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Original Paper

The Utility and Acceptability of a New Noninvasive Ventilatory Assist Device, Rest-Activity Cyclor-Positive Airways Pressure, During Exercise in a Population of Healthy Adults: Cohort Study

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Abstract

Background: Noninvasive ventilation has been demonstrated to benefit people who have moderate to severe chronic obstructive pulmonary disease during acute exacerbations. Studies have begun to investigate the effectiveness of noninvasive ventilation during pulmonary rehabilitation to improve outcomes for people with chronic obstructive pulmonary disease; however, the lack of portability and humidification of these devices means their use is limited, especially when performing activities of daily living. A new prototype device, RACer-PAP (rest-activity cyclor-positive airways pressure), delivers battery-operated positive airway pressure via a nasal interface while regulating nasal airway apportionment bias, removing the need for supplementary humidification. This device may offer people with chronic obstructive pulmonary disease an improved ability to participate in pulmonary rehabilitation and activities of daily living.

Objective: To assess the feasibility of exercising with the RACer-PAP in situ and the acceptability of the device during exercise in normal, healthy individuals.

Methods: A total of 15 healthy adults were invited to attend 2 exercise sessions, each 1 week apart. Sessions lasted approximately 1 hour and included 2 baseline 6-minute walk distance assessments, once with and once without the RACer-PAP in situ. Vital signs and spirometry results were monitored throughout, and spirometry was performed pre- and posttesting with RACer-PAP. Subjective questionnaires ascertained participant feedback on exercising with the device in situ.

Results: Of the 15 initial participants, 14 (93%) completed both sessions. There were no adverse events associated with exercising with the device in situ. There were no differences in vital signs or 6-minute walk distance whether exercising with or without the device in situ. There were small increases in maximum dyspnea score (on the Borg scale) when exercising with the device in situ (median score 2.0, IQR 0.5-3.0, vs 3.0, IQR 2.0-3.25). There were small increases in forced vital capacity following exercise with the RACer-PAP. None of the participants reported symptoms associated with airway drying. Participant feedback provided recommendations for modifications for the next iteration of the device prior to piloting the device with people with chronic obstructive pulmonary disease.

Conclusions: This study has shown RACer-PAP to be safe and feasible to use during exercise and has provided feedback for modifications to the device to improve its use during exercise. We now propose to consider the application of the device in a small pilot feasibility study to assess the safety, feasibility, and utility of the device in a population of people with moderate to severe chronic obstructive pulmonary disease.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12619000478112; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375477>

KEYWORDS

noninvasive ventilation; exercise; feasibility; humans; COPD; physiotherapy; pulmonary rehabilitation; rehabilitation

Introduction

Chronic obstructive pulmonary disease (COPD) is a term for progressive chronic lung diseases that cause airflow limitation, including emphysema, chronic bronchitis, and chronic asthma [1]. Based on large epidemiological studies, the global prevalence of COPD is estimated to be around 11.7% (95% CI 8.4%-15%), with around 3 million deaths occurring annually [2]. It is the fourth leading cause of mortality worldwide [1]. Guidelines for the management of COPD support a combination of interventions, including pharmacological therapy, smoking cessation, self-management of exacerbations, and pulmonary rehabilitation (PR) to improve health outcomes. Pulmonary rehabilitation is widely considered the gold standard intervention in patients with COPD to reduce dyspnea, improve exercise capacity, and improve health-related quality of life (QOL) [3].

Noninvasive ventilation (NIV) has been demonstrated to benefit people who have moderate to severe COPD during acute exacerbations and can help to reduce respiratory rate, mortality and intubation rates, and improve arterial oxygenation [4,5]. Studies have begun to investigate the effectiveness of NIV during exercise or PR to improve outcomes for patients with COPD. A recent meta-analysis [4] investigating NIV during exercise training found that NIV may help people with COPD to exercise at a greater intensity and duration and to achieve better training results compared to exercise training alone or exercise with sham NIV.

Most NIV devices are impractical for undertaking everyday activities and exercise because they are large, heavy, expensive, and rely on an AC power source. A further problem with many devices is the lack of humidification of inspired gases, which can dry the airways and airway secretions and cause problems for people with COPD. Additionally, most devices use a face mask interface, which is often unacceptably claustrophobic during exercise for people with COPD [6]. A lightweight, portable, humidified NIV device with a more user-friendly interface has the potential to improve PR outcomes and impact the lives of those with COPD who are restricted in their day-to-day lives due to their reduced exercise tolerance and breathlessness.

The RACer-PAP (rest activity cyler-positive airway pressure) is an NIV device designed by author DW and his design team at the BioDesign Laboratory of the Auckland University of Technology, which specializes in biomedical engineering. The prototype device was originally designed to increase comfort for patients with sleep apnea. It has been safely tested in a small sample of this population and has been found to reduce drying of the airways and nasal congestion [7]. The prototype RACer-PAP operates on room air and works in a similar manner to a continuous positive airway pressure (CPAP) machine. CPAP

is a widely utilized form of NIV and has been shown to splint open the airways at end expiration, counter intrinsic positive end-expiratory pressure (PEEP), and reduce the work of breathing [6,8]. Use of CPAP during exercise has also been shown to reduce breathlessness and improve exercise tolerance in people with COPD [6,9,10]. However, while using CPAP, the nasal cycle (where one nostril periodically conducts a greater apportionment of tidal airflow than the other [11]) is abolished [12], leading to airway drying [13,14]. Current CPAP machines use supplementary humidification to prevent this airway drying, which is impractical if using the device during travel or mobility. The prototype RACer-PAP device delivers the same positive airway pressure to the nose as a CPAP machine while simultaneously regulating nasal airflow apportionment bias. This device effectively reinstates the body's natural air-conditioning and protection systems and removes the need for supplementary humidification [15]. RACer-PAP technology, if acceptable to people with COPD, may be useful for applying positive airway pressure during travel, exercise, and activities of daily living.

The prototype RACer-PAP uses nasal pillows (Figure 1) as the interface. While the nasal breathing cycle is not fully understood, it is thought that, under usual circumstances, one nostril allows more airflow to pass through than the other, with flow alternating between nostrils approximately every three hours [11]. This is caused by periodic unilateral obstruction by turbinate hypertrophy and is believed to aid in the removal of contaminants [11]. A unique feature of the RACer-PAP is that the device determines the natural flow-dominant nostril for each individual within its first few assisted breaths, and following this, the device ramps up to an operator-set positive pressure to ensure that the dominant nostril passes a higher airflow than the nondominant nostril. PEEP is adjusted to each person's comfort level, with a range from 6 to 20 cm H₂O, and accommodates each person's intrinsic PEEP [8]. This airflow bias between nostrils continues for a preset time, then switches, so that the other nostril receives the higher flow rate. This cycle time is predetermined by the therapist. The device can deliver up to 73 liters per minute of room air through each of the hoses (via each side of the nasal pillow), ensuring that the device is able to meet the high air flow demands of users, even during exercise. Through this process, the RACer-PAP device eliminates the need for supplementary humidification. The device can be battery operated, offering the convenience of treatment portability. We believe the RACer-PAP may have the potential to improve the ability of people with moderate to severe COPD to participate in PR and in activities of daily living. Prior to testing the acceptability, utility, and effectiveness of this device in people with COPD, the prototype RACer-PAP device requires evaluation in healthy volunteers.

