of virtual embodiment to influence body perception is beginning to receive more attention, and it might have clinical

implications for disorders such as chronic pain that include altered body image [21].

Various studies have reported the positive impact of VR games, but there is a need to explore the comparison and combination of different routine VR games. Different VR games can help manage chronic LBP. This study aimed to assess the effects of 2 games, the Reflex Ridge and Body Ball VR games, in patients with chronic LBP. We hypothesized that the VR games used would constitute an acceptable exercise program for patients with chronic LBP.

Methods**Design**

This was a quasi-experimental study conducted in Lahore, Pakistan. Initially, a randomized controlled trial had been intended; however, due to the COVID-19 pandemic and the uncertainties caused by it, the study design was changed to a quasi-experimental study. The institutional review board of the University of Lahore approved the amendments made to the research project.

Ethical Considerations

The ethical approval of the study was obtained from The University of Lahore (IRB-UOL-FAHS/696-IV/2020).

Participants and Settings

A total of 70 patients with LBP were screened for the study, and 40 participants (10 in each group) were recruited from the Department of Physiotherapy, Government Services Hospital, Lahore, Pakistan. The participants were recruited using the nonprobability, convenient sampling technique.

Sample Size

The sample size was calculated as follows:

$$n = \frac{z_{1-\alpha/2}^2 (\mu_1^2 + \mu_2^2)}{d^2}$$

where $z_{1-\alpha/2}$ was the level of significance, μ_1 was the expected mean of the visual analogue scale (4.0) in group A [22], μ_2 was expected mean of the visual analogue scale (5.0) in group B [22], the expected SD was 0.75 in group A and 2.0 in group B, the power of study was 80%, and the expected sample size was 40 ($n=10$ for each group).

Patient Characteristics

Basic information regarding age, BMI, marital status, occupation, and symptoms with a complete history was obtained before enrollment.

Interventions and Procedures

Pretest assessment was made after informed consent from all participants. In all, 40 patients with chronic LBP were equally divided into 4 groups following the inclusion and exclusion criteria (Textbox 1).

Textbox 1. Study selection criteria of patients with low back pain.

Inclusion criteria
<ul style="list-style-type: none"> All genders Aged 25-50 years Low back pain that lasted more than 12 weeks Nonradiating pain
Exclusion criteria
<ul style="list-style-type: none"> Recurrent low back pain Neurological symptoms Any previous history of fracture in the spine or lower limb, cardiac or endocrine disease, or neurological disorders such as Parkinson disease and stroke

Group A was given the Reflex Ridge game, and group B was given the Body Ball game. Group C combined the Reflex Ridge game with the Body Ball game without back-strengthening exercises; the rest of treatment protocol was same. Group D combined the Reflex Ridge game with the Body Ball game along with back-strengthening exercises, including bridging, prone leg raises, trunk extension while keeping the arms on the back, and trunk rotation exercises [23]. After the VR exercises, all groups were given moist heat therapy with transcutaneous electrical nerve stimulation for 10 minutes, with a frequency of 10 repetitions. The participants received 8 treatment sessions, with 3 sessions/wk.

VR was provided through the Kinect Xbox 360 device (v.2 model; Microsoft) [24]. This sensitive device for motion sensing incorporates time-of-flight and red-green-blue cameras for the detection of body skeletal movements and real-time gesture evaluation. This is attached to an LCD monitor. In the Reflex Ridge game, participants performed different movements (lumbar side bending, lumbar movement with shoulder elevation, sitting, and jumping) to avoid hitting the obstacle. In the Body Ball game, arm and leg movements were used to hit the ball.

Outcomes

The outcome measures were pain intensity, low back disability, and lumbar range of motion (ROM), measured through a numerical pain rating scale, the Oswestry disability index (ODI), and pre- and posttest evaluations.

Pain Intensity

Pain intensity was measured using the numerical pain rating scale. Patients were asked to select a circle that best describes the current level of pain, from 0 (no pain) to 10 (severe pain) [25].

Low Back Disability

Low back disability was measured using the ODI. It is considered valid and suitable for the assessment of disability among patients with LBP [26]. It consists of 10 sections including pain, personal care, sitting, lifting, walking, sleeping,

standing, traveling, social life, and sexual life, each having scores from 0-5 with a total score of 50. It is a broader level assessment of disability compared to pain intensity alone [27].

Lumbar ROM

Lumbar ROM was recorded using a gravity-based inclinometer in the standing position. The inclinometer was placed at the T12-L1 level of the spinal column, marked, and zeroed. Flexion and extension were measured at the T12-L1 level with a command to bend forward and backward, respectively. The right and left lumbar lateral flexion ROMs were measured by keeping the inclinometer parallel to the axis of the spinal column, and patients were asked to bend on their respective sides with fingertips pointed down toward the respective side of the thigh [28]. The inclinometer has a good reliability for measuring spinal ($r=0.97$), flexion ($r=0.98$), and extension ($r=0.75$) ROMs [29].

Data Analysis

All data were encoded and entered anonymously and remained confidential. IBM SPSS (version 24.0) was used for statistical analysis. The means and SDs of quantitative data were measured. However, frequencies and percentages were used to present categorical data. Normality tests were applied for data distribution using skewness, kurtosis, and the Shapiro-Wilks test. The distribution of data was normal as the P value was $>.05$. For pre- and posttest evaluations, parametric repeated measurement ANOVA was used to analyze intragroup comparisons and measure mean intergroup differences for pain intensity, low back disability, and lumbar ROM. The tests were conducted at a significance level of $P \leq .05$.

Results

Patient Characteristics

The study comprised 40 patients with LBP; 12 (40%) were female and 28 (60%) were male, with a mean age of 37.85 (SD 12.15) years. All the participants were married. Most had a BMI in the normal ($n=13$, 32%) and overweight ($n=18$, 45%) categories (Table 1).

Table 1. Patient characteristics.

Demographics and category	Value (n=40), n (%)
Sex	
Male	28 (60)
Female	12 (40)
BMI	
Underweight	6 (15)
Normal	13 (32)
Overweight	18 (45)
Obese	3 (8)
Occupation	
Teacher	14 (35)
Shopkeeper	16 (40)
Computer worker	8 (20)
Banker	2 (5)

Outcomes

Pain Intensity

The pre- and posttest mean pain scores were 7.60 (SD 1.84) and 4.20 (SD 1.62) in group A, 6.60 (SD 1.776) and 5.90 (SD 1.73) in group B, 6.90 (SD 1.73) and 5.40 (SD 1.07) in group C, and

7.10 (SD 1.53) and 3.60 (SD 0.97) in group D, respectively (Table 2). The mean pain score differences of group D compared to groups A, B, and C were $-.60$ ($P=.76$), -2.30 ($P<.001$), and -1.80 ($P=.03$), respectively (Table 3). There was a significant improvement in pain rating in all groups (all $P<.05$), but pre- and posttest differences showed a significant improvement in group D for pain ($P<.001$).

Table 2. Intragroup comparison for pain and disability index.

Group and evaluation	Pain rating			ODI ^a		
	Mean (SD)	Mean SE	<i>P</i> value ^b	Mean (SD)	Mean SE	<i>P</i> value ^b
Group A			.001			<.001
Pretest	7.60 (1.84)	.58		25.10 (3.035)	.959	
Posttest	4.20 (1.62)	.51		13.10 (1.85)	.586	
Group B			.02			<.001
Pretest	6.60 (1.776)	.56		25.30 (2.791)	.88	
Posttest	5.90 (1.73)	.54		17.30 (3.35)	1.05	
Group C			.01			<.001
Pretest	6.90 (1.73)	.54		24.30 (2.75)	.87	
Posttest	5.40 (1.07)	.33		13.20 (4.661)	1.47	
Group D			<.001			<.001
Pretest	7.10 (1.53)	.48		24.20 (2.098)	.66	
Posttest	3.60 (.97)	.30		3.30 (1.49)	.47	

^aODI: Oswestry disability index.

^b*P* values are significant at $\leq .05$.

Table 3. Intergroup comparison for pain and disability index.

Group and compared group	Pain rating		ODI ^a	
	Mean difference	<i>P</i> value	Mean difference	<i>P</i> value
Group A				
Group B	-1.70	.04	-4.20	.002
Group C	-1.20	.23	-.10	>.99
Group D	.60	.76	9.80	.001
Group B				
Group A	1.70	.04	4.20	.02
Group C	.50	.85	4.10	.02
Group D	2.30	.00	14.00	.001
Group C				
Group A	1.20	.23	.100	.68
Group B	-.50	.85	-4.10	.02
Group D	1.80	.03	9.90	<.001
Group D				
Group A	-.60	.76	-9.80	<.001
Group B	-2.30	<.001	-14.00	<.001
Group C	-1.80	.03	-9.90	<.001

^aODI: Oswestry disability index.

Low Back Disability

After 8 sessions, the pre- and posttest ODI were 25.10 (SD 3.035) and 13.10 (SD 1.85) in group A, 25.30 (SD 2.791) and 17.30 (SD 3.35) in group B, 24.30 (SD 2.75) and 13.20 (SD 4.661) in group C, and 24.20 (SD 2.098) and 3.30 (SD 1.49) in group D, respectively (Table 2). In the intergroup analysis, group D showed dominant effects on the disability index compared to groups A, B, and C, with mean differences of -9.80, -14.00, and -9.90 (all $P < .001$), respectively (Table 3).

Lumbar ROM

The pre- and posttest mean scores for lumbar flexion were 36.10 (SD 4.91) and 42.50 (SD 5.78) in group A, 37.20 (SD 3.43) and 38.90 (SD 2.64) in group B, 36.10 (SD 4.91) and 41.50 (SD 5.42) in group C, and 37.20 (SD 3.42) and 46.30 (SD 1.95) in group D, respectively. The pre- and posttest mean scores for right lateral lumbar flexion were 12.90 (SD 1.19) and 16.70 (SD 1.05) in group A, 13.60 (SD 1.95) and 14.30 (SD 2.35) in group B, 12.90 (SD 1.197) and 15.60 (SD 0.966) in group C, and 13.50 (SD 1.96) and 19.5 (SD 3.57) in group D,

respectively. The pre- and posttest mean scores for left lateral lumbar flexion were 12.90 (SD 1.19) and 16.0 (SD 1.76) in group A, 13.60 (SD 1.96) and 14.00 (SD 1.24) in group B, 14.60 (SD 2.41) and 16.60 (SD 2.17) in group C, and 14.60 (SD 1.35) and 18.80 (SD 1.32) in group D, respectively. The pre- and posttest mean scores for lumbar extension were 8.6 (SD 1.71) and 11.60 (SD 1.84) in group A, 7.90 (SD 1.10), and 8.70 (SD 0.94) in group B, 8.20 (SD 1.686) and 10.70 (SD 1.636) in group C, and 7.90 (SD 1.37) and 13.50 (SD 0.85) in group D, respectively (Table 4).

The mean differences in forward lumbar flexion ROM for group D compared to groups A, B, and C were 3.80 ($P = .21$), 4.80 ($P = .07$), 7.40 ($P < .001$), respectively. The mean differences in right lateral lumbar flexion ROM for group D compared to groups A, B, and C were 2.80 ($P = .04$), 3.90 ($P < .001$), and 5.20 ($P < .001$), respectively. The mean differences in left lateral lumbar flexion ROM for group D compared to groups A, B, and C were 2.80 ($P < .001$), 2.20 ($P = .02$), and 4.80 ($P < .001$), respectively. The mean differences in lumbar extension ROM for group D compared to groups A, B, and C were 1.90 ($P = .02$), 2.80 ($P < .001$), and 4.80 ($P < .001$), respectively (Table 5).

Table 4. Intragroup comparison for lumbar range of motion.

Range of motion and evaluation	Group A			Group B			Group C			Group D		
	Mean (SD)	Mean SE	P value	Mean (SD)	Mean SE	P value	Mean (SD)	Mean SE	P value	Mean (SD)	Mean SE	P value
Lumbar forward flexion			<.001			.38			<.001			<.001
Pretest	36.10 (4.91)	1.55		37.20 (3.43)	1.08		36.10 (4.91)	1.55		37.20 (3.42)	1.08	
Posttest	42.50 (5.78)	1.83		38.90 (2.64)	0.83		41.50 (5.42)	1.71		46.30 (1.95)	0.61	
Right lateral lumbar flexion			<.001			.10			<.001			<.001
Pretest	12.90 (1.19)	0.37		13.60 (1.95)	0.61		12.90 (1.197)	0.37		13.50 (1.96)	0.61	
Posttest	16.70 (1.05)	0.33		14.30 (2.35)	0.74		15.60 (0.966)	0.3		19.5 (3.57)	1.13	
Left lateral lumbar flexion			<.001			.49			<.001			<.001
Pretest	12.90 (1.19)	0.37		13.60 (1.96)	0.61		14.60 (2.41)	0.76		14.60 (1.35)	0.42	
Posttest	16.0 (1.76)	0.27		14.00 (1.24)	0.39		16.60 (2.17)	0.68		18.80 (1.32)	0.41	
Lumbar extension			<.001			<.001			<.001			<.001
Pretest	8.6 (1.71)	0.54		7.90 (1.10)	0.34		8.20 (1.686)	0.53		7.90 (1.37)	0.43	
Posttest	11.60 (1.84)	1.55		8.70 (0.94)	0.30		10.70 (1.636)	0.51		13.50 (0.85)	0.26	

Table 5. Intergroup comparison for lumbar range of motion.

Groups and compared group	Forward lumbar flexion		Right lateral lumbar flexion		Left lateral lumbar flexion		Lumbar extension	
	Mean difference	P value	Mean difference	P value	Mean difference	P value	Mean difference	P value
Group A								
Group B	3.60	.25	2.40	.09	2.00	.05	2.90	<.001
Group C	1.00	.95	1.10	.69	-.600	.85	.90	.47
Group D	-3.80	.21	-2.80	.04	-2.80	<.001	-1.90	.02
Group B								
Group A	-3.60	.25	-2.40	.09	-2.00	.05	-2.90	<.001
Group C	-2.60	.53	-1.30	.57	-2.60	<.001	-2.00	.01
Group D	-4.80	<.001	-5.20	<.001	-4.80	<.001	-4.80	<.001
Group C								
Group A	-1.00	.95	-1.10	.69	.60	.85	-.90	.47
Group B	2.60	.53	1.30	.56	2.60	<.001	2.00	.01
Group D	-4.80	.07	-3.90	<.001	-2.20	.02	-2.80	<.001
Group D								
Group A	3.80	.21	2.80	.04	2.80	<.001	1.90	.02
Group B	4.80	.07	3.90	<.001	2.20	.02	2.80	<.001
Group C	7.40	<.001	5.20	<.001	4.80	<.001	4.80	<.001

Discussion

Principal Findings

LBP is one of the major musculoskeletal health issues prevalent among the general population. This quasi-experimental study was conducted among 40 patients with chronic LBP who were treated with VR exercises along with traditional exercises. VR exercises were found to have dominant effects in improving pain, low back disability, and lumbar ROM in the different groups, but the combination of VR games, including the Reflex Ridge and Body Ball games with back-strengthening exercise, was better than other groups.

Comparison With Prior Work

This study was conducted among 40 patients. We hypothesized that VR exercises through the Reflex Ridge and Body Ball games could be one of the effective methods used in the clinical management of LBP and improve lumbar ROM and disability index, similar to the findings of dodge ball games in the literature [6]. Our study results favored VR exercises for improving pain, low back disability, and lumbar ROM. Park et al [30] used the Nintendo Wii exercise program for LBP and reported that exercise programs significantly improved physical function related to LBP. In health-related quality of life, the Nintendo Wii exercise program showed significant improvements in both the mental and physical health composites, but other groups showed significant improvement only in the physical health composite.

The integration of VR with physiotherapy was found to be effective for pain, ROM, disability index, and kinesiophobia. Experimental treatment with VR reduced pain and improved physical function in patients with acute and chronic pain as well [15]. In another study, a VR dodgeball intervention provided evidence of safety and feasibility and can be used to encourage spinal flexion in individuals with chronic LBP [6]. Group D reduced pain intensity compared to other groups that were treated with the Body Ball or Reflex Ridge game alone (group A: $P=.76$; group B: $P<.001$; and group C: $P=.03$), showing significant and better results than all other groups.

One of the reasons for using VR games is that it induces a postexercise hypoalgesic effect and a significant reduction in thinking of pain, which further enhances its implication in clinical studies for pain management [12]. This study correlated with our study, as the Body Ball and Reflex Ridge VR games along with exercises are intended to allow movements in the lumbar region within a virtual environment, and the involvement of participants while playing the game elicits enthusiasm and eagerness to perform activity throughout the session. In our study, low back disability index differences in the groups had P values $<.05$, showing improvement in all 4 groups. Yilmaz

Yelva et al [15] stated that VR had a positive impact on pain and kinesiophobia in individuals with chronic pain. In their study among patients with subacute and chronic nonspecific LBP, virtual walking integrated with physiotherapy decreased pain and improved function in the short term. Their findings are similar to our study, but the games administered were different. Wiederhold et al [31] stated that VR as a distraction technique is effective in reducing pain intensity and discomfort with significance ranging from $P=.05$ to $P=.001$. A previous study has shown significant effects of VR exercises for improving pain, disability, and ROM but has not compared which VR exercise game is more feasible and effective [23]. In our study, the lumbar ROM—including flexion, extension, and lateral flexion on both sides—improved in all groups, but intragroup comparisons showed that group D with a combination of VR and exercise had superior effects in improving the lumbar ROM with significant pre- and posttest differences. This finding demonstrated that the VR exercises had an additive effect and led us to assume that these exercises can be an option for the treatment of LBP, similar to the effects seen in core stability exercises [32]. This emerging technology has been used for the nonpharmacological management of LBP and resulted in less use of nonsteroidal anti-inflammatory drugs. VR has been considered as an analgesic as it works based on the distraction phenomenon to decrease pain [33]. VR exercises compared to traditional exercises exert a positive impact on psychological, physiological, and rehabilitative outcomes, but there is a need trial different games to better rehabilitation programs [34].

Despite the novelty of the technique, different VR games may lead to rapid pain relief in addition to routine management strategies. Different VR games in different age groups and clinical trials are recommended for better generalization of the results.

Limitations

The study conditions and participant characteristics may not represent the broader population of interest due to limited generalizability to other populations and settings. There was no random assignment of participants and this lack of randomization can introduce selection bias. Despite these limitations, a quasi-experimental study is valuable especially in a situation where a randomized controlled trial was not feasible due to the COVID-19 pandemic.

Conclusion

VR exercises are effective as treatment strategies in the management of LBP. Both VR games had significant effects in improving lumbar ROM, pain intensity, and low back disability, but a combination of the Reflex Ridge and Body Ball games along with back-strengthening exercises was found to be more effective.

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Conflicts of Interest

None declared.

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Abbreviations

- LBP:** low back pain
- ODI:** Oswestry disability index
- ROM:** range of motion
- VR:** virtual reality

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Original Paper

Clinicians' Perspective on Implementing Virtual Hospital Care for Low Back Pain: Qualitative Study

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Abstract

Background: Alternate “hospital avoidance” models of care are required to manage the increasing demand for acute inpatient beds. There is currently a knowledge gap regarding the perspectives of hospital clinicians on barriers and facilitators to a transition to virtual care for low back pain. We plan to implement a virtual hospital model of care called “Back@Home” and use qualitative interviews with stakeholders to develop and refine the model.

Objective: We aim to explore clinicians' perspectives on a virtual hospital model of care for back pain (Back@Home) and identify barriers to and enablers of successful implementation of this model of care.

Methods: We conducted semistructured interviews with 19 purposively sampled clinicians involved in the delivery of acute back pain care at 3 metropolitan hospitals. Interview data were analyzed using the Theoretical Domains Framework.

Results: A total of 10 Theoretical Domains Framework domains were identified as important in understanding barriers and enablers to implementing virtual hospital care for musculoskeletal back pain. Key barriers to virtual hospital care included patient access to videoconferencing and reliable internet, language barriers, and difficulty building rapport. Barriers to avoiding admission included patient expectations, social isolation, comorbidities, and medicolegal concerns. Conversely, enablers of implementing a virtual hospital model of care included increased health care resource efficiency, clinician familiarity with telehealth, as well as a perceived reduction in overmedicalization and infection risk.

Conclusions: The successful implementation of Back@Home relies on key stakeholder buy-in. Addressing barriers to implementation and building on enablers is crucial to clinicians' adoption of this model of care. Based on clinicians' input, the Back@Home model of care will incorporate the loan of internet-enabled devices, health care interpreters, and written resources translated into community languages to facilitate more equitable access to care for marginalized groups.

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KEYWORDS

back; barrier; barriers; care model; eHealth; e-Health; enabler; enablers; facilitator; facilitators; health services research; healthcare delivery; implementation; interview; interviews; low back pain; model of care; pain; qualitative; remote care; service delivery; service; services; telehealth; telemedicine; virtual care; virtual hospital

Introduction

Overview

In Australia, back pain is the fifth most common reason for emergency department (ED) visits and ranks third for those aged between 40 and 69 years [1]. About one-third of patients presenting to the ED with back pain are subsequently admitted to the hospital, staying an average of 9 days [2]. Not only is hospital admission for back pain costly (US \$10,000 per admission), but it also contributes to increased patient morbidity and a delay in recovery time [3]. With an increasingly aging population [4], hospital inpatient admissions have continued to steadily rise, while the number of available beds has consistently reduced [5].

Alternate “hospital avoidance” models of care are required to manage the increasing demand on acute inpatient beds by facilitating hospital-level health care delivery for patients in their own place of residence. “Hospital in the home” models of care are now well established worldwide and are associated with decreased length of stay and increased patient and caregiver satisfaction [6,7]. A recent evolution of these models is the “virtual hospital,” such as the one recently implemented by the Sydney Local Health District (rpavirtual) [8].

We plan to implement a virtual hospital model of care for back pain called “Back@Home” and to use qualitative interviews with stakeholders to develop and refine the model. The “Knowledge to Action Framework” [9] encourages clinicians’ involvement in developing evidence-based solutions for health care delivery while adapting these to the local context. This approach to the research cycle helps to address barriers to implementation, optimizing successful clinician engagement and care delivery [10].

A cohort study comparing more than 15,000 in-person consults to over 5000 telehealth consults for acute low back pain in primary care found that telehealth was associated with a lower rate of referral for lumbar imaging [11] while yielding comparable quality performance measures. This finding suggests that the provision of high-value, low back pain care through telehealth is possible.

There is currently a knowledge gap regarding the perspectives of hospital clinicians on reasons for hospital admission for acute back pain, as well as their perspectives on barriers and facilitators of a transition to virtual care for this condition. This study will have a significant impact on the successful implementation of a novel virtual hospital model of care (Back@Home). By influencing hospital policy and procedures, it will also potentially positively affect clinical outcomes for hospital back pain presentations.

Objective

The objective of this study was to explore clinicians’ perspectives on a virtual model of care for back pain and identify barriers to and enablers of successful implementation of this new model of care.

Methods

Ethical Considerations

This study was approved by the Sydney Local Health District (LHD) Human Research Ethics Committee (X21-0094). Participants provided informed consent after reading the participant information sheet and being given an opportunity to ask questions. All study data was stored on a password-secured server. No compensation was provided for participants.

Study Design, Setting, and Recruitment

This study was a qualitative study using semistructured interviews conducted from June to December 2021.

Participants were recruited from 3 metropolitan hospitals in Sydney LHD: Royal Prince Alfred Hospital, Concord Repatriation General Hospital, and Canterbury Hospital, through purposive sampling. Sydney LHD has approximately 400 admissions per year, with a primary admission reason of musculoskeletal low back pain [12,13] and an ED admission rate of nearly 17% [14].

The inclusion criteria were as follows: clinicians (physicians, physiotherapists, occupational therapists, social workers, and nurses) employed in Sydney LHD who had experience managing people presenting with low back pain. All clinicians involved in the management of low back pain in Sydney LHD were invited to participate in initial interviews by email and at staff meetings. All participants were provided with a participant information statement and provided written consent to participate. Participants were able to withdraw their consent at any stage, up until the data had been analyzed.

Participants were not familiar with the interviewer before the commencement of the study. An interview guide ([Multimedia Appendix 1](#)) provided structure but allowed scope for additional questions as the interview progressed. The interview guide was developed to explore the key barriers and enablers to virtual hospital care and was piloted with 3 participants. An experienced qualitative researcher (RD) then reviewed the recordings and provided feedback on improvements to the structure and delivery of interview questions. Pilot data were included in the final analysis.

Semistructured interviews were conducted through videoconferencing (Zoom; Zoom Video Communications) or telephone, lasting up to 30 minutes. Interviews were digitally audio recorded, transcribed verbatim, and then proofread. Recruitment for participants was discontinued when the research

team concluded that no new emerging themes had developed from consecutive interviews [15].

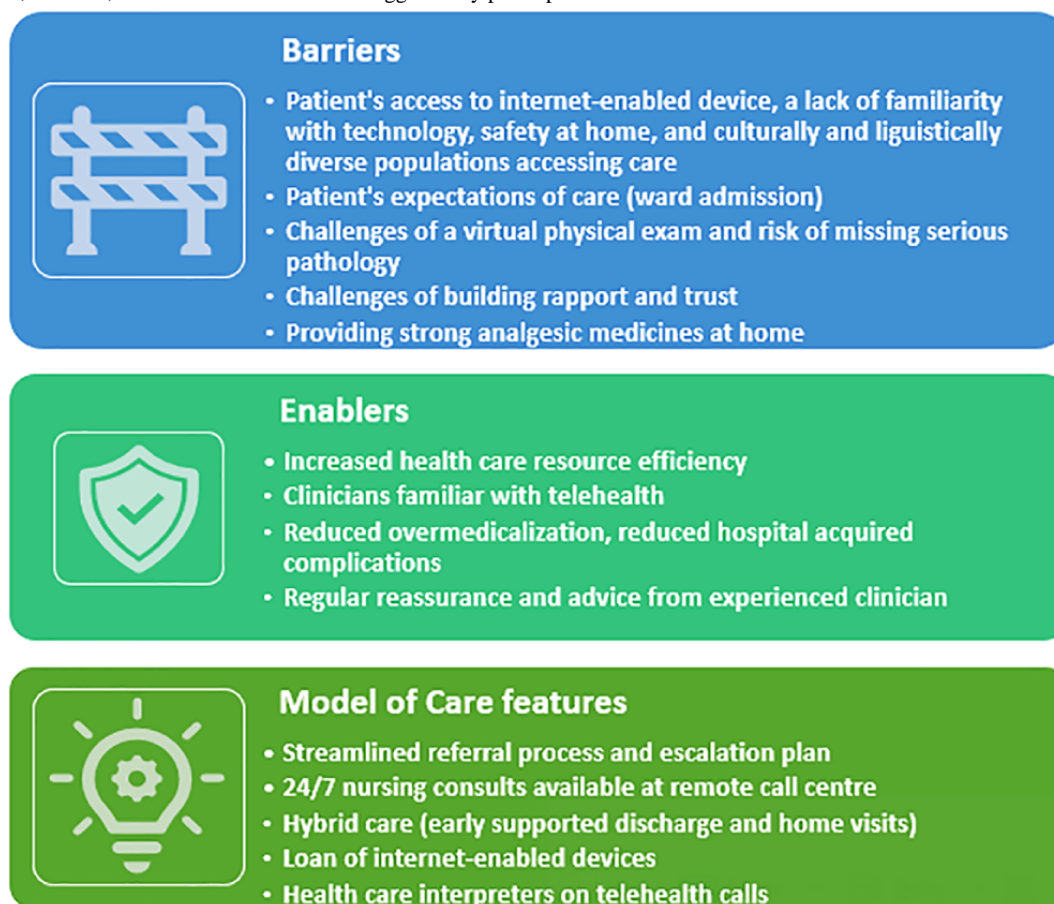
Analysis

Samples of transcript data (5 interviews) were independently annotated by 4 authors (AM, SV, GCM, and RD), creating a bank of initial ideas and phrases. Emerging concepts were then compared between authors and merged to develop a coding framework of key themes [16]. Themes were identified as significant based on frequency and relevance to the implementation of the model of care. All interviews were then coded by 1 author (AM), using the coding framework that was agreed upon.

Key themes and participant quotes were mapped to subcategories according to the Theoretical Domains Framework (TDF) [17,18]. The TDF [19] provides 14 domains with which to explore the determinants of health care professionals' behavior change, thus informing implementation strategies. A summary of barriers to and enablers of virtual hospital care from the point of view of clinicians was developed. Demonstrative quotes supporting key themes were identified and used to support the findings.

Data were analyzed using NVivo (QSR International) software and reported according to the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [20]. A summary of the findings is provided in Figure 1.

Figure 1. Barriers, enablers, and model of care features suggested by participants.



Reflexivity

Disclosure of researchers' backgrounds allows the reader to understand how the authors' viewpoints may have influenced data interpretation. Several researchers have clinical experience working with people experiencing back pain (AM, SV, GCM, CGM, DMC, BR, ER, and MJT). The remaining authors (RD and NG) were involved for research methodology expertise. All interviews were conducted by a single researcher (AM), an experienced musculoskeletal physiotherapist (of more than 18 years) and a PhD student.

Results

Participant Characteristics

A total of 19 clinicians participated in this study, of which 9 participants were rheumatology consultants (RC 1-9), with admitting rights to the hospital for patients with low back pain. Another 3 participants were rheumatologists-in-training (trainees; RT 1-3), and 1 was an emergency physician trainee (ET 1). A total of 4 participants were senior physiotherapists (PH 1-3), and 2 were senior emergency nurses (EN 1 and 2).

All participants had direct clinical experience managing patients with back pain, either in the ED or as inpatients. These clinicians would likely be involved in referring patients to Back@Home but not delivering virtual hospital care. However, many

clinicians at Sydney LHD have been involved in remote care services such as hospital-in-the-home at the virtual hospital since the beginning of the COVID-19 pandemic.

Thematic Analysis of Clinician Interviews

Insight into barriers and enablers is essential to providing an understanding of the complexities of implementing a novel model of care where there is potential for clinical benefit and a need for due consideration of patient safety. A total of 10 of the 14 key TDFs [17] were identified as being most relevant and important: “Environmental Context and Resources”; “Knowledge”; “Skills”; “Emotion”; “Beliefs about Consequences”; “Reinforcement”; “Social Influences”; “Professional Role and Identity”; “Beliefs about Capabilities”; and “Memory, Attention, and Decision Processes.” TDF dimensions that were not seen in the data or were well covered by a similar theme were not presented (“Goals,” “Optimism,” and “Intentions and Behavioral Regulation”).

Barriers to a Virtual Model of Care: Resources and Expectations

Environmental Context and Resources, Knowledge, and Skills

Perceived barriers to virtual care included patients’ lack of access to internet-enabled devices and a lack of competence in the use of web-based exercise applications and videoconferencing platforms. Clinicians were especially concerned about how telemedicine could change the dynamics of access, potentially amplifying inequities. This was especially true for patients from culturally and linguistically diverse (CALD) communities and older patient cohorts unfamiliar with technology.

I think the barriers for our patients are around social deprivation....people who don't speak English, people who are uncomfortable with technology, and that will be our older patients who are often the people who will present to hospital. [Consultant rheumatologist, RC5]

Emotion (Fear, Anxiety, and Stress)

Participants were worried that telehealth treatment would adversely impact the patient-clinician relationship as it is more difficult to establish rapport and trust. This could have consequences for patient outcomes. For instance, physiotherapists and rheumatologists thought that patients would mobilize less without the motivation of face-to-face physiotherapy.

Having that face-to-face interaction establishing rapport...sharing examples of previous patients that have been through similar things and providing that reassurance face to face, comparatively, can be...a little bit more reliable. [Physiotherapist, PH4]

Knowledge (of Condition), Beliefs About Consequences (Outcome Expectancies), and Reinforcement (of Patient Behavior)

Patient care expectations were noted as a major barrier to virtual care. While clinicians agreed with guideline-based advice [21]

that back pain is generally self-limiting, with a good prognosis, and therefore not requiring hospitalization, they noted that many patients expected to receive spinal imaging, pharmacological pain relief, or to be admitted to the hospital.

Managing patients’ care expectations and encouraging proactive self-management were therefore recognized as important roles for frontline clinicians. On this point, a consultant rheumatologist commented that:

[The] expectation is that if they go to the hospital that the hospital will be able to resolve that problem for them, so there's often quite a complex education piece...to help the patient to understand that with non-serious back pain...the person who's going to make that better is primarily them. There's nothing we can do to them that's going to make them...instantly better. [Consultant rheumatologist, RC5]

Hospital staff may therefore find themselves forced to advocate for options the patient finds difficult to accept.

When people are in a significant amount of pain and you're telling them that physiotherapy and time and analgesia are the answer rather than procedures necessarily. Some people find that difficult to reconcile. [Rheumatologist in-training, RT3]

Clinicians explained that if a patient is admitted to the hospital for back pain, it sets a precedent that reinforces the patient’s expectation of being admitted again in the future. To avoid this reinforcement pattern, participants agreed that admissions are best avoided when possible, and care in the community or through hospital outpatient care was preferred.