Figure 1. RACer-PAP prototype in situ.



The aims of this study were to (1) assess the feasibility of exercising with the RACer-PAP prototype in situ; (2) investigate the utility and acceptability of the RACer-PAP prototype during rest and exercise; and (3) identify potential safety issues while utilizing the RACer-PAP prototype during exercise.

Methods

Ethics Approval

Ethical permission for the study was granted by the Health and Disability Ethics Committee of New Zealand on December 5, 2018 (study number 18/NTB/191). Institutional ethics approval was granted by the Auckland University of Technology Ethics Committee on April 15, 2019 (study number 19/129). The study was prospectively registered and approved on ANZCTR (ACTRN12619000478112) on March 22, 2019.

Study Design

This was a feasibility study to establish the utility and acceptability of the prototype RACer-PAP device during exercise in normal, healthy individuals. Participants individually attended 2 sessions at the Auckland University of Technology (Auckland, NZ) that were held a maximum of 1 week apart. At session 1, participants completed baseline screening and became familiar with the prototype RACer-PAP device and the 6-minute walk test (6MWT). At session 2, participants completed exercise testing with and without the prototype RACer-PAP in situ in

randomized order and provided feedback on exercise with the RACer-PAP. Both sessions were at a similar time of day (to negate circadian variability) and lasted a maximum of 1.5 hours.

Participants

Participants were purposefully selected to include a diversity of ages, sexes, and ethnicities. Subjects were included if they were healthy adults aged >25 years and were able to attend both scheduled sessions. Subjects were excluded if they had facial deformities, nasal polyps, or turbinate abnormalities, such as a sinus infection or other conditions, that might have influenced nasal airflow regulation; were unwilling to wear the device or unable to tolerate the nasal pillow interface; had a diagnosis of heart disease, high blood pressure, respiratory disease, or any illness or injury that impaired physical performance; had an active infection; had positive findings from the Physical Activity Readiness Questionnaire (PAR-Q) and Electronic Physical Activity Readiness Medical Examination (ePARmed-X+) risk assessment tools; were under advice from a medical practitioner to avoid exercise; had spirometry results indicating airflow obstruction, with a forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) ratio of less than 70% [1]; or were unable to understand written or spoken English (this study lacked funding for translators).

Procedures

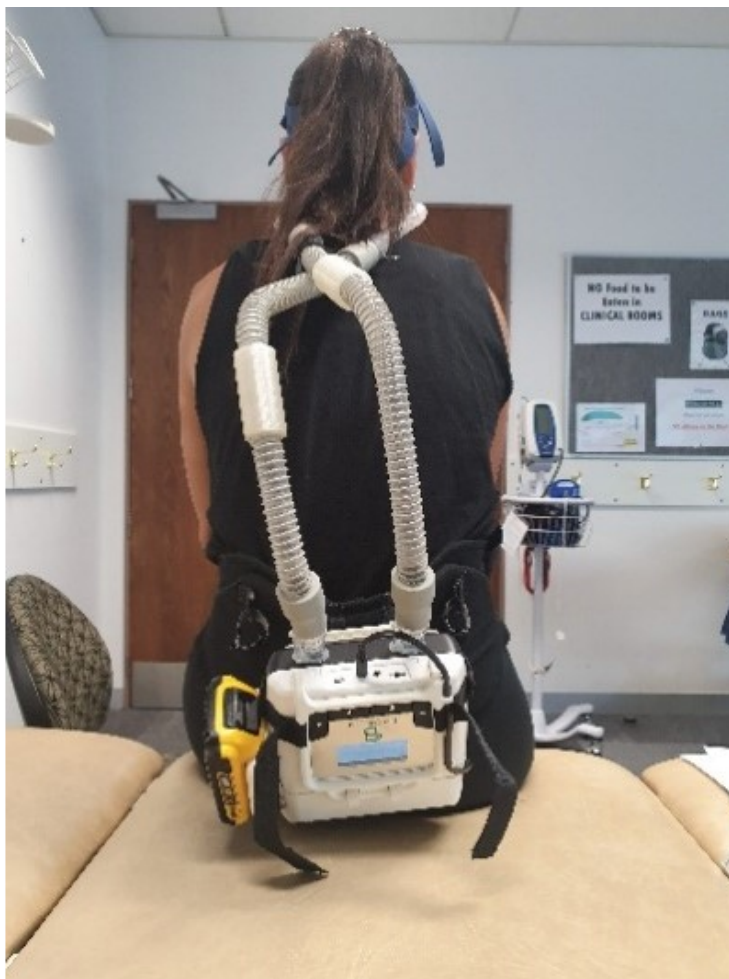
Two health care professionals were present at each session. The participants were screened for their suitability to participate using the PAR-Q risk assessment tool. If the PAR-Q result was positive, the participant completed an ePARmed-X+ [16] assessment to determine if they required referral to a medical professional for exercise clearance. If a participant was eligible to take part in the study, baseline screening of vital signs (heart rate, blood pressure, oxygen saturation) and spirometry (FEV1, FVC, and FEV1/FVC ratio) were undertaken. A trial 6MWT was undertaken following best practice guidelines [17]. This

was followed by a 30-minute rest and was then followed by a second 6MWT.

Following baseline testing, the participant was shown the RACer-PAP, the device was explained, and the participant was fitted with the device at rest and during exercise (see Figure 2, Figure 3, and Figure 4). The device was worn at rest for 10 minutes at a participant-selected PEEP level between 6 to 10 cm H₂O. The participant-selected PEEP level was noted for further testing purposes at session 2. Participants were instructed to nose breathe, if possible, but to mouth breathe when necessary.

Figure 2. RACer-PAP at rest (side view).



Figure 3. RACer-PAP at rest (posterior view).

Immediately following removal of the RACer-PAP, spirometry testing and vital sign measurement were undertaken and the “RACer-PAP at rest” questionnaire was completed. Participants were allocated their own RACer-PAP nasal interface and tubing, which were sterilized and used for both assessments. After 1 week, the participants underwent baseline testing of vital signs and spirometry (as per session 1) and then completed two 6MWT assessments, one with the PACer-PAP in situ, and one without. The order in which these assessments were undertaken was randomized using computer-generated numbers to wash out any order effect. The allocation of the first assessment was

stored in a sealed envelope and was either 6MWT with RACer-PAP in situ at the participant-determined comfortable PEEP level or 6MWT without RACer-PAP in situ. Immediately following the 6MWT, vital signs and spirometry were assessed. Participants then had a 30-minute rest, completed the second 6MWT, and underwent spirometry and vital sign measurements. The second RACer-PAP questionnaire (on exercise) was completed prior to the end of the session, when participants were encouraged to provide feedback through a Likert scale and an open-ended question requesting “any other comments.”

Figure 4. RACer-PAP during exercise.



Data Analysis

As this was a small feasibility study (N=15), the only reason to conduct statistical testing was to ascertain a measure of variance and within-subject differences. Demographic data were analyzed using descriptive statistics. Normally distributed data were described using the mean (SD) and nonnormally distributed data using the median (IQR). Data were analyzed for within-subject differences using paired-sample 2-tailed *t* tests to determine any differences in interval or ratio measures with and without the RACer-PAP in situ. The Wilcoxon signed-rank test was used to analyze nonparametric data. Results of the Likert scale questions about the acceptability and comfort of the device were collated, and open comments were themed for commonality.

Results

Participants

Fifteen participants were recruited via display posters at the Auckland University of Technology between December 2019 and December 2020. Fifteen participants attended session 1. One participant dropped out following session 1 (no reason for the dropout was given); thus, session 2 was attended by 14 participants. Although there was an 18-week study shutdown period in the middle of data collection due to COVID-19 lockdowns, the target sample size was achieved. The authors consider that the data from the sample of 15 participants is adequate to provide useful information about the feasibility, usability, and acceptability of this device [18]. Baseline characteristics of the participants are shown in [Table 1](#).

Table 1. Baseline characteristics of all participants (N=15).

Characteristics	Values
Sex, n (%)	
Female	6 (40)
Male	9 (60)
Ethnicity, n (%)	
New Zealander European	8 (54)
Māori	2 (13)
Asian	2 (13)
Pacific Peoples	1 (7)
European	1 (7)
Other	1 (7)
Age (years), mean (SD, range)	50.6 (12.6, 26-68)
Height (cm), mean (SD, range)	171.4 (9.2, 154-184)
Weight (kg), mean (SD, range)	79.7 (15.7, 51.9-105.8)
Resting heart rate (bpm), mean (SD, range)	74.2 (12.9, 55-100)
Systolic blood pressure (mm Hg), mean (SD, range)	127.9 (14.9, 105-152)
Diastolic blood pressure (mm Hg), mean (SD, range)	79.1 (8.4, 66-99)
Resting SpO ₂ (%), mean (SD, range)	97.4 (1.5, 95-100)
Forced expiratory volume in 1 second (L/min), mean (SD, range)	3.14 (0.77, 1.57-4.76)
Forced vital capacity (L/min), mean (SD, range)	3.95 (0.98, 2.28-5.87)
Forced expiratory volume in 1 second/forced vital capacity ratio, mean (SD, range)	0.79 (0.06, 0.69-0.92)
6-minute walk distance (meters), mean (SD, range)	651.3 (86.6, 490-751)

Outcomes

Table 2 shows outcomes following 6MWT with and without the RACer-PAP in situ at session 2. The Wilcoxon signed-rank test revealed a significant increase in maximum dyspnea

experienced during the 6MWT with the RACer-PAP in situ, with a moderate effect size ($r=-0.45$). A significant increase in FVC was seen following the 6MWT with the RACer-PAP in situ (Table 2). There were no significant changes in any other outcomes measured during this testing.

Table 2. Outcomes following 6-minute walk test with and without the device (rest-activity cyclers-positive airways pressure) in situ.

Outcome	Subjects, n	After test 1 (without RACer-PAP ^a)	After test 2 (with RACer-PAP)	Test statistic	P value
Six-minute walk distance (meters), mean (SD)	14	657.9 (109.5)	653.5 (103.4)	$t_{13}=0.274$.79
Forced expiratory volume in 1 second (L/min), mean (SD)	12 ^b	3.19 (0.68)	3.18 (0.79)	$t_{11}=0.237$.82
Forced vital capacity (L/min), mean (SD)	12 ^b	3.95 (0.98)	4.11 (1.02)	$t_{11}=-2.506$.03
Forced expiratory volume in 1 second/forced vital capacity ratio, mean (SD)	12 ^b	0.81 (0.11)	0.77 (0.03)	$t_{11}=1.294$.22
Resting heart rate (bpm), mean (SD)	14	87.1 (18.6)	91.3 (16.3)	$t_{13}=-1.537$.15
Systolic blood pressure (mm Hg), mean (SD)	8 ^b	129 (9.8)	132 (11.1)	$t_7=-1.240$.26
Diastolic blood pressure (mm Hg), mean (SD)	8 ^b	81.9 (5.1)	84.1 (6.3)	$t_6=-0.949$.38
Resting SpO ₂ (%), mean (SD)	14	97.8 (0.89)	97.6 (1.3)	$t_{13}=0.715$.49
Maximum dyspnea (Borg scale), median (IQR)	14	2.0 (0.5-3.0)	3.0 (2.0-3.25)	$Z=-2.41$.02

^aRACer-PAP: rest-activity cyclers-positive airways pressure

^bThe number of participants was lower for these outcomes, as data were unavailable due to equipment error, malfunction, or poor participant technique.

There were no adverse events at any time during the testing period and no participants asked for the RACer-PAP to be removed at any point. Participants were asked to select their own breathing pressure (range 6-10 cm H₂O). Six of 15 participants (40%) selected 6 cm H₂O pressure, 3/15 participants (20%) selected 7 cm H₂O, 4/15 participants (27%) selected 8

cm H₂O, and 2/15 participants (13%) selected 10 cm H₂O. The mean pressure selected was 7.3 (SD 1.4) cm H₂O.

Participants were asked to rate the utility and comfort of the RACer-PAP at rest and during exercise using a Likert scale. The results are shown in [Table 3](#) and [Table 4](#).

Table 3. Likert scale ranking of utility and comfort of the device (rest-activity cyclers-positive airways pressure) at rest (N=15).

Question	Scale	Participant ratings, n (%)					Rank mode (mean)
		1	2	3	4	5	
How easy was it to fit the device?	Very easy (1) to very difficult (5)	0	5 (33)	5 (33)	5 (33)	0	2 (2.93)
How do you find wearing the device?	Very comfortable (1) to very uncomfortable (5)	0	8 (53)	4 (27)	2 (13)	1 (7)	2 (2.63)
How would you rate the overall comfort of wearing this device?	Very comfortable (1) to very uncomfortable (5)	0	7 (47)	5 (33)	3 (20)	0	2 (2.7)
How well does the device fit at rest?	Very well (1) to not well at all (5)	1 (7)	9 (60)	3 (20)	2 (13)	0	2 (2.4)
How would you rate the comfort of the waist strap?	Very comfortable (1) to very uncomfortable (5)	3 (20)	7 (47)	1 (7)	2 (13)	1 (7)	2 (2.29)
How would you rate the overall comfort with the nasal mask whilst wearing this device?	Very comfortable (1) to very uncomfortable (5)	0	6 (40)	5 (33)	4 (27)	0	2 (2.77)
How do you rate the weight of the device?	Very light (1) to very heavy (5)	2 (13)	2 (13)	5 (33)	6 (40)	0	3 (2.93)
How would you rate your overall ability to breathe whilst wearing the device at rest?	Very easy (1) to very difficult (5)	1 (7)	4 (27)	5 (33)	5 (33)	0	3 (2.90)
How would you rate the dryness in your nose (mouth) whilst wearing the device at rest?	Very moist (1) to very dry (5)	1 (7)	3 (20)	9 (60)	1 (7)	1 (7)	3 (2.83)

Table 4. Likert scale ranking of utility and comfort of the device (rest-activity cyclor-positive airways pressure) during exercise (N=14).