[It is] counterproductive for people to be admitted to hospital...they're likely to fall into that same pattern again. [Consultant rheumatologist, RC6]

Social Influences (Social Support and Alienation) and Emotion (Depression)

Participants described that it can be difficult to discharge patients home from the ED due to concern for their safety and well-being. This was especially the case for patients who had no social support and were not coping at home. In older patients, back pain was recognized as being one aspect of a complex presentation, and the decision to admit them to the hospital would include an assessment of their ability to manage the basic activities of daily living.

Concerns were also raised about sending home patients with mental health comorbidities, such as depression or suicidal ideation related to their pain. An ED nurse described the interplay between severe chronic pain and mental health:

I've seen...chronic pain manifest as an acute mental health issue. That represents some risk to the patient...I've certainly seen people express suicidal ideations because they've been in a state of chronic pain. [Emergency nurse, EN1]

Barriers to a Virtual Model of Care: Medicolegal Concerns

Skills, Professional Role and Identity, and Beliefs About Capabilities

Participants had reservations regarding performing a thorough neurological examination virtually, with concerns about missing serious pathology without a face-to-face consult. A physiotherapist shared their concerns regarding identifying serious pathologies such as myelopathy or cauda equina using telehealth.

My concern would be identifying the deteriorating patient. So if they had deteriorating neurological signs...how can we do that, virtually...can we assess their gait? How can we assess that they have now developed a foot drop? Can we assess that their reflexes are changed? What if they've got urinary retention? We can't assess that remotely. [Physiotherapist, PH1]

Employing new graduate inexperienced Physios could potentially leave...the model of care open to harm because the inexperienced Physio may miss things that are being told to them" [Physiotherapist, PH2]

Other concerns raised included being unable to discharge patients home if they were not mobilizing safely and potential liability if they were to fall at home. A consultant rheumatologist speculated as to the mechanisms in place to protect clinicians should a patient be transferred to virtual care and have a fall at home, specifically:

Whether there's a legal framework to protect a clinician against...indemnity claims in that circumstance. [Consultant rheumatologist, RC1]

A practical concern was how to safely administer analgesia, including opioids, in a virtual care model. Considerations included what types of analgesia to prescribe in virtual care and which patients would be considered fit to manage administration of sedating medication independently. For example:

The patient would have to be savvy enough with their medications to understand...what to do when, not just pop pills regardless. Sometimes we are dishing out quite heavy-duty pain relief to these people to try and get them through. [Consultant rheumatologist, RC3]

Enablers of a Virtual Model of Care: Organizational and Professional

Environmental Context and Resources (Organizational Culture)

For hospitals, the prospect of more efficient use of limited health care resources was seen as an important enabler of virtual models of care such as Back@Home. Participants believed these models had the potential to create cost savings by shortening the length of stay, increasing bed availability, and improving patient flow in the ED setting.

From a hospital perspective, especially given the current climate, it certainly frees up bed space

and...allows us to ensure good patient flow through so we can...dedicate our workforce to people who...need that care. [Physiotherapist, PH4]

There's really no reason why people can't be managed in an environment outside hospital. [Consultant rheumatologist, RC8]

Social and Professional Role and Identity (Professional Identity, Professional Role, and Patients' Role)

The familiarity that clinicians had developed with telehealth during the pandemic was seen as a key enabler for the ongoing implementation of virtual care models. In addition, clinicians were aware of the advantages of these models, which could help overcome resistance to their implementation. For instance, it was noted that virtual models of care reduced unnecessary hospital admissions and permitted more frequent contact with patients.

I feel like a lot of our care is now becoming virtual...I think that would be great if it would keep them out of hospital...It'll take a lot of pressure off us to be honest. [Emergency nurse, EN2]

The secret is the fact that you've got the regular contact. I mean, that's really what you're buying in hospital...regular contact with clinicians. [Consultant rheumatologist, RC8]

Reduction in unnecessary admissions was seen as particularly advantageous as it could reduce medicalization of low back pain and avoid reinforcing illness behaviors and institutionalization that can contribute to functional decline.

[Admission] might present as a message to the patient that they're sick...they're lying in bed, and it's okay to be in bed, which is not the message we want to give to the patient. It may also generate extra incidental investigations which may not be required otherwise if it was managed in the community. [Consultant rheumatologist, RC9]

Patients do get a bit institutionalised...if they're there for a long time. [Rheumatologist in-training, RT1]

They stay in their pyjamas or their gown. They assume the role of the patient and can potentially become...more passive and not as active, which we know is not helpful for back pain, so I think being in their own environment sooner is absolutely an advantage. [Physiotherapist, PH1]

Avoiding unnecessary hospital admission was also seen as important for avoiding risks associated with unnecessary procedures (eg, spinal imaging), bed rest and immobility, acquiring infections, and other complications. For instance, a rheumatology trainee noted:

I think the recovery will be quicker once they're at home and there's less risk of...infections... patients will come in, they won't mobilize much, they'll get a chest infection. [Rheumatologist-in-training, RT1]

While a rheumatologist summarized the issue as:

You don't want to go to hospital because as people have pointed out, they're full of sick people and you don't particularly want to expose yourself to a lot of people being unwell or potential for infections. You're also at some risk of reinforcing illness behaviour, and conviction that there is something serious wrong. [Consultant rheumatologist, RC8]

Memory, Attention, and Decision Processes (Decision-Making)

Participants felt that for virtual health models to be successful, effective decision support and guidance were needed. This included access to both information about the virtual care option and support for patients who chose to take that option. With regard to the provision of information, it was suggested that intranet shortcuts, patient handouts, and posters in the ED would be useful in directing patients to virtual care and thereby avoiding unnecessary admissions. Patient-facing wording suggestions included:

Did you know we can manage this remotely? We can manage this virtually and you can be in comfort of your own home, but still have all the care that you need. [Physiotherapist, PH1]

However, to implement such a system effectively, it was recognized that experienced clinicians were needed to monitor patients, provide them with reassurance, and effectively screen for serious pathology. Ideally, access to a clinician would be 24/7, and an escalation pathway would be in place in cases of deterioration or if a patient was not coping at home.

If this isn't working out, there's an option...there's an escape clause...so the patient says look if I can't cope, is there a number I can ring, and someone will pick me up? And take me to hospital again. [Consultant rheumatologist, RC8]

Overall, care in the home was championed, with early supported discharge being regarded as the safest option to balance thorough evaluation with decreased risks of hospitalization. The benefits of care at home, with social support and a familiar environment, were promoted.

[It would] encourage the patient to be mobilising within an environment that they're familiar with and feel safe in. They get the support of their family. And they will probably integrate what they learn...the physiotherapy and movements in their day-to-day lives much quicker. [Consultant rheumatologist, RC9]

Beliefs About Capabilities (Perceived Competence, Professional Confidence, and Empowerment)

For patients to accept virtual care over hospital admission, participants felt it was important to build trust with patients through effective communication. In particular, it was important to ensure that patients did not feel they were being dismissed or a victim of a cost-cutting measure.

The important thing is how it's framed to the patient, that we have a number of ways of potentially looking after you. And we believe that the one that's going to result in the best outcomes for you would be to be

looked after at home. So it's about that framing and...providing concrete and appropriate reassurance. [Consultant rheumatologist, RC9]

Participants expressed valuing a multidisciplinary team working collaboratively, with a focus on physiotherapy involvement to encourage patient mobility. To ensure patient safety, there was a strong preference for hybrid care combining virtual and home visits.

My preference would be to have a nurse visit the next day...then I would be much happier about the system...I would have a Physio go out the next day and/or maybe a nurse. But someone making sure they're taking their medication. That they're able to get to the toilet, and that they're safe. [Consultant rheumatologist, RC2]

I don't think doctors have a great role to play in most back pain patients apart from firstly diagnosing the issue and excluding anything serious...we kind of leave it in the hands of the Physiotherapist to get people moving. [Consultant rheumatologist, RC3]

Discussion

Overview

This study used the TDF to explore clinician views on barriers to and enablers of implementation of a virtual model of care for low back pain, which will inform efforts to reduce avoidable hospital admissions for back pain. By engaging stakeholders, the development of the virtual hospital model can be tailored to their specific needs and context, thereby increasing the likelihood of a successful implementation of a novel model of care [22,23]. Below, we explore some key barriers to implementation that arose from this study and potential solutions.

Overcoming Challenges to Access

Our participants' observations regarding the challenges associated with access and availability of virtual platforms are consistent with the literature [24-26]. It raises important questions regarding how the introduction of virtual models of care may inadvertently introduce new types of inequity. While virtual health services may improve access for some (eg, patients living in rural areas), for patients without internet access or who do not have sufficient digital literacy skills to avail themselves of these services, access may be compromised. Specific groups that are known to engage with virtual care less include cultural and ethnic minority groups, older people, and socioeconomically disadvantaged groups [27]. Physiotherapists delivering virtual musculoskeletal care during the pandemic have also reported challenges with delivering quality care in the case of poor internet quality, poor room setup (lighting, camera angles, and space), and low levels of patients' technological skills [28].

A number of solutions to these concerns have been proposed, including having a technologically competent caregiver present during virtual sessions, simple email links to access services that do not require passwords or other configuration, simplified dashboards, and access to closed captioning if required for patients with hearing impairment [24]. Other strategies

considered helpful for delivering care include ensuring access to a high-quality telehealth platform with a reliable internet connection and camera; providing patient resources (written or web-based information), videos or exercise apps, follow-up email summaries; and providing patient telehealth instructions ahead of the appointment [28]. We have incorporated all these suggestions into our model, and we intend to offer patients the option to loan internet-enabled devices to support effective and equitable delivery. It is estimated that 15% of patients eligible for our service would require interpreter services [13]. Therefore, we will use back pain care handouts translated into 10 key community languages to further support equitable access to health care information for CALD communities.

Overcoming Concerns About Safety and Effectiveness

Our participants were comfortable with using virtual platforms, but they had reservations about the impact of these on their capacity to build patient rapport and trust and to complete a thorough examination. Clinicians were particularly concerned about missing serious pathologies, patients that present a high fall risk, and the safe management of analgesia at home. Participants also expressed potential difficulty managing patient and family expectations of traditional admission when presenting to the ED, as well as patients presenting with multimorbidity or who may be socially isolated. Some participants in senior roles shared concerns about the medicolegal liability of delivering virtual care should a safety issue arise.

Despite these concerns, evidence suggests that, when done well, virtual care for the treatment of lower back pain is not inferior to in-person treatment. While there can be increased challenges in the provision of virtual care, physical examinations of low back pain can be adapted effectively for the virtual environment [29]. It has also been shown that active listening can help uncover serious pathologies that may otherwise be overlooked [30]. A recent systematic review on the effectiveness and safety of telehealth for treatment of low back pain [31] suggests that remote clinical management is safe, effective, and does not compromise patient satisfaction. However, evidence is based on observational studies, and clinical trials aimed at optimizing telehealth delivery are needed.

Several strategies will be implemented in our Back@Home model of care to address these safety concerns, based on input provided by clinicians with experience in outpatient musculoskeletal virtual care [32]. First, referrals will only be accepted if the patient would otherwise have been admitted under the rheumatology or general medicine specialties. Patients with low back pain who would otherwise have been admitted under the neurosurgery or geriatrics teams are excluded from the program due to their higher risk profile and need for more intensive management [12]. Second, a clear escalation plan will be implemented for the clinically deteriorating patient, and police welfare checks will be conducted if both the patient and

their next of kin are uncontactable. Third, to ensure appropriate weaning of stronger analgesia provided in the ED, all Back@Home patients are reviewed by a virtual hospital general practitioner, and a discharge summary is sent to the patient's community general practitioner to ensure continuity of care and linking into outpatient services. Fourth, to build trust and rapport regular physiotherapy contact (daily if required) has been integrated into our model.

Advantages of Virtual Care Despite Challenges

Despite multiple challenges, clinicians could see the potential benefits of delivering virtual care for acute back pain. These include health care cost-saving and improved patient flow, which are important considerations given the rising demands on public health care infrastructure and increased health spending. Participants also noted that there are benefits associated with avoiding hospital admission. These include reducing patients' excessive dependence on the health care system, reducing inappropriate bedrest that could lead to deconditioning, and reducing the risk of hospital-acquired infection. These findings are supported by studies that have found that, for specific groups of patients, avoiding hospital admission provides similar benefits to patients as inpatient treatment [7].

Strengths and Limitations

A strength of this study is the purposive sampling of rheumatologists, ED physicians, nurses, and physiotherapists likely to be involved in referring to the proposed virtual care model. A sample of transcripts was coded by 4 authors, adding to the richness of emerging themes.

However, clinicians were all based in urban tertiary care centers in 1 health district. Further investigation of barriers and enablers in other districts, including rural and regional centers, and in communities with more CALD individuals, would be helpful before implementation in those areas.

We were unable to include patient stakeholder perspectives due to COVID-19 pandemic-related hospital restrictions. For the next phase of our research, we have recruited patient participants and look forward to sharing their experience with virtual hospital care.

Conclusion

The successful implementation of Back@Home relies on key stakeholder buy-in. Addressing barriers to implementation (where feasible) and building on enablers will be crucial for clinician adoption of this model of care. Based on clinicians' input, the Back@Home model of care will incorporate the loan of internet-enabled devices, health care interpreters, home visits, and translated written resources in community languages to facilitate more equitable access to care for marginalized groups.

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Data Availability

The data sets generated during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

MJT is a clinician at RPA Virtual Hospital.

Multimedia Appendix 1

Interview guide.

[[DOCX File, 15 KB - rehab_v10i1e47227_app1.docx](#)]

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Abbreviations

- CALD:** culturally and linguistically diverse
COREQ: Consolidated Criteria for Reporting Qualitative Research
ED: emergency department
LHD: Local Health District
TDF: Theoretical Domains Framework

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Original Paper

Stakeholders' Perspectives, Needs, and Barriers to Self-Management for People With Physical Disabilities Experiencing Chronic Conditions: Focus Group Study

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Abstract

Background: While self-management programs have had significant improvements for individuals with chronic conditions, less is known about the impact of self-management programs for individuals with physical disabilities who experience chronic conditions, as no holistic self-management programs exist for this population. Similarly, there is limited knowledge of how other stakeholders, such as caregivers, health experts, and researchers, view self-management programs in the context of disability, chronic health conditions, and assistive technologies.

Objective: This study aimed to obtain insight into how stakeholders perceive self-management relating to physical disability, chronic conditions, and assistive technologies.

Methods: Nine focus groups were conducted by 2 trained facilitators using semistructured interview guides. Each guide contained questions relating to stakeholders' experiences, challenges with self-management programs, and perceptions of assistive technologies. Focus groups were audio recorded and transcribed. Thematic analysis was conducted on the focus group data.

Results: A total of 47 individuals participated in the focus groups. By using a constructivist grounded approach and inductive data collection, three main themes emerged from the focus groups: (1) perspectives, (2) needs, and (3) barriers of stakeholders. Stakeholders emphasized the importance of physical activity, mental health, symptom management, medication management, participant centeredness, and chronic disease and disability education. Participants viewed technology as a beneficial aide to their daily self-management and expressed their desire to have peer-to-peer support in web-based self-management programs. Additional views of technology included the ability to access individualized, educational content and connect with other individuals who experience similar health conditions or struggle with caregiving duties.

Conclusions: The findings suggest that the development of any web-based self-management program should include mental health education and resources in addition to physical activity content and symptom management and be cost-effective. Beyond the inclusion of educational resources, stakeholders desired customization or patient centeredness in the program to meet the overall needs of individuals with physical disabilities and caregivers. The development of web-based self-management programs should be holistic in meeting the needs of all stakeholders.

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KEYWORDS

self-management; physical disabilities; physical disability; chronic condition; chronic illness; mental health; physical activity; barrier; disability; chronic; technology; interview; data; symptom; support; digital; development; need; perspective; barrier; qualitative; focus group; assistive technology; assistive technologies

Introduction

Approximately 25% of Americans have a disability, which is nearly 61 million individuals. About 13.7% of the population experiences a mobility or physical disability, which affects daily activities such as walking or climbing stairs [1]. This demographic is more physically inactive than individuals without physical disabilities [2,3]. The increase in physical disabilities has led to higher rates of chronic conditions compared to individuals without physical disabilities, including obesity, heart disease, and diabetes [4]. For example, individuals with physical disabilities have a significantly higher heart disease rate (12%) compared to individuals without physical disabilities (4%) [1].

Self-management programs are used to manage health conditions. A primary goal of self-management programs is to include the person as a central role in their health and wellness. Within this central role, a person with a chronic health condition is intimately and actively involved with health care providers and the health care system, regularly obtains skills and knowledge to manage symptoms, and increases self-efficacy to handle health-related issues [5]. Additionally, these programs promote self-care, regular physical activity, healthy nutrition behaviors, and medication adherence [5,6]. Within self-management, there are core skills that include problem-solving, decision-making, resource use, health care provider partnership, and action taking [7,8]. These core skills include involvement in all areas of self-management, ranging from identifying symptoms, using web-based resources to learn about safe exercise, and communicating with health care providers [7]. The multifaceted approach of self-management programs has shown significant improvements in chronic conditions, including stroke, diabetes, and hypertension [9-11].

While self-management can be viewed solely from the perspective of the individual, self-management is a collective process that includes a strong social and professional network, including caregivers and health care providers. Self-management is not an individual endeavor experienced by those with physical disabilities and chronic health conditions. In many instances, caregivers are intimately involved in providing daily assistance through various duties, including but not limited to activities of daily living, nutritional needs, medication management, and coordination of care with health care providers [12,13]. Because self-management is complex due to its multiple components, caregivers can experience numerous barriers that prevent adequate caregiving, such as being overworked, economic status, and the lack of educational resources [12]. Therefore, an understanding of the self-management from the perspective of caregivers is warranted. Additionally, self-management is not confined to the home setting but also includes health care professionals and experts who initiate, guide, inform, and direct medical care. Individuals with chronic health conditions typically maintain regular contact with health care professionals

or seek out relevant resources to ensure that symptoms and disease progression are well managed. Health care professionals and experts typically emphasize skills and behaviors that are typically associated with self-management, including obtaining regular physical activity, drinking water, following a healthy diet, and symptom tracking [14]. However, because individuals with chronic health conditions may not be able to maintain regular contact with health care professionals or experts, it is necessary to understand the perspectives of experts on self-management programs.

Despite improvements in self-management programs, less is known about how these programs affect individuals with physical disabilities [10,15]. Unfortunately, there is no such holistic chronic disease management program for individuals with physical disabilities. Compared to individuals without physical disabilities, those with physical disabilities are prone to poorer health outcomes and are more likely to participate in unhealthy behaviors, such as smoking [16]. Although self-management programs are successful, they are fragmented with content targeting specific behaviors or symptoms rather than using a holistic approach. For example, programs may focus on a specific health-related domain (ie, medication adherence) but may not focus on other significant health components, including nutrition, physical activity, or other health behaviors.

Since self-management is a collaborative endeavor between individuals, caregivers, and health care providers, understanding collective viewpoints is needed to ensure that future programs include acceptable, comprehensive content for all users [17]. Therefore, the purpose of this study was to gain insight using focus groups into how stakeholders perceive self-management in the context of physical disability, chronic conditions, and assistive technologies. The stakeholders included individuals with physical disabilities who experience chronic conditions, caregivers, health experts, and researchers.

Methods

Ethical Considerations

This study was approved by the institutional review board of the University of Alabama at Birmingham (IRB 300009485). Participants provided consent to participate following a screening questionnaire. All study data, including identifying information, audio recordings, and transcriptions, were deidentified. Upon the completion of each focus group, participants were compensated with a US \$25 gift card.

Participants

Upon approval from the university institutional review board, all participants were purposively recruited using advertisements through the National Center on Health Physical Activity and Disability website and its social media channels. Based on how individuals answered screening questions, they were filtered

into 1 of the 8 groups. This study was conducted in the United States. Interested participants completed screening and consented to participate in a focus group (Table 1). Individuals with diabetes, heart conditions, and lung conditions were specifically chosen due to the high prevalence of these

conditions [18-20]. Focus groups were prescheduled, and only participants who were able to attend on the dates were eligible. Participants were required to be at least 18 years old and attend a Zoom (Zoom Technologies, Inc) call with up to 20 participants per group.

Table 1. Stakeholders of focus groups (n=47).

Group	Stakeholders	Value, n (%)
1	People with disabilities and diabetes	6 (13)
2	People with disabilities and heart conditions	5 (11)
3	People with disabilities and lung conditions	7 (15)
4	Caregivers of people with disabilities and diabetes	8 (17)
5	Caregivers of people with disabilities and heart conditions	2 (4)
6	Caregivers of people with disabilities and lung conditions	1 (2)
7	People with disabilities and any chronic condition (eg, no specific health condition required)	6 (13)
8	Health experts and researchers	12 (26)

Focus Group Procedures

Under the oversight of the principal investigator (MT), postdoctoral fellow (EE), and predoctoral student (AZ), 2 trained facilitators conducted the focus groups. No prior relationship between participants and facilitators was established. MT, EE, and AZ were present during the focus groups but did not actively participate to avoid bias. The facilitators were given a study description and met with the research team prior to the focus groups to discuss study goals and interview guides. Three semistructured interview guides were developed for each stakeholder group and contained questions regarding chronic conditions and physical disabilities, self-management, psychological perspectives, and assistive technologies (Multimedia Appendix 1). Focus groups lasted up to 90 minutes, and participants were encouraged to speak freely. Field notes were collected during each focus group. No additional focus groups were conducted as data saturation was achieved. Focus groups were conducted between August and September 2021.

Qualitative Analysis: Data Collection and Analysis

In terms of ontology, we adopted the constructivist grounded theory (CGT) approach within an epistemological position of subjectivism. We acknowledge that researchers cannot be fully objective and there is an interrelationship between participants and researchers. By adopting this approach, we focused on developing the themes through inductive analysis of the raw data gathered from our participants [21].

Using this approach, 3 main themes—perceptions, needs, and barriers—were identified. Perceptions included thoughts and attitudes toward self-management and self-management-related behaviors. Needs included elements that are required to assist

in overall care and barriers included elements of health that were difficult to maintain. Using a constructivist grounded approach and inductive data collection allowed us to uncover many nuanced understandings by providing comprehensive and contextually embedded explorations of the stakeholders' experiences [22]. Focus groups were audio recorded and transcribed using a web-based transcription service. Transcribed files were imported and coded by MT, EE, and AZ using the Nodes feature in NVivo software (NVivo 12, QSR International). A coding tree was developed using the identified themes, and the transcripts were reviewed by the research team and were matched with the field notes. Elements of the coding tree are represented by the categories in Multimedia Appendices 2 and 3 (sample coding tree from NVivo provided in Multimedia Appendix 4). Any coding changes were determined in discussions among MT, EE, and AZ. All disputes were resolved by MT. All findings were presented to the project advisory board, a panel of 12 individuals with chronic conditions and physical disabilities, caregivers, health experts, and researchers.

Results

Overview

A total of 268 participants were eligible to participate in the focus group study, with 47 individuals participating due to scheduling availability. Three groups were part of the study: individuals with physical disabilities and chronic conditions (n=24), caregivers of individuals with physical disabilities and chronic conditions (n=11; Table 2), and health experts and researchers (n=12). Additional relevant quotes are provided in Multimedia Appendix 2.

Table 2. Descriptive characteristics of caregivers in focus groups.

Characteristics	Caregivers (n=11), n (%)
Mobility disabilities and health conditions in which caregivers provide care	
Spinal cord injury	1 (9)
Muscular dystrophy	1 (9)
Diabetes	6 (55)
Asthma	2 (18)
Food allergies	1 (9)
Attention-deficit/hyperactivity disorder	1 (9)
Down syndrome	1 (9)
Asperger	1 (9)
Congestive heart failure	1 (9)
Parkinson disease	2 (18)
Depression	1 (9)
Posttraumatic stress disorder	1 (9)
Chronic pain	1 (9)
Chronic obstructive pulmonary disorder	1 (9)
Renal failure	2 (18)
Role of caregivers	
Informal (spouse, family member, etc)	10 (91)
Professional	1 (9)
Areas of caregiving provided	
Medication adherence	6 (55)
Dietary assistance	5 (45)
Medical appointments	7 (64)
Activities of daily living (driving, bathing, dressing, etc)	5 (45)
Emotional support	2 (18)

^aUnrelated to participants with physical disabilities and chronic health conditions.

Participants with physical disabilities indicated that they experienced other chronic health conditions outside of diabetes, heart conditions, and lung conditions ([Multimedia Appendix 5](#)). All caregivers were informal (ie, spouse and family member) and were unrelated to any participants in any other focus group. Health experts included health and wellness experts (n=2), researchers (n=6; administration, investigator, etc), and community outreach and development experts (n=4).

Perceptions of Stakeholders

Overview

Stakeholders were asked multiple questions to obtain thoughts about self-management and self-management programs. By using the semistructured interview guides, participants shared their experiences, either performing self-management or providing self-management services. By using CGT and inductive analysis, perceptions of stakeholders became a resulting theme from the focus groups. Relevant codes and explanations of the codes are provided in [Multimedia Appendix 2](#).

Individuals With Physical Disabilities and Chronic Conditions

Many participants expressed that physical activity was an important component of their usual self-management. Walking or wheeling was the most mentioned activity, followed by water-based activities such as water aerobics. Participants expressed a desire to join a community center where they could participate in group classes or use exercise equipment. Nutritional behaviors were also discussed as an important element of self-management. Emphasis was placed on eating fruits and vegetables, reducing high-carbohydrate foods, taking vitamins and supplements, avoiding excess sodium, preparing meals, and reducing sugar intake.

(I) try to move around as much as I can, because I think moving is good for me. I think I also just try to do as much as I can, while accepting that some days are going to be better than others, in terms of how much I can do.

Interestingly, individuals indicated that managing mental health was also a significant component of self-management. Anxiety

and fear were the most common emotions cited. In addressing anxiety and fear, familial support and religion were the primary ways to manage emotions. Other forms of managing mental health include meditation, yoga, breathing exercises, and regular social interactions.

When I think of health, I think of mental health, but then my physical health, too, and kind of how it all goes together. I'm trying to figure out why I react certain ways to everything I have going on lately with my emotions and mental wellbeing.

Participants also shared what motivated them to manage their health. The most common motivation was the desire to live a long life with family and friends. Similarly, social support received from friends was an additional motivation for maintaining health. Additionally, working with health care providers was provided as a mode of self-management.

I see my primary care once a month. I see my therapist once a week, my cardiologist every three months. I get an EKG every, every month when I see my primary care. I see my COP doctor every three months, three to five months.

Technology use was discussed as a mechanism for self-management. Participants stated that using mobile apps helped with physical activity, nutritional habits, and communication with health care providers. Web-based support groups were perceived to be helpful for communicating with others with similar experiences. Additionally, participants used teleconferencing technology for group exercise classes. When asked whether web-based self-management programs are helpful, most indicated that such programs would be beneficial for daily self-care. Specifically, peer support and social capabilities were highlighted as the most useful components of web-based programming. Additionally, a program that would be regularly updated with the latest health recommendations would be considered for daily use.

I use my different technologies a lot, like my phone. I have an iPhone, a iPad, and so I use my like reminders features. I use the different apps, like the CVS app to manage my medication, you know, check and see how many refills I have.

Caregivers

Caregivers expressed views about self-management programs and caregiving duties. Most shared that having an educational resource for daily caregiving would be beneficial. Specifically, caregivers believed that self-management programs with educational resources about medications would aid in managing health, such as medication reminders, side effects, and dosages.

It's mostly arranging for medications and appointments and taking him to appointments. (It) can be a full-time job. But I'm lucky I have help. My family's very supportive.

When asked for perspectives on web-based self-management programs, caregivers believed technologies and programs would be able to aid in daily responsibilities. Specifically, they

preferred web-based platforms that include peer support and educational resources for a wide variety of health conditions.

I would love something like that especially if we can interact with people like this and talk. I like to talk and learn about other people and you know what they're going through. I have a lot of empathy and that's just the person that I've always been. I feel like I can learn from someone else. Even if it's not the same exact disease, I can talk to somebody who has fatigue, and they'll understand, and maybe they can give me ideas.

Health Experts and Researchers

Health experts provided perspectives on their role in self-management. For example, experts shared how they provided assistance to individuals, including teleconferencing technology for at-home exercise and modifiable exercise equipment during exercise sessions. Additionally, due to the COVID-19 pandemic, experts emphasized telehealth for interacting with their clients.

So, what I will say is I was shocked when, when lockdown happened originally and I had to transfer everything online, how quickly all of my clients were just like, "Yep. I do Zoom now." Like, I've really not had, a ton of barriers in terms of user ability with Zoom. Of course, internet access is an issue for anyone. But generally speaking, I think, like all of my clients did a great job with that.

For working with caregivers, health experts noted that maintaining independence may be a barrier as the individual may not seek assistance during an exercise or therapy session. Caregivers explained that the individual they care for may not want assistance during a session. Therefore, the ability to work with the caregiver could be hindered. Educating staff about family dynamics may be helpful for caregiving [23].

Health experts were asked to give ways they help clients who have chronic conditions and physical disabilities. The most common form of assistance given included sharing contact information. Through communication, experts could answer health-related questions concerning exercise or nutrition.

Ongoing motivation and support. So, I'm readily available by email. I also, really love connecting people. So, just like she said, if we can't physically be in the same room, are you comfortable, if you guys share your information? Can I have you guys swap emails?

Researchers provided perspectives on self-management programs. Due to the COVID-19 pandemic, researchers perceived that delivering programs in a hybrid or completely digital version was beneficial. Researchers noted that individuals who could not attend in-person programs due to inaccessible transportation would be able to participate remotely. However, broadening access to programs requires internet capabilities, which may be a barrier. Additionally, researchers noted that web-based programs need to accommodate visual and hearing impairments.

We've got some trainings that we flipped to virtual because of COVID, and they're staying virtual because people are able to have greater participation and connect in a better way, and that has made people kind of stay in programs longer, so you might get better retention.

Summary of Perceptions

In summary, stakeholders emphasized the importance of healthy behaviors including physical activity and healthy eating. Interestingly, stakeholders included managing mental health in the context of self-management as an important component for overall health and relied on social support. Many also provided positive statements related to using technological aides to assist in their daily self-management programs. Elements within technological aides cited included educational resources and web-based social support groups.

Needs of Stakeholders

Overview

Stakeholders were asked questions related to areas of self-management and self-management programs that lacked essential resources or support to provide individuals with the optimal level of self-management, whether it applied to personal or professional experience. By using CGT and inductive analysis, the needs of stakeholders became the second theme in the focus group study.

Individuals With Physical Disabilities and Chronic Conditions

Participants shared areas of self-management that they wanted to improve. The primary focus was symptom management. Specifically, participants wanted to learn how to identify triggers that preceded symptoms such as pain or fatigue. Increasing physical activity was another area where participants wanted to improve. Most wanted to increase time spent walking or wheeling, while some preferred structured exercise. Similarly, identifying triggers for symptom management and avoiding foods that exacerbate symptoms were common.

For me, the two main things that I wish I was better at is tracking how I'm feeling so I can try and identify triggers or things that make my pain level, for example, better or worse.

Participants provided several suggestions on needed elements for self-management programs. Peer-to-peer support was the most cited feature that participants wanted. Participants indicated that being able to communicate with other individuals would facilitate their ability to manage their symptoms. Additionally, a regularly updated program with educational resources was discussed as being relevant for a web-based self-management program.

I think that an online health application would be wonderful. I would love to be able to see any features as developed as the app or the program itself went along. Peer-to-peer support, online support with possibly the specialists. That could be an optional thing... application reminders such as: medication reminders, pharmacy pick up reminders, coordinating

with your doctor or specialist should any problems arise.

Caregivers

Caregivers discussed needed areas of self-management to provide adequate care. Understanding symptoms and medication was the primary need. They desired a centralized mechanism to retrieve relevant information on various conditions and physical disabilities. Additionally, caregivers conveyed their desire to have emotional well-being resources.

There are things that I, we come across that are just brand new to us and, some of the things that my immediate family and immediate support system haven't come across at all. So just having more knowledge and more access to resources that have that knowledge is something that I strongly desire.

Caregivers provided suggestions on what components of web-based self-management programs would assist them in their roles as caregivers. The most common element included a resource bank with educational information about conditions and disabilities. Additionally, caregivers recommended peer-to-peer groups, where caregivers could interact with other caregivers who experience similar challenges.

Health Experts and Researchers

Health experts discussed areas of self-management where they assist clients. The most common area was technology use. Specifically, health experts helped clients use teleconferencing technology and features such as closed captions or specialized audio settings. For in-person assistance, health experts would help their clients navigate physical and environmental structures. Subsequently, experts would have conversations about client preferences and goals.

I would say that the people with disabilities or the chronic conditions, they not only need the support that a physical medication or something like that, but emotional and moral of support is also important to them. So basically, what to do is a support group and one of the people that we engage there, we, try to encourage each other. Also, the medication that we make sure that everyone is getting the right medication.

Researchers were asked to share their thoughts on needed elements of self-management programs. Person centeredness was the most common component recommended. Allowing individuals to customize for their needs would be essential for overall well-being. The researchers also expressed the need for regularly maintained programs with evidence-based recommendations. Lastly, implementing user-friendly language was suggested to make programs more appealing.

It's really important that people with disabilities be involved in all aspects of these things, planning leadership roles. There is such a big difference having people with disabilities thinking about the program and then developing the program, and doing the outreach, and leading the programs.