Question	Scale	Participant ratings, n (%)					Rank mode (mean)
		1	2	3	4	5	
How did you find the weight of the device during exercise?	Very light (1) to very heavy (5)	0	4 (29)	5 (36)	4 (29)	1 (7)	3 (3.10)
How did you rate the overall portability of the device during exercise?	Very portable (1) to not portable (5)	4 (29)	3 (22)	1 (7)	5 (36)	1 (7)	4 (2.71)
How did you rate the overall comfort of the nasal mask during exercise?	Very comfortable (1) to very uncomfortable (5)	1 (7)	5 (36)	3 (22)	5 (36)	0	2 and 4 (2.82)
How did you rate the overall comfort of the waist strap during exercise?	Very comfortable (1) to very uncomfortable (5)	1 (7)	4 (29)	7 (50)	1 (7)	1 (7)	3 (2.75)
How do you rate your overall ability to move whilst exercising with the device compared to exercising without the device?	Much easier (1) to much harder (5)	0	0	3 (21)	11 (79)	0	4 (3.71)
How stable did the device feel during exercise?	Very stable (1) to very unstable (5)	0	7 (50)	5 (36)	1 (7)	1 (7)	2 (2.64)
How do you rate your overall ability to breathe while exercising with the device, compared to exercising without the device?	Much easier (1) to much harder (5)	0	0	0	11 (79)	3 (21)	4 (4.14)
How do you rate your overall ability to exercise with the device, compared to exercising without the device?	Much easier (1) to much harder (5)	0	2 (14)	2 (14)	8 (57)	2 (14)	4 (3.68)
How would you rate the dryness in your nose (mouth whilst wearing the device during exercise)?	Very moist (1) to very dry (5)	0	7 (50)	3 (21)	2 (14)	2 (14)	2 (2.93)

Open Comments

Participant feedback was obtained both at rest (during session 1) and following exercise (during session 2). At both time points, comments centered around 3 emergent themes: the device and related interfaces, the effect of the device on breathing, and recommendations for future use.

Session 1: Device and Related Interfaces (RACer-PAP at Rest)

The weight of the device was a dominant theme, with several participants describing the weight of the device as unfavorable. A smaller device was recommended to enhance the clinical utility of the device and allow future users to use the device more discreetly. Participants also suggested that shorter, less bulky tubing would be desirable. The nasal interface was described by a small number of participants as uncomfortable, causing their noses to become wet.

Session 1: Device Effect on Breathing (RACer-PAP at Rest)

Several participants commented on the effect of the device on their breathing. One participant reported that their breathing was easier, one reported that their breathing felt “strange,” resulting in increased awareness, one reported difficulty synchronizing their breathing at rest, and one person described the removal of the device as resulting in “...a wave of relaxed sensation lasting 5 seconds.”

Session 2: Device and Related Interface (RACer-PAP After Exercise)

The weight of the device was again considered too heavy and potentially cumbersome, with some participants recommending a smaller device. Participants found that the device bounced against the lower back, noting that improved stabilization of the device was necessary. Some participants felt that the belt with the device in situ felt “unbalanced,” requiring frequent adjustment. Some suggested that this might impact breathing or cause discomfort during exercise. Some comments noted that the tubing was too long and that the nasal interface was uncomfortable. A softer, smaller, more discreet interface was suggested for use during activities of daily living. Some participants also noted mild discomfort during exercise in relation to the air temperature: they experienced nostril dampness and their spectacles steamed up.

Session 2: Device Effect on Breathing (RACer-PAP After Exercise)

Several participants commented on the effect of the device on their breathing during exercise. For some, breathing required increased awareness and effort, especially during the expiratory phase. One participant described difficulty with nose breathing during exercise.

Recommendations for Further Use

Suggestions from participants included reduced device operating noise and a smaller, lighter device, which would be more discreet and aesthetically pleasing when undertaking activities.

They also suggested that improved portability and flexibility of the interfaces (tubing, head strap, and nasal interface) would improve the usability of the device. It was also recommended that the device be simple and compact, to ensure that individuals can assemble and put on the device independently.

Discussion

This small study found that in healthy individuals, exercising with the RACer-PAP in situ was safe, feasible, and acceptable to participants. Suggestions to increase comfort and utility of the device for exercise rehabilitation purposes and everyday activity were provided and will enable the development team to make ongoing modifications to the device.

Enabling people with respiratory disease to improve exercise capabilities, reduce dyspnea, and improve QOL has been the focus of PR for several decades. High quality evidence has shown PR to be a cornerstone intervention in achieving such outcomes [1], but patients with severe to very severe COPD may have difficulty achieving a sufficient training intensity with PR to achieve improvements in outcomes [19]. In a Cochrane review undertaken in 2014 [4], the use of NIV during PR was found to be safe; it improved exercise tolerance and dyspnea in a single treatment session, but evidence of improvement compared to controls was less consistent with longer-term training. It is currently unclear whether the demonstrated benefits of NIV during exercise training are clinically worthwhile or cost-effective [4]. The main limitations of the studies mentioned in a review by Menadue et al [4] were that NIV was applied only during exercise training, not during normal, day-to-day activities. Most devices lack portability and the ability to humidify during longer periods; these factors may also limit the use of NIV devices during PR. Additionally, the cost and time required to closely supervise exercise with such devices is prohibitive. The RACer-PAP, while still a prototype, offers a potential solution to overcoming these limitations and may provide patients with the ability to undertake activities of daily living in community settings due to its portability and humidification features. To our knowledge, this is unique in today's assisted ventilation market. Prior to testing the device in a population of patients with COPD, assessing the device in healthy individuals was necessary.