Summary of Needs

Individuals with physical disabilities and chronic health conditions indicated that for them to improve in self-management behaviors, accessible and educational resources would be beneficial. Similar thoughts were expressed by caregivers, in addition to understanding health conditions, symptoms, and medication side effects and interactions. Health experts and researchers emphasized that resources provided to individuals with physical disabilities and chronic health conditions and caregivers should be individualized and participant centered.

Barriers of Stakeholders

Overview

The stakeholders were asked to provide their perspectives on areas within self-management and self-management programs that prevent the ability to successfully manage health behaviors and health conditions. Through using CGT and inductive analysis, the third theme elicited from the data was barriers of stakeholders. Relevant codes and explanations of the codes are provided in [Multimedia Appendix 2](#).

Individuals With Physical Disabilities and Chronic Conditions

Participants discussed different barriers that affect daily self-management. Symptom management was common among nearly all participants. Most participants indicated that symptom severity makes it difficult to perform daily activities, such as housekeeping and cooking. The most common symptoms were fatigue and pain, followed by mental health issues, including depression, fear, and anxiety. Most anxieties and fears stem from losing independence and a shortened lifespan. The economic burden of self-management was another barrier to maintaining health. Participants indicated that covering costs for medication, even with insurance, is a financial barrier to health. Additionally, participants expressed that healthy food options are more expensive than processed foods and that they have difficulty determining what foods are appropriate for their diet.

I would say one of the biggest issues for me that no one has mentioned is financial. I live at the poverty level. It definitely freaks me out. I mean, I'd be homeless if I didn't have help. So that's like one of the main concerns I have. I mean, all my money goes to my secondary insurance and my medications, and I didn't get to work long enough to really end up making that much money.

Caregivers

Caregivers were asked to share barriers they experienced when providing daily assistance to whom they provided care. Many stated that medical care was the most challenging aspect of self-management, including medications and working with health care providers. The most challenging aspect of medication management was handling multiple prescriptions that were taken at different times throughout the day. Subsequently, prescriptions are regularly updated, which would cause confusion. Similarly, due to having multiple conditions or

physical disabilities, managing medical appointments with physicians is a significant challenge. Specifically, understanding the symptoms and side effects of medications is a constant challenge for caregiving. Caregivers also shared fears and anxieties related to self-management. The primary concern was maintaining the balance between providing adequate assistance and allowing maximal autonomy.

My painstaking needle in the foot is medications. It starts picking up the medications, refilling the medications. Then I go home and I have a book this big with about twenty different medications and I have to pull apart every little thing that's on the tab.

Researchers and Health Experts

Researchers and health experts were asked to give thoughts on barriers for self-management programs. Stakeholders suggested that health care providers need specialized training to work with individuals with physical disabilities. Specifically, emphasis should be placed on learning to communicate with an individual with a physical disability. Additionally, researchers highlighted the importance of addressing mental health concerns for these populations while not solely focusing on the physical symptoms.

So some people have mental health as a priority because they're coping with the changes to their life given the diagnosis, some people are very focused on pain management, others are focused on, what biomarkers are they getting measured for at the doctor's offices? ...but I think making it patient-centered so that people can actually have a say in what they want out of treatment or a program in this case, as opposed to kind of it being dictated to them.

Summary of Barriers

In summary, individuals with physical disabilities and chronic health conditions indicated that the symptoms experienced were the most common concerns that prevented adequate self-management, followed by economic concerns. Caregivers experienced challenges in medication management. The health experts and researchers suggested that health care providers lack training to work with those with chronic health conditions, especially those with physical disabilities.

Discussion

Principal Findings

The purpose of this study was to gain insight into how stakeholders perceive self-management of health in the context of physical disability, chronic conditions, and assistive technologies. Regular physical activity or exercise was noted as the most important facilitator of good health but also the most challenging activity. Participants indicated that these activities were conducted in individual or group settings. According to the Centers for Disease Control and Prevention, individuals with physical disabilities are less likely to achieve physical activity recommendations, and this effect is increased if one has a physical disability and chronic condition [1,24]. For needs, patient centeredness, continuing education, and emotional needs

were deemed important. Including stakeholders in the creation of web-based self-management programming was also considered a necessary element in self-management [25-27]. For barriers, participants with chronic conditions and physical disabilities indicated that managing symptoms was the most prevalent barrier to participating in physical activity such as fatigue and pain. These symptoms have been shown to negatively impact physical activity participation [28,29]. Self-management programs are designed to address different barriers to promote participation in safe physical activity [7]. Research has shown that self-management programs that include physical activity promotion are feasible and effective for individuals with physical disabilities or chronic conditions [30-34]. Thus, any self-management program should include accessible and inclusive physical activity recommendations.

Interestingly, mental health was also perceived to be a barrier to health. Participants shared that they experience emotional barriers, including depression, fear, and anxiety. These perspectives are consistent with research showing that similar psychological elements are common in different disability-related populations, such as multiple sclerosis, spinal cord injury, or stroke [35-37]. The remaining stakeholders expressed similar concerns about mental health. Specifically, caregivers expressed their desire to have mental health resources available to assist family members or friends with emotions stemming from experiencing physical disabilities or chronic conditions. This supports the need to implement mental health education in self-management programs [38].

Caregivers addressed the need for educational content regarding physical activity recommendations, symptoms, and medications. Health experts and researchers also expressed the need for inclusive education. Within the literature, caregivers and experts believe that there needs to be ongoing education that is accessible and inclusive [39,40]. In addition, caregivers expressed physical and emotional stress during daily caregiving. Mental burdens were prevalent as managing multiple conditions causes confusion as they evolve. It is suggested that low levels of caregiving assistance and working outside the home are associated with more health and wellness problems for caregivers [41]. Thus, providing mental health support to both people with physical disabilities and their caregivers can influence the efficacy of self-management programs.

Additionally, caregivers expressed challenges they experienced when managing medication. Understanding medication, side effects, daily administration, and autonomy in using medication were the most common challenges. Caregivers discussed difficulties in understanding how medications worked, especially with other medications. These challenges made managing medications difficult because several medications are needed to manage multiple conditions and disabilities. These findings are consistent with caregivers who handle medications on a daily basis [42]. Because caregivers contribute significantly to the preparation of daily medications, they are likely to experience stress with such duties. Caregivers cited that preparing daily medication and the lack of knowledge add to the burdens they experience. Research has shown that multiple conditions, medications, medication interactions and the lack of medical knowledge make caregiving responsibilities

problematic [43-45]. Accordingly, self-management programs should include education about multiple conditions and medications.

Other barriers that were common among participants were economic strains. Caregivers and individuals with chronic conditions and physical disabilities indicated the complexities of navigating the health care system, including Medicare and Medicaid. Additionally, medication costs made sustaining a healthy lifestyle more difficult. These concerns are similar across multiple conditions and physical disabilities [46-49]. Self-management programs should consider serving as a resource in navigating the tough financial landscape.

Stakeholders discussed perspectives, needs, and barriers when incorporating technology into self-management programs. Many individuals with physical disabilities and chronic health conditions indicated that they used mobile apps to assist with monitoring exercise and physical activity, nutrition, and medication adherence. Overall, stakeholders emphasized the benefit of using digital technologies in self-management programs. More specifically, stakeholders expressed support for technology platforms that included peer-to-peer support functions, which would allow users to be able to communicate with other individuals. Individuals with chronic conditions and physical disabilities conveyed that they used teleconferencing technology to attend group exercise classes. Videoconferencing technology is a feasible way to promote physical activity participation [50]. Caregivers emphasized the benefit of using digital technology with educational resources to aid in daily responsibilities. These perceptions are consistent with prior literature indicating support for technology-integrated programs for daily self-management [51,52]. These features have been implemented in web-based programs to promote behavioral change, goal setting, and symptom management [32,53-55]. Several participants noted that although several technologies were available, there was a burden with finding technologies, and many fragmented pieces of technologies were needed to accomplish their goals. Thus, self-management programs should consider providing holistic technological solutions or serving as a resource for finding such solutions.

Limitations

While stakeholders provided valuable perspectives on self-management, there are limitations that need to be addressed. First, the sample size of stakeholders may be perceived as a limitation; more specifically, the caregivers and the health experts and researchers groups. Next, participants' responses to questions may have been influenced by a prior participant's answer [56]. For participants with chronic health conditions and physical disabilities, inclusion criteria for chronic health conditions included diabetes, heart conditions, and lung conditions. The focus group responses may not be fully representative of other health conditions.

Conclusions

This study sought to gain information from stakeholders who have experience with chronic conditions and physical disabilities. Stakeholders shared common views regarding the importance of physical activity, nutrition, and medication

adherence. Interestingly, stakeholders emphasized that mental health was generally missing from self-management programs. Due to the COVID-19 pandemic, stakeholders suggested that web-based self-management programs could be a viable method to manage health. Based on the findings, web-based

self-management programming with mental health resources would be beneficial for long-term care. Overall, programs should take a holistic view of the needs of people with physical disabilities and chronic conditions.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

TM received fees from Novo Nordisk, New Balance Foundation, Heart Rhythm Clinical and Research Solutions, The Obesity Journal, and PLOS One. All other authors have no conflicts to declare.

Multimedia Appendix 1

Semistructured interview guides for stakeholder groups.

[[DOCX File, 17 KB - rehab_v10i1e43309_app1.docx](#)]

Multimedia Appendix 2

Additional demonstrative quotes.

[[DOCX File, 33 KB - rehab_v10i1e43309_app2.docx](#)]

Multimedia Appendix 3

Code tree for focus groups.

[[DOCX File, 14 KB - rehab_v10i1e43309_app3.docx](#)]

Multimedia Appendix 4

Sample NVivo screenshot for code tree.

[[DOCX File, 542 KB - rehab_v10i1e43309_app4.docx](#)]

Multimedia Appendix 5

Physical disabilities and health conditions experienced by individuals with physical disabilities and chronic health conditions.

[[DOCX File, 17 KB - rehab_v10i1e43309_app5.docx](#)]

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Abbreviations

CGT: constructivist grounded theory

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Original Paper

Telerehabilitation Delivery in Canada and the Netherlands: Results of a Survey Study

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Abstract

Background: Following the onset of the COVID-19 pandemic, telerehabilitation (TR) has been expanding to address the challenges and risks of in-person delivery. It is likely that a level of TR delivery will continue after the pandemic because of its advantages, such as reducing geographical barriers to service. Many pandemic-related TR initiatives were put in place quickly. Therefore, we have little understanding of current TR delivery, barriers and facilitators, and how therapists anticipate integrating TR into current practice. Knowing this information will allow the incorporation of competencies specifically related to the use and provision of TR into professional profiles and entry-to-practice education, thereby promoting high-quality TR care.

Objective: This study aimed to obtain a descriptive overview of current TR practice among rehabilitation therapists in Canada and the Netherlands and identify perceived barriers to and facilitators of practice.

Methods: A web-based cross-sectional survey was conducted with occupational, physical, and respiratory therapists and dietitians in Canada (in French and English) and the Netherlands (in Dutch and English) between November 2021 and March 2022. Recruitment was conducted through advertisements on social media platforms and email invitations facilitated by regulatory and professional bodies. The survey included demographic and practice setting information; whether respondents delivered TR, and if so, components of delivery; confidence and satisfaction ratings with delivery; and barriers to and facilitators of use. TR satisfaction and uptake were measured using the Telehealth Usability Questionnaire and modified Technology Acceptance Model. Data were first summarized descriptively, and then, comparisons were conducted between professions.

Results: Overall, 723 survey responses were received, mostly from Canada (n=666, 92.1%) and occupational therapists (n=434, 60%). Only 28.1% (203/723) reported receiving specific training in TR, with 1.2% (9/723) indicating that it was part of their professional education. Approximately 19.5% (139/712) reported not using TR at all, whereas most participants (366/712, 51.4%) had been using this approach for 1 to 2 years. Services delivered were primarily teleconsultation and teletreatment with individuals.

Respondents offering TR were moderately satisfied with their service delivery and found it to be effective; 90.1% (498/553) indicated that they were likely to continue offering TR after the pandemic. Technology access, confidence, and setup were rated the highest as facilitators, whereas technology issues and the clinical need for physical contact were the most common barriers.

Conclusions: Professional practice and experience with TR were similar in both countries, suggesting the potential for common strategic approaches. The high prevalence of current practice and strong indicators of TR uptake suggest that therapists are likely to continue TR delivery after the pandemic; however, most therapists (461/712, 64.7%) felt ill prepared for practice, and the need to target TR competencies during professional and postprofessional education is critical. Future studies should explore best practice for preparatory and continuing education.

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KEYWORDS

telerehabilitation; digital health; telehealth; eHealth; competencies; capabilities; mobile phone

Introduction

Background

The use of digital technologies in the health care sector is developing rapidly. The term, *eHealth*, is an umbrella term for combining technology and health, defined by the World Health Organization as “the cost-effective and secure use of information and communications technologies (ICT) in support of health and health-related fields, including healthcare services, health surveillance, health literature, and health education, knowledge and research” [1]. Recently, *digital health* was described as a term “encompassing eHealth, as well as emerging areas, such as the advanced computing sciences in ‘big data,’ genomics and artificial intelligence” [2]. Digital *interventions* are further defined as “a discrete functionality of digital technology that is applied to achieve health objectives” [2]. Within this broad field of digital health, *telehealth*, *telemedicine*, and *telerehabilitation* (TR) are often used interchangeably [3]. Telehealth encompasses the use of information and communications technology (ICT) for “the application of evaluative, consultative, preventative, and therapeutic services” [4], whereas telemedicine applies to the use of ICT for the delivery of direct clinical services and TR refers to the digital delivery of rehabilitation services [5,6].

TR and the COVID-19 Pandemic

With the increasing advancement and availability of ICT, TR has become more attractive to health care professionals, service recipients, and insurance companies. Although TR was becoming more common before the COVID-19 pandemic, occupational therapists (OTs), physical therapists (PTs), and respiratory therapists (RTs) were compelled to quickly adopt these alternative strategies to address access, efficiency, and effectiveness in clinical service provision during the COVID-19 pandemic [7,8]. However, barriers to broad TR adoption and access persist. Accessibility is affected by factors at the *service provider* level, such as comfort or competence with eHealth delivery or the availability and systemic support of eHealth apps, or at the *service recipient* level, such as access to technology and internet and the applicability of eHealth apps for users with impaired health, digital literacy, or variations in cultural backgrounds [9-11].

Therapists have turned to TR as a strategy to maintain continuity of care and access to treatment during the COVID-19 pandemic [12]. TR delivery can include web-based coaching sessions

(either group or individual), by using existing eHealth apps and wearables such as activity trackers, through telephone or video consultations, and by sharing educational material through the web (such as instructive videos on YouTube) [13,14]. In the Canadian and Dutch contexts, we have limited information about how therapists have chosen to implement eHealth services as part of rehabilitation interventions. As we approach a point where COVID-19 conditions stabilize, we are uncertain about which of these new or alternative ways of providing interventions will remain as *current practice* moving forward. However, given that TR was already gaining momentum in both countries before the pandemic, it is a reasonable assumption that it will be applied more frequently in daily clinical practice.

Importantly, many TR initiatives imposed owing to COVID-19 conditions were expedient, without adequate preparation of the provider or recipient of service [15,16]. TR is likely to continue after the pandemic, because of some of the advantages it affords, and thus, it is increasingly important that therapists entering practice are equipped with the necessary eHealth competencies. Currently, newly graduated rehabilitation professionals have limited exposure to, or experience with, the delivery of digital interventions, let alone competence to assess the efficacy of such interventions [9,15,16]. Some studies have started trying to identify the competencies required for TR delivery to help guide educational programs and professional continuing education. Davies et al [17] recently released a capability framework for quality care videoconferencing delivered by PTs, which includes 7 domains: compliance, patient privacy and confidentiality, patient safety, technology skills, telehealth delivery, assessment and diagnosis, and care planning and management. However, without knowing the current state of TR delivery, it is difficult to know how to apply these competencies or whether they address the knowledge needs of different types of rehabilitation therapists currently delivering these services.

Context of Practice

Between Canada and the Netherlands, a similar need for exploration and further development of TR services can be identified, albeit for different reasons. In Canada, TR may deliver health care services to rural and remote areas, creating solutions for patients who are otherwise not able to receive face-to-face services at hospitals or clinics [18]. In the Netherlands and Canada, TR services may help to deliver health care services to the growing number of people with complex

health care needs in the context of increasing shortages of health care professionals and health care funding [19,20]. Although there are fundamental differences between the Canadian and Dutch health care systems, many similarities can be identified. Both countries offer universal health care access; however, in Canada, a single government-run scheme is funded through taxation, whereas the Netherlands uses mandatory private insurance plans and predominantly private hospitals. Both countries emphasize building a strong primary care system through primary care renewal [21,22]. In both Canada and the Netherlands, access to rehabilitation is being addressed by the inclusion of technology. However, a substantial proportion of PTs in both countries work in a fee-for-service model, in which care recipients must either pay out of pocket or arrange third-party coverage; this is particularly true for neuromusculoskeletal conditions. Another similarity has been the increased emphasis on population health, with increased rehabilitation services targeting health promotion and disease prevention [23].

Given these similarities in practice and health priorities, a collaborative research group with investigators at the University of Manitoba and the Amsterdam University of Applied Sciences explored current (peri-COVID-19) TR practice in the Canadian and Dutch contexts and therapists' perceptions of barriers to and facilitators of TR practice. We were specifically interested in documenting whether therapists were using TR in daily practice and for what purposes, which types of platforms and services were used, barriers and facilitators associated with these services, perceptions of preparation for and current delivery of TR, and uptake and intent for future TR delivery. If such information exists, appropriate evaluations of service delivery and strategic planning for rehabilitation service delivery after the pandemic can be performed. Therefore, this study aimed to obtain a descriptive overview of current TR practice among rehabilitation professionals in Canada and the Netherlands and identify perceived barriers to and facilitators of practice.

Methods

Design

We administered a web-based survey, using the SurveyMonkey platform (Momentive), to gather participants' experiences with TR practice. The survey method was the most efficient and accessible approach to access various disciplines across wide geographical regions and in multiple languages (ie, English, French, and Dutch). The survey questions addressed demographics, description of current practice, identification of facilitators and barriers, and rating of several TR use metrics and included validated measures of TR usability and uptake.

Participants

We specifically targeted rehabilitation therapists from the professional programs in our universities. In Canada, this included OTs, PTs, and RTs, and in the Netherlands, this included OTs, PTs, exercise therapists (ETs), and dietitians (DTs). Participation was restricted to therapists with a minimum of 6 months of work experience at the time of the survey but was open to those who had not used TR in their practice.

Recruitment

Recruitment in Canada followed 2 main strategies. First, provincial regulatory and professional organizations for OTs, PTs, and RTs were contacted with a request to distribute survey invitations to their registrants or members using their email distribution lists. Both French-language and English-language invitations were made available. For organizations that agreed, introductory emails were distributed, followed by subsequent reminder emails at 2 and 4 weeks. Second, invitations to participate were posted on a variety of social media pages including those of all 3 national professional associations and several provincial regulatory or professional bodies and via social media accounts of the research team (eg, Twitter, Facebook, Instagram, and LinkedIn).

Recruitment in the Netherlands was conducted via social media posts (eg, LinkedIn and Facebook) and through direct email invitations sent to lecturing staff at the university PT, OT, DT, and ET programs and therapists participating in the Rehabilitation After Critical Illness and Hospital Discharge interprofessional primary care network [24]. In addition, a web page was designed and placed on the website of the Amsterdam University Medical Center and the Amsterdam University of Applied Sciences expertise center, *Nutrition and Exercise Now* [25]. The recruitment strategies used in both Canada and the Netherlands invited participation from therapists working in any context (ie, age or diagnostic group and private or public funding).

Survey Development

The survey tool was developed by the research team and included members with expertise in TR practice and survey development and implementation. Survey development was informed by the Association for Medical Education in Europe Guidelines for educational research [26] and a review of the literature, including previously published TR surveys. Particular attention was given to the quality of the survey questions, avoiding common pitfalls such as agreement response items, unevenly spaced and unlabeled response options, and multibarreled questions [27]. Although all questions were structured to select ≥ 1 options, some also provided open text space for comments to further elaborate or explain. A draft version was pilot-tested by a rehabilitation graduate student, resulting in several content and formatting improvements. The first section included questions about demographics, training, and clinical practice and ended with a question about current TR delivery. The second section, provided only to those delivering TR, asked about the type of TR offered, how this was provided, experiences with TR delivery including facilitators and barriers, and usability of TR. The final section, provided to all respondents, inquired about TR acceptability and uptake.

Overall, 4 self-rating questions, using 5-point Likert scales, were developed to assess *experience* and *confidence* in providing TR (for all respondents) and perceived *effectiveness* and *satisfaction* with TR delivery (for respondents who had used TR). We also incorporated 2 standardized and validated measures: the Telehealth Usability Questionnaire (TUQ) [28] and the modified Technology Acceptance Model (mTAM) [29].

The TUQ is composed of 21 statements regarding the usability of TR, each with 7 response options ranging from completely disagree to completely agree; this was provided only to those respondents who had used TR. The mTAM assesses factors related to acceptance and uptake of TR as a clinical tool and was included for all respondents. It is composed of 33 statements with 7 response options regarding agreement; 1 item was removed because it was not relevant to the target population.

The final survey was translated into French using key elements for evidence-informed translation [30]. The translation was conducted by a research assistant fluent in French and English and then blindly back-translated by a bilingual coinvestigator. Both documents were reviewed by a fully bilingual third party to verify the accuracy for French grammar and cultural relevance. After piloting this version, minor wording changes were made to improve clarity. Next, the survey was translated into Dutch by a research assistant who is a native speaker and fluent in English. The translated version and the original survey were carefully reviewed by bilingual members of the research team. The survey was administered using the SurveyMonkey web-based platform with an anonymous response option (excluding email address and IP address) to ensure anonymity. Potential participants were provided with a direct link to the survey via the invitation email. Data were collected between November 2021 and March 2022.

Analysis

Data from each survey were exported directly from the SurveyMonkey platform into Microsoft Excel (Microsoft Corp) spreadsheets and then consolidated in a single document. Qualitative (open text) responses were then extracted into a separate spreadsheet with corresponding respondent ID numbers, where they could be sorted. Analysis was conducted using Microsoft Excel (version 16.54) and SPSS (version 27; IBM Corp). Survey responses were reported with summary statistics, using frequency and distribution (mean, SD, and percentage). Group comparison of continuous data was conducted using independent samples *t* test (2-tailed) or ANOVA (with adjustment when equal variance could not be assumed). For comparisons with categorical data, we used chi-square tests.

There was response attrition in some surveys, resulting in some partially complete data sets. The available responses for each survey question were included in descriptive statistics (with the appropriate *n* indicated), and pair-wise deletion was used for variable comparisons. In most cases, the small number of

responses among DTs and RTs resulted in their exclusion from comparative analyses.

Open-ended responses were analyzed in 2 different ways, depending on the nature of the open-ended question. For questions to which the open-ended response was the “other” option, we incorporated responses back into the close-ended response options where appropriate. The remaining responses were categorized by one researcher (JA) and reviewed by a second researcher (CB). Each individual open-ended response potentially contained multiple content topics. Thus, each response was broken down into these individual topics, and similar topics were grouped together to form a coding framework. Once the initial coding framework was completed, the number of responses in each code was counted, and codes with very few responses were examined to determine whether there were similar ideas that could be combined. This process was continued until the codes were developed into categories that were representative of the results. Any discrepancies between the 2 researchers were resolved through discussion.

Ethics Approval

All participants confirmed that they were providing informed consent at the beginning of the survey questionnaire before proceeding to the questions, in accordance with the regulations at both universities. Ethics approval was obtained from the University of Manitoba human research ethics board (HS25158[H2021:330]) in Canada and the Amsterdam University of Applied Science research ethics committee (2021-131350) in the Netherlands.

Results

Participant Demographics

We received a total of 723 usable survey responses (ie, those responding to at least one question), with 666 (92.1%) from Canada and most (*n*=434, 60%) from OTs; only 6 (0.8%) responses were from DTs, and no ETs responded. Complete responses (ie, all questions are answered) were available for 83.8% (606/723) of the surveys. Respondents predominantly had >10 years of clinical experience; approximately half of the respondents (321/723, 44.4%) reported private practice being at least part of their practice, and most respondents (597/723, 82.6%) worked with the adult population. [Table 1](#) shows respondents' characteristics.

Table 1. Respondent characteristics with number of responses.

	Total respondents (N=723), n (%)	Site, n (%)		Profession, n (%)			
		Canadian (n=666, 92.1%)	Dutch (n=57, 7.8%)	OT ^a (n=434, 60%)	PT ^b (n=233, 32.2%)	RT ^c (n=50, 6.9%)	DT ^d (n=6, 0.8%)
Complete data	606 (83.8)	565 (84.8)	41 (71.9)	375 (86.4)	190 (81.5)	36 (72)	5 (83.3)
Time in practice (years)							
0-3	77 (10.7)	66 (9.9)	11 (19.3)	43 (9.9)	25 (10.7)	5 (10)	4 (66.7)
3-5	59 (8.2)	55 (8.3)	4 (7)	45 (10.4)	12 (5.2)	2 (4)	0 (0)
5-10	95 (13.1)	86 (12.9)	9 (15.8)	61 (14.1)	28 (12)	5 (10)	1 (16.7)
>10	492 (68)	459 (68.9)	33 (57.9)	285 (65.7)	168 (72.1)	38 (76)	1 (16.7)
Practice location^e							
Private practice	321 (44.4)	290 (43.5)	31 (54.4)	189 (43.5)	125 (53.6)	5 (10)	2 (33.3)
Hospital	164 (22.7)	154 (23.1)	10 (17.5)	66 (15.2)	61 (26.2)	34 (68)	3 (50)
Rehabilitation center	116 (16)	104 (15.6)	12 (21)	91 (20.9)	20 (8.6)	3 (6)	2 (33.3)
Community	96 (13.3)	96 (14.4)	0 (0)	67 (15.4)	29 (12.4)	0 (0)	0 (0)
Education system	35 (4.9)	29 (4.4)	6 (10.5)	22 (5.1)	12 (5.2)	1 (2)	0 (0)
Long-term care	26 (3.6)	18 (2.7)	8 (14)	21 (4.8)	3 (1.3)	1 (2)	1 (16.7)
Primary care	13 (1.8)	10 (1.5)	3 (5.3)	5 (1.2)	4 (1.7)	3 (6)	1 (16.7)
Other	88 (12.2)	82 (12.3)	6 (10.5)	66 (15.2)	13 (5.6)	9 (18)	0 (0)
Age of patients^e							
Newborn to 12 years	160 (22.1)	152 (22.8)	8 (14)	114 (26.3)	41 (17.6)	5 (10)	0 (0)
13 to 17 years	171 (23.7)	157 (23.6)	14 (24.6)	103 (23.7)	64 (27.5)	4 (8)	0 (0)
18 to 54 years	405 (56)	368 (55.3)	37 (64.9)	265 (61.1)	118 (50.6)	18 (36)	4 (66.7)
55 to 69 years	364 (50.3)	329 (49.4)	35 (61.4)	231 (53.2)	109 (46.8)	20 (40)	4 (66.7)
≥70 years	294 (40.7)	262 (39.3)	32 (56.1)	173 (39.9)	96 (41.2)	21 (42)	4 (66.7)
All age groups	169 (23.4)	161 (24.2)	8 (14)	43 (9.9)	94 (40.3)	30 (60)	2 (33.3)
Other	13 (1.8)	13 (1.9)	0 (0)	9 (2.1)	3 (1.3)	1 (2)	0 (0)

^aOT: occupational therapist.^bPT: physical therapist.^cRT: respiratory therapist.^dDT: dietitian.^eRespondents could select ≥1 practice setting and ≥1 patient age group.

Use of TR and Training Received

A summary of responses to items about TR-related training and use is provided in [Table 2](#). In our sample, 19.5% (139/712) indicated that they had never used TR in their practice, and 8.8% (63/712) had been using TR before the COVID-19 pandemic (ie, >2 years). Half of the respondents (366/712, 51.4%) had been using TR for 1 to 2 years. PTs were late adopters and less likely to have used TR than OTs ($\chi^2_1=16.6$; $P<.001$), and RTs were less likely than PTs and OTs ($\chi^2_2=87$; $P<.001$). Overall, three-fourths (520/712, 73%) of all respondents (and 508/568, 89.4% of those currently using TR) indicated that their use of TR was specifically because of COVID-19; OTs were the most likely and RTs were the least

likely to identify this as the reason ($\chi^2_2=70.9$; $P<.001$). When those currently providing TR (553/712, 77.7%) were asked about continuing use of TR after the COVID-19 pandemic, 66.9% (370/553) indicated “yes,” 23.1% (128/553) indicated “maybe,” and 9.9% (55/553) indicated “no.” Across the 5 discrete age categories shown in [Table 1](#), there was a gradual decline in the proportion of respondents using TR: children (145/158, 91.8%), youth (150/168, 89.3%), adults aged between 18 and 54 years (334/401, 83.3%), adults aged between 55 and 69 years (288/360, 80%), and adults aged >70 years (212/291, 72.9%).

Overall, respondents used TR for similar purposes, with most using it for teleconferencing (543/573, 94.8%) and teletreatment (478/573, 83.4%) and few for telemonitoring (137/573, 23.9%). Both video (546/573, 95.3%) and telephone (471/573, 82.2%)

platforms were used frequently. Patients were most typically seen individually (549/573, 95.8%), but 23.7% (136/573) of the therapists used TR for groups. OTs were more likely than PTs to use TR for groups (104/379, 27.4% vs 23/173, 13.3%) and more commonly used video (371/379, 97.9% vs 159/173,

91.9%) and telephone (324/379, 85.5% vs 130/173, 75.1%) formats for TR delivery. Only 28.1% (203/723) of the respondents reported receiving specific training on TR delivery, with only 1.2% (9/723) indicating this to be part of their professional education (Table 2).

Table 2. Summary of telerehabilitation training and use responses.

Survey questions and response options	Total responses, n (%)	Site, n (%)		Profession ^a , n (%)		
		Canadian	Dutch	OT ^b	PT ^c	RT ^d
Have you received any training in the provision of telerehabilitation services (or remote rehabilitation services)?^e (total responses: n=723; Canadian: n=666; Dutch: n=57; OT: n=434; PT: n=233; RT: n=50)						
Yes	203 (28.1)	196 (29.4)	7 (12.3)	120 (27.6)	79 (33.9)	4 (8)
Part of my university professional training	9 (1.2)	9 (1.3)	0 (0)	5 (1.2)	4 (1.7)	0 (0)
Professional continuing education offered at my place of work	125 (17.3)	122 (18.3)	3 (5.3)	76 (17.5)	45 (19.3)	4 (8)
Professional continuing education offered other than my place of work	76 (10.5)	73 (10.9)	3 (5.3)	44 (10.1)	32 (13.7)	0 (0)
Other	22 (3)	21 (3.2)	1 (1.8)	11 (2.5)	11 (4.7)	0 (0)
How long have you been using telerehabilitation? (total responses: n=712; Canadian: n=657; Dutch: n=55; OT: n=430; PT: n=228; RT: n=48)						
I have never used telerehabilitation	139 (19.5)	129 (19.6)	10 (18.2)	51 (11.9)	55 (24.1)	32 (66.7)
<6 months	61 (8.6)	54 (8.2)	7 (12.7)	37 (8.6)	21 (9.2)	2 (4.2)
6 months to 1 year	83 (11.7)	78 (11.9)	5 (9.1)	38 (8.8)	38 (16.7)	4 (8.3)
1 to 2 years	366 (51.4)	344 (52.4)	22 (40)	258 (60)	101 (44.3)	6 (12.5)
2 to 5 years	47 (6.6)	37 (5.6)	10 (18.2)	36 (8.4)	10 (4.4)	1 (2.1)
>5 years	16 (2.2)	15 (2.3)	1 (1.8)	10 (2.3)	3 (1.3)	3 (6.3)
Are you using telerehabilitation due to the COVID-19 pandemic? (total responses: n=712; Canadian: n=657; Dutch: n=55; OT: n=430; PT: n=228; RT: n=48)						
Yes	520 (73)	484 (73.7)	36 (65.5)	350 (81.4)	153 (67.1)	13 (27.1)
Which telerehabilitation services do you currently deliver or have delivered in the past (last 5 years)? (total responses: n=573; Canadian: n=528; Dutch: n=45; OT: n=379; PT: n=173; RT: n=16)						
Teleconsultation (video)	507 (88.5)	472 (89.4)	35 (77.8)	348 (91.8)	147 (84.9)	8 (50)
Teleconsultation (phone)	432 (75.4)	396 (75)	36 (80)	294 (77.6)	121 (69.9)	12 (75)
Teletreatment (video)	444 (77.5)	412 (78)	32 (71.1)	299 (78.9)	137 (79.2)	6 (37.5)
Teletreatment (phone)	326 (56.9)	299 (56.6)	27 (60)	230 (60.7)	87 (50.3)	7 (43.8)
Telemonitoring (video)	115 (20.1)	105 (19.9)	10 (22.2)	64 (16.9)	45 (26)	6 (37.5)
Telemonitoring (phone)	108 (18.8)	95 (17.9)	13 (28.9)	66 (17.4)	33 (19.1)	8 (50)

^aDietitians are not included in the table owing to the small number of respondents (6/723, 0.8%).