Our study has focused on assessing the feasibility and utility of this new novel assistive ventilatory device in healthy individuals during exercise, with a view to extending this to a population of people with COPD. The prototype device has previously been investigated and found to be safe in several populations (including in healthy people at rest and in those with sleep apnea) [7,20], but has not previously been tested during exercise. During this study, we observed no adverse events with the RACer-PAP during either rest or exercise. There were no significant differences between pre- and posttest results for any cardiovascular, oxygenation, or exercise tolerance measures. There was a significant increase in the participants' subjective assessment of their breathlessness during the 6MWT with the RACer-PAP in situ. While this difference was modest (a change in mean score of 2 to 3 on the Borg dyspnea scale), a change of 1 unit represents the minimal clinically important difference

for this scale [21]. This increase in dyspnea score while using the RACer-PAP during the 6MWT in healthy individuals was anticipated by the research team prior to the study. The research team expected that healthy participants might find the increased inspiratory flow and expiratory pressure uncomfortable during exercise testing. An increase in the perceived work of breathing was also reflected in the subjective comments by participants. At rest, participants reported that the device was comfortable, although 5/15 participants (33%) reported that breathing at rest with the device was "harder." During exercise, all participants (14/14, 100%) found it "harder" or "much harder" to breathe with the RACer-PAP, and 10 participants (10/14, 71%) rated their overall ability to exercise with the RACer-PAP "harder" or "much harder." All participants' dyspnea scores reverted to baseline within 2 minutes of ceasing the exercise test. All participants fully completed the exercise testing with the prototype RACer-PAP in situ and no participants requested the device be removed during the testing.

In people with COPD, it is possible that dyspnea and the perceived work of breathing may improve with the use of the RACer-PAP. One study of people with oxygen-dependent COPD found that using nasal high flow oxygen therapy (HFOT) increased tidal volume and end-expiratory lung volume and reduced respiratory rate at rest [22]. The mechanisms considered likely to be responsible for these changes were the probable reduction in anatomical dead space, the end-expiratory pressure of the HFOT device, and that the device functioned to match the participants' increased flow demands to the flow provided by the device, reducing the airflow resistance and work of breathing. We hypothesize that the RACer-PAP has the potential to be equivalent to humidified high flow therapy and optimum end-expiratory pressures, potentially offering a viable option for improving outcomes in people with COPD.

Interestingly, in this study, there was a significant increase in FVC following exercise with the RACer-PAP in situ. This was not accompanied by an increase in FEV1 or FEV1/FVC ratio. Nonetheless, the actual mean difference in FVC with and without RACer-PAP in situ was only 160 ml (95% CI 19 ml-295 ml), which is unlikely to be clinically significant in healthy adults. It is possible that this data is either spurious or dependent on improvement in participant technique; it requires ongoing evaluation.

The use of other types of NIV during exercise in people with COPD has shown an unloading of both the inspiratory and expiratory respiratory muscle pumps [23], with the reduction in dyspnea being proportional to the respiratory muscle unloading [24]. Similarly, improvements in gas exchange and breathing pattern [24-27] have been demonstrated. Improved regional muscle perfusion [28] and decreased exercise-induced lactic acidosis [28] have been shown with the use of NIV during exercise training, resulting in an associated reduction in symptoms of muscle fatigue [28,29]. We hypothesize that the RACer-PAP may also provide similar benefits to people with COPD.

Dynamic hyperinflation (DH) of the lungs occurs in people with COPD during exercise when inspiration is initiated prior to complete exhalation of the previous breath, resulting in an

increase in end-expiratory lung volume and subsequent restrictions on inspiratory capacity. Patients with airflow obstruction and subsequent gas trapping breathe at higher lung volumes, which requires a greater inspiratory effort to overcome elastic load. During exercise, an increase in respiratory rate, air trapping, expiratory flow limitation, and reduced expiratory time occurs. These changes can become significantly disabling and lead to exertional dyspnea. The use of strategies to reduce DH during exercise has been investigated, including pursed lip breathing, expiratory positive airway pressure devices, and NIV. A recent systematic review and meta-analysis [30] investigated the use of low-cost expiratory positive airway pressure (EPAP) devices, which increase resistance on expiration, increasing expiratory time and allowing for improved emptying of the lungs. While that study found that EPAP did not change DH, there was a reduction in respiratory rate. Limitations of the intervention included the use of face masks as the interface, a lack of additional inspiratory flow, no humidification, and that the EPAP levels were determined by the study authors, rather than by patient preference. It should be noted that if EPAP levels are too high, DH can increase dyspnea. Due to the low number of studies, low methodological quality, and small sample sizes of the studies in that review, further studies should be undertaken to assess the impact of EPAP on reducing DH and increasing exercise capacity in patients with COPD. The RACer-PAP offers an opportunity to further research in this area by offering a humidified, portable CPAP device with the addition of increased inspiratory flow to determine the impact on DH, exertional dyspnea, associated cardiovascular hemodynamics, and exercise capacity.

No limitations of the study design were identified by the research team. Several limitations related to the device were identified—participants' comments about the prototype

RACer-PAP highlight feasibility and utility issues. Prior to recruitment, participants were informed that the purpose of this initial study was to test the RACer-PAP during exercise in healthy individuals, with a view to determining the comfort and ease of use of the device prior to assessing the device in those with lung disease. Many participants commented on the device with this future objective in mind. It should be noted that none of the participants had previously used any form of positive pressure device and that their study experiences were not compared to any other NIV or positive pressure technologies. The participants made the following suggestions for future prototypes: reduce device weight and bulk, reduce length and size of tubing, improve device appearance (including the interfaces) to increase aesthetic discreetness when patients exercise or perform activities of daily living away from home, develop an alternative to the waist straps, increase the ease of self-administration of the RACer-PAP device, and develop an alternative to the current nasal interface.

Given the findings of this study, the research team hypothesizes that in those with COPD, the physiological effect of exercising with RACer-PAP in situ may reduce exercise-induced dyspnea, potentially leading to improvements in exercise and health-related QOL outcomes. We now propose to consider the application of the device in a small pilot feasibility study to assess the safety, feasibility, and utility of the device in a population of patients with moderate to severe COPD.

The current study has shown the prototype RACer-PAP to be safe and feasible to use during exercise in healthy participants. Further modifications to the device, as highlighted by the participants, are underway, and studies to assess the feasibility of use of the RACer-PAP with people with COPD have been proposed.

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Data Availability

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

Conflicts of Interest

DW is listed as co-inventor in the RACer-PAP patent.

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Abbreviations

6MWT: 6-minute walk test
BP: blood pressure
COPD: chronic obstructive pulmonary disease
CPAP: continuous positive airways pressure
DH: dynamic hyperinflation
EPAP: expiratory positive airways pressure
ePARmed-X+: Electronic Physical Activity Readiness Medical Examination
FEV1: forced expiratory volume in 1 second
FVC: forced vital capacity
HFOT: high flow oxygen therapy
HR: heart rate
NIV: noninvasive ventilation
PAR-Q: Physical Activity Readiness Questionnaire
PEEP: positive end-expiratory pressure
PR: pulmonary rehabilitation
QOL: quality of life
RACer-PAP: rest-activity cyclers-positive airways pressure
SpO₂: peripheral oxygen saturation

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Original Paper

Mobility-Focused Physical Outcome Measures Over Telecommunication Technology (Zoom): Intra and Interrater Reliability Trial

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Abstract

Background: Rehabilitation provided via telehealth offers an alternative to currently limited in-person health care. Effective rehabilitation depends on accurate and relevant assessments that reliably measure changes in function over time. The reliability of a suite of relevant assessments to measure the impact of rehabilitation on physical function is unknown.

Objective: We aimed to measure the intrarater reliability of mobility-focused physical outcome measures delivered via Zoom (a commonly used telecommunication platform) and interrater reliability, comparing Zoom with in-person measures.

Methods: In this reliability trial, healthy volunteers were recruited to complete 7 mobility-focused outcome measures in view of a laptop, under instructions from a remotely based researcher who undertook the remote evaluations. An in-person researcher (providing the benchmark scores) concurrently recorded their scores. Interrater and intrarater reliability were assessed for Grip Strength, Functional Reach Test, 5-Time Sit to Stand, 3- and 4-Meter Walks and Timed Up and Go, using intraclass correlation coefficients (ICC) and Bland-Altman plots. These tests were chosen because they cover a wide array of physical mobility, strength, and balance constructs; require little to no assistance from a clinician; can be performed in the limits of a home environment; and are likely to be feasible over a telehealth delivery mode.

Results: A total of 30 participants (mean age 36.2, SD 12.5 years; n=19, 63% male) completed all assessments. Interrater reliability was excellent for Grip Strength (ICC=0.99) and Functional Reach Test (ICC=0.99), good for 5-Time Sit to Stand (ICC=0.842) and 4-Meter Walk (ICC=0.76), moderate for Timed Up and Go (ICC=0.64), and poor for 3-Meter Walk (ICC=-0.46). Intrarater reliability, accessed by the remote researcher, was excellent for Grip Strength (ICC=0.91); good for Timed Up and Go, 3-Meter Walk, 4-Meter Walk, and Functional Reach (ICC=0.84-0.89); and moderate for 5-Time Sit to Stand (ICC=0.67). Although

recorded simultaneously, the following time-based assessments were recorded as significantly longer via Zoom: 5-Time Sit to Stand (1.2 seconds), Timed Up and Go (1.0 seconds), and 3-Meter Walk (1.3 seconds).

Conclusions: Untimed mobility-focused physical outcome measures have excellent interrater reliability between in-person and telehealth measurements. Timed outcome measures took approximately 1 second longer via Zoom, reducing the reliability of tests with a shorter duration. Small time differences favoring in-person attendance are of a similar magnitude to clinically important differences, indicating assessments undertaken using telecommunications technology (Zoom) cannot be compared directly with face-to-face delivery. This has implications for clinicians using blended (ie, some face-to-face and some via the internet) assessments. High intrarater reliability of mobility-focused physical outcome measures has been demonstrated in this study.

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KEYWORDS

reliability; mobile health; telemedicine; telehealth; rehabilitation; mobility; consultation; physical function; assessment; Zoom

Introduction

Globally, many people suffer from health conditions that require ongoing care from health professionals [1]. Telehealth can enable an effective and equitable service to help overcome current pandemic-induced and preexisting geographical and service-related barriers to accessing health care systems [2]. Telehealth is any health service that is being implemented or provided over telecommunication technologies [3], including assessment or service provision using audio, video, or app-based communication [4]. The provision of services via telehealth has rapidly increased over the last 2 years [5]; however, measurement of the effectiveness of such services in rehabilitation is hampered by the lack of research on the reliability of clinically relevant assessments, and in particular, mobility-focused physical outcome measures, recorded over telehealth technologies.

A handful of studies with small numbers of participants (less than 20) have included an element of mobility in their telehealth reliability measures; for example, Sit to Stand for patients with liver transplant [6], and Timed Up and Go for patients with knee arthroplasty [7], patients with Parkinson disease [8], and those with heart failure [9]. Validation of the reliability of a comprehensive suite of mobility-focused outcome measures delivered by telehealth is particularly relevant to rehabilitation services, where accurate assessment and tracking of changes in patient status, especially remotely, is crucial [10].

Given the likelihood and opportunity for ongoing growth of telehealth services, the reliability of mobility-focused physical outcome measures completed via telehealth technology is of interest and needs to be further explored, and the differences in these measures compared to face-to-face delivery need to be investigated. Simultaneous measurement of telehealth and conventional assessments has the advantage of ensuring that there is no potential for variance in the state of the patient [10]. In this study, we aimed to determine the reliability of several commonly used mobility-focused physical outcome measures when delivered via telehealth in a healthy population of individuals aged 18-60 years. The specific research questions addressed were the following:

- What is the interrater reliability of mobility-focused physical outcome measures assessed face-to-face and via Zoom, simultaneously?

- What is the level of agreement between mobility-focused physical outcome measures recorded face-to-face and via telehealth, simultaneously?
- What is the intrarater reliability of mobility-focused physical outcome measures recorded via telehealth?

Methods

Study Design

This was an observational measurement study designed to measure the reliability of mobility-focused physical outcome measures recorded using telecommunication technology. All testing was performed in a locked room to prevent disruption during data collection at the University of Tasmania, Launceston, Australia, between August and September 2021. The participant data collection area was a carpeted room, 10 meters long, with a standard-height chair (45 cm), a table, a laptop, and the equipment needed for each physical assessment: marker cones, handheld dynamometer, and measuring tape.

Participants and Recruitment

Participants were recruited via posters placed around the campus and emails from the university administration that provided information and contact details for the research staff. Inclusion criteria were the following: individuals aged 18-60 years, willing and safe to participate, as measured by the Adult Preexercise Screening System tool. Exclusion criteria were any ongoing illness or mobility issues that would prevent the ability to safely perform physical measures. A total of 30 participants met the inclusion criteria and participant recruitment ceased when the sample size was met.

Ethics Approval

The study protocol was explained to participants, and written informed consent was obtained prior to study entry. Ethical approval for the study was obtained from the University of Tasmania Human Research Ethics Committee (project ID 21690).

Sampling

A suite of 7 commonly used clinical and research mobility-focused physical outcome measures were assessed. Measures and the number of trials completed in the assessment are shown in [Table 1](#).

Table 1. Physical outcome measures assessed in the reliability study.

Measurement items	Number of trials
5-Time Sit-To-Stand Test [11]	2
3-Meter Walk Test [12]	2
4-Meter Walk Test [13]	2
Timed Up and Go Test [14]	2
Grip Strength Test [15]	3
Functional Reach Test [16]	3
Static Balance Test [12]	1

The 3-Meter Walk Test used a standing start, and the timing started when the telehealth researcher said “go,” as this comprises part of the Short Physical Performance Battery protocol [12]. In contrast, the walking speed for measuring the 4-Meter Walk timing started when the participant passed a marker on the floor, so it was not dependent on the reaction of the participant to start and then the researcher to see that start (to record usual walking speed more closely).