^bOT: occupational therapist.

^cPT: physical therapist.

^dRT: respiratory therapist.

^eRespondents could select ≥ 1 response.

Experience—Satisfaction and Confidence

A summary of respondents' ratings on the 4 investigator-developed scales and the 2 standardized measures is provided in Table 3. Among all respondents (ie, those who did and those who did not provide TR services), many (197/712, 27.7%) reported having "some" experience with TR and being "moderately" confident with TR delivery. In follow-up with those providing TR, participants reported being "moderately to

quite" satisfied with the care they provided and perceived it to be "moderately to quite" effective. Regarding the usability of the modes of TR that respondents had access to, the mean TUQ rating was 4.5 (SD 1.1) on a 7-point scale. The mTAM scores, indicating potential uptake of TR technology, were somewhat higher than usability, with a mean score of 4.9 (SD 1) on a 7-point scale. Among respondents who were currently using TR, the mean mTAM score was 5.01 (SD 0.92; 491/601,

81.7%), which was significantly higher than that of nonusers (mean 4.14, SD 1.1; $t_{141.9}=7.5$; $P<.001$). There was no significant difference among professions on either the TUQ or mTAM measure (Table 3).

Table 3. Respondents' mean (SD) ratings on perceptions of telerehabilitation use.

Rating scale	All responses, mean (SD)	Site, mean (SD)		Profession ^a , mean (SD)		
		Canadian	Dutch	OT ^b	PT ^c	RT ^d
Experience (n=712)	3.0 (1.2)	3.1 (1.2)	2.9 (1.2)	3.3 (1.2)	2.7 (1.1)	2.0 (1.2)
Confidence (n=712)	3.0 (1.1)	3.0 (1.1)	3.1 (1.2)	3.2 (1.1)	2.8 (1.2)	2.4 (1.2)
Effectiveness (n=553)	3.3 (0.9)	3.3 (0.8)	3.3 (0.9)	3.4 (0.9)	3.2 (0.9)	3.6 (0.8)
Satisfaction (n=553)	3.3 (0.9)	3.3 (0.9)	3.4 (1)	3.4 (0.9)	3.2 (0.9)	3.4 (0.9)
TUQ ^e —usability (n=524)	4.5 (1.1)	4.5 (1.1)	4.9 (0.9)	4.5 (1.1)	4.5 (1.1)	4.6 (1)
mTAM ^f —uptake (n=606)	4.9 (1)	4.8 (1)	5.3 (0.8)	4.9 (1)	4.8 (1.1)	4.9 (1)

^aDietitians are not included in the table owing to the small number of respondents (6/723, 0.8%).

^bOT: occupational therapist.

^cPT: physical therapist.

^dRT: respiratory therapist.

^eTUQ: Telehealth Usability Questionnaire; scored on a 7-point Likert scale: 1=disagree to 7=agree.

^fmTAM: modified Technology Acceptance Model; scored on a 7-point Likert scale: 1=totally disagree to 7=totally agree.

Barriers to and Facilitators of Using TR With Patients

Access to and confidence with technology were the most frequently selected facilitators of TR use. Among the 81 free-text responses in the “other” category, only 2 categories were mentioned by a minimum of 10 respondents: having an appropriate physical space (17/81, 21%) and access to appropriate technology for both provider and patient (10/81, 12%). Technology issues (463/520; 89%) and the need for

physical contact (324/520, 62.3%) were the barriers selected by most respondents. Among the 101 “other” responses, 3 categories were reported by a minimum of 10 respondents: difficulty in observing movement or nonverbal responses (15/101, 14.9%), challenges with establishing a therapeutic relationship (10/101, 9.9%), and mismatch between patient's characteristics and the available modalities (10/101, 9.9%; Table 4).

Table 4. Factors selected as facilitators of and barriers to telerehabilitation use.

Telerehabilitation factors and response options	All respondents (n=520), n (%)	Site, n (%)		Profession ^a , n (%)		
		Canadian (n=490, 94.2%)	Dutch (n=30, 5.8%)	OT ^b (n=354, 68.1%)	PT ^c (n=152, 29.2%)	RT ^d (n=14, 2.7%)
Which requirements are needed for you to be able to provide telerehabilitation?						
Patients' electronic resources (e.g., access to internet, devices)	442 (85)	420 (85.7)	22 (73.3)	294 (83.1)	134 (88.2)	14 (100)
Good technology self-efficacy	395 (75.9)	383 (78.2)	12 (40)	284 (80.2)	97 (63.8)	14 (100)
Technology setup support	319 (61.3)	298 (60.8)	21 (70)	211 (59.6)	99 (65.1)	9 (64.3)
Educational material about the issue or condition	192 (36.9)	183 (37.3)	9 (30)	120 (33.9)	62 (40.8)	10 (71.4)
Use of online written information, or booklets	186 (35.8)	180 (36.7)	6 (20)	124 (35)	54 (35.5)	8 (57.1)
Good fit within workflow	183 (35.2)	167 (34.1)	16 (53.3)	118 (33.3)	62 (40.8)	3 (21.4)
Apps for a smart phone or tablet	167 (32.1)	157 (32)	10 (33.3)	114 (32.2)	48 (31.6)	5 (35.7)
Videos	146 (28.1)	137 (27.9)	9 (30)	98 (27.7)	42 (27.6)	6 (42.9)
Patient must have a chronic condition	14 (2.7)	14 (2.9)	0 (0)	5 (1.4)	3 (1.9)	6 (42.9)
I don't know	10 (1.9)	10 (2)	0 (0)	8 (2.3)	2 (1.3)	0 (0)
Other	81 (15.6)	72 (14.7)	9 (30)	55 (15.5)	25 (16.4)	1 (7.1)
What barriers have you experienced delivering telerehabilitation?						
Technology issues (therapist or patient)	463 (89)	429 (87.6)	24 (80)	319 (90.1)	133 (87.5)	11 (78.6)
Lack of physical touch required to deliver services	324 (62.3)	308 (62.9)	16 (53.3)	211 (59.6)	105 (69.1)	8 (57.1)
Poor technology self-efficacy	194 (37.3)	190 (38.8)	4 (13.3)	136 (38.4)	53 (34.9)	5 (35.7)
Safety concerns	143 (27.5)	138 (28.2)	5 (16.7)	97 (27.4)	44 (28.9)	2 (14.3)
Privacy	116 (22.3)	106 (21.6)	10 (33.3)	91 (25.7)	23 (15.1)	2 (14.3)
Lack of appropriate training opportunities for therapists	115 (22.1)	110 (22.4)	5 (16.7)	82 (23.2)	31 (20.4)	2 (14.3)
Patients with acute conditions	99 (19)	94 (19.2)	5 (16.7)	61 (17.2)	32 (21.1)	6 (42.9)
Online platforms not designed for telerehabilitation	97 (18.7)	92 (18.8)	5 (16.7)	66 (18.6)	26 (17.1)	5 (35.7)
Poor fit within workflow as therapist	94 (18.1)	85 (17.3)	9 (30)	52 (14.7)	41 (26.9)	1 (7.1)
Lack of reimbursement by insurer for appropriate technology	70 (13.5)	59 (12)	11 (36.7)	42 (11.9)	26 (17.1)	2 (14.3)
Regulatory body policies	42 (8.1)	37 (7.6)	5 (16.7)	25 (7.1)	16 (10.5)	1 (7.1)
Inability to consult/collaborate with other professionals	31 (5.9)	30 (6.1)	1 (3.3)	24 (6.8)	6 (3.9)	1 (7.1)
I don't know	7 (1.3)	7 (1.4)	0 (0)	4 (1.1)	3 (1.9)	0 (0)
None	1 (0.2)	0 (0)	1 (3.3)	1 (0.3)	0 (0)	0 (0)
Other	101 (19.4)	91 (18.6)	10 (33.3)	79 (22.3)	21 (13.8)	1 (7.1)

^aDietitians are not included in the table owing to the small number of respondents (6/723, 0.8%).

^bOT: occupational therapist.

^cPT: physical therapist.

^dRT: respiratory therapist.

Discussion

Principal Findings

This study aimed to obtain a descriptive overview of current TR practice among OTs, PTs, and RTs in Canada and the Netherlands and identify perceived barriers to and facilitators of practice. Most of our respondents (565/723, 78.1%) were

OTs and PTs, with several years of clinical experience, working in primary care settings. Most respondents (366/712, 51.4%) had provided TR for approximately 1 to 2 years. Despite barriers such as technology issues and the limitations of not being able to provide hands-on care, 90.1% (498/553) of the respondents indicated that they were likely to continue to offer TR. This finding, in combination with emerging evidence suggesting that TR can be as effective as face-to-face care [31], points to the

importance of continuing to attend to the needs of providers and consumers regarding ensuring effective TR delivery, beyond the COVID-19 pandemic.

In our survey findings, the application of TR was more frequent among OTs and PTs, compared with that among RTs. This finding may be more related to the practice areas of the RTs who responded to the study than a reflection of professional inclination toward TR use [32]. For example, most RTs (34/50, 68%) who responded worked in a hospital setting, whereas a high percentage of OTs and PTs who responded worked in private practice. A study by Almojaibel et al [33] surveying practitioners who provide pulmonary rehabilitation (primarily RTs) found that 79% of respondents had the intention of using TR to deliver pulmonary rehabilitation, with perceived usefulness, such as improving access for those in geographically remote locations, being the variable that most predicted planned use. Although this study did not specifically indicate the type of pulmonary rehabilitation setting, it is typically delivered via outpatient programs, suggesting that the practice setting rather than the profession may be a factor influencing therapists' acceptance and uptake of TR.

In both Canada and the Netherlands, the COVID-19 pandemic drove a change in how rehabilitation services were delivered. Although the specifics of how each country has approached this change varied depending on the specific health care system and infrastructure in place and the severity of the COVID-19 outbreak in each country, it did not seem to influence the process of practice. For example, the use of TR remained quite close to traditional clinical practice such as conducting an intake or intervention via videoconferencing. Telemonitoring was less frequently used, especially among OTs, and this may be related to therapist-level factors, such as a lack of knowledge about or familiarity with the potential benefits of telemonitoring, or system-level factors, such as a lack of use of or support for this type of technology. Telemonitoring is not yet used to its full potential, and this mode of TR—and other options that are not investigated in this study—could become an integral part of rehabilitation interventions [34].

Despite limited training and equivocal self-efficacy for TR delivery, respondents who were providing TR were moderately to quite satisfied with their delivery, and 90.1% (498/553) of them indicated a desire to continue using TR in their daily clinical practice. Overall ratings of TR usability were moderate, suggesting that therapists felt competent to use the technology as intended. This is interesting considering that only 28.1% (203/723) of all respondents received any type of training related to TR delivery, most of which was “on the fly” rather than being part of their entry-to-practice education. Post hoc analysis (not reported in the *Results* section) indicated that more recent graduates were not more likely to have received training or to identify such training as having been obtained during their university program. Thus, there is no way to know if the therapists' reports of being satisfied with TR delivery represent quality care through TR, as reported in recently published TR competencies, such as Health Information Technology Competencies [35]. This document identifies competence as baseline to expert skill level across 5 domains: direct patient care; administration; informatics; engineering, information

systems, and ICT; and research and biomedicine. If TR is to become an integral part of rehabilitation practice, the curricula of OT, PT, and RT programs need to address TR competencies. A recent scoping review explored existing digital health competency frameworks for health care workers and provided recommendations for future digital health training initiatives and framework development [36]. They suggest that telehealth training initiatives should focus on competencies relevant to a particular health care profession, role, level of seniority, and practice setting. For rehabilitation professions, this could include skills such as functional strength assessments through observation only and enhancing communication tools such as motivational interviewing.

Therapists were increasingly less likely to use TR with older patients. This could be related to the level of acceptability of TR among older adults, as they have been found to be less likely than other age groups to choose TR [37]. However, the attitude of the therapist is also a factor in TR delivery, which leaves the question of whether agism is a factor in choosing a service delivery mode for older adults [38]. Respondents identified the need to ensure access, not just to the technology, but the right or appropriate technology that supports the needs of rehabilitation. Technical support for both health care provider and service recipient can create a smooth, more seamless delivery. In addition, TR modalities should be designed in an accessible manner so that they are easy to understand and use by people with impaired (digital) literacy, be available in several languages, and include different interfaces that are adjusted to user needs (eg, spoken language and pictograms instead of texts).

In terms of what facilitated TR use, it was primarily about the access and implementation of technology—ensuring that both recipient and provider of TR had access to the equipment required (ie, devices and internet access and bandwidth), there was technical support to set up the technology, and the provider felt confident in their TR delivery. To a lesser extent, having access to electronic resources relevant to their patient's needs (eg, educational materials, websites, videos, and appropriate apps) was seen as an important facilitator. We may speculate that the therapists responding to this survey were seeking both the technology infrastructure and the skills and comfort in using this technology to reduce the multitasking demands of TR delivery so that they could focus on the *rehabilitation* component rather than the *tele* component. These findings highlight the context-specific experience of TR delivery among therapists in Canada and the Netherlands. As identified in the World Health Organization [2] recommendations document, TR benefit is dependent upon the specific health domain being addressed; development and evolution of interventions specific to that domain; available technology specific to these interventions; and a national infrastructure to support TR delivery including strategic prioritization, implementation and compliance policies and sufficient human resources and training to ensure equitable access to quality services.

The barriers that were identified through our survey echo findings in other studies of TR, indicating that these have yet to be adequately addressed. These barriers include concerns regarding patient safety, lack of technical support, loss of

physical contact needed to conduct assessments, and more difficulty in developing rapport with the patient [39-41]. The loss of physical contact was of particular concern for PT respondents, corroborating the literature linking concerns related to remote contact impeding on safe monitoring of patients [42-44]. The lack of physical contact is an important area for further exploration, as best practice guidelines, while emphasizing the need for enhanced web-based intervention (such as improved education and advice), indicate that a hands-on physical assessment is key in musculoskeletal pain care [45]. However, so far, practice guidelines have not considered the mode of intervention delivery (ie, in person vs telehealth). Studies are needed to support decision-making among therapists regarding the type of therapy delivery that should be used for different diagnostic or functional issues and the most appropriate therapy delivery for different phases of the rehabilitation process. Furthermore, telemonitoring should be explored more as a potential tool to support safety monitoring during the initial PT assessment.

Limitations

To the best of our knowledge, this is the first study to provide insight on TR uptake by multiple rehabilitation professionals during and after the COVID-19 pandemic. These insights contribute to further development of strategic planning for rehabilitation service delivery after the pandemic and addressing education needs related to TR competencies in professional preparation and educational programs. We were able to recruit many study participants from 2 different international contexts. However, the response rate was considerably high in Canada. The limited response from Dutch therapists can likely be attributed to our recruitment methods and the timing of the recruitment period. Despite this imbalance, the responses were generally quite comparable between the 2 countries, suggesting similar perspectives among therapists. Caution should be exercised in generalizing the study findings beyond the Canadian and Dutch contexts. For example, in the Netherlands, physiotherapists are regulated nationally, allowing them to

practice TR across the country. In contrast, Canadian physiotherapists are regulated provincially. This structure requires physiotherapists to provide services only to individuals residing in their own jurisdiction. These jurisdictional boundaries may have influenced the responses by Canadian physiotherapists. Furthermore, given the low response rate, results from the Netherlands should be interpreted cautiously. Although the completion rate was quite high (606/723, 83.8%), we experienced some response attrition, which may have affected the reliability of questions further along in the survey. As with any voluntary survey, there is potential for response bias among therapists who chose to participate, such as private versus public practice, and responses may not be reflective of all practicing rehabilitation therapists. However, the relatively large sample size that included both TR users and nonusers provides us with great confidence in the validity of our findings. Low response rates from ETs and DTs precluded their inclusion in the analyses. Furthermore, conclusions about RTs' perspectives should be approached with caution owing to the low response rate and the small proportion of therapists incorporating TR into their practice.

Conclusions

In conclusion, to the best of our knowledge, this was the first study investigating rehabilitation professionals' insight on TR uptake during and after the COVID-19 pandemic. TR practice was widely adopted in Canada and the Netherlands because of the COVID-19 pandemic, and most rehabilitation therapists (498/553, 90.1%) anticipate continuing to use TR in the future. Despite successful adaptation to this approach, rehabilitation therapists generally felt unprepared for TR delivery, and support for this transition was limited. Access to technology and confidence and competency with technology use were central barriers. Given the expectation that future practice will entail some combination of in-person and web-based delivery, great emphasis needs to be placed on enhancing TR competency through entry-to-practice education and continuing professional education.

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Conflicts of Interest

None declared.

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Abbreviations

DT: dietitian

ET: exercise therapist
ICT: information and communications technology
mTAM: modified Technology Acceptance Model
OT: occupational therapist
PT: physical therapist
RT: respiratory therapist
TR: telerehabilitation
TUQ: Telehealth Usability Questionnaire

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Original Paper

SARS-CoV-2–Related Adaptation Mechanisms of Rehabilitation Clinics Affecting Patient-Centered Care: Qualitative Study of Online Patient Reports

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Abstract

Background: The SARS-CoV-2 pandemic impacted access to inpatient rehabilitation services. At the current state of research, it is unclear to what extent the adaptation of rehabilitation services to infection-protective standards affected patient-centered care in Germany.

Objective: The aim of this study was to determine the most relevant aspects of patient-centered care for patients in inpatient rehabilitation clinics under early phase pandemic conditions.

Methods: A deductive-inductive framework analysis of online patient reports posted on a leading German hospital rating website, Klinikbewertungen (Clinic Reviews), was performed. This website is a third-party, patient-centered commercial platform that operates independently of governmental entities. Following a theoretical sampling approach, online reports of rehabilitation stays in two federal states of Germany (Brandenburg and Saarland) uploaded between March 2020 and September 2021 were included. Independent of medical specialty groups, all reports were included. Keywords addressing framework domains were analyzed descriptively.

Results: In total, 649 online reports reflecting inpatient rehabilitation services of 31 clinics (Brandenburg, n=23; Saarland, n=8) were analyzed. Keywords addressing the care environment were most frequently reported (59.9%), followed by staff prerequisites (33.0%), patient-centered processes (4.5%), and expected outcomes (2.6%). Qualitative in-depth analysis revealed SARS-CoV-2–related reports to be associated with domains of patient-centered processes and staff prerequisites. Discontinuous communication of infection protection standards was perceived to threaten patient autonomy. This was amplified by a tangible gratification crisis of medical staff. Established and emotional supportive relationships to clinicians and peer groups offered the potential to mitigate the adverse effects of infection protection standards.

Conclusions: Patients predominantly reported feedback associated with the care environment. SARS-CoV-2–related reports were strongly affected by increased staff workloads as well as patient-centered processes addressing discontinuous communication and organizationally demanding implementation of infection protection standards, which were perceived to threaten patient autonomy. Peer relationships formed during inpatient rehabilitation had the potential to mitigate these mechanisms.

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KEYWORDS

patient-led care; patient autonomy; patient report; satisfaction; pandemic; coronavirus; inpatient; health care delivery; service delivery; rehabilitation; internet; web-based; reviews; complaint; rating; COVID-19

Introduction

In modern health systems, the relevance of patient-centered care (PCC) continues to progress as it is associated with improved patient satisfaction, self-management, and perceived quality of care [1,2]. The SARS-CoV-2 pandemic impacted endeavors of PCC on inpatient rehabilitation services (IRS). In Europe, an estimated range of 1.3 to 2.2 million patients were required to pause their rehabilitation program in March 2020 [3]. Since then, inpatient rehabilitation clinics have learned to adapt their services to incorporate infection-protective standards while trying to equally uphold the quality of care [4,5]. For instance, geriatric rehabilitation clinics faced capacity shortages; consistent admission delays to rehabilitation services; restricted access to therapists, social workers, or pharmacists; and impacted process parameters such as reduced interprofessional team meetings, structured discharge planning, or shared decision-making efforts [6]. However, it is evident that the extent of adaptation mechanisms varied internationally [7]. Compared to other high-income countries, Germany opted for lockdowns early on, accepting high socioeconomic costs to protect society [7]. It is therefore reasonable that the rigorous implementation of the German infection-protection policy not only affected societal lives but also general health care such as IRS. At present, there is insufficient evidence of the extent to which these adjustments influenced PCC in German inpatient rehabilitation clinics. As a growing number of patients use web-based tools to provide feedback on their experience during medical service claims [8], the aim of this study was to systematically analyze patient experience reports of a clinic rating website in Germany considering patients' perspectives on how SARS-CoV-2-related adaptation mechanisms affected PCC during inpatient rehabilitation.

In Germany, approximately 85% of medical rehabilitation services are provided in inpatient care settings [9]. The central objective of German inpatient rehabilitation is to reduce the effects of disabled conditions on social inclusion so as to prevent occupational incapacity or the need for long-term care [10]. In most countries, the initiation of rehabilitation follows a serious medical event and/or a major surgical intervention. However, in Germany, 75% of rehabilitation services target preventive services addressing chronic diseases and disabilities with a progressive course [11].

Due to a historically grown separation of acute care and medical rehabilitation, the German system faces declining trends of rehabilitation claims as patients are self-responsible to initiate application processes to IRS and intersection communication among health care sectors is fragmented [9]. Since patients can mostly choose the facilities of rehabilitations themselves, there has traditionally been a culture of competitive advertising, not only with regard to medical equipment but also in response to PCC components. The SARS-CoV-2 pandemic intensified this situation as the number of medical rehabilitation requests decreased by 14.5% in the first year of the pandemic [12].

Looking at other inpatient care settings, Andersson et al [13] investigated adaptation mechanisms of critical care nurses affecting person-centered care structures. The interviewed nurses

felt unprepared to deal with conditions associated with the SARS-CoV-2 pandemic. Considering PCC processes, they experienced limited patient communication, and evaluated care to be impersonal and driven by routines. Overall, they sensed patients to be objectified as they perceived a main focus on diagnosing SARS-CoV-2 in new arrivals. Ward managers of a university hospital in Denmark additionally reported influences of the pandemic on person-centered leadership endeavors: holding an intersection position between the clinic management and the nursing staff, they experienced a lack of appropriate involvement in decision-making structures and acknowledgment of individual perspectives [14]. The authors argued that this top-down management approach negatively affected the engagement of ward managers, potentially affecting the quality of care.

Considering limited or delayed admission to IRS, changed process parameters, reduced availability of services, and nontransparent longitudinal leadership structures, it is unclear to what extent these adaptations affected PCC during rehabilitation in Germany. Moreover, an appropriate inclusion of patient perspectives is currently pending. Thus, the particular interest of this study was to evaluate which aspects of PCC were important for IRS recipients during the early phase of the SARS-CoV-2 pandemic in Germany. In that regard, the following research question motivated this study:

Which aspects of PCC are relevant for patients in inpatient rehabilitation clinics and how do they evaluate these aspects to be achieved under conditions of the SARS-CoV-2 pandemic?

By identifying SARS-CoV-2-related aspects affecting PCC in inpatient rehabilitation, the research team aimed at informing rehabilitation clinics to not only become resilient health care organizations but also to meet patient needs in highly demanding and exceptional circumstances of the future. Despite stating palpable organizational interests, this ambition also reflects a moral attitude being of central relevance to any health care organization.

Methods

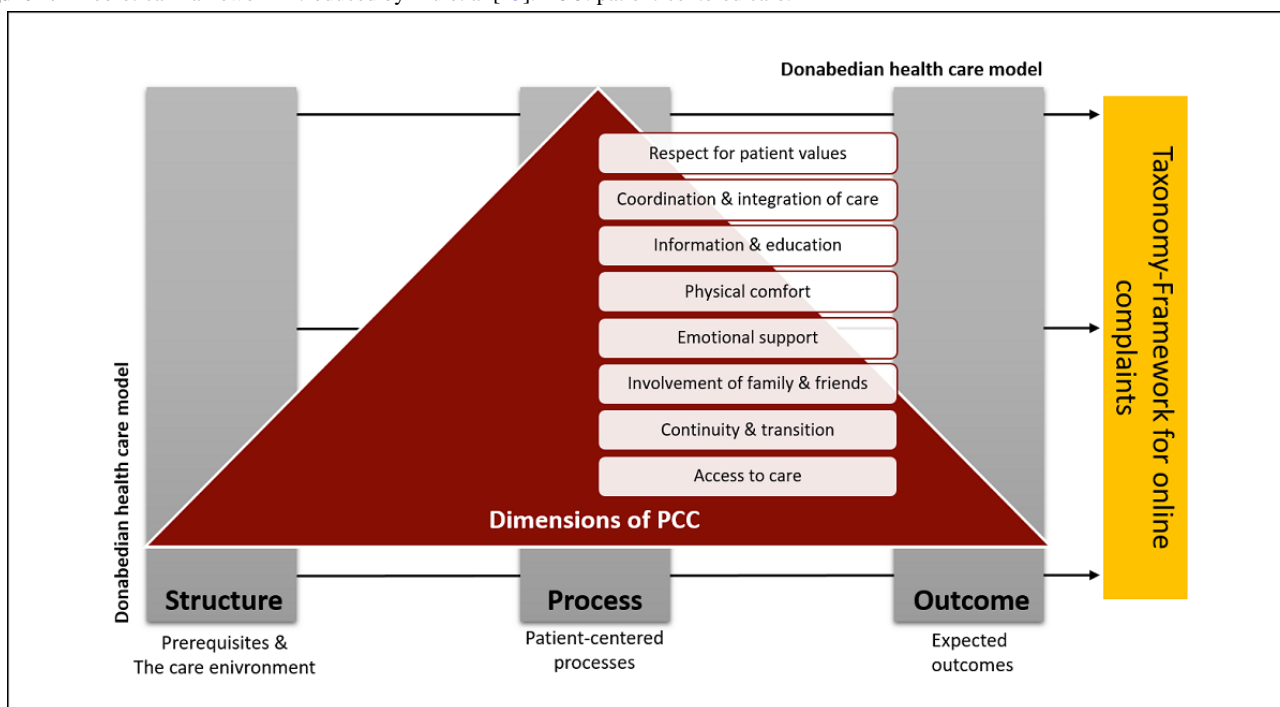
Theoretical Framework

In this qualitative analysis, a deductive-inductive framework approach was used. The applied framework was developed by Liu et al [15] aiming at categorizing online patient complaints into a PCC perspective. The development was guided by the best fit framework synthesis technique [16] and tailored accepted PCC-framework models to the data source of online patient complaints. According to Coulter [17], PCC is a form of care that meets and responds to patients' wants, needs, and preferences, and is prevalent where patients are autonomous and able to decide for themselves. The main dimensions affecting PCC are: (1) respect for patient values, preferences, and expressed needs; (2) coordination and integration of care; (3) information and education; (4) physical comfort; (5) emotional support and alleviation of fear and anxiety; (6) involvement of family and friends; (7) continuity and transition; and (8) access to care [15,18]. Grounded by this concept, Liu et al [15] integrated the dimensions of PCC into the Donabedian

structure-process-outcome model containing the following four constructs: (1) prerequisites, (2) the care environment, (3) patient-centered processes, and (4) expected outcomes [19]. In a second step, the taxonomy was tested by assigning themes

derived from the quantitatively selected patient online complaints data into the framework. Figure 1 illustrates the applied framework.

Figure 1. Theoretical framework introduced by Liu et al [15]. PCC: patient-centered care.



Sample Selection and Data Source

The sample of online posted patient reports was guided by a theoretical selection process. Reports on hospital stays posted on the most commonly used German hospital rating website Klinikbewertungen (Clinic Reviews) [20] were included if written between March 2020 and September 2021. This time period represents the phase in which initial hygiene protection standards (eg, mandatory masks, distance regulations, test obligation) were implemented and maintained across German rehabilitation clinics [21]. The selected hospital rating website is a third-party, patient-centered commercial platform that operates independently of governmental entities. Whether hospitals encourage patients to rate their hospital stay on this platform cannot be answered with certainty.

Given that this was an exploratory study, patient reports were included regardless of their medical indications. To contrast results, reports of IRS were included if referred rehabilitation clinics were located in the federal states of Brandenburg and Saarland, as these states demonstrated the highest and lowest decrease of applications for IRS provided by the Federal German Pension Fund, respectively (Saarland=58.3%, Brandenburg=23.9%) [12]. The federal state of Saarland is located in southwest Germany with a population density of 186 citizens/km² [22]. Brandenburg is located in northeast Germany with a density of 85 residents/km² [22]. Despite infrastructural differences, differences in IRS application rates may imply different coping strategies of resident patients of the respective states or may further reflect different political strategies at the federal policy level.

Ethical Considerations

In this study, open-access online patient reports were used. Therefore, no ethical approval was required. However, we carefully anonymized all cited reports in the manuscript to avoid a linkage of patients' user names of the hospital rating websites with referenced citations.

Data Extraction

Data on patient reports were extracted using a web-scraping technique based on the computing package "Rvest" of the R Project for Statistical Computing [23]. The web-scraping code of included data is provided in [Multimedia Appendix 1](#). Scraped data were transferred to Microsoft Excel (Redmond, USA) and imported into the qualitative analysis software MAXQDA (Berlin, Germany).

Data Analysis

Quantitative Analysis

The total and relative numbers of included rehabilitation clinics and their representing specialties were calculated. Keywords representing domains and categories of the applied framework were analyzed descriptively by reporting absolute and relative frequencies. Additionally, geographic differences in keyword distributions between the included federal states of Brandenburg and Saarland were tested by the χ^2 distribution with a set significance threshold of $P \leq .05$. State-specific average word count differences per online report were tested for significance by applying t -test statistics. Quantitative text data management was ensured by MAXQDA, which offers an analytical software

for qualitative data management. Statistical analysis of text data was conducted via Microsoft Excel.

Qualitative Analysis

A deductive-inductive framework analysis was performed. Two researchers (LK and LL) independently pilot-coded patient reports of two rehabilitation clinics (n=72 online reports), which were randomly selected. After discussing discrepancies and achieving consensus, one researcher (LK) coded the pending data. The coding tree comprised 4 domains, 8 categories, and 25 subcategories of PCC reflecting the introduced framework of Liu et al [15]. Additional themes were coded inductively. By following this approach, the credibility of qualitative data analysis was guaranteed by investigator and theory triangulation.

Anchor quotes representing key findings of the qualitative analysis were preselected and translated into the English language by one researcher (LK). The selection and translation were cross-validated for representativeness and consistency by a second researcher (AC). Data management was provided by using MAXQDA. Data reporting was guided by the COREQ (consolidated criteria for reporting qualitative research) checklist [24] and is provided in [Multimedia Appendix 2](#). The research group has occupational experience in health services research (AC, LL, LK, PK), psychology (AC, PK), physiotherapy (LK), and rehabilitation science (LL).

Results

In total, 43 rehabilitation clinics are located in the federal states of Brandenburg and Saarland, 31 of which are listed on the investigated hospital rating website. Within clinics, 11 medical specialty groups are settled with orthopedic (n=14, 23%), internal medicine (n=17, 28%), and psychiatric/psychosomatic (n=13, 22%) facilities, representing the most frequent specialty groups. During the targeted time period, a sample of 659 posted patient reports was identified. As 10 reports were recognizably

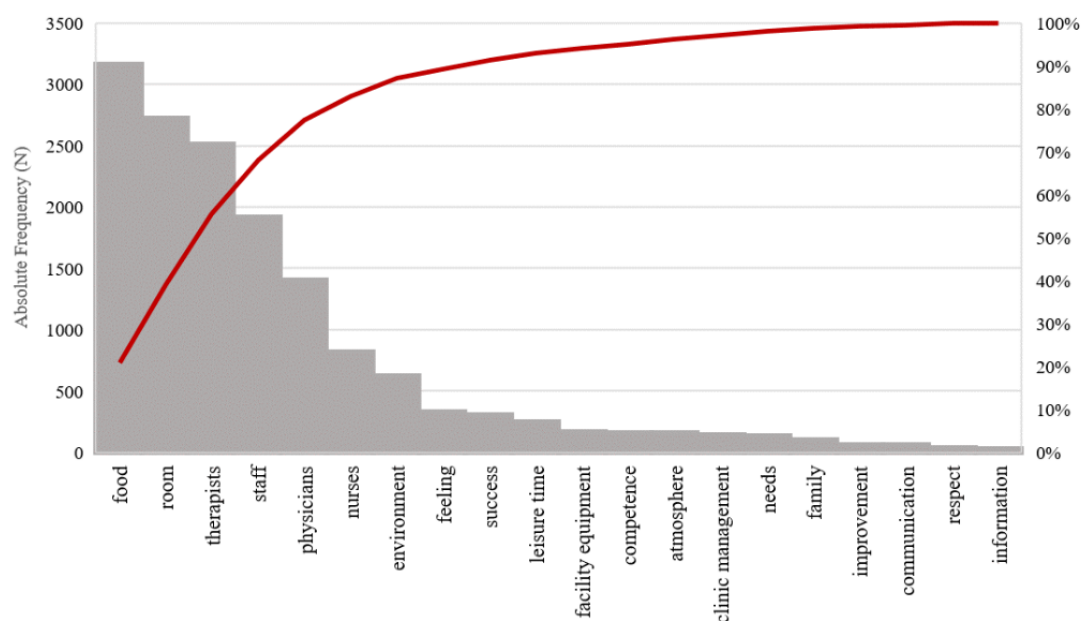
related to rehabilitation stays prior to the SARS-CoV-2 pandemic, the final included sample size was 649 reports. State-specific sample characteristics are summarized in [Table 1](#).