Data Collection Process

Two researchers (MLB and FP) concurrently recorded the participant’s performance in each outcome measure. MLB is a physiotherapist with 20 years of clinical experience, and FP is a postgraduate researcher with 3 years of experience in measuring these clinical outcome measures. One researcher was present in the room with the participant, while a second researcher provided the assessment instructions and recorded measurements via a standard Zoom meeting, in another room. The participant’s laptop (brand Dell; latitude 7480, with a 35-cm screen) was set up and connected to the remote evaluator, via a call through Zoom. All assessments were completed in view of the laptop’s camera. Concurrently, the researcher in the room with the participant, who had limited interaction with the participant and did not provide any instructions, also recorded results of each physical assessment independently. Both researchers recorded results for each assessment on a paper-based form, which was later transcribed into a database; they also took field notes on the quality of assessments and so as to capture any potential issues with the technology. The measures were performed in a random order to account for any participant fatigue and to reduce any ordering bias. Randomization was undertaken via a free web-based randomizer [17]. There were no time constraints on the participants performance for the duration of the assessment. Appointments were scheduled 30 minutes apart.

Statistical Analysis

Statistical analyses were undertaken using RStudio software (version 1.4; RStudio, PBC) [18] and tidyverse, blandr, ggplot2, and irr packages. Interrater reliability was determined between in-person (gold standard) and telehealth recorded results with a 1-way agreement intraclass correlation coefficient (ICC95), using the percentage method. If both raters recorded the same response, the ICC would be 100. For larger variations, the ICC

would be lower. Each test had repetitions of the trials analyzed together, with missed trials excluded from the data. The ICCs were rated as excellent (>90), good (75-90), moderate (50-75), or poor (<50) [19]. Bland-Altman plots were created to assess agreement and biases between researchers. Intrarater reliability was assessed between consecutive telehealth trials for all measures in the same session. A sample size of 30 participants was chosen a priori for this reliability study, based on previous reliability trials using Functional Reach outcome measure (ie, 3 trials for intrarater data collection) [20].

Results

Participant Characteristics

A total of 30 individuals (11 female, 19 male) with a mean age of 36.2 (SD 12.5) years were recruited. Of them, 21 participants identified English as their first language, whereas 9 identified English as their second language, with various first languages including French, Mandarin, and Persian. Among the participants, 22 were familiar with at least one of the assessments prior to the study.

Excellent interrater reliability was seen for Grip Strength and Functional Reach Test (Table 2 and Figure 1). For the timed tests, there was good reliability in 5-Time Sit to Stand and 4-Meter Walk, moderate reliability in Timed Up and Go, and poor reliability in 3-Meter Walk (Table 2 and Figure 2). Intrarater reliability was excellent for Grip Strength; it was good for Timed Up and Go, 4-Meter Walk, and Functional Reach Test (ICC=0.84-0.89); and moderate for 5-Time Sit to Stand (Table 3). The number of trials for the intrarater reliability was determined by the use of standard protocols for face-to-face evaluation.

Bland-Altman analysis indicated a bias for the timed tests with a reaction time dependent component (ie, there was a lag between the Zoom instructor saying “go” and the participant moving). These biases led to longer times for the following telehealth results: 5-Time Sit to Stand (1.2 seconds), Timed Up and Go (1.0 seconds), and 3-Meter Walk (1.3 seconds).

A ceiling effect was observed for the static balance task from the Short Physical Performance Battery, and interrater and intrarater reliability could not be calculated.

Table 2. Intraclass correlation coefficient (ICC) for interrater (1:1) and intrarater reliability measures..

Measurements	Total trials, n	Telehealth measures, mean (SD)	In-person measures, mean (SD)	ICC ^a (95% CI)	ICC ^b (95% CI)
5-Time Sit to Stand (s)	58	10.46 (2.10)	9.25 (2.09)	0.84 (0.75-0.90)	0.67 (0.42-0.83)
Timed Up and Go (s)	60	7.61 (1.13)	6.63 (1.07)	0.64 (0.47-0.77)	0.84 (0.70-0.92)
3-Meter Walk Test (s)	59	3.48 (0.41)	2.23 (0.40)	-0.46 (-0.64-0.24)	0.89 (0.79-0.95)
4-Meter Walk Test (s)	58	3.48 (0.54)	2.48 (0.45)	0.76 (0.62-0.85)	0.86 (0.72-0.93)
Functional Reach Test (cm)	86	36.37 (8.22)	36.17 (8.24)	0.99 (0.98-0.99)	0.86 (0.76-0.92)
Grip Strength (kg)	180	38.47 (9.95)	38.43 (0.97)	0.99 (0.99-0.99)	0.91 (0.42-0.96)
Static Balance Test (points)	30	12 (0)	12 (0)	NA ^c	NA

^aInterrater reliability of telehealth (Zoom) versus in-person trials.

^bIntrarater reliability between telehealth trials.

^cN/A: not applicable.

Figure 1. Interrater reliability and levels of agreement between in-person and Zoom measures for performance-based outcome measures.