Among the total of 15,125 keywords across federal states and medical specialty groups, keywords relating to food (n=3160, 20.89%) and room amenities (n=2721, 17.99%) were predominantly reported. This was followed by keywords associated with medical and administrative specialty groups, with therapeutic professions being the most commonly cited, including therapists (n=2513, 16.61%), staff (n=1915, 12.66%), physicians (n=1402, 9.27%), and nurses (n=820, 5.42%). Keywords relating to outcome expectancies and information provision were numerically the least represented categories (improvement: n=67, 0.44%; communication: n=66, 0.44%; information: n=30, 0.20%). The cumulative distribution of included keywords is additionally illustrated in [Figure 2](#).

Comparing the average word count per online report, no significant differences across states were identified (Brandenburg, n=140.1 words; Saarland, n=148.3 words; $P=.75$). According to differences of keyword distributions across the federal states of Brandenburg and Saarland, significant differences were identified in PCC domains of prerequisites as well as the care environment. Within the domain of prerequisites, keyword distributions addressing medical specialty groups of therapists, nurses, and physicians significantly differed between states. Within the domain of the care environment, keyword distributions addressing food, room amenities, the environment, and administrative staff significantly differed between states. Within domains of patient-centered processes as well as expected outcomes, no significant differences of distributions were observed. Detailed information on observed keyword frequencies within the included patient reports is provided in [Table 2](#).

Table 1. Sample characteristics of online patient reports.

Characteristics	Brandenburg	Saarland	Total
Rehabilitation clinics, n (%)	27 (64)	15 (36)	42 (100)
Rehabilitation clinics listed online in the rating portal, n (%)	23 (74)	8 (26)	31 (100)
Represented specialty groups, n (%)	11 (100)	8 (73)	11 (100)
Patient reports, n (range)	478 (2-85)	181 (8-64)	659 (2-85)

Figure 2. Frequencies of keywords addressing PCC domains. PCC: patient-centered care.**Table 2.** Differences of keyword frequencies across two federal states in Germany.

Patient-centered care domain	Brandenburg (n=11,234), n (%)	Saarland (n=3891), n (%)	Total (n=15,125), n (%)	P value
Prerequisites				
Competence	121 (1.1)	43 (1.1)	164 (1.1)	.88
Therapists	1757 (15.6)	756 (19.4)	2513 (16.6)	<.001
Nurses	751 (6.7)	69 (1.8)	820 (5.4)	<.001
Physicians	1074 (9.6)	328 (8.4)	1402 (9.3)	.03
Patient-centered processes				
Respect	26 (0.2)	10 (0.3)	36 (0.2)	.78
Family	78 (0.7)	23 (0.6)	101 (0.7)	.50
Feeling	234 (2.1)	98 (2.6)	332 (2.2)	.11
Needs	100 (0.9)	39 (1.0)	139 (0.9)	.53
Communication	48 (0.4)	18 (0.5)	66 (0.4)	.77
Information	18 (0.2)	12 (0.3)	30 (0.19)	.07
The care environment				
Food	2292 (20.4)	868 (22.3)	3160 (20.9)	.01
Room	1881 (16.7)	840 (21.6)	2721 (18.0)	<.001
Environment	527 (4.7)	101 (2.6)	628 (4.2)	<.001
Leisure time	188 (1.7)	60 (1.5)	248 (1.6)	.58
Staff	1498 (13.3)	417 (10.7)	1915 (12.7)	.001
Clinic management	101 (0.9)	40 (1.0)	141 (0.9)	.47
Atmosphere	126 (1.1)	37 (1.0)	163 (1.1)	.37
Facility equipment	126 (1.1)	41 (1.1)	167 (1.1)	.72
Expected outcomes				
Success	242 (2.2)	67 (1.7)	309 (2.0)	.10
Improvement	45 (0.4)	22 (0.6)	67 (0.4)	.18

The following sections provide a qualitative in depth-analysis of online composed patient reports guided by the domains of the introduced PCC framework.

Prerequisites

Within this domain, attributes of the patient-centered professional emerged to be of major significance for patients utilizing the referred hospital rating website. As a main result, patients felt a decreased sensitivity and a lack of empathy in interpersonal interactions between themselves and the medical staff. They perceived some physicians and therapists to exploit the naturally prevalent hierarchy among them and interpreted this patronizing human interaction as an expression of an imminent gratification crisis.

If you complain, they shoot back immediately and you have to shut up and pull yourself together [...]. I have also noticed that some doctors and therapists think that patients are inferior and are here to be re-educated. In general, it seems to me that everyone has lost the desire to do their job. [...] Of course: there are exceptions [Orthopedic-psychosomatic rehabilitation clinic, Saarland]

Patient-Centered Processes

Among reports, a discontinuous communication of curfew legislation supported a perceived sense of disempowerment. This was further endorsed by hygiene rules, which were rated to be arbitrary as they noticeably differed across rehabilitation clinics and impacted the perceived autonomy of a relevant number of patients. Complaints addressing a decrease of autonomy were particularly prevalent in psychiatric facilities. However, a majority of patients rated existing hygiene rules to be appropriate.

In general, a prison character arises from the incapacitating, uncomprehending habitus of some therapists. Those to whom self-determination is an important value will not be happy here. [Psychiatric rehabilitation clinic, Saarland]

Referring to care continuity, intersectoral care was not always maintained. Patients criticized a lack of involvement of their family physician or their psychologist in charge. Apparently, this was reflected by the fact that diagnostic reports and treatment plans of ambulatory care were frequently not taken into account during IRS. Conversely, results of IRS were not transferred to the ambulatory health care practitioner. Moreover, patients reported to have limited access to structured ambulatory follow-up rehabilitation programs as responsible social workers were hard to reach. Despite stated constraints, established clinician-patient relationships had the potential to mitigate adverse effects of the pandemic on IRS as patients valued empathetic, personal contact.

I was in [rehabilitation clinic] for four weeks for rehab of my cervical spine and diabetes. Even the 12-hour quarantine (it was Corona time) flew by, as even during that time everyone from the kind staff and nurses cared about my well-being. [Orthopedic-diabetic rehabilitation clinic, Brandenburg]

The Care Environment

Availability of therapeutic and nursing care was mainly attributed to the care environment. Patients reported having limited access to therapeutic and nursing procedures. In some cases, this limited availability of care led to a termination of the inpatient rehabilitation stay.

In 3 months I was showered three times. When I asked for a shower as an incomplete paraplegic, I was told maybe tomorrow due to sparse staff availability. Sorry, but what? [...] Even after talking to doctors, nothing has really changed. All in all, I have mixed feelings and it is very important not to blame everything on Corona. [Oncological rehabilitation clinic, Brandenburg]

Despite availability issues, it became apparent that hygiene legislations were more likely to be accepted if they were easily integrated into organizational routines. This was also seen as having the advantage to create a more familiar environment as, for instance, therapeutic care groups decreased in size. One factor not directly attributable to the pandemic was the available food, which was perceived to be inconsistent with nutrition education events offered during rehabilitation.

Due to the Corona pandemic, procedures were changed which wasn't only bad: For instance, I perceived the cutting of the reference group actually very pleasant and more personal. I perceived the sessions to be more intense and individual. Perhaps, it should be considered whether this can be maintained after the pandemic. [Psychiatric rehabilitation clinic, Brandenburg]

Expected Outcomes

In general, the domain of expected outcomes was of minor significance for patients in German rehabilitation clinics. However, it became apparent that a distinct communication of patient-relevant outcomes and their respective change after rehabilitation was positively associated with patient satisfaction. The communication of changes in outcomes seemed to be more straightforward to be implemented in somatic care facilities. Furthermore, available emotional support during IRS was perceived to facilitate the individual healing process by having a direct impact on activating self-efficacy and self-management potential.

I want to compliment the care provided by doctors and therapists. I arrived here with severe swelling and effusion in the knee and leave the rehab with great mobility and stability in my joint (70° on arrival 115° on departure). [Orthopedic rehabilitation clinic, Saarland]

I arrived as a diabetic with overweight, having taken medication for three years, including for high blood pressure. The holistic care of the staff has resulted in, me losing 12 kilograms in four weeks and I am now medication free. My long-term blood sugar now is 5.9 and I'm coming from over 8. [Orthopedic-diabetic rehabilitation clinic, Brandenburg]

Peer Relationship

The domain of “peer relationship” inductively emerged during the process of analysis. Empowering peer-to-peer relationships was valued to have the potential to mitigate adverse effects of the pandemic on IRS. Thus, some patients reported that their stay remains unforgotten mainly due to their peers, who compensated for negative inconveniences. Patients also appealed to the personal responsibility of their peers. In their understanding, only active engagement allows expectations of rehabilitation success.

A rehab is not a vacation, your own participation is expected and necessary- success depends on you and

your attitude toward rehab and your own illness; a rehab facility is not a hotel with many stars... [Psychiatric rehabilitation clinic, Brandenburg]

The first week was shaped by uncertainty of the unknown, but the great people I met supported me to deal with the problems that arose. Usually, we would meet for lunch to tell each other what had happened during the day. Many times, we were just listeners when a colleague of ours was feeling bad. [Psychiatric rehabilitation clinic, Brandenburg]

A comprehensive summary of online reported patient experiences addressing PCC domains and attributes is provided in [Table 3](#).

Table 3. Key statements from patient reports related to inpatient rehabilitation service (IRS) during the SARS-CoV-2 pandemic.

Domain and attributes	Experiences
Prerequisites ^a : attributes of the patient-centered professional	Perceived gratification crisis of medical staff
Patient-centered processes^a	
Patient as a source of control	Discontinuous communication of curfew legislation creates a sense of disempowerment
Patient autonomy	To maintain hygiene legislation, the patient decision-making autonomy is restricted, which is frequently perceived as arbitrariness
Family and friends as supported caregivers	Lacking leisure time activities for companions
Transition and continuity of care	Intersectoral care continuity is not always maintained
Care based on a continuous healing relationship	Members of the nursing and therapy professions are perceived to be more trustworthy than physicians
Clinician-patient relationship	Established clinician-patient relationships have the potential to mitigate adverse effects of the pandemic on IRS
The care environment^a	
Availability	Availability of therapeutic and nursing services was in part severely limited
Supportive organizational system	Acceptance of hygiene legislations increases if they can easily be integrated into organizational routines
Therapeutic environment	Adapted routines create a personal, familiar environment; nutritional theory and lived practice are inconsistent
Expected outcomes^a	
Physical comfort	Distinct communication of therapeutic outcomes supports patient satisfaction
Emotional support; alleviation of anxiety	Emotional support promotes the healing process and self-management
Peer relationship^b	
Peer as a supported person of trust	Established peer-to-peer relationships have the potential to mitigate adverse effects of the pandemic on IRS
A call for personal responsibility	IRS is to be appraised in addition to personal responsibility

^aDeductive domain.

^bInductive domain.

Discussion

Principal Findings

For patients receiving IRS, aspects of the care environment, staff prerequisites, and patient-centered processes were predominantly relevant to evaluate their inpatient stay. SARS-CoV-2–related adaptation mechanisms affecting these

domains comprised discontinuous communication and elaborate implementation of infection protection standards, which were perceived to threaten the personal autonomy of action. These mechanisms were amplified by tangible gratification crises of medical staff. However, the prevalence of established and emotional supportive relationships to clinicians and peer groups provided the potential to mitigate the adverse effects of hygiene protection standards on IRS. Moreover, a distinct

communication of therapeutic outcome variation seemed to support patient satisfaction. These insights provide the opportunity to develop informed strategies fostering resilient organizations that sustainably embody PCC within the setting of rehabilitative care.

Comparison to Prior Work

Our findings are partly in line with those of Liu et al [15] who demonstrated country-specific differences in patient complaint behaviors. Although British and Canadian reviewers tend to complain about staff prerequisites, Germans are more likely to criticize the care environment and patient-centered processes [25]. Considering the context of inpatient rehabilitation clinics, Sander et al [26] conducted an initial examination of web-based patient reports to investigate determinants associated with recommending inpatient rehabilitation clinics, and identified perceived therapy successes as well as process of care parameters to be associated with clinic recommendations. Although aspects of patient-centered processes and expected outcomes were quantitatively subordinate, the qualitative in-depth analysis of the present study indicates a relationship between positively reported expected outcomes and patient satisfaction. This is also in line with Kraska et al [27], who demonstrated outcome quality to be a predictor for patient satisfaction during hospital stays in Germany.

Considering the suitability of the applied PCC framework [15], this analysis revealed that the inductively originated domain of “peer relationships” has been of relevance for inpatient rehabilitation programs. As the overall accuracy of the applied taxonomy to the setting of PCC in inpatient rehabilitation was rated high, the “peer relationships” domain may be a meaningful extension of the taxonomy for settings in which patients have the opportunity to interact with their peers over a longer period of time.

In this analysis, patients perceived a significant number of medical staff to present aspects of a developing gratification crisis reflecting generic psychological distress. This finding is supported by Dobson et al [28], who identified health care workers to face moderate levels of depression and anxiety. This observation is particularly prevalent for the nursing profession, which experienced high levels of burnout and emotional exhaustion during the SARS-CoV-2 pandemic [29,30]. To facilitate the resilience of health systems for future pandemic events, it will be of interest to meet health care providers’ needs not only to foster employee health but also to support quality of care. As psychological distress of medical staff was perceived to be an amplifying factor for reduced patient autonomy, it is relevant to refer to the scoping review of Klemmt et al [31] supporting the influence of medical staff on patient autonomy, while further emphasizing domains of the rehabilitation system, the rehabilitation facility, and patients themselves to have a bidirectional influence on autonomy. Following their conclusion, it is important to be aware that IRS not only aims to foster social inclusion as a summative outcome but should also be requested for structures and stakeholders during rehabilitation.

Despite illustrated challenges of IRS during the early phase of the SARS-CoV-2 pandemic, most patients felt safe and supported infection protection standards. This is underpinned

by a survey of oncological patients treated in German rehabilitation clinics, 87% of whom reported to feel safe in facilities [32]. Although the implementation of infection-protection standards was associated with a tangible workload increase, 84% of staff members assisted the implementation [32].

Strengths and Limitations

First, one limitation of our study is the limited representativeness of findings for other rehabilitation settings within Germany as hygiene regulations differed across states. Moreover, online reported patient complaints as a scientific data source produce concerns of representativeness and subjectivity as sample characteristics are uncontrolled and widely unknown. However, an analysis of Facebook reviews demonstrated that contents of reviews do not correlate with inpatient quality assessment indicators but instead correlate with a standardized national survey of patient experiences in German obstetrics [33]. Moreover, a Dutch investigation of online patient ratings identified a positive correlation of these ratings with evaluation reports of the Dutch Healthcare Inspectorate referring to underperforming, high-risk hospitals [34]. Demonstrating initial representativeness concerns of online ratings, Dutch health care inspectors valued online ratings as an additional source of information after being confronted with negative ratings and emphasized to cautiously interpret them under referral to standardized quality and safety indicators [35].

Second, using online reported patient complaints is accompanied by unknown sample characteristics and thereby associated with hazards of selection bias. In this context, Han and colleagues [36] identified prognostic factors of patient characteristics associated with patient intentions and behaviors on physician rating websites. In their survey study, they identified health-related variables (seeking physician information online, usage of web-based medical consultation services, prevalence of a serious disease, good medical experiences) to be directed to the active rating behavior. Conversely, cognitive variables (altruism, self-efficacy to perform online ratings, trust in online ratings of peers) affected the rating intention. These results may help to further understand the patient population using this feedback opportunity.

Moreover, research activities of economic sciences identified online product ratings to be influenced by social dynamics. It is acknowledged that product ratings are not only affected by individual experiences but rather by prior ratings of one’s peer group [37,38]. At this stage of research, it is reasonable to question to what extent these dynamics equally occur on physician and hospital rating websites.

Along with these stated limitations, this analysis faces unique restrictions. As the distribution of reports across included clinics varied strongly, a cluster bias of included rehabilitation clinics with disproportionately strong patient rating activities of some facilities cannot fully be ruled out. In this regard, it will be of interest to further investigate which clinic-related parameters affected ratings of clinics with above-average report numbers. Additionally, the current selection of keywords reflecting PCC domains was made inductively and potentially implies an

incomplete list of keywords supporting a distortion of distributed domains.

Despite these limitations, patient rating portals became increasingly popular over the last 10 years [8,39], which suggests that patients claim these portals as a trusted source of information. Beyond a growing number of physicians acknowledging patient reports for in-house quality improvement initiatives [40], by systematically investigating online reported patient reviews, this analysis provides the potential to integrate patient perspectives into the discussion on how to maintain PCC structures under the stress and strains of a pandemic. Integrating online-reported patient complaints offers the opportunity to extend scientific data sources by providing the advantage to reduce the social desirability bias of common qualitative research formats, as this analysis demonstrates that patients perceive a hospital rating website to be a protective platform supporting the exchange of individual experiences.

Taking the present results into account, future research direction should investigate country-specific differences in the perceived significance of PCC domains. For instance, it remains to be answered why online reports of German inpatient care recipients are currently dominated by reports about the care environment, whereas health-relevant outcome expectations seem to have a subordinate role.

Conclusion

This analysis reflects previous research as German patients predominantly reported feedback associated with the care environment. SARS-CoV-2-related reports were strongly affected by aspects of patient-centered processes addressing discontinuous communication and an organizationally demanding implementation of infection protection standards, which was in some cases perceived to threaten patient autonomy. This perceived threat in reduced autonomy was amplified by a tangible increase in staff workload. Developed peer relationships during the rehabilitation stay had the potential to mitigate these mechanisms.

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We would like to thank every patient who conducted online reports about their experiences on visiting inpatient rehabilitation clinics during the early phase of the SARS-CoV-2 pandemic. Without your willingness to share your experiences, this study would not have been possible.

Data Availability

The open-access data are available on Klinikbewertungen [20]. Extracted raw data of included rehabilitation clinics can also be requested from the corresponding author (LK). A synopsis of key statements (German version) can be accessed via [Multimedia Appendix 3](#).

Conflicts of Interest

The research group is funded by the German Pension Fund (Deutsche Rentenversicherung Berlin-Brandenburg). One of the included rehabilitation clinics is operated by the German Pension Fund. However, the German Pension Fund had no influence on planning and execution of this study. Publication fees were funded by the Brandenburg Medical School publication fund supported by the German Research Foundation (Deutsche Forschungsgemeinschaft, DFG).

Multimedia Appendix 1

Data extraction code for web scraping.

[\[DOCX File , 22 KB - rehab_v10i1e39512_app1.docx \]](#)

Multimedia Appendix 2

COREQ (Consolidated criteria for Reporting Qualitative research) checklist.

[\[DOCX File , 16 KB - rehab_v10i1e39512_app2.docx \]](#)

Multimedia Appendix 3

Synopsis online reports (original German Version).

[\[DOCX File , 29 KB - rehab_v10i1e39512_app3.docx \]](#)

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Abbreviations

- COREQ:** consolidated criteria for reporting qualitative research
IRS: inpatient rehabilitation service
PCC: patient-centered care

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Original Paper

Role of Oral Intake, Mobility, and Activity Measures in Informing Discharge Recommendations for Hospitalized Inmate and Noninmate Patients With COVID-19: Retrospective Analysis

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Abstract

Background: Patients who were incarcerated were disproportionately affected by COVID-19 compared with the general public. Furthermore, the impact of multidisciplinary rehabilitation assessments and interventions on the outcomes of patients admitted to the hospital with COVID-19 is limited.

Objective: We aimed to compare the functional outcomes of oral intake, mobility, and activity between inmates and noninmates diagnosed with COVID-19 and examine the relationships among these functional measures and discharge destination.

Methods: A retrospective analysis was performed on patients admitted to the hospital for COVID-19 at a large academic medical center. Scores on functional measures including the Functional Oral Intake Scale and Activity Measure for Postacute Care (AM-PAC) were collected and compared between inmates and noninmates. Binary logistic regression models were used to evaluate the odds of whether patients were discharged to the same place they were admitted from and whether patients were being discharged with a total oral diet with no restrictions. Independent variables were considered significant if the 95% CIs of the odds ratios (ORs) did not include 1.0.

Results: A total of 83 patients (inmates: n=38; noninmates: n=45) were included in the final analysis. There were no differences between inmates and noninmates in the initial ($P=.39$) and final Functional Oral Intake Scale scores ($P=.35$) or in the initial ($P=.06$ and $P=.46$), final ($P=.43$ and $P=.79$), or change scores ($P=.97$ and $P=.45$) on the AM-PAC mobility and activity subscales, respectively. When examining separate regression models using AM-PAC mobility or AM-PAC activity scores as independent variables, greater age upon admission decreased the odds (OR 0.922, 95% CI 0.875-0.972 and OR 0.918, 95% CI 0.871-0.968) of patients being discharged with a total oral diet with no restrictions. The following factors increased the odds of patients being discharged to the same place they were admitted from: being an inmate (OR 5.285, 95% CI 1.334-20.931 and OR 6.083, 95% CI 1.548-23.912), "Other" race (OR 7.596, 95% CI 1.203-47.968 and OR 8.515, 95% CI 1.311-55.291), and female sex (OR 4.671, 95% CI 1.086-20.092 and OR 4.977, 95% CI 1.146-21.615).

Conclusions: The results of this study provide an opportunity to learn how functional measures may be used to better understand discharge outcomes in both inmate and noninmate patients admitted to the hospital with COVID-19 during the initial period of the pandemic.

KEYWORDS

incarceration; Functional Oral Intake; Activity Measure for Postacute Care; speech language pathology; physical therapy; occupational therapy; COVID-19

Introduction

Background

Discharge destination is often used as an outcome metric for hospitalized patients [1-3]. To optimize care strategies, it is important to understand the factors that may influence or predict this outcome, particularly for those with COVID-19 [1-3]. As multidisciplinary rehabilitation approaches facilitate improved functional status for hospitalized patients, it is important to understand how the combination of functional measures, such as oral intake, mobility, and activity measures, is related to discharge destination [4-7]. A better understanding of these factors could help optimize rehabilitation interventions and outcomes (including discharge destination) in hospitalized patients with COVID-19 and other acute respiratory diseases [7].

For example, deficiencies in functional oral intake, as measured by the Functional Oral Intake Scale (FOIS), are prevalent (42%-61%) in individuals following mechanical ventilation and result in an increased risk of poor outcomes [8-11]. In addition, functional status as measured by the Activity Measure for Postacute Care (AM-PAC) mobility and activity scores have been shown to be independent predictors of outcomes in individuals hospitalized with and without COVID-19, including discharge destination, mortality, and length of hospital stay [2,3]. However, the impact of using a combination of these measures (eg, FOIS and AM-PAC) in predicting the discharge destination is unknown.

Furthermore, it is important to understand how outcomes may vary in different patient populations with COVID-19. Patients who were incarcerated were disproportionately affected by COVID-19 compared with the general public [12-15]. More specifically, prisoners demonstrated a more severe presentation of disease characteristics and had worse outcomes (eg, higher intensive care unit [ICU] admissions, higher hospital mortality rate, and higher 30-day mortality rate) than nonincarcerated patients [13-15]. Constrained mobility, confined and overcrowded spaces, limited access to resources, and high prevalence of mental health disorders contribute to increased risk of individuals who are incarcerated acquiring transmissible diseases such as COVID-19 [14,16-18]. Furthermore, approximately 16% (male) and 10% (female) of prisoners in federal and state prisons were aged 50 years in 2021 [19]. As many incarcerated individuals aged ≥ 55 years have chronic conditions, such as heart and lung conditions, this puts them at an even greater health risk [18,20,21]. Given the greater disease risk and burden of COVID-19 in those who were incarcerated, it is important to understand whether rehabilitation assessments and interventions have similar impacts in those who are and are not incarcerated. However, the impact of rehabilitative care and related outcomes for prisoners with COVID-19 has not been reported. Considering the disproportionate impact of COVID-19

on those who were incarcerated, it is important to understand the functional outcomes in this population [12-15].

Purpose

The first purpose of this study was to compare the functional outcomes (FOIS and AM-PAC scores) between inmates and noninmates who were diagnosed with COVID-19 and received rehabilitation services (eg, speech, physical, and occupational therapy) while admitted to an inpatient hospital in the initial months of the COVID-19 pandemic. The second purpose of this study was to examine the relationships among FOIS scores, AM-PAC scores, and discharge destination in this same sample of patients given the interdisciplinary nature of rehabilitation care. A better understanding of these results, particularly during the initial phase of the COVID-19 pandemic, may inform care plan development, including discharge planning, to maximize outcomes in patients with COVID-19 and other acute respiratory diseases. Our first hypothesis was that there would be no difference in the FOIS and AM-PAC scores between inmates and noninmates. Our second hypothesis was that initial AM-PAC and FOIS scores would predict whether patients were discharged on a total oral diet with no restrictions (FOIS score=7). Our third hypothesis was that the initial AM-PAC and FOIS scores would predict whether patients were discharged to the same destination as they were admitted from.

Methods

Study Design and Setting

A retrospective analysis was performed on patients admitted to the hospital for COVID-19 at a large academic medical center between February 2020 and August 2020. Data were obtained from the academic medical center. The hospital where the data collection occurred was the primary referral source of the state correctional facilities in the region and disproportionately saw the majority of inmates with COVID-19 compared with other hospitals in the region. Furthermore, the medical center was a transfer facility for all patients requiring an escalation of medical interventions. The patients' care in this study was based on medical necessity and was not based on incarceration status.

Ethics Approval

The study was approved by The Ohio State University's institutional review board (protocol #2020H0367), as well as the State Department of Rehabilitation and Corrections.

Data Collection

The inclusion criteria for this study were as follows: (1) patients who were deemed COVID-19 positive and admitted to the medical center between February 2020 and August 2020, (2) those who had both baseline and discharge FOIS scores (meaning they were referred for a swallowing evaluation), and (3) those who had at least a baseline and discharge AM-PAC

(mobility and activity) score. Patients were included if they were admitted with a COVID-19 diagnosis or were found to have a COVID-19 diagnosis during their admission to the hospital for another reason. The exclusion criteria were as follows: (1) patients who were not diagnosed with COVID-19 at the medical center or (2) those with COVID-19 who died during the hospital stay or were placed on comfort care or hospice as either they did not have a living discharge destination or their diets were often adjusted for comfort care, thus impacting their final FOIS score.

Patient and clinical data were obtained via a manual chart review. Data obtained included inmate status (yes or no); admission and discharge dates and admission source (eg, home, skilled nursing facility, other hospital, or correctional facility); discharge destination and sex (male or female); hospital length of stay; intubation status (yes or no); days requiring mechanical ventilation and baseline and discharge FOIS score; baseline and discharge AM-PAC scores (mobility and activity subscales); height, weight, and BMI upon admission; age upon admission; and race.

Variables

The dependent variables included (1) whether patients achieved an FOIS score of 7 at discharge from the hospital and (2) whether patients were discharged to the same destination as they were admitted from. Initially, admission and discharge destinations were categorized as (1) home, (2) correctional facility, (3) outside the hospital, (4) skilled nursing facility, (5) extended care facility, (6) long-term acute care hospital, and (7) inpatient rehabilitation facility. Discharge destination was then dichotomized to either “discharge to same destination of admittance” or “discharge to different destination than admittance.” If a patient was discharged to the same destination from which they were admitted (eg, home or correctional facility), this was considered a positive outcome. However, if a patient was discharged to a different type of facility, location, or institution than that they were admitted from (eg, admitted from home but discharged to a skilled nursing facility), this was considered an inferior outcome based on the need of higher care intensity. There were two exceptions to this coding: (1) if a patient was admitted from an extended care facility but discharged to a skilled nursing facility or vice versa ($n=4$) or (2) if an inmate patient was admitted from an outside hospital but discharged to a correctional facility ($n=5$). These 2 exceptions were considered better outcomes and the data were coded as “discharge to same destination source.” As we were interested in better understanding how intake or baseline information may be used to prognosticate outcomes in patients with COVID-19, the initial FOIS and AM-PAC (mobility and activity subscales) scores were the primary independent variables of interest.

An initial bedside swallowing evaluation was performed by a speech language pathologist when the patients were deemed medically stable and appropriate by the ordering provider and speech language pathologist. Being medically stable was determined on a patient-by-patient basis and was fundamentally based on the patients’ vital signs stabilizing or not degrading. If patients were on a ventilator, they would need to be off the

ventilator before the FOIS could be administered. An order for a swallowing evaluation may have occurred in the ICU or outside the ICU (eg, step-down unit). The FOIS was used to rate a patient’s functional oral intake during the swallowing evaluation. These evaluations occurred on average 13 to 14 days following hospital admission for noninmates and inmates, respectively. There was no difference between noninmates and inmates with regard to when the FOIS was administered. The FOIS scores were based on clinical bedside swallowing evaluation. The FOIS is a commonly used tool and has excellent agreement (85%-95%) and excellent interrater reliability ($k=0.86-0.91$) [22,23]. The FOIS has also been shown to have strong consensual validity ($W=0.90$) [22]. FOIS scores are used to categorize (levels 1-7) and document clinical changes in oral intake of food and liquids in patients with dysphagia. Levels 1 to 3 relate to varying degrees of tube-dependent or nonoral feeding, and levels 4 to 7 relate to varying degrees of oral feeding without feeding tube use or nonoral supplementation [22,23]. Levels 4 to 6 relate to both diet modifications and patient compensations, whereas a level 7 relates to a total oral diet with no restrictions [22,23].

The AM-PAC short-form measure “6-Clicks” was administered to patients by a physical therapist (mobility subscale) and an occupational therapist (activities of daily living subscale) during their respective initial evaluations and subsequent treatment sessions [24]. The referral for physical or occupational therapy was made based on the physician team’s determination that the patient would benefit from physical or occupational therapy interventions. This referral may have occurred in the ICU or outside the ICU. The administration of the AM-PAC could occur while the patient was on a ventilator. On average, the AM-PAC was administered between 8 and 9 days following hospital admission for noninmates and inmates, respectively. There was no difference between noninmates and inmates with regard to when the AM-PAC was administered. The AM-PAC has two scales that are used to assess patient physical function: (1) basic mobility (eg, walking and moving positions) and (2) activities of daily living (eg, dressing and toileting) [24,25]. The AM-PAC “6 Clicks” has been validated in the acute care setting and has good overall reliability for the basic mobility (intraclass correlation coefficient=0.849) and daily activity (intraclass correlation coefficient=0.783) subscales [24,25]. Patient status on the AM-PAC scales is based on assistance needed on a scale of 1 (“total”) to 4 (“none”) with 6 mobility- and daily living-related activities [24,25]. For each scale, values are summed and raw scores are standardized, with higher scores indicating higher levels of function [24,25].

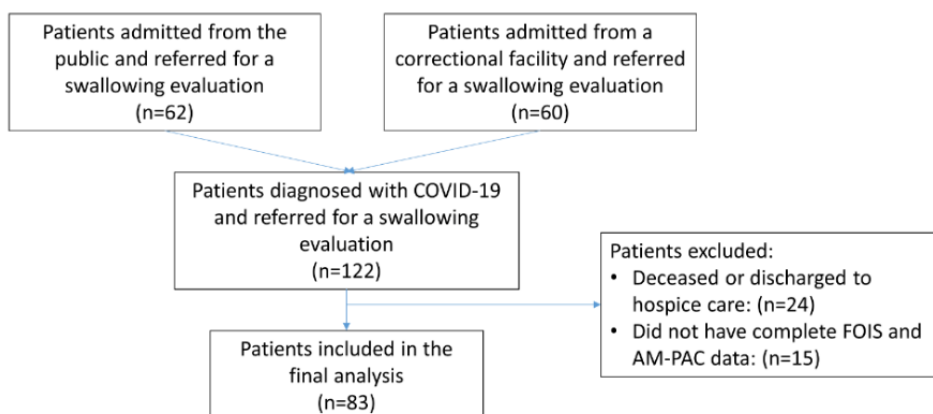
Other variables that were included as covariates were nonmodifiable demographic characteristics that have been shown to impact outcomes in patients with COVID-19 [2,26-30]. These variables included race, age, and sex. Race was categorized as “White,” “Black,” or “Other” [2,27]. The “Other” category was created owing to the limited numbers of patients who did not fit the racial categories of “White” or “Black.” In addition, this category also included patients who “refused to answer” or “did not know.” Sex was categorized as “male” or “female” [28,30]. Age was used as a continuous variable [26,29,30]. In addition, as incarceration status has been

associated with worse outcomes in patients with COVID-19, this variable was also included [12-15].

Statistical Analysis

The data obtained were deidentified. The flow diagram in Figure 1 illustrates the inclusion and exclusion of the obtained data. A total of 62 patients from the public and 60 patients from correctional facilities were admitted to the hospital and were referred for a swallow evaluation as well as physical therapy and occupational therapy. A total of 24 patients were excluded secondary to being deceased or discharged to a hospice care.

Figure 1. A flowchart outlining patients who were included in the analysis. A total of 62 patients from the public and 60 patients from correctional facilities were admitted to the hospital and were referred for a swallow evaluation as well as physical therapy and occupational therapy. A total of 24 patients were excluded secondary to being deceased or discharged to a hospice care. Furthermore, 15 patients were excluded secondary to not having a complete data set of Functional Oral Intake Scale (FOIS) or Activity Measure for Postacute Care (AM-PAC) data. A total of 83 patients (38 inmates and 45 noninmates) were included in the analysis.



Descriptive and frequency statistics were used to characterize the sample. Shapiro-Wilk tests were used to determine whether the variables were normally distributed. Mann-Whitney *U* tests were used to compare AM-PAC scores between inmates and noninmates. Chi-square tests were used to compare the distributions of categorical variables between inmates and noninmates. Wilcoxon signed-rank tests were used to compare pre-post AM-PAC scores in inmates and noninmates separately to examine the change in scores between baseline and final measurements. Significance was set at $P < .05$ for any comparison tests. For the second purpose of this study, it was determined a priori that if there was no difference between the inmate and noninmate groups based on the results of the Mann-Whitney *U* tests among the primary variables of interest, then the data would be pooled for the logistic regression analysis. As there was no difference between the groups, binary logistic regression was performed on the entire data set to evaluate the relationships between (1) the identified variables and achieving a total oral diet with no restrictions (FOIS score=7) and (2) whether functional scores (FOIS and AM-PAC scores) would predict whether patients were discharged to the same destination as they were admitted. AM-PAC mobility scores and AM-PAC activity scores were determined to be multicollinear. Thus, separate logistic regressions were conducted, one with AM-PAC mobility scores as an independent variable and the other with AM-PAC activity scores as an independent variable. The goodness of fit of the model to the data was evaluated using the Omnibus test of the model, the Hosmer and Lemeshow test,

Furthermore, 15 patients were excluded secondary to not having a complete data set of FOIS or AM-PAC data. A total of 83 patients (38 inmates and 45 noninmates) were included in the analysis. In addition, the baseline FOIS scores were initially categorized as 1 to 7 (nothing by mouth through total oral diet without restrictions); however, owing to the lack of variability in each of the categories, the baseline FOIS scores were ultimately categorized on the basis of whether the patients were on a total oral diet with (FOIS score=1-6) or no restrictions (FOIS score=7).

and Nagelkerke R^2 value. The independent variables were entered into the model together using the “enter” method. All assumptions of logistic regression were met for the final models. There was no evidence of multicollinearity (based on tolerance, 0.786-0.945, and variance inflation factor, 1.058-1.272 statistics) among the independent variables. Furthermore, the independent continuous variables were linearly related to the log odds, as determined by the Box-Tidwell test. Independent variables were considered statistically significant if the 95% CIs of the odds ratios (ORs) did not include 1.0. Statistical analyses were performed using SPSS software (version 28; IBM Corp).

Results

Demographics

Overall, 83 patients were included in the final sample, with an average age of 62 (SD 13.31) years. Most of the patients were male (61/83, 73%), White (46/83, 54%), and intubated at least 1 time (59/83, 71%), and approximately half (27/59, 46%) of those who were intubated were inmates. There were no differences in age ($P = .38$), length of hospital stay ($P = .42$), length of intubation ($P = .37$), or BMI ($P = .90$) between the inmates ($n = 35$) and noninmates ($n = 45$; Table 1).

There were differences between inmate and noninmate patients in terms of race distribution ($P < .001$; Table 2). Furthermore, there was no difference in terms of intubation ($P = .99$), being “discharged to the same admittance source” ($P = .13$), or being discharged with an FOIS score of 7 ($P = .18$; Table 2).

Table 1. Continuous demographics (n=83).

Characteristics	Inmates (n=38), mean (SD)	Noninmates (n=45), mean (SD)
Age at admission (years)	61.3 (10.2)	63.4 (15.5)
Length of hospital stay (days)	24.9 (12.0)	24.8 (15.4)
Length of intubation (days; if intubated)	14.0 (6.1)	13.0 (8.2)
Height at admission (cm)	178.4 (10.2)	167.4 (9.7)
Weight at admission (kg)	100.9 (30.9)	88.3 (24.8)
BMI at admission (kg/m ²)	31.6 (8.3)	31.3 (7.7)

Table 2. Categorical demographics (n=83).

Descriptors	Inmates (n=38), n (%)	Noninmates (n=45), n (%)
Race		
White	21 (55)	25 (56)
Black	17 (45)	6 (13)
Other	0 (0)	14 (31)
Sex		
Male	38 (100)	23 (51)
Female	0 (0)	22 (49)
Intubation		
Yes	27 (71)	32 (71)
No	11 (29)	13 (29)
Discharged to the same admittance source		
Yes	28 (74)	26 (58)
No	10 (26)	19 (42)

FOIS and AM-PAC Scores Between Inmate and Noninmate Patients

The majority of patients (inmates: 24/38, 63%; noninmates: 29/45, 64%) had a baseline FOIS score of 1 (nothing by mouth) while the majority (inmates: 25/38, 66%; noninmates: 23/45,

51%) also had a discharge FOIS score of 7 (total oral diet with no restrictions; [Table 3](#)).

Although both groups demonstrated improvement in their AM-PAC mobility and activity scores when compared within each group ($P < .001$), there were no significant differences between inmates and noninmates at the initial, final, or change scores (all $P > .05$; [Table 4](#)).

Table 3. Functional Oral Intake Scale (FOIS) scores (n=83).

FOIS scores ^a	Inmates, n (%)	Noninmates, n (%)
Initial		
1	24 (63)	29 (64)
4	1 (3)	0 (0)
5	11 (29)	10 (22)
7	2 (5)	6 (13)
Discharge		
1	1 (3)	3 (7)
5	12 (32)	19 (42)
7	25 (66)	23 (51)

^aA comparison of the distribution of initial FOIS score ($P = .39$) and distribution discharge FOIS score ($P = .27$) between inmates and noninmates.

Table 4. A comparison of Activity Measure for Postacute Care (AM-PAC) score measures between inmates and noninmates (n=83).

AM-PAC score ^a	Inmates (n=38), mean (SD)	Noninmates (n=45), mean (SD)	P value
Basic mobility AM-PAC			
Initial score	10.4 (4.3)	9.0 (4.6)	.06
Final score	14.5 (5.0)	13.6 (5.8)	.43
Change score	4.0 (4.6)	4.6 (6.2)	.97
Daily activity AM-PAC			
Initial score	11.6 (4.6)	10.8 (4.5)	.46
Final score	14.2 (4.7)	14.4 (4.8)	.79
Change score	2.6 (5.3)	3.6 (5.9)	.45

^aComparisons using the Mann-Whitney *U* test between inmates and noninmates.

Predictors of Being Discharged With Total Oral Diet With No Restrictions

Results from the logistic regression models examining the odds of achieving an FOIS score of 7 at discharge demonstrated that greater age upon admission to the hospital decreased the odds of a patient being discharged with an FOIS score of 7 (total oral

diet with no restrictions). This was true for both regression models using the independent variable AM-PAC mobility scale (OR 0.922, 95% CI 0.875-0.972) or the independent variable AM-PAC activity scale (OR 0.918, 95% CI 0.871-0.968; [Table 5](#)). Inmate status, race, sex, baseline AM-PAC mobility score or activity score, and baseline FOIS score were not significant variables within the regression models ([Table 5](#)).

Table 5. Odds of being discharged from the hospital with a Functional Oral Intake Scale score of 7.

Predictors	Odds ratio (95% CI)
Model 1^a	
Inmate status (yes)	1.04 (0.255-4.248)
Race	
White (reference)	— ^b
Black	0.973 (0.289-3.277)
Other	0.195 (0.035-1.100)
Female sex	1.171 (0.285-4.819)
Age on date of hospital admission (years) ^c	0.922 (0.875-972)
Baseline mobility AM-PAC^{d,e} score	1.12 (0.987-1.284)
Baseline FOIS ^f score	1.094 (0.854-1.401)
Model 2^g	
Inmate status (yes)	1.327 (0.340-5.180)
Race	
White (reference)	—
Black	0.942 (0.278-3.188)
Other	0.249 (0.048-1.287)
Female sex	1.36 (0.339-5.459)
Age on date of hospital admission (years) ^h	0.918 (0.871-0.968)
Baseline activity AM-PAC score^e	1.062 (0.947-1.191)
Baseline FOIS score	1.149 (0.906-1.458)

^aNagelkerke $R^2=0.298$; Hosmer and Lemeshow Test: $P=.96$.

^bNo data as the independent variable “White” is used as the reference variable for the other categorical variables (“Black” and “Other”) in the regression model.

^cOverall model: $P=.004$.

^dAM-PAC: Activity Measure for Postacute Care.

^eBaseline basic mobility AM-PAC and baseline basic activity AM-PAC scores highlight the different independent variables included in each of the models.

^fFOIS: Functional Oral Intake Scale.

^gNagelkerke $R^2=0.268$; Hosmer and Lemeshow Test: $P=.08$.

^hOverall model: $P=.01$.

Predictors of Being Discharged to the Same Admittance Source

When examining the logistic regression results related to discharge destination, inmate status increased the odds (OR 5.285, 95% CI 1.334-20.931 and OR 6.083, 95% CI 1.548-23.912) that a patient was to be discharged to the same destination as where they were admitted from in both models

(Table 6). Moreover, being categorized as “Other” race increased the odds on a magnitude of 7 to 8.56 times (Table 6) when using those who were “White” as the reference group. Being female also increased the odds of being discharged to the same place of admission (OR 4.671, 95% CI 1.086-20.092 and OR 4.977, 95% CI 1.146-21.615). Age, AM-PAC scores, and FOIS scores were not significant variables in the regression models examining the discharge destination (Table 6).

Table 6. Odds of being discharged from the hospital to the same admission source.

Predictors	Odds ratio (95% CI)
Model 1^a	
Inmate status (yes) ^b	5.285 (1.334-20.931)
Race	
White (reference)	— ^c
Black	1.837 (0.529-6.375)
Other ^b	7.596 (1.203-47.968)
Female sex ^b	4.671 (1.086-20.092)
Age on date of hospital admission (years)	1.009 (0.964-1.055)
Baseline mobility AM-PAC^d score^e	1.13 (0.973-1.313)
Baseline FOIS ^f score	1.018 (0.796-1.303)
Model 2^g	
Inmate status (yes) ^h	6.083 (1.548-23.912)
Race	
White (reference)	—
Black	1.961 (0.557-6.908)
Other ^h	8.515 (1.311-55.291)
Female sex ^h	4.977 (1.146-21.615)
Age on date of hospital admission (years)	1.003 (0.959-1.050)
Baseline activity AM-PAC score^e	1.109 (0.973-1.264)
Baseline FOIS score	1.042 (0.820-1.324)

^aNagelkerke $R^2=0.230$; Hosmer and Lemeshow Test: $P=.82$.

^bOverall model: $P=.03$.

^cNo data as the independent variable “White” is used as the reference variable for the other categorical variables (“Black” and “Other”) in the regression model.

^dAM-PAC: Activity Measure for Postacute Care.

^eBaseline basic mobility AM-PAC and baseline basic activity AM-PAC scores highlight the different independent variables included in each of the models.

^fFOIS: Functional Oral Intake Scale.

^gNagelkerke $R^2=0.226$; Hosmer and Lemeshow Test: $P=.53$.

^hOverall model: $P=.04$.

Discussion

Principal Findings

Patients who are incarcerated are a vulnerable population in health care systems, have been disproportionately affected by COVID-19, and have been shown to have worse health outcomes than the general population [12-15,31]. Some factors suggested to contribute to these findings may include an increased virus exposure and transmission risk owing to the potential for overcrowding and high contact with others as well as increased preexisting health conditions (eg, chronic obstructive pulmonary disease or cardiovascular disease) compared with nonincarcerated individuals [12-15,31]. However, in our study, there were no differences in health outcomes between inmates and noninmates related to the FOIS

and AM-PAC. Functional scores from the FOIS and AM-PAC did not change the odds of being discharged with an FOIS score of 7; however, older age did decrease these odds. The FOIS and AM-PAC scores did not change the odds of patients being discharged to the same admission source. However, inmate status, “Other” race, and female sex did increase the odds of being discharged to the same admittance source. No prior studies have compared FOIS and AM-PAC scores between inmate and noninmate patients nor has the relationship between the use of AM-PAC scores and FOIS scores in patients hospitalized with COVID-19 been examined.

FOIS and AM-PAC Scores Between Inmate and Noninmate Patients

This is the first study to compare functional measures using the FOIS and AM-PAC between inmate and noninmate patients with COVID-19 or otherwise. Previous literature during a similar period of the COVID-19 pandemic has demonstrated that inmate patients with COVID-19 have higher rates of ICU admissions, intubation, hospital mortality, and 30-day mortality rate and a higher incidence of acute kidney injury compared with noninmate patients with COVID-19 [13-15]. However, there was no difference in the FOIS and AM-PAC scores in our study when comparing inmates to noninmates. Furthermore, both inmate and noninmate patients demonstrated improvement in their initial FOIS and AM-PAC scores compared with the scores at discharge. This lack of difference in outcomes (based on the FOIS and AM-PAC) is contrary to previous literature, comparing inmates with noninmates [13-15]. However, the FOIS and AM-PAC measure different constructs of outcomes (eg, functional) than outcomes measured or reported comparing inmates with noninmates. These functional measures are likely one of many components of potential outcomes. This illustrates how these measures (FOIS and AM-PAC) may provide additional input regarding function over time and their potential relationship with other outcome measures and constructs in these populations.

Predictors of Being Discharged With Total Oral Diet With No Restrictions

This is the first study to examine the predictors of being discharged with a total oral diet with no restrictions (eg, an FOIS score of 7) in patients with COVID-19. Previous literature examining functional oral intake in patients with COVID-19 admitted to the hospital demonstrated that FOIS scores are associated with the number of days in the hospital but improve from the initial assessment to discharge [32]. Our study supports these results, demonstrating an improvement from the initial to discharge FOIS scores. However, the initial functional measures of FOIS and AM-PAC (mobility and activity scales) scores did not contribute to either model regarding patients with COVID-19 being discharged from the hospital with a normal diet (FOIS score=7; Table 5). Greater age consistently decreased the odds of being discharged with a normal diet (FOIS score=7; Table 5). This is not surprising and supports previous literature demonstrating that older patients with COVID-19 are more likely to have worse outcomes [26,29,30].

Predictors of Being Discharged to the Same Admittance Source

Function and mobility (using multiple measures) have been shown to be predictors of discharge destination in general medical and rehabilitation [1,24,33-38]. More specifically, Tevald et al [2] demonstrated that AM-PAC mobility and activity scores were independent predictors of discharge disposition in patients with COVID-19. However, our findings demonstrate contrary results that neither the AM-PAC mobility nor the activity scales changed the odds of discharge destination in those with COVID-19. Our study adds to these findings while also including functional oral intake as an additional measure of functional status in the logistic regression models. Although

FOIS scores did not change the odds of discharge destination among the other variables, their inclusion did improve the overall regression model.

In addition, results from this preliminary investigation showed that inmate status was a strong predictor in our regression models of whether patients were discharged to their same admittance source (or better discharge destination outcome). The results demonstrate that being an inmate increased the odds on a magnitude of 5 to 6 times of being discharged to the same admittance source (Table 6). Including inmate status as an independent variable in the regression analysis improved model fit. These results should be interpreted with caution, as inmates were more likely to have fewer choices of discharge destinations than the general population. However, inmates would have to reach a level of stability and health before being able to be discharged back to their respective correctional facility. Other options for discharge destination for inmates included a correctional facility hospital that provided less medical care than the academic medical center but more care than their respective correctional facility. This illustrates that it may be important to consider whether patients are inmates when examining outcomes, especially as it relates to discharge destination. However, this also requires further investigation to clarify the potential differences in outcomes between inmates and noninmates.

In addition, race also affected the discharge destination. When using "White" as the reference category, "Other" races increased the odds of patients being discharged to the same admission source between 7 and 8.5 times (Table 6), thus suggesting lower care needs or intensity. This is a notable finding, considering that racial and ethnic minority individuals with COVID-19 have been shown to have worse outcomes than non-racial and ethnic minority individuals and delayed access to services such as palliative care [2,27,39,40]. This may be because of the limited number of patients in this category. However, this finding is in contrast with other studies examining relationships among race and discharge destination in other patient populations [39,41]. For example, being "Black" or "Asian" has been shown to be associated with being discharged to an extended care facility versus home in patients following total hip arthroplasties [39,41]. It has been suggested that discharge destination is determined not only by clinical parameters but also by other social determinants of health that may be associated with race, such as home proximity, social and community support, and other markers of social deprivation [39,41-43]. Thus, the opposite phenomenon identified in our results, at least pertaining to "Other" races, requires further investigation to better understand the relationship of race and discharge destination in those with COVID-19.

In addition, being female increased the odds (4-5 times) of being discharged to the same source of admission. Lewis et al [44] demonstrated that female patients with COVID-19 were more often discharged home than to a rehabilitation facility when compared with male patients. Furthermore, male patients with COVID-19 have been shown to have worse health outcomes than female patients [45,46]. As such, female patients being more likely to be discharged to the same admission source may be reflective of better outcomes.

Finally, although greater age was an important factor related to being discharged with an FOIS score of 7 (Table 5), it was not an important factor related to discharge destination (Table 6). This is contrary to the findings of Lewis et al [44] who demonstrated that patients with COVID-19 that were older were more likely to be discharged to a rehabilitation facility than home. However, a systematic review examining factors predicting discharge destination in patients with stroke deemed age to be a “controversial” variable to consider related to discharge destination [47]. Furthermore, it is suggested that age may have a lower influence on discharge destination compared with other factors, such as function [47]. As our study was primarily focused on examining functional health outcomes (eg, FOIS and AM-PAC scores) among others, these factors may be overshadowing any effect age may have on the discharge destination.

Limitations and Future Research

The results of this study have limitations that are worth considering. First, the data were obtained from a large academic medical center in a large midwestern metropolitan area. This may limit the generalizability of the results to other hospitals and geographic locations that were differently impacted by COVID-19 [48-53]. Furthermore, our data are focused on the first wave of the pandemic and a limited time frame when medical and rehabilitation providers were most challenged with identifying optimal management strategies for patients with COVID-19 and encountered different challenges (shortage of personal protective equipment, lack of vaccination availability, etc) [54-60]. At that time, clinical practice guidelines specific to the COVID-19 population were only emerging [61]. However, we felt it important to focus on this initial stage to reflect on and inform future rehabilitation management strategies for patients with COVID-19 or otherwise. In addition, our analysis was limited by the accuracy and consistency of the information entered into the electronic medical record. Errors and omissions by clinicians and others entering the data have the potential to influence the results. Furthermore, we did not categorize patients

based on ICU admission. We felt it was important to include all patients based on the ultimate outcomes of them being discharged. However, in future, categorizing patients by ICU status may provide additional insights based on patient severity. In the regression analysis, there were a low number of patients who were categorized as “Other” for race and were not appropriate to be included in the other defined categories. Thus, the regression results should be interpreted with caution.

Opportunities for future research may include conducting a similar analysis during different phases of the pandemic to better understand how treatment strategies and other factors may impact results and how patient outcomes may change over the course of the pandemic for both inmate and noninmate populations. There is a need for descriptive and correlational studies to better understand the effects and outcomes of patients diagnosed with COVID-19 and the impact of rehabilitation services. Furthermore, as our results indicate that inmate status and race also influence discharge destination, factors related to incarceration, race, and discharge destination require clarification. In addition, examining the current functional status of this included cohort of patients may help provide important information regarding the long-term outcomes of patients with COVID-19 who require hospitalization.

Conclusions

The results of this study provide an opportunity to learn how functional measures, such as the FOIS and AM-PAC, may be used to better understand discharge outcomes in both inmate and noninmate patients admitted to the hospital with COVID-19 during the initial period of the pandemic. Our preliminary findings provide input on how inmate status, age, race, and sex may impact the outcomes (eg, discharge destination and oral intake) examined in patients diagnosed with COVID-19. These factors require further clarification as they relate to outcomes in patients with COVID-19. Finally, additional investigation is necessary regarding the utility of the FOIS and AM-PAC scores in understanding patient outcomes in those with COVID-19.

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Conflicts of Interest

None declared.

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Abbreviations

AM-PAC: Activity Measure for Postacute Care

FOIS: Functional Oral Intake Scale

ICU: intensive care unit

OR: odds ratio

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Original Paper

Technologies in Home-Based Digital Rehabilitation: Scoping Review

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Abstract

Background: Due to growing pressure on the health care system, a shift in rehabilitation to home settings is essential. However, efficient support for home-based rehabilitation is lacking. The COVID-19 pandemic has further exacerbated these challenges and has affected individuals and health care professionals during rehabilitation. Digital rehabilitation (DR) could support home-based rehabilitation. To develop and implement DR solutions that meet clients' needs and ease the growing pressure on the health care system, it is necessary to provide an overview of existing, relevant, and future solutions shaping the constantly evolving market of technologies for home-based DR.

Objective: In this scoping review, we aimed to identify digital technologies for home-based DR, predict new or emerging DR trends, and report on the influences of the COVID-19 pandemic on DR.

Methods: The scoping review followed the framework of Arksey and O'Malley, with improvements made by Levac et al. A literature search was performed in PubMed, Embase, CINAHL, PsycINFO, and the Cochrane Library. The search spanned January 2015 to January 2022. A bibliometric analysis was performed to provide an overview of the included references, and a co-occurrence analysis identified the technologies for home-based DR. A full-text analysis of all included reviews filtered the trends for home-based DR. A gray literature search supplemented the results of the review analysis and revealed the influences of the COVID-19 pandemic on the development of DR.

Results: A total of 2437 records were included in the bibliometric analysis and 95 in the full-text analysis, and 40 records were included as a result of the gray literature search. Sensors, robotic devices, gamification, virtual and augmented reality, and digital and mobile apps are already used in home-based DR; however, artificial intelligence and machine learning, exoskeletons, and digital and mobile apps represent new and emerging trends. Advantages and disadvantages were displayed for all technologies. The COVID-19 pandemic has led to an increased use of digital technologies as remote approaches but has not led to the development of new technologies.

Conclusions: Multiple tools are available and implemented for home-based DR; however, some technologies face limitations in the application of home-based rehabilitation. However, artificial intelligence and machine learning could be instrumental in redesigning rehabilitation and addressing future challenges of the health care system, and the rehabilitation sector in particular. The results show the need for feasible and effective approaches to implement DR that meet clients' needs and adhere to framework conditions, regardless of exceptional situations such as the COVID-19 pandemic.

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KEYWORDS

digital rehabilitation; digital technologies; home-based rehabilitation; digital health intervention; scoping review; artificial intelligence; AI; machine learning; COVID-19 pandemic; mobile app; remote health; mobile phone

Introduction

Background

Rehabilitation is an essential part of caring for people with acute or chronic health conditions, impairments, or injuries that limits functioning [1]. It is estimated that 2.5 billion people worldwide live with health conditions that benefit from rehabilitation [1]. Owing to population growth, aging, and the increasing number of people with chronic diseases and disabilities, the need for rehabilitation is steadily increasing worldwide [1].

Two of the most challenging aspects of rehabilitation are the high costs of inpatient and long-term rehabilitation programs [2] and the poor continuity of rehabilitation when patients are transferred to their homes [3,4]. To address these challenges, a shift in rehabilitation from inpatient care or rehabilitation centers to home settings is essential [5,6]. Therefore, various models have been developed to offer early home-based rehabilitation [7,8]. However, for effective home-based rehabilitation, sufficient support must be provided to clients (persons who receive health care services) and health care professionals (persons who provide health care services).

Incorporating new digital technologies into rehabilitation could help to meet these demands. Digital rehabilitation (DR) can be defined as using digital technologies as a part of the rehabilitation process [9]. DR aims to optimize functioning and reduce disability of individuals with health conditions in interaction with their environment [9]. This includes, but is not limited to, the use of tele- and remote rehabilitation applications and services, automatic services, robot-assisted technologies, wearables, emails, video, speech, and SMS text messaging solutions [9]. By using tele- and remote rehabilitation applications and services, for example, sensors and wearables, opportunities exist for monitoring clients' health status at home [10-12]. In addition, DR improves rehabilitation outcomes in clients with heart failure, diabetes, and respiratory disease [13]. They also help clients to manage pain; increase their physical activity; and improve mental health, diet quality, and nutrition [13]. Furthermore, it appears that some parts of the DR are cost-effective [13]. With the combination of commercially

available technologies, Internet of Things (IoT), and artificial intelligence (AI), there is also the possibility of remote health assessments and personalized rehabilitation interventions [14]. In addition, DR can have a positive impact on self-management [15-17]. Self-management aims to improve clients' ability to manage their disability and improve their lifestyles. It underlines the active participation of clients, emphasizing the interactive and collaborative relationship between clients and health care professionals. Similarly, an important aspect of self-management is client responsibility, which is particularly important in home-based rehabilitation [18].

However, for the effective application of DR, it is not only important to identify digital technologies and their potential applications that can be integrated into home-based rehabilitation but also essential to equip health care professionals with the skills needed to provide high-quality rehabilitation, conferring them with the potential to develop the field multi-professionally.

The COVID-19 pandemic has exacerbated the challenges faced by individuals in need of rehabilitation [19]. In addition, there has been increased pressure on higher education institutions and health care professionals to develop DR practices that meet the needs of target populations [20].

To develop and implement DR solutions that meet client needs and ease the growing pressure on the health care system, it is necessary to provide a broad overview of existing, relevant, and future solutions shaping the constantly evolving market of technologies for home-based DR.

Objective

The scoping review aimed to identify digital technologies for home-based rehabilitation, predict new and emerging trends in DR, and report the influences of the COVID-19 pandemic on DR.

Methods

Overview

The scoping review was performed based on an adapted framework described by Arksey and O'Malley [21] by adding

the improvements proposed by Levac et al [22]. This framework includes 5 phases: identifying research questions, determining relevant studies, selecting studies, charting data, and consulting with key stakeholders and experts. The scoping review was reported consistent to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews; [Multimedia Appendix 1](#)). A protocol of this scoping review does not exist.

Identification of Research Questions

As the first step, the following research questions were identified:

- Research question 1: What are the types of existing new or emerging digital technologies in home-based rehabilitation?
- Research question 2: Which trends can be identified for the home-based DR technologies and what are their advantages and disadvantages?
- Research question 3: How does the COVID-19 pandemic influence the development of DR?

Identification of Relevant Studies

To identify references related to the research questions, a scientific database search in PubMed, Embase, CINAHL, PsycINFO, and the Cochrane Library was performed in July 2021.

The search strategy was first developed for PubMed and adapted to each database by using keywords; their synonyms; and related terms of “rehabilitation,” “home-based,” and “digital

technologies.” These terms were connected with the Boolean operators “AND” and “OR” to obtain a wide spectrum of results from the various databases. The full search strategy for each database is presented in [Multimedia Appendix 2](#). The search for relevant references was designed in 2 phases. The first phase involved searching references published from January 2015 to July 21, 2021. In the second phase, an additional search was performed in January 2022 to retrieve recent publications.

To complement the findings regarding the trends of home-based DR, as well as the impact of the pandemic, gray literature sources were searched for unpublished materials in the native languages by the member institutes of the project “Competences for the new era of user-driven Digital Rehabilitation (DIRENE)” (Greek, Spanish, Finnish, German, and English). The gray literature was searched using Google, Google Scholar, Yahoo, OpenGrey, specific websites from each country’s government, thesis repositories, and university library websites that offer a comprehensive list of gray literature databases.

Study Selection

Study selection was performed using the web-based software, Covidence (version 2021; Veritas Health Innovation) [23]. After a training period, 7 independent researchers from the DIRENE consortium performed study selection based on the eligibility criteria presented in [Textbox 1](#). For every reference, 2 randomized researchers individually assessed the reference in terms of inclusion or exclusion. In cases of disagreement, a third researcher was included to resolve conflicts.

Textbox 1. Eligibility criteria for study selection.

<p>Inclusion</p> <p>Article type</p> <ul style="list-style-type: none"> • Every article type that is existing as a full text <p>Language</p> <ul style="list-style-type: none"> • English <p>Publishing date</p> <ul style="list-style-type: none"> • First phase: references published since January 1, 2015 • Second phase: references published since July 21, 2021 <p>Technology</p> <ul style="list-style-type: none"> • Digital technology directly related to home-based rehabilitation • Fully developed devices, applications, software, or prototypes and ideas <p>Intervention</p> <ul style="list-style-type: none"> • Every intervention in which a digital technology was used <p>Exclusion</p> <p>Article type</p> <ul style="list-style-type: none"> • Articles that were not available as full texts via common publishers, universities databases or directly requested from the publishing authors <p>Language</p> <ul style="list-style-type: none"> • Other languages than English <p>Publishing date</p> <ul style="list-style-type: none"> • First phase: references published before January 1, 2015 • Second phase: references published before July 21, 2021 <p>Technology</p> <ul style="list-style-type: none"> • Nondigital technologies • Technologies used after invasive procedures (eg, surgery to implant a device) <p>Intervention</p> <ul style="list-style-type: none"> • Intervention via telephone as a stand-alone intervention • Intervention in a laboratory setting

Data Extraction and Data Charting

A bibliometric analysis was performed as the first overview of the included publications. The software Zotero (version 6.0.10; Roy Rosenzweig Center for History and New Media, George Mason University) [24] was used to indicate the number of publications per year and the journals of the included references.

To identify new and emerging technologies for home-based rehabilitation, a co-occurrence analysis was performed. The software VOSviewer (version 1.6.18; Leiden University) [25] was used for the analysis. The co-occurrence analysis was intended to map the results of the included publications, categorize the technologies mentioned in the publications, and provide a visualization of the output [26]. For this purpose, a Research Information Systems (RIS) file of all included

publications was uploaded to the program, and a text-based analysis was performed using a binary counting method of the most frequently occurring keywords [26]. On the basis of the relevance score, the program automatically selected the most applicable keywords for the final analysis.

Furthermore, a full-text analysis of all included reviews was conducted to filter the trends for home-based DR technologies and to present its advantages and disadvantages. The analysis aimed to extract relevant information about the technologies in terms of the goal, specification and application, population, and advantages and disadvantages of the technologies.

The data of the gray literature search were analyzed to complement the results of the review analysis and to determine the influence of the COVID-19 pandemic on the development

of DR. Each participating institution used an extraction sheet to obtain the information with respect to the research questions. All data were then summarized according to the following categories: type, aim, description of the technology, target population, and statements regarding the influence of the COVID-19 pandemic.

Stakeholder Consultation

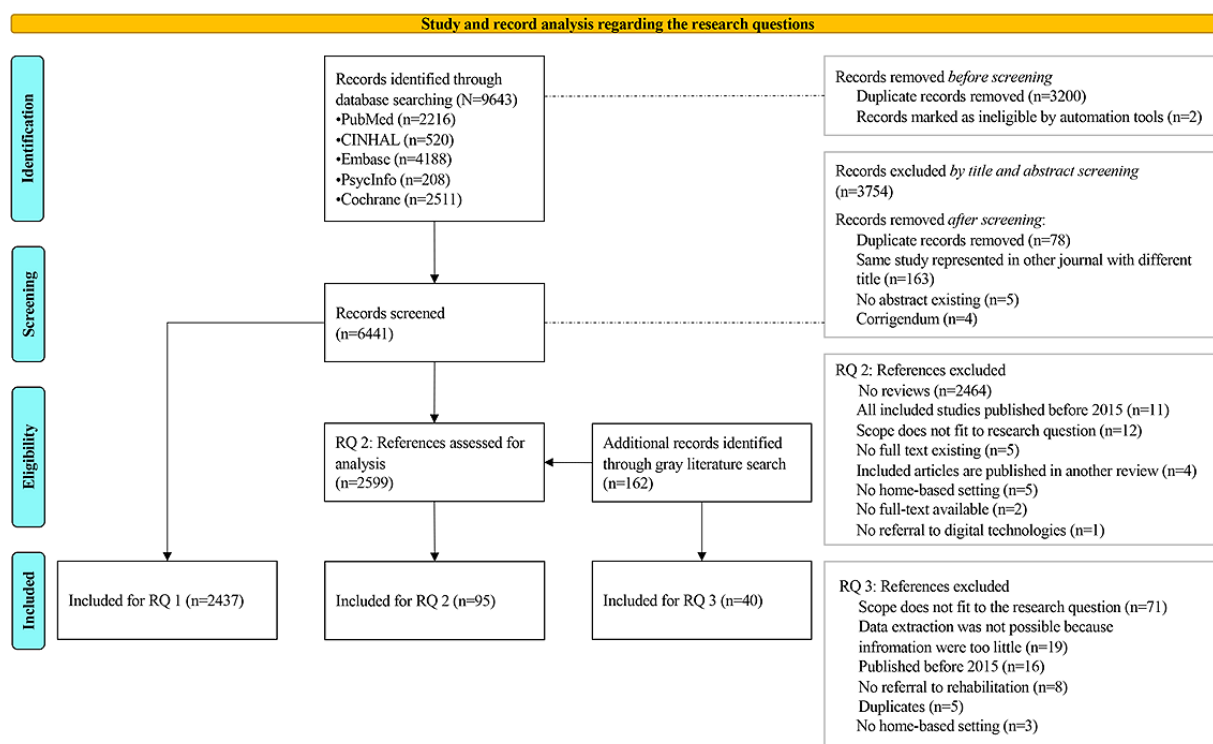
The aim of the stakeholder consultation was to complement the results regarding the trends of digital technologies and the impact of the pandemic on DR from different perspectives. Therefore, a meeting with key stakeholders and experts was organized by 4 of the 5 collaborating universities of the DIRENE consortium (Greece, Finland, Austria, and Germany). Participants included clients with experience or specific interest in using digital technologies at home (10/56, 18%); rehabilitation professionals (13/56, 23%); experts from companies for future trends in health care (9/56, 16%); experts in digitalization (11/56, 20%); and representatives of public health administrations (6/56, 11%), social and welfare departments (4/56, 7%), and national platforms for digitalization in rehabilitation (3/56, 5%).

The meetings consisted of a short introduction to the project and the presentation of the preliminary results of the review. Stakeholders shared their views on the identified trends in digital technologies used in rehabilitation. They discussed the potential synthesis of technologies in home-based rehabilitation and examined factors influencing DR. All the information was summarized in a final standardized report by each participating institution. The results were then analyzed in line with the Framework Approach [27]. On the basis of the research questions, a deductive approach was used to form the key themes and subthemes. After reviewing the results of the stakeholder consultation for each participating institution, the subthemes were adjusted inductively. Subsequently, the results of each stakeholder consultation were coded. Each code in a report was then summarized, abstracted, and tabulated for each subtheme. Then, the statements of all stakeholder consultations were summarized per key theme.

Results

The process of paper selection for each research question is shown in Figure 1.

Figure 1. Flowchart of the paper-selection process. RQ: research question.



Research Question 1: New or Emerging Digital Technologies in Home-Based Rehabilitation

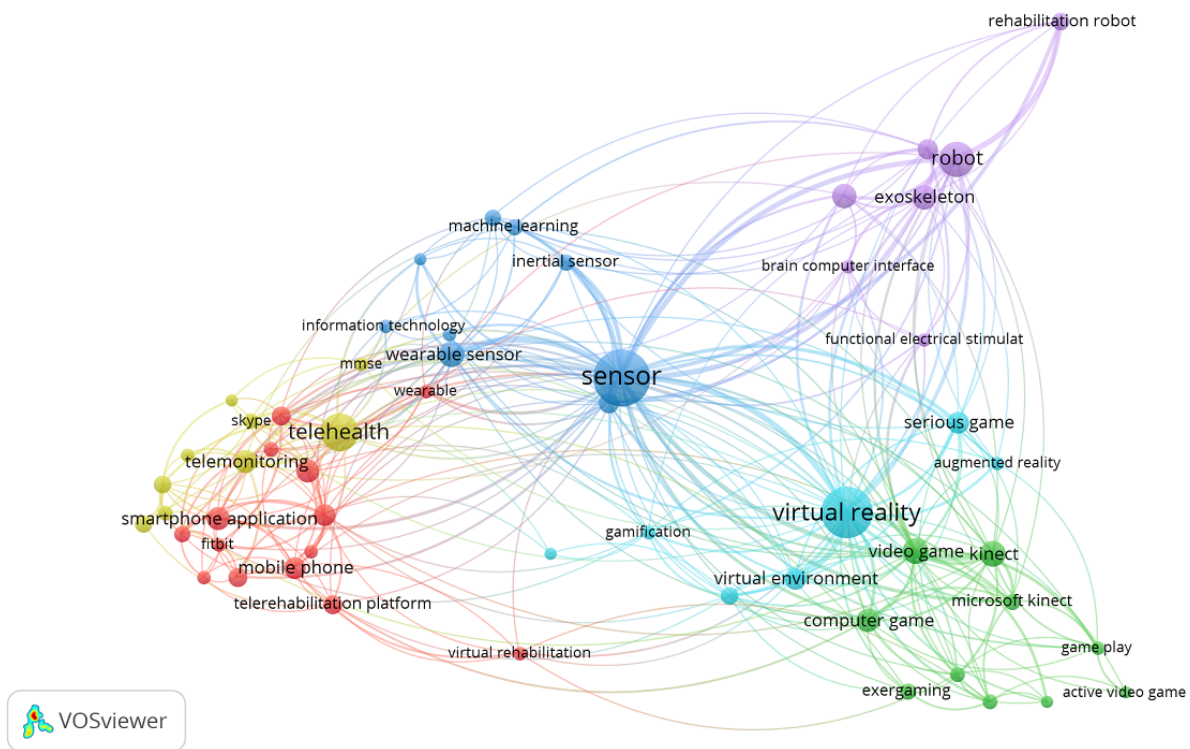
Bibliometric and co-occurrence analyses were performed to provide an overview of the included references and identify new or emerging technologies in home-based rehabilitation. For these analyses, 2437 records were included.

All 2437 included records for the bibliometric and co-occurrence analyses were published between January 2015 and January

2022. Over the past years, the number of publications has steadily increased annually, from 211 (8.66%) in 2015 to 544 (22.32%) in 2021. In addition, most research papers were published in 2021 (n=544, 22.32%).

In total, 53 keywords with a frequency of ≥10 were selected from 59,718 keywords, and a co-occurrence analysis was performed, as shown in Figure 2.

Figure 2. VOSviewer co-occurrence analysis of the most mentioned keywords referring to home-based rehabilitation. Map generated in VOSviewer version 1.6.18; Leiden University.



As presented in [Figure 2](#), the research themes of home-based DR can be divided into 6 clusters: sensors (blue), robotics (purple), gamification (green), virtual reality (VR) and augmented reality (AR; turquoise), mobile apps (red), and digital platforms (yellow). Each node represents a keyword. The size of the node indicates the number of occurrences of that keyword, and the link connecting the 2 nodes indicates that a keyword appears in common with another keyword. The thickness of the connection line indicates the strength of co-occurrence between the 2 keywords. The visualization indicates that the keyword “sensor” is the most frequently occurring term throughout the included publications compared with other keywords represented in this cluster.

Further analysis of keywords that occurred ≥ 10 times provided an overview of the mentioned populations in which the identified technologies were used in home-based rehabilitation, as shown in [Table 1](#).

It can be seen that the cumulative sum of stroke and related synonyms are the most occurring conditions related to home-based rehabilitation among the publications. Chronic obstructive pulmonary disease (COPD) and its synonyms ranked second. The third most common disease mentioned in the included publications is multiple sclerosis (MS).

Table 1. Population or symptoms groups sorted per occurrence in the bibliometric analysis.

Population	Occurrences, n
Stroke patient	100
Chronic stroke	38
Chronic stroke patient	29
Chronic stroke survivor	21
Poststroke patient	15
COPD ^a	102
Chronic obstructive pulmonary disease	77
Severe COPD	13
MS ^b	116
MS patient	17
Parkinson	98
Parkinson disease	13
Spinal cord injury	61
Traumatic brain injury	48
Aphasia ^c	30
Hemiplegia ^c	16
Cardiovascular disease	55
Heart failure	55
Myocardial infarction	26
Coronary heart disease	23
Hypertension ^c	22
Acute coronary syndrome	19
Chronic heart failure	18
Ischemic heart disease	17
Coronavirus disease	57
Chronic respiratory disease	12
Dyspnoea ^c	14
Knee osteoarthritis	30
Osteoarthritis	25
Hip fracture	21
Chronic low back pain	17
Knee injury ^c	13
Total hip arthroplasty	13
Total knee arthroplasty	12
Depressive symptom ^c	32
Breast cancer	16
Diabetes	16
Alzheimer	17

^aCOPD: chronic obstructive pulmonary disease.

^bMS: multiple sclerosis.

^cThe given groups represent symptoms that occurred in the bibliometric analysis.

Research Question 2: Trends in Home-Based DR and its Advantages and Disadvantages

Overview

To identify the trends for home-based DR technologies and display their advantages and disadvantages, 95 reviews (systematic reviews: n=51, 54%; reviews: n=44, 46%) were included (Figure 1) in the review analysis. For the technologies “brain-computer interface” and “machine learning,” no reviews could be found. However, the co-occurrence analysis showed results for these 2 technologies (Figure 2). All references were screened again these topics. Therefore, 22 articles were additionally considered for the analysis.

It is essential to note that each publication addressed one or more types of technologies that are often used in combination

with another. For example, exergames or serious games that are used with a head-mounted display are grouped in the category “virtual/augmented reality,” and the games in which a client plays in a virtual environment without using technology for an immersive experience are categorized as “gamification.” Likewise, the technology was not named in either category to avoid duplication.

To provide a definition for each identified technology, the DIRENE consortium developed definitions based on the current literature using a Delphi process until a consensus was reached [28] (Multimedia Appendix 3 [1,29-46]).

Table 2 provides an overview of the identified technologies for home-based DR and shows their advantages and disadvantages.

Table 2. Summary of the identified technologies discussed in home-based rehabilitation ordered by the specification of technology, specification of application, advantages, and disadvantages or limitations.

Category of technologies and specification of technologies	Specification of application	Advantage	Disadvantage or limitation	Included reviews or articles
Sensors				
Inertial sensors	Measuring, assessing, capturing, and tracking movement, motor activity, gait analysis, falls, blood flow, and respiratory rate; movement coding for control keyboards and displays; control and implementation of tasks and human-machine interfaces such as wheelchairs, smart shoes, and robots; and gesture recognition to aid communication between people with hearing impairments and listeners	Relatively inexpensive, portable, and user-friendly; provide sufficiently accurate and fast movement data for rehabilitation analysis and evaluation; simple principles of operation	Loss of accuracy due to factors such as position of sensor placement, reliability of skin attachment, or an interaction effect with the sensors	[47-49]
IMUs ^a	Measuring, assessing, capturing, or tracking movement and posture; predicting falls; and providing biofeedback	Small design, low cost, simple handling, capable of delivering accurate and valid analysis, and captures 3-dimensional linear accelerations from accelerometers and angular velocities from gyroscope. Combination of linear and rotational data enables a more complete picture of motion, as it has many <i>df</i>	Lack of validation in terms of capturing posture and motion and providing biofeedback. To measure accurately, at least 3 sensors are necessary. Multiple sensors require connection via wires and attachment to the body, often by strapping, and they may be challenging to remove and reattach	[47,50-54]
Accelerometer	Measuring, assessing, capturing, and monitoring movement, motor activity, physical activity, posture, respiratory rate, steps, falls, sleep, and gait analysis and providing biofeedback	Capture linear acceleration data in 1-3 planes of motion, can be used when magnetic interference is a concern, uses the gravity vector as a reference, can be easily attached to clients at low cost, and simple principles of operation	Sparse data-collection, often multiple sensors required	[48,49,51,53,55-57]
Gyroscope	Measuring, assessing, and capturing movement and motor activity	Can be easily attached to clients	Have no reference as gravity and are therefore unable to establish an initial state, leading to error accumulation	[53,56,57]
Infrared sensors	Measuring, assessing, capturing, and monitoring motor activity and posture	User-friendly	No data could be extracted from the included literature	[47,58]
Flex sensors	Control and implementation of tasks and human-machine interfaces such as wheelchairs, smart shoes, and robots; and gesture recognition to aid communication between deaf people and listeners	No data extracted from included literature	No data extracted from included literature	[47,51]
GPS and smartwatch	Measuring and monitoring steps and physical activity	No data extracted from included literature	No data extracted from included literature	[55,59]
Photo sensors	Measuring temperature, respiratory rate, and emotion recognition	User-friendly	No data extracted from included literature	[56,58]
(Vision) cameras	Measuring, assessing, and capturing movement, heart and respiratory rate, gait analysis, and blood flow; control and implementation of tasks and human-machine interfaces such as wheelchairs, smart shoes, or robots, and emotion recognition	Available commercially and at low costs	When measuring motion, vision cameras without an optical motion-tracking system provide 2D information about the captured scene; lack of the third dimension's information imposes limits on the evaluation accuracy	[47,48,56]

Category of technologies and specification of technologies	Specification of application	Advantage	Disadvantage or limitation	Included reviews or articles
EMG ^b	Measuring heart rate, gait analysis, movement coding for control keyboards and displays; gesture recognition to aid communication between deaf people and listeners; and recognition of facial expressions	Available commercially and at low costs	To measure bioelectric signals, often inertial sensors have to be added	[47,50]
Microphone	Measuring and tracking social activity	Available commercially and at low costs	No data extracted from included literature	[47,56]
Electrodes	Prevention of dementia, treatment for behavioral change, activating muscle contraction, and biofeedback	No data extracted from included literature	Multiple sensors are often required	[47,60,61]
Chemical and glucose sensors	Glucose monitoring	No data extracted from included literature	Requires a regular calibration to reduce errors	[47]
Robotics and brain-computer interface				
Robotic gloves	Measuring, assessing, capturing, and tracking motor function; supporting hands and finger movement; strengthening muscular activity and hand and finger coordination; and assisting ADLs ^c	Promotes engagement and motivation in therapy	Different operating characteristics, high costs, and predominantly passive in nature when used without a therapist	[62-64]
Exoskeleton for upper and lower limbs	Active, passive, and triggered assistance of movement; implementing movement; and gait training	Promotes engagement and motivation in therapy, delivers high-intensity training compared with therapist-only training and assists or helps to perform movement even if the client cannot initiate movement	General: individual physical characteristics (cognitive, communication, visual problems, and motor impairments) may limit the use of exoskeletons; the need to be assisted by others to operate the rehabilitation robot at home; skills required to operate the system; high purchase and maintenance costs; and limited accessibility. Exoskeletons lower limbs: high risk of falls, there is a need to learn how to use the exoskeleton while walking, and there are special adaptation requirements when using the device	[54,63-67]
Robotic device for upper and lower limbs	Active and passive assistance, supporting movement, improving movement, and assisting gait	Able to generate a wide variety of forces and motions and deliver measurable doses and intensities of therapy	Require large amounts of physical space and appropriate facilities such as tables and chairs for setup; some robots generate large forces, which can create theoretical safety concerns during unsupervised use at home	[49,54,62,64-66]
Brain-computer interface	Active and passive assistance of movement, implementing movement, supporting ADLs, and enable or support communication with environment	Home use is possible and enables movement through brain activity	In its infancy, low usability rate, and often costly	[68-76]
Social robots	Supporting ADLs	Could reduce loneliness, older individuals are willing to use robotic technologies	Acceptance rate in healthy participants is low	[77]
Gamification				
Serious games	Improving balance; gait; mobility; postural control; motor, physical, and cognitive functioning; adherence; and self-management	Promote engagement and motivation in therapy; specific exercises are provided based on clients' aims. The training process is monitored, and the training plan is adapted accordingly	Additional hardware is costly, requires certain skills for client and the therapist to operate, health professional should monitor the compliance with the prescribed tasks at a regular basis to make adaptations to the rehabilitation plan, and diverse acceptance rate	[54,78-80]

Category of technologies and specification of technologies	Specification of application	Advantage	Disadvantage or limitation	Included reviews or articles
Exergames	Improving balance; gait; mobility; postural control; and motor, physical, and cognitive function; preventing falls; and reducing symptoms of chronic respiratory diseases	Commercially available, promote engagement and motivation in therapy, and many are low-cost systems	Specific guidance and tailored interventions to the clients' needs is often lacking. Devices are not always designed for people with disabilities. Diverse adherence rate	[52,54, 59,81-92]
Virtual and augmented reality				
Augmented reality	Improving physical functioning, range of motion, and gait	Promotes engagement and motivation in therapy, no proof to cause symptoms of "simulator sickness"	In its infancy and requires further investigation with regard to their effectiveness. Dizziness may occur during use	[93,94]
Virtual reality	Improving physical functioning, fitness, balance, postural control, vestibular dysfunction, and anxiety	Promotes engagement and motivation in therapy. Some systems are commercially available at low costs	Potential side effect known as "motion sickness" may occur during use. Fully immersive systems are not commercially available and not at low costs	[93,95-99]
Digital and mobile apps				
App	Measuring, assessing, capturing, and tracking rehabilitation process and health behavior, medication and rehabilitation adherence, and active and passive movement; providing and performing assessments; promoting self-management, physical activity, and healthy lifestyle; reducing falls; improving physical functioning, trunk control, dexterity, cognitive and language skills, and mobility; providing psychosocial support, coaching, secondary prevention; and obtaining support from other people	Low cost, commercially available, provides access to some rehabilitation measure, beneficial to combine app solutions (eg, for diagnosis, intervention, or monitoring), increase engagement in therapy, and supports connection between health care professional and client through real-time transmission of health data	Accuracy of measuring ROM ^d is not tested or validated yet. Access and use can be different between countries due to cultural background, availability of high-speed connection, and trust in health care professionals. Correct use of digital technology may be affected by health condition itself (eg, motor disability, visual impairment, psychiatric comorbidities, cognitive dysfunction). Some of the apps could only be used in combination with another technology (eg, smartwatch). Some apps did not offer a platform to facilitate interaction with health professionals; some apps are outdated; some apps lack of disclosing sponsorship, authors' affiliations, credentials, and sources or references of information; and some apps do not always cover all the rehabilitation needs for the client. Security aspects are not always considered	[49,52, 55,59, 100-114]
Web-based program	Measuring, assessing, capturing, and tracking, rehabilitation process, health behavior, and medication and rehabilitation adherence; providing and performing assessments; promoting self-management, physical activity, and healthy lifestyle; improving physical functioning, balance, postural control, endurance, strength, and cognitive skills; obtaining support from other people	Real-time feedback is possible, low cost, commercially available, access to some rehabilitation measures, beneficial to combine app solutions (eg, for diagnosis, intervention, or monitoring), engagement in therapy, supports connection between health care professional and client through real-time transmission of health data	Access and use can be different between countries due to cultural background, availability of high-speed connection, and trust in health care professionals; correct use of digital technology may be affected by health condition itself (eg, motor disability, visual impairment, psychiatric comorbidities, and cognitive dysfunction); sometimes unreliable connections	[49,52, 55,59, 100,104, 107-111, 113,115-122]
Videoconferrence	Promoting self-management and healthy lifestyle, improving mobility and physical functioning, monitoring rehabilitation process and exercises, and obtaining support from other people	Remote rehabilitation and real-time feedback possible, supports motivation in rehabilitation, low cost, commercially available, possibility to reduce duration of inpatient hospitalization, may reduce costs	Workability is not always practical, lack of physical interaction between clients and therapists, technical skills are necessary for the use of some services. Main policy challenges related to home-based telerehabilitation are not yet fully resolved (eg, costs, reimbursement, data protection, liability, and system security). Access and use can be different between countries due to cultural background, availability of high-speed connection, and trust in health care professionals. Correct use of digital technology may be affected by health condition itself (eg, motor disability, visual impairment, psychiatric comorbidities, and cognitive dysfunction)	[49,52, 54,59, 61,103, 104,113]

Category of technologies and specification of technologies	Specification of application	Advantage	Disadvantage or limitation	Included reviews or articles
Internet of Things				
Smart homes and ambient-assisted living	Detecting and preventing mild cognitive impairments and dementia, improving cognitive functioning, supporting tasks of daily living, and monitoring health status	Monitoring clients' health status in their natural environment	Use of the technology is complex for clients with disabilities. Technology could be expensive—costs for installation, repair and maintenance occur, ethical considerations. Privacy concerns and clients' safety are often discussed issues	[47,58,101,115]
Living labs	Assessing motor performance	Testing is possible in the home environment, records sufficient objective measures, and variable test administration by clients is bypassed	Clients may not be fully informed about the possibilities and limitations of the technologies or are not cognitively able to understand their implications; too many data are collected, most important information has to be filtered, may violate client privacy, and challenging to comply with ethical and data protection guidelines. Sometimes additional technologies have to be attached to clients such as electrodes; this can be demanding and uncomfortable (eg, constant use and attachment or detachment of electrodes)	[115,123]
AI^d and machine learning				
AI and machine learning	Providing individualized therapy, trainings plan, motion feedback in real time, and classification of movement	Have the potential to predict adherence and client conditions	In its infancy; some decisions could be taken over from AI and machine learning algorithms; and acceptable model accuracy can be reached after using the technology multiple times	[124-136]
Chatbots and conversational agents	Organizing rehabilitation process, treatment of mental disorders, and assisted living	Rehabilitation management is supported, entertaining tool for rehabilitation, low cost, and no stigmatization in mental disorder treatment	In its infancy, more research is needed; most conversational agents are not commercially available; some individuals may become overly attached, some chatbots give inappropriate responses related to the health problem; there are no laws and regulations for the use of chatbots, and the legal responsibility for adverse events related to chatbots has not yet been clarified	[121,137-139]
Virtual humans	Secondary prevention, promoting physical activity, and treatment of mental illness	Appear natural for human-machine interaction and give the illusion of liveness of interaction with a real person, exude trustworthiness and credibility	There is the fear of replacing a health care professional, which can lead to considerable disadvantages	[121]

^aIMU: inertial measurement unit.

^bEMG: electromyography.

^cADL: activity of daily living.

^dAI: artificial intelligence.

Sensors

In 14 reviews, sensors were used as an assessment and diagnostic tool, as an intervention, as support for daily living, and as a monitoring solution. Sensors were the most used technology in the included reviews and were often used in combination with other technologies (Figure 2).

Thirteen groups of sensors could be identified for use in rehabilitation. The groups can be divided into 4 subgroups depending on their purpose: motion-capturing sensors (motor activity [51], posture [53], falls [140], and gait [141]); vital parameter sensors (heart rate [142], pulse, respiratory rate [143],

blood oxygen [144], glucose [145], and skin and body temperature [146]); activity-tracking sensors (steps [147] and physical activity [148]); and sensors intended to capture behavior (sleep [149] and social behaviors [150]).

Sensors are embedded in wearables that are worn as normal clothes or in footwear (eg, insole pressure sensors [151]); cameras; accessories (eg, smartwatches [152], bracelets [148], rings, chest belts, and glasses [131]); or smartphones, or they can be directly attached to the skin (eg, electrodes [61]).

Inertial measurement units (IMUs) are the combination of inertial sensors, namely, the combination of one or more accelerometers, one or more gyroscopes, and, potentially, one

or more magnetometers, to measure the force, angular rate, and orientation of the body [53]. These IMUs are designed to capture physical movement and posture in a markerless fashion, with the intention of detecting dysfunctions, motor impairments, activity limitations, and unhealthy conditions [47,52-54,153].

Given the existence of IoT, sensors can collect data and transfer them to other devices to visualize the output and thus provide biofeedback to the client. Biofeedback systems consist of an input sensor, a data-processing system, and an output device that displays the feedback [50]. The output can be provided through the visualization displayed on a screen, auditory feedback via voice outputs, or vibrotactile feedback of the input sensor. For example, robotic gloves can be used as sensor gloves equipped with flex sensors and vibrotactile motors that provide vibrotactile feedback through the motors at the fingertips. Sometimes, biofeedback systems are embedded in games for rehabilitation purposes in which the client must playfully perform movement tasks that are displayed on a screen. Biofeedback can improve outcomes by engaging clients and has the potential to support clients in targeted exercises during home-based rehabilitation [50].

It is useful to apply vital parameter sensors to monitor the health status of clients during rehabilitation. Kwon et al [144] developed an app for clients with COPD and monitored their heart rates and blood oxygen saturation via sensors embedded in smartphones. An alarm function alerts the client regarding any critical health status during physical activity, such as when the values (S_pO_2 and heart rate) fall below certain thresholds. Thus, the client has the opportunity for self-monitoring, that is, to receive feedback on the correlation between physical activity and body reactions to adjust such behavior as needed. Health care professionals can also estimate these data using a dashboard where the data are collected. After 6 weeks, the application led to a significant reduction in symptoms associated with COPD compared with the control group. The intervention group's self-assessment of the impact of the disease also improved significantly.

Overall, stakeholders emphasized the importance of sensors in DR.

Robotics and Brain-Computer Interfaces

In total, 9 reviews investigated the use and effects of robots in rehabilitation. Furthermore, 9 articles that explained the use of brain-computer interfaces (BCIs) in rehabilitation were included.

Robotic gloves [154] are categorized as rehabilitation robots, and they are machines with sensors and actuators [40]. There are several types of robotic gloves [154]. For example, soft robotic gloves are used in upper-limb rehabilitation for clients with neurological conditions, such as stroke and spinal cord injury. These are used to assist, replace, or promote the movement of fingers, hands, and wrists and to facilitate activities of daily living (ADLs) [155]. They can also be used for motion capture to assess arm function and movement control [156]. Robotic gloves have the potential to be easily used by someone who is at home alone.

Exoskeletons are wearable robotic units controlled by computer boards [157,158]. A distinction is made between “rigid” and

“soft” exoskeletons. Because of the perspective of home-based rehabilitation in this review, only soft exoskeletons were used in the identified references. Exoskeletons can be applied to the upper or lower limbs in home-based rehabilitation to assist clients and help perform passive movements in clients with neurological diseases such as stroke, spinal cord injuries, and cerebral palsy [159]. Furthermore, these devices can assist in the ADLs.

The application of noninvasive BCIs has changed over the last decade. This change allows health care professionals to offer this treatment in a home-based setting, although this approach remains under development. In the past, the application of BCI technologies in a home environment was hampered by the fact that the operation of these systems required the supervision of an expert. In a home-based setting, BCI technologies are used for people with severe motor impairments, such as those who have experienced a stroke, traumatic brain injury, spinal cord injury, or locked-in syndrome. These technologies can help such clients to enable or support communication with their environment or performing daily tasks.

BCI-based applications can be used to control daily aids such as wheelchairs, prosthetics, video games, and various computer applications [72,75]. Yang et al [75] proposed a system that helps physically disordered people to control external devices using gazing and eye blinks. It offers the opportunity to conduct routine daily tasks using brain signals directly, without any physical movement.

Zulauf-Czaja et al [76] developed a system for hand rehabilitation based on a BCI interface that uses an electroencephalographic device combined with functional electrical stimulation. The hand therapy consisted of the attempted movement of one hand to lower the power of the sensory-motor electroencephalography and thereby activate the functional electrical stimulation, which causes flexion and extension of the wrist.

Stakeholders saw high potential in the use of exoskeletons in rehabilitation if the devices are able to make their own adjustments in terms of speed and level of assistance based on data collected from the client. Furthermore, stakeholders indicated rehabilitation robots' low accessibility to clients, as these are mostly available at research level. The stakeholders also emphasized the possibility of the combined use of robotic devices with gamification to encourage clients' motivation during the rehabilitation process due to gaming elements or appealing environments.

Gamification

In 19 reviews, games were used either specifically for rehabilitation (serious games: $n=4$, 21%) or commercial use (exergames: $n=15$, 79%).

Gamification was mostly used as an intervention in neurological rehabilitation to improve physical function, balance, gait [84,90], and motor function [89,92]. One review applied gaming elements in rehabilitation to improve cognitive function in patients with neurological disorders (stroke, MS, and cognitive impairment) [91]. Mura et al [91] stated that no conclusion can be drawn regarding the effectiveness of exergames in improving

the cognitive function in persons with neurological disabilities. The small sample sizes of the selected studies, dissimilarity in outcomes and assessments used to measure the cognitive function, and heterogeneity of populations included in the analysis restricted the explanatory power of the review.

In a number of reviews [54,78-80] in which serious games were described, hardware such as robotic devices and gloves and leap motion sensors were used as supplements to the game.

Publications deployed exergames using commercial hardware, such as the PlayStation, Nintendo Wii, Xbox Kinect, and associated elements such as the Wii balance board and games for these consoles [59,83,84,88-90,92,160]. Biomarkers such as leap motion sensors and Microsoft Kinect are used in motion capturing and creating physical images on the screen.

Overall, a low strength of evidence has been shown until now regarding exergames and serious games in improving physical functioning. This is due to a lack of long-term randomized controlled trials (RCTs) with homogeneous population and large sample sizes and specific outcome measures [80,82,84,88,89,91,92]. Stakeholders also stated that the long-term effects of gamification are yet to be proven.

VR and AR Technologies

For the recent past and as this review shows, more VR technologies (5/7, 71%) have been the focus of research in relation to rehabilitation compared with AR technologies (2/7, 29%).

In home-based rehabilitation, VR and AR are used to improve physical functioning [93], balance [161] and anxiety [162] in older individuals and people with neurological diseases. It was further revealed that VR is used by people with vestibular dysfunction to improve balance and postural control [96].

VR technologies were mostly used in combination with games that had not been developed for rehabilitation purposes, with the exception of 6 studies [161-166]. In the included studies, AR was used in combination with other devices, such as a robotic glove [167] or motion-capturing devices [168], to display an avatar on a screen, allowing clients to see their own movements. All software applications used for AR were developed for research purposes.

In 1 study [167], AR was used as a mirror therapy in combination with a robotic glove to improve the motor function of paretic limbs in clients after stroke. Participants saw a mirror image of themselves on a screen, with the paralyzed arm being mimicked by the virtual arm. They were instructed to perform tasks by first moving the uninjured arm and then the paralyzed arm—the animation of the virtual arm—was triggered by signals from markers on the glove.

In addition to VR and AR, stakeholders added “Mixed reality” and “Digital twins” as a further trend in rehabilitation. Mixed reality is the merging of real and virtual worlds to produce new environments and visualizations in which physical and digital objects coexist and interact in real time. It includes VR and AR and thus represents the entire spectrum between the physical and digital worlds [38]. A digital twin is a digital representation of tools, people, processes, and systems. In rehabilitation, digital

twins are used to create digital representations of health-related data, such as data regarding hospital environments, laboratory results, and human physiology, through computer models [169]. No application of digital twins in home-based rehabilitation has been reported. However, digital twins are not yet applicable in home-based settings.

Currently, there is a lack of strong evidence supporting the use of VR and AR for rehabilitation [49]. Stakeholders summarized that VR emerged in the market for rehabilitation 10 years ago and that the use of VR had been rather limited in the past because of its low usability. They further indicated that AR had greater potential than VR.

Digital and Mobile Apps

In this study, we identified 3 subcategories within the 26 reviews regarding digital and mobile apps: apps (19/43, 44%), web-based programs (17/43, 40%), and videoconference systems (7/43, 16%). The large number of published papers in this area illustrates their broad use in rehabilitation.

Apps, web-based programs, and videoconference systems can be used for remote and home-based rehabilitation as adjuncts to face-to-face therapy or to replace some parts of it. It is noticeable that the use of these technologies is not limited to certain target groups, rather the client must fulfill some preconditions to use these technologies, such as access to the internet, mobile devices, or computers, as well as possessing necessary skills.

Apps and web-based programs are used as assessments, specifically providing questionnaires via apps, or delivering guidance regarding assessments, or measuring movement through special sensors embedded in a smartphone [52,106,170-172]. These technologies can promote physical activity; improve physical functioning, mobility, and language and speech skills; and provide secondary prevention through exercises and (real-time) feedback, information, (self-) monitoring, and reminder functions [105,111,114].

Moreover, these technologies are used to improve cognitive functions [60,173] and provide psychological support [102]. Two articles [174,175] additionally described the function of web-based programs to improve balance, strength, mobility, and postural control of people with MS by providing physical exercise.

Apps and web-based programs can help improve self-management and encourage a healthy lifestyle, rehabilitation, and adherence through individual goal setting, displaying rehabilitation progress, showing motivational messages, providing educational modules, and enabling symptom recording and social support [49,52,108,109,112].

Digital and mobile apps can further offer the possibility to connect with other people and become part of a social support community [176].

Stakeholders have criticized the lack of a solution that combines all the requirements of the rehabilitation process in one holistic approach. Even if the applications are available at a low price, the stakeholders emphasized that equal access to the internet and hardware should be ensured to decrease social inequality.

They also expressed concerns that some clients may be excluded because they did not have the required competences and skills. Appropriate support is required for these clients. Furthermore, stakeholders have critically noted that digital and mobile apps encourage the replacement of face-to-face interventions, which they believe represents a clear disadvantage in terms of the outcomes of the rehabilitation process. In addition to all the benefits and limitations of digital and mobile apps, stakeholders identified this technology as one of the trends in the future health care sector.

IoT Principles

In total, 4 reviews explored the functionality of IoT principles.

In rehabilitation, the IoT is beneficial for the collection of clients' data through various technologies. These data can be sent to health care professionals to monitor clients' health in their normal environment. In this manner, data can be collected to provide a complete picture of clients without blind spots. This information can be used to make medical decisions and treatment plans.

IoT approaches include smart homes and ambient-assisted living (AAL). A smart home is a residence equipped with smart technologies aimed at providing tailored services to clients [177]. AAL can be defined as the use of information and communication technologies in a person's daily living and work environment [178]. Smart homes and AAL make it possible to monitor and support residents in ADLs or create a safe environment, which can enhance quality of life and promote independent living. For example, in 1 project [179], the client's house was equipped with intelligent sensors to monitor the client and provide reminder to perform tasks such as taking medication or resting.

Piau et al [58] raised the question of whether the principles of smart homes can be applied to detect mild cognitive impairment or dementia in older individuals. For this purpose, data were gathered through either digital biomarkers, such as passive sensors, that were installed in homes (motion, light, temperature, and activity sensors) or wearables. Data from dedicated or purposive technological solutions can be used to monitor a client's activities. Nevertheless, the authors concluded that most technologies were far removed from everyday life experiences and were not sufficiently mature for use under nonoptimal or uncontrolled conditions.

Stakeholders emphasized the complexity of using the devices and high costs of the technologies, as well as expenses for installation, repair, and maintenance, as further barriers to implementing smart homes [177].

Referring to IoT, another approach that could benefit rehabilitation is living labs. The term "living labs" refers to the use of sensors to objectively record and evaluate people's behavior and physical functioning without interruption over a long period [123]. Personal or ambient technologies can be used for this purpose. Personal technologies include wearables that are attached to clothing or rest on the skin, such as smart watches or bracelets. Ambient technologies are placed in a client's home, such as cameras and pressure and motion sensors, which are almost not perceived during use. These technologies can record

various vital parameters, as well as collect information about physical activity, muscle activity, falls, and sleeping behavior.

Stakeholders emphasized the benefits of linking the digital and physical worlds through IoT to enable a holistic approach to rehabilitation. In contrast, stakeholders have stated that clients often have great fears about the use of these technologies with an IoT approach owing to lack of safety.

AI and Machine Learning

In total, 4 reviews describing the principles of AI were included. In addition, 13 articles were selected to explore its use in rehabilitation with machine learning processes.

AI and machine learning processes can be used as diagnostic and prognostic tools in rehabilitation. Abdollahi et al [124] used a wearable system of sensors (IMUs) and machine learning processes to classify clients with nonspecific low back pain into subgroups according to quantitative kinematic data, for example, trunk motion- and balance-related measures. On the basis of this home assessment, a personalized rehabilitation plan was created following practical guidelines.

Similarly, several articles have developed a home-based monitoring system based on AI and machine learning for use in executing a rehabilitation plan, even in the absence of a rehabilitation professional. For example, Chae et al [127] developed a home-based rehabilitation system on a smartwatch, as well as an app and AI processes that can recognize and record the type and frequency of rehabilitation exercises conducted by the client. This can facilitate participation in home training and improve the functional scores of patients with chronic stroke. Lydakis et al [131] designed a system of wearable glasses and smart bracelets to provide interactive corrective feedback to clients with neurological diseases in home settings.

Chatbots and conversational agents are key technologies for AI and machine learning processes in rehabilitation. They could be based on AI and machine learning processes that simulate and process human conversations. They enable communication via text or audio on websites, mobile apps, or telephone [137].

Vaidyam et al [137] further identified the potential of chatbots for use in psychoeducation and for encouraging self-adherence by providing information and motivation. The RCTs performed by Fitzpatrick et al [180] and Fulmer et al [99] reported health-related outcomes. They found that interaction with conversational agents led to decreased symptoms of depression and anxiety compared with the control groups.

In their reviews, Schachner et al [139] and Vaidyam et al [137] found that the acceptance rating of conversational agents and chatbots was positive, suggesting that they would be effective and enjoyable tools for use in rehabilitation.

Virtual human technology is based on AI and machine learning processes and used in rehabilitation. Virtual humans are computer-generated cartoon-like characters that have the ability to initiate and respond to verbal and nonverbal communications. The use of virtual humans in assisted care has mainly been implemented for healthy participants [181-183], with the aim of improving their health behaviors and reducing risk factors or physical inactivity. Furthermore, they have been used to

provide advice and serve as motivators to increase physical activity in older individuals [184].

From a systemic perspective, the stakeholders expressed that AI and machine learning processes are the most relevant technologies for the future. AI and machine learning processes define future opportunities in the rehabilitation sector because they enable evidence to be generated based on the data collected. This can lead to resource optimization for the client and the health care system. However, stakeholders have stated that technologies such as chatbots and conversational agents have not yet been sufficiently developed for use in rehabilitation. Most of the work is still in the pilot phase, and the effectiveness of the technology has not yet been verified [139].

Research Question 3: Influence of COVID-19 on the Development of DR

The 3-year pandemic (with May 5, 2023, as the end) has changed many rehabilitation processes for clients and health care professionals. To present the influence of the COVID-19 pandemic on DR, 40 records were included.

To continue rehabilitation during the pandemic, remote digitally driven rehabilitation approaches, such as videoconferencing, apps, and web-based programs, were frequently used in practice. However, the crisis did not lead to the development of new DR technologies but rather to an increased use of technologies that were already on the market.

This has led to more experiences with DR among clients, health care professionals, and health care providers. Clients accepted DR remotely as a substitute for face-to-face therapy during the pandemic [110,185-188]. However, they also identified barriers to the use of technologies [186,188,189]. To increase clients' adoption, recommendations have been developed [110]. Because many health care professionals are not trained to use virtual approaches in low-income countries [190], as well as in industrialized countries [191], additional training was offered to build competences in this area. Bernocchi et al [192] further stated that not only clients but also health care professionals require adequate training to use digital approaches.

The pandemic has led to an increased awareness of the need to develop further digital health measures (eg, digital vaccination certificate, digital sick note, improvement of digital tools, and simplified access to digital processing). In many countries, efforts have been made to implement digital solutions in the health care sector or help meet the preconditions for their use. However, the COVID-19 pandemic acted as an additional driver in the implementation of these applications. This was supported by political measures such as the softening of strict guidelines, which made it possible to launch and use digital solutions even without proof of their effectiveness [193]. However, clients have expressed concerns regarding their effectiveness and safety [194].

In addition, in some countries (Austria and Germany), videoconference (therapy via videoconferencing) was legally approved, considering individual requirements, such as a specific diagnosis, the confirmation of the service provided, safe technical equipment, and a positive prognosis regarding the success of the application [195,196]. In Germany, this

permission remains permanent regardless of the pandemic situation [197].

However, the rapid implementation has also led to the frequent implementation of incomplete solutions that have met the clients' short-term needs but are not sustainable in the long term, as pointed out by stakeholders. In addition, evaluations of the measures have been less rigorous or have not been conducted, leading to the risk of perpetuating rapidly implemented solutions after the pandemic [193].

Discussion

Principal Findings

This scoping review revealed various digital technologies intended for use in home-based rehabilitation. Trends were identified, and the advantages and disadvantages of each technology were presented. In addition, the influences of the pandemic on the development of DR were shown.

The findings of this review reveal that sensors, robotic devices, gamification, VR and AR, and digital and mobile apps are already widely used in home-based rehabilitation. However, AI and machine learning, exoskeletons, and digital and mobile apps represent emerging trends in rehabilitation. Compared with the other identified technologies, VR, AR, and robotics cannot be used independently for home-based rehabilitation for usability and safety reasons. Thus, there is a need to develop sufficient and feasible DR practices that demonstrate clinically relevant effectiveness. Furthermore, we discovered that the COVID-19 pandemic has led to an increased use of digital technologies in a remote approach, especially apps, web-based programs, and videoconferencing, but not to the development of new technologies. Clients and health care professionals accepted this approach during the pandemic, but they also expressed concerns about it. The pandemic acted as a driver for implementing remote approaches for health care systems. However, sustainable solutions that can be applied even after the pandemic should be implemented.

One major finding was that the relevance of AI and machine learning will increase in the field of rehabilitation in the future, especially for diagnostic procedures, decision-making, and the development of client-centered care, even though they are not yet broadly applied in rehabilitation. Furthermore, it was found that AI, machine learning, and digital and mobile apps would be essential to process and optimize resources in the health care sector. This finding is consistent with that in the current literature. For example, Hamet and Trembley [198] stated that electronic medical or health records are essential tools for use in personalized medicine, early detection, and targeted prevention, with the aim of increasing their clinical value and decreasing health costs. Moreover, Róman-Belmonte et al [199], who investigated the influence of AI on musculoskeletal disorders, highlighted that AI can produce a paradigm shift in musculoskeletal health, a move from descriptive to predictive medicine.

Nevertheless, there are challenges that need to be overcome when applying AI and machine learning widely in the health care sector. Jiang et al [200] report a lack of ethical and legal

supervision. No globally unified laws or regulations regarding the application of AI in medicine are currently in place to standardize the behavior of practitioners [200]. In addition to ethical and legal issues, one major challenge is the clear need for a standardized, comparative evaluation of the effects of AI on health indicators and measures of changes in psychological and physical status, side effects, and outcomes [198]. The findings regarding acceptance were incoherent. Health care professionals support the application of AI in rehabilitation and desire training for its application. However, people who are less well informed about AI fear being replaced by this technology, often because of a lack of knowledge about AI [200]. Therefore, it is important to outline the benefits and barriers of using AI for rehabilitation within society.

One further result was that technologies such as gamification, VR and AR, and digital and mobile apps that are already used in home-based rehabilitation have the potential to improve client adherence and motivation. Similarly, approaches based on IoT can increase client participation in the rehabilitation process because they allow self-monitoring; thus, client self-management can be increased. This represents an important factor for successful therapy of chronic diseases to improve quality of life and reduce the use of health care resources [201].

This study revealed that most technologies could be used in home-based rehabilitation without the presence of health care professionals. The emerging developments in the design and possibility of asynchronous or synchronous monitoring via apps, web-based programs, or videoconferencing make the remote rehabilitation approach possible. In other studies [54,56,202], the results showed that the independent use of VR and AR technologies and robotics in a home setting is limited owing to low usability and safety concerns. Clients with disabilities may require assistance in attaching or using the device or face the risk of harming themselves when excessive force is transferred to the body. However, to provide independent, usable, and safe rehabilitation at home, trained caregivers supporting the clients [76,203] or the construction of the rehabilitation device have the ability to overcome this challenge. For example, attachment mechanisms could be designed to enable the client to don and doff the device [159]. Furthermore, Kim et al [204] used emergency stop buttons and added safety features limiting ROM and joint velocity and stopping the robot in case of excessive force and torque interaction.

In order to offer client-friendly rehabilitation in the home setting, sufficient space for the equipment must also be ensured. Furthermore, the technical equipment needs to meet requirements such as access to the internet or a digital and mobile device, and the costs of purchasing, repairing, and maintaining the technology need to be low [62] because such costs are not always covered by health insurance funds.

In addition to the safety and usability factors, the use of DR should be based on an individual rehabilitation goal, considering the motivation of clients and health care professionals to use technologies and the possibility of receiving support when using such technologies [205]. Furthermore, individual physical conditions should be considered, which may affect the use of the selected therapy (grade of dementia, disability of vision or

hearing, and degree of impairment). It must be noted that Cottrell and Russell [205] limited their recommendations to videoconferencing in physiotherapy practice. Given that the technology must be customized to the client's body, these recommendations can also be considered when using other technologies.

Another major finding is that the effectiveness of many technologies has not yet been confirmed scientifically. Several studies have described projects in which the technology is currently under development or tested in laboratory settings. However, it can also be seen that 221 RCTs referring to DR are already registered via ClinicalTrials.gov for 2021 and 2022 (September 15, 2022). Because many technologies have only been used under controlled conditions, their application in daily life cannot be assessed.

In addition, we found that feasible approaches to the implementation and integration of digital technologies for the rehabilitation process are lacking. Accordingly, it is essential to consider not only the effectiveness of the intervention in terms of dedicated outcomes, the design of the intervention itself, and the characteristics of individuals but also the setting in which the approach will be applied, the process of implementation, and factors influenced by policies and government regulations [206].

Therefore, studies are required that present an effective and valid concept that can enable clients and health care professionals to apply digital technologies for (home-based) rehabilitation. This includes the presentation of plans for the modus of DR (blended therapy or replacing face-to-face therapy), the reimbursement of health care professionals, and cost coverage for the technologies needed by clients and rehabilitation units. Other issues must be addressed for a feasible implementation, such as privacy compliance, data protection, insurance coverage, and the assumption of responsibility and liability if harm occurs during remote or unsupervised rehabilitation.

The social distancing regulations enacted during the COVID-19 pandemic caused many clients and health care professionals to use DR, especially videoconferencing, apps, and web-based programs. Clients and professionals described their relatively high level of DR positivity along with improvements over the course of the COVID-19 lockdown. However, the question of whether this therapy model will continue to be accepted without exceptional circumstances remains.

The literature shows contrary results regarding the acceptance of digital interventions by clients and health care professionals [13,207]. However, it is noteworthy that many terminologies exist for *Digital Rehabilitation* that are associated with various technologies. It is likely that the acceptance rates of different technologies vary, which does not allow for a general statement about their acceptance among clients and health care professionals.

Through the COVID-19 pandemic, more training opportunities for health care professionals were offered to allow them to gain competence in the field of DR. To be adequately prepared for working life and systematize the acquisition of competencies,

health care professionals should already have acquired the necessary skills in higher education. Because DR technologies have already been implemented in rehabilitation, it is crucial that health care professionals are sensitized to the possibility of integrating digital options, acquire useful competencies, and have the ability to recognize which clients will benefit from this approach and then provide adequate assistance to them.

Although the pandemic was, in many ways, a driver of the use of DR, it also led to the rapid introduction of solutions that were not based on an efficient concept and left many questions unanswered with regard to realistic implementation. Therefore, careful planning with a phased, linear implementation approach is crucial for establishing sustainable DR practices that will last beyond the pandemic and have the potential to meet the challenges of rehabilitation in the future [208].

The results of this study paint a very broad picture of existing and emerging technologies in rehabilitation because a large number of records were included in the analyses, which were not limited to a specific target group or rehabilitation outcomes. The results derived from the scientific databases were complemented by a search of the gray literature. Through a meeting with key stakeholders, insights were gained beyond those reported in the literature. In addition to health care professionals, politicians, experts in the field of digitalization in rehabilitation, and clients with experience or a specific interest in DR were included.

Limitations

Bibliometric and co-occurrence analyses were performed with a minimum of 10 occurrences per keyword. This may have influenced the completeness of the representation of technologies if newer technologies occurred fewer than 10 times throughout the data set. However, the stakeholder meeting served to close this gap. Moreover, we did not weigh the strength of the evidence from all papers or appraise the efficacy of the approaches, which would have been beyond the scope of this

review. In addition, new technologies may have been developed in the meantime and were not presented here because of the rapid development of the market.

In the search for relevant literature, we used the word “rehabilitation” and not other terms commonly used in the context, such as “therapy,” “training,” “intervention,” or “treatment,” because we wanted to stick to the concept of rehabilitation, which implies a multimodal, collaborative, and patient-centered process rather than the stand-alone interventions suggested by those terms [209]. However, it resulted in few articles being included related to mental and psychosocial disorders, despite the Cochrane definition of rehabilitation states that rehabilitation also includes people with mental problems [209]. Thus, rehabilitation seems to be still more closely associated with the improvement or optimization of physical functions.

Conclusions

These findings reflect the growing interest in the use of digital technologies in rehabilitation. Multiple tools are already available and implemented for home-based rehabilitation; however, there are some limitations to their use, such as low usability, safety concerns, ethical challenges, and a lack of efficacy and legal frameworks. DR implementation should be based on the clients’ goals and motivation. AI and machine learning could be of particular interest in redesigning rehabilitation to address future challenges in the rehabilitation sector.

On the one hand, the pandemic acted as a driver for the application and acceptance of existing digital solutions in rehabilitation. On the other hand, digital solutions that only met the requirements of the clients during the pandemic were implemented. The results of this research reflect the need for feasible and effective approaches to implement DR sufficiently to meet clients’ needs and adhere to framework conditions to be sustained apart from exceptional situations.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist. [[PDF File \(Adobe PDF File\), 506 KB - rehab_v10i1e43615_app1.pdf](#)]

Multimedia Appendix 2

Search strategies.

[[DOCX File , 16 KB - rehab_v10i1e43615_app2.docx](#)]

Multimedia Appendix 3

Definitions.

[[DOCX File , 19 KB - rehab_v10i1e43615_app3.docx](#)]

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Abbreviations

AAL: ambient-assisted living

ADL: activity of daily living

AI: artificial intelligence

AR: augmented reality

BCI: brain-computer interface

COPD: chronic obstructive pulmonary disease

DIRENE: Competences for the new era of user-driven Digital Rehabilitation

DR: digital rehabilitation

IMU: inertial measurement unit

IoT: Internet of Things

MS: multiple sclerosis

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

RCT: randomized controlled trial

RIS: Research Information Systems

VR: virtual reality

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Original Paper

Using Wearable Technology to Quantify Physical Activity Recovery: Secondary Report From the AFTER (App-Facilitated Tele-Rehabilitation) Program for COVID-19 Survivors Randomized Study

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Abstract

Background: Knowledge on physical activity recovery after COVID-19 survival is limited. The AFTER (App-Facilitated Tele-Rehabilitation) program for COVID-19 survivors randomized participants, following hospital discharge, to either education and unstructured physical activity or a telerehabilitation program. Step count data were collected as a secondary outcome, and we found no significant differences in total step count trajectories between groups at 6 weeks. Further step count data were not analyzed.

Objective: The purpose of this analysis was to examine step count trajectories and correlates among all participants (combined into a single group) across the 12-week study period.

Methods: Linear mixed models with random effects were used to model daily steps over the number of study days. Models with 0, 1, and 2 inflection points were considered, and the final model was selected based on the highest log-likelihood value.

Results: Participants included 44 adults (41 with available Fitbit [Fitbit LLC] data). Initially, step counts increased by an average of 930 (95% CI 547-1312; $P < .001$) steps per week, culminating in an average daily step count of 7658 (95% CI 6257-9059; $P < .001$) at the end of week 3. During the remaining 9 weeks of the study, weekly step counts increased by an average of 67 (95% CI -30 to 163; $P < .001$) steps per week, resulting in a final estimate of 8258 (95% CI 6933-9584; $P < .001$) steps.

Conclusions: Participants showed a marked improvement in daily step counts during the first 3 weeks of the study, followed by more gradual improvement in the remaining 9 weeks. Physical activity data and step count recovery trajectories may be considered surrogates for physiological recovery, although further research is needed to examine this relationship.

Trial Registration: ClinicalTrials.gov NCT04663945; <https://tinyurl.com/2p969ced>

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KEYWORDS

Fitbit; steps; COVID-19; hospitalization; rehabilitation; digital health intervention; physical activity; step count; mHealth application; tele-rehabilitation

Introduction

Low physical functioning and physical inactivity are observed among people who were hospitalized with severe COVID-19 [1,2]. Understanding how COVID-19-related hospitalization and subsequent rehabilitation impacts postdischarge physical activity trajectories may inform prognosis and care.

Few studies have detailed data on physical activity levels after SARS-CoV-2 infection and hospitalization. A large-scale population-based study found that those who previously reported performing aerobic and muscle strengthening activities that met or surpassed physical activity recommendations in the 2 years prior to the COVID-19 pandemic had a lower risk of infection, severe illness when infected, and COVID-19-related death [3]. Another longitudinal study found a link between persistent symptoms and significantly decreased self-reported walking times at 3 and 6 months after symptom onset when these walking times were compared to preillness estimates [4].

Wearable fitness trackers, including smartwatches, enable objective, continuous, long-term monitoring and have various applications in health care settings, such as health monitoring and medication adherence monitoring [5]. However, research examining the use of wearables to monitor COVID-19 survivors' physical activity over the course of recovery is limited. To our knowledge, a study conducted by Hunter et al [1] is the only study that has used smartwatches to assess step count changes in COVID-19 survivors following critical care hospital admission. They found that, on average, participants took 4359 steps per day in the first month after discharge and that their average step counts increased by 37% between discharge and 3 months after hospitalization and by 82% at 1 year after discharge when compared to baseline [1].

The AFTER (App-Facilitated Tele-Rehabilitation) program for COVID-19 survivors was a pilot study that randomized participants to either education and unstructured physical activity or a telerehabilitation program following discharge for COVID-19-related hospital admissions [6]. Step count data were collected as a secondary outcome, which was specified a priori as the change in average daily step counts from baseline to 6 weeks. As reported in the primary trial paper, we found no significant differences in total step count trajectories between groups at 6 weeks [6]. Since little is known regarding step count recovery after COVID-19 illness, we sought to further investigate these data across the entire study period (12 weeks). The purpose of this analysis was to examine step count trajectories and correlates among all participants (combined into a single group) across the entire study period. We hypothesized that upon discharge, participants' baseline step counts would be below those of healthy adults, with continued improvements observed across the 12-week study.

Methods**Data, Sample, and Outcome Measures**

A detailed description of the AFTER study methods can be found elsewhere [6]. Briefly, the AFTER trial randomized participants (N=44) in a 2:1 ratio to either (1) one-on-one sessions (n=12) of telerehabilitation that were delivered remotely by a physical therapist (n=29) or (2) a comprehensive educational handout that covered domains of COVID-19 recovery, including physical activity, sleep, and cognitive health (n=15). Participants in the AFTER trial had SARS-CoV-2 confirmed via polymerase chain reaction testing, were aged ≥ 35 years, had a hospitalization that lasted for ≥ 24 hours, were within 6 weeks of hospital discharge, and had internet access. The exclusion criteria were unstable medical comorbidities that precluded exercise, current pregnancy, or concurrent physical therapy during the study period. All participants received the Fitbit Inspire 2 activity monitor (Fitbit LLC) and a Kindle Fire tablet (Amazon Inc) with preloaded Fitbit software and the Health in Motion app (Blue Marble Health), which provided physical function testing, a health diary, education, and exercises. Participants were instructed to wear the Fitbit on their wrist at all times (except when charging). Research team members checked the synced accounts and reminded participants to wear their Fitbit during the physical therapy sessions (experimental group) and weekly check-in calls (control group). Participants were provided with the passwords for their web-based accounts for activity monitoring; the research team also had access to these accounts. Step counts were calculated by using the standard Fitbit algorithm. Data from each participant's Fitbit account were downloaded and used in the data analysis.

The education and exercise components of the app were only prescribed to the intervention group, although participants in the control group could access educational modules and physical function testing on their own.

Ethics Approval

The AFTER trial was approved by the University of Colorado Institutional Review Board (reference number: COMIRB 20-2415) and registered on ClinicalTrials.gov (trial number: NCT04663945).

Statistical Analysis

We analyzed all participants, who were combined into a single group. Linear mixed models with random effects were used to model daily steps over the number of study days. Models with 0, 1, and 2 inflection points were considered, and the final model was selected based on the highest log-likelihood value. The final model included a random intercept and random effects on both the pre- and post-inflection point trajectories. All participants with any synced Fitbit activity data were included. Model robustness was evaluated by reviewing results after excluding records with a daily step count beyond 2 SDs from

the participants' overall average. The adjustment variables considered in the analysis included treatment group, sex, age, and BMI. Baseline demographics and COVID-19 hospitalization information were presented by treatment group and were compared by using a chi-square test or the Mood median test, as appropriate. All statistical analyses were performed in SAS 9.4 (SAS Institute Inc); we assumed a significance level of $P < .05$, and there was no adjustment for multiple comparisons. R software (R Foundation for Statistical Computing) was used for all data cleaning, summary statistics, and graphics.

Results

Participants included 44 adults who enrolled between December 2, 2020, and July 2, 2021. Fitbit data were available for 41 participants, with a median of 78 (IQR 64-83) contributing days. [Table 1](#) presents participant characteristics.

The median age of participants was 53 (IQR 44-61) years, and 46% (19/41) were female. The median number of days that participants spent in the hospital was 4 (IQR 2-8), and 22% (9/41) of participants were admitted to the intensive care unit. The average length of time between hospital discharge and enrollment was 3.5 weeks. The median number of steps for the cohort at baseline was 4928 (IQR 3083-7574).

Although there was substantial variation in baseline step counts between and within individuals ([Multimedia Appendix 1](#)), in general, participants showed a marked improvement in daily

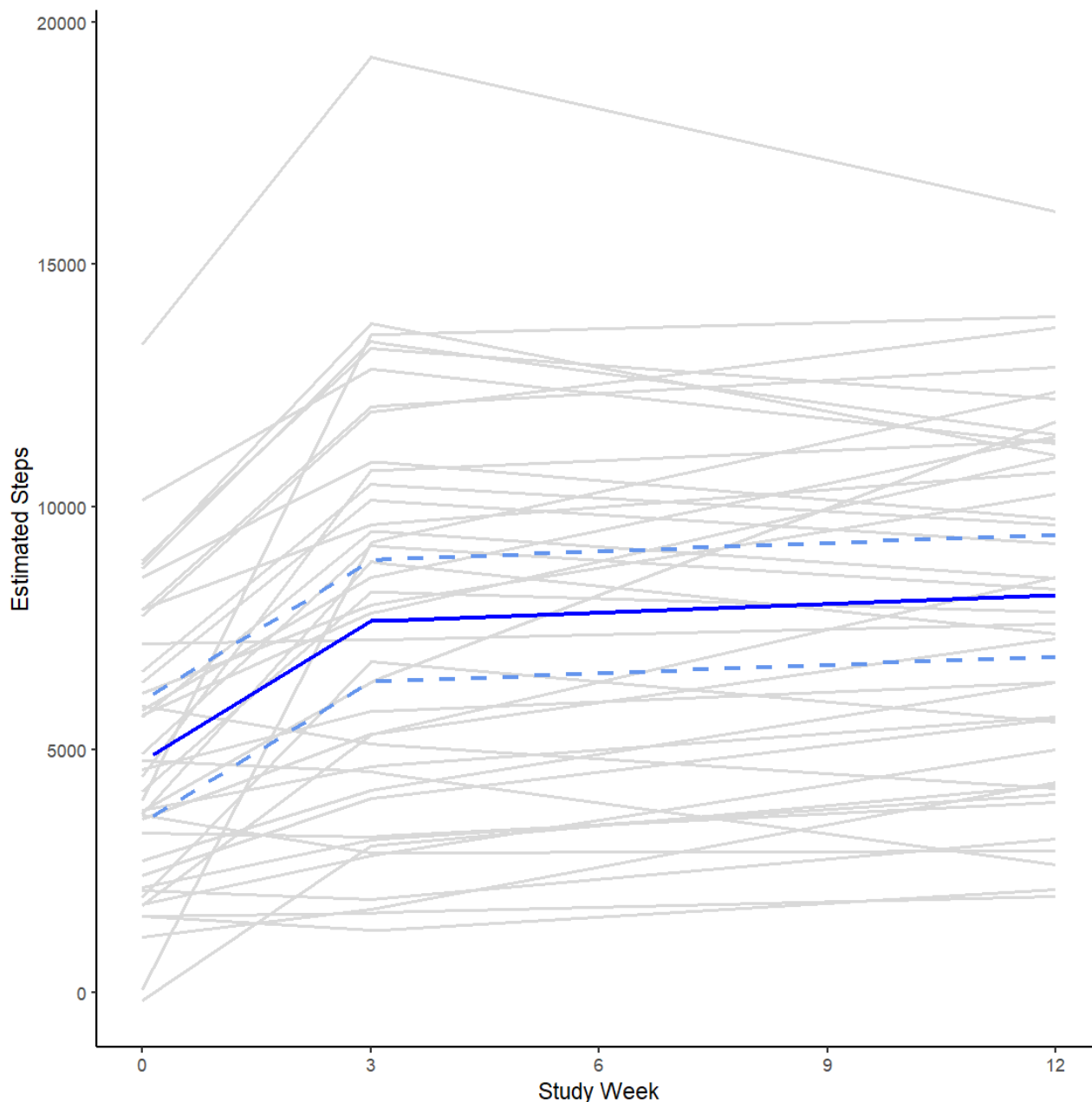
step counts during the first 3 weeks, followed by more gradual improvement in the remaining 9 weeks. Initially, step counts increased by an average of 930 (95% CI 547-1312; $P < .001$) steps per week, culminating in an average daily step count of 7658 (95% CI 6257-9059; $P < .001$) at the end of week 3. During the remaining 9 weeks of the study, weekly step counts increased by an average of 67 (95% CI -30 to 163; $P < .17$) steps per week, resulting in a final estimate of 8258 (95% CI 6933-9584; $P < .001$) daily steps ([Figure 1](#)). These results were minimally impacted when low step count days (defined as 2 SDs below the participants' geometric mean) were removed from the analysis.

Covariates that were considered potentially predictive of an increase in daily steps over the 12-week study period were put into a fully adjusted model, including sex, BMI, age, and treatment group. Given substantial variation in steps, differences between treatment groups and sex failed to reach statistical significance. Participants in the control group had a higher average daily step count (mean 866; 95% CI -932 to 2664; $P = .35$) compared to that of the intervention arm. Female participants had 1153 (95% CI -2887 to 581; $P = .19$) fewer daily steps compared to those of male participants. On average, older participants and those with a higher BMI had a lower daily step count. For every 1-year increase in age, the daily step count was lower by 67 (95% CI -159 to 25; $P = .15$) steps on average. Similarly, for every 1-point increase in BMI, the average daily step count was lower by 182 (95% CI -280 to -84; $P < .001$) steps.

Table 1. Demographic information (by treatment arm) of participants with available Fitbit data.

	Control group (n=14)	Intervention group (n=27)	All participants (N=41)	P value
Age (years), median (IQR)	52 (45-60)	53 (44-60)	53 (44-61)	.71
Sex, n (%)				.75
Female	6 (43)	13 (48)	19 (46)	
Male	8 (57)	14 (52)	22 (54)	
BMI (kg/m ²), median (IQR)	33 (27-40)	33 (28-38)	33 (28-38)	.91
Race, n (%)				.36
Black or African American	1 (7)	4 (15)	5 (12)	
White	7 (50)	17 (63)	24 (59)	
Other or multiracial	6 (43)	6 (22)	12 (29)	
Ethnicity, n (%)				.17
Hispanic or Latino	6 (43)	6 (22)	12 (29)	
Not Hispanic or Latino	8 (57)	21 (77)	29 (71)	
Hospital stay (days), median (IQR)	6 (3-8)	4 (2-7)	4 (2-8)	.16
Admitted into the hospital intensive care unit, n (%)				.39
Yes	2 (14)	7 (26)	9 (22)	
No	12 (86)	20 (74)	32 (78)	
Steps in week 1				.09
Missing data, n	1	2	3	
Number of steps, median (IQR)	6492 (4000-7783)	4412 (2274-6536)	4928 (3083-7574)	

Figure 1. Step count estimates during the 12-week study period from a linear mixed model. Individual participant projections are shown in light grey, and the population mean, with 95% CIs, is shown in blue. To compensate for different fitness levels, a linear mixed model with a random intercept and random slopes before and after the inflection point was used.



Discussion

Principal Findings

This study demonstrates that the largest improvements in step counts following recovery from COVID-19 occurred during the first 3 weeks after study enrollment. Both the intervention group and the control group demonstrated similar improvements in step count recovery. Despite the fact that the control group did not engage in any formal structured rehabilitation, the materials (including handouts, devices, and an app with a health diary) that were provided to the control group and the regular check-ins with the study team may help to explain the similar between-group results [7]. In the Hunter et al [1] study on the recovery of COVID-19 survivors, participants indicated that smartwatches motivated them to recover and increase their

physical activity levels. This is important, as the use of smartwatches is a relatively low-cost, low-burden, and easily implementable posthospital intervention.

Our study is among the first to report objective physical activity data (step counts) from COVID-19 survivors. In the only other study that we are aware of, Hunter et al [1] found that individuals who were recovering from COVID-19 and were admitted to a critical care unit had an average of 4359 (SD 3488) steps per day in the first month after discharge and increased their step counts to an average of 7914 (SD 4146) steps per day at 1 year ($P=.003$) [1]. In our study, participants had a similar median baseline step count of 4928 (IQR 3083-7574) at 1 week after study enrollment (mean 3.5 weeks after hospital discharge), which is below the targets for healthy adults (around 8000-10,000 daily steps) [8]. Our participants' average daily

step count was 7658 at 3 weeks after study enrollment, which is very similar to the 1-year follow-up estimates (mean 7914, SD 4146 steps) reported by Hunter et al [1], suggesting that the baseline level of activity may be achieved relatively quickly and maintained over the subsequent year. Like our study, Hunter et al [1] included an interventional component in which a subgroup of the cohort had their smartwatch data reviewed monthly by a multidisciplinary team, and rehabilitation goals were remotely communicated to the patients. This may have influenced step count recovery estimates for the overall cohort. An important distinction to note is that our study population was not restricted to patients who were admitted to the hospital and required critical care and ventilation [1]. Therefore, it is possible that the step count recovery in our study was accelerated in comparison and was more representative of a general population of individuals recovering after hospital discharge.

A limitation of our data set is that we do not have metrics regarding wear time for those who had Fitbit devices; thus, our

daily average step counts may not reflect true activity and may have been underestimated. Moreover, this trial occurred at a single center in Colorado; therefore, our results are most generalizable to similar populations. Finally, our sample is small, and a 12-week follow-up is considered short-term. However, given that this is the first study to report post-hospital discharge step count data from a heterogeneous group of COVID-19 survivors, we believe that our results are noteworthy.

Conclusion

Our findings, in combination with prior studies, suggest that physical activity data and step count recovery trajectories may be considered surrogates for physiological recovery, although further research is needed. Further, while activity trajectories may differ based on the presence or absence of post-COVID-19 conditions, monitoring changes over time can provide immediate, objective feedback to patients and support patient-specific goals in the return to prior levels of function following a hospitalization.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Daily Fitbit step counts for individuals over the duration of the study. Low step count days, in which the Fitbit device may not have been worn consistently, are highlighted.

[\[DOCX File, 620 KB - rehab_v10i1e43436_app1.docx\]](#)

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Abbreviations

AFTER: App-Facilitated Tele-Rehabilitation

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