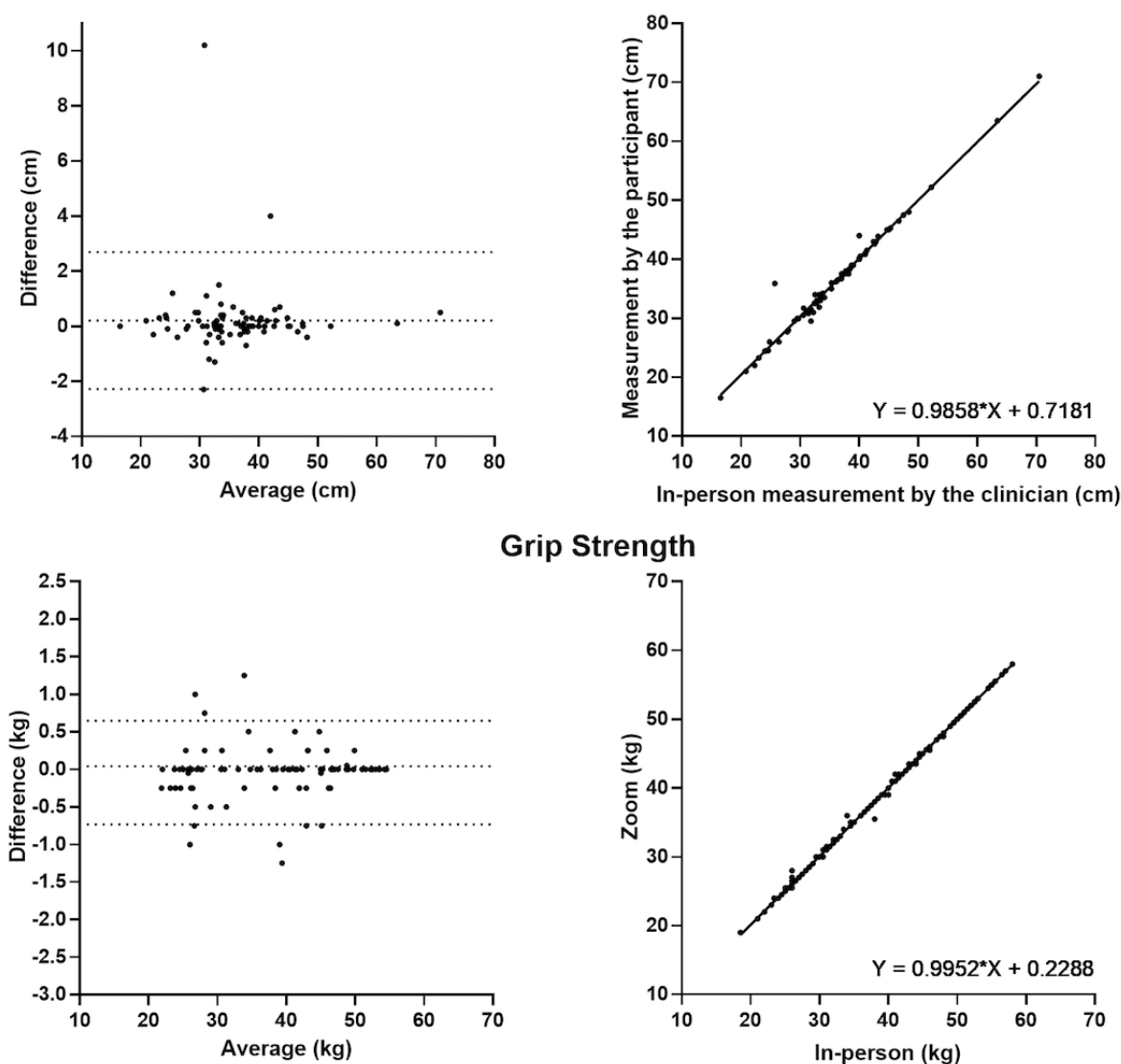


Figure 2. Interrater reliability and levels of agreement between in-person and Zoom measures for time-based outcome measures.

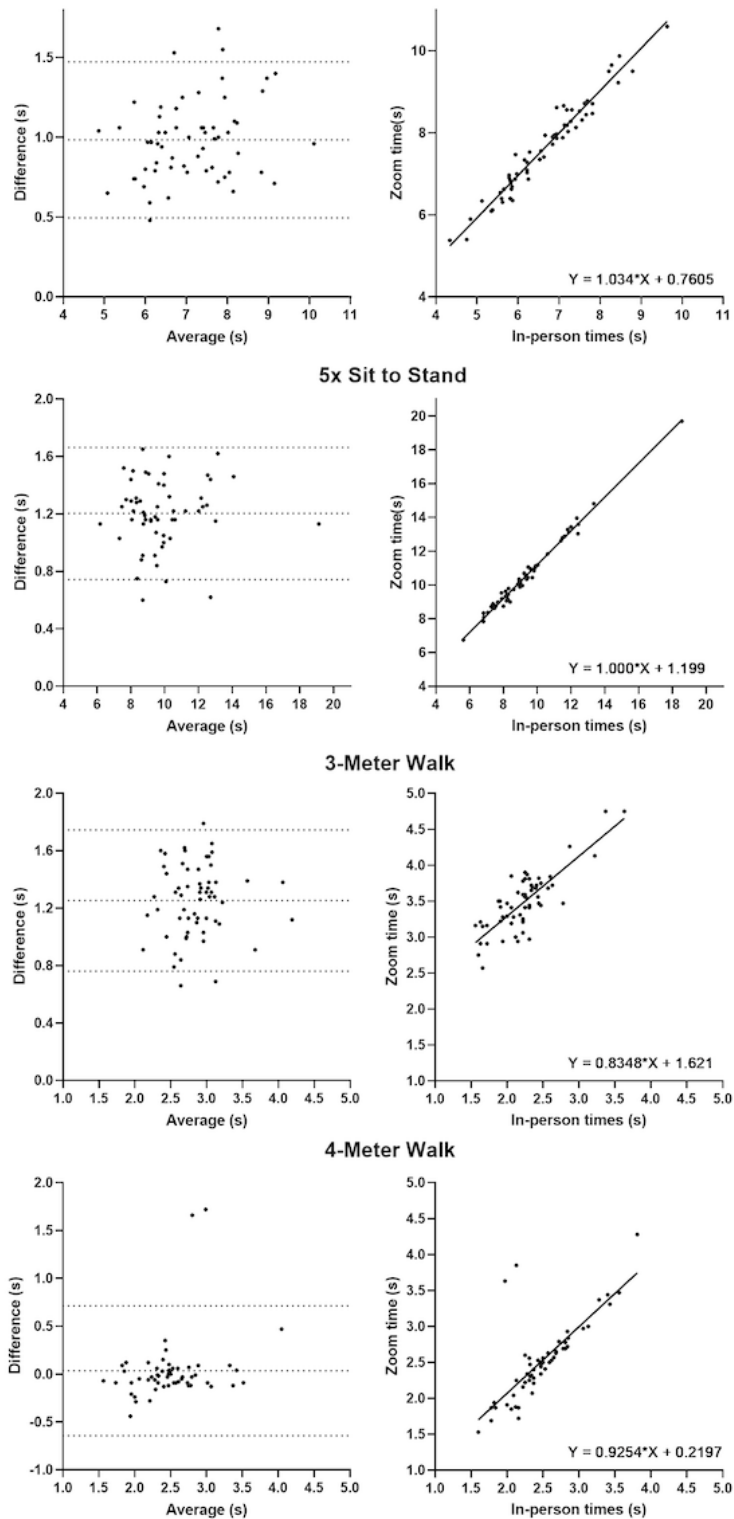


Table 3. Intrarater reliability of mobility-focused physical outcome measures recorded over telehealth technology (Zoom).

Assessment	Trial 1, mean (SD)	Trial 2, mean (SD)	Trial 3, mean (SD)
5-Time Sit to Stand (s)	10.82 (2.48)	9.92 (1.64)	N/A ^a
Timed Up and Go (s)	7.75 (1.23)	7.47 (1.02)	N/A
3-Meter Walk (s)	3.45 (0.42)	3.5 (0.40)	N/A
4-Meter Walk (s)	2.58 (0.58)	2.42 (0.50)	N/A
Functional Reach Test (cm)	35.58 (8.76)	36.63 (8.21)	37.44 (8.67)
Grip Strength (kg)	38.24 (9.92)	38.62 (10.20)	38.48 (9.90)
Static Balance Test (points)	12 (0)	N/A	N/A

^aN/A: not applicable.

Field Notes Describing Difficulties Encountered

The camera was in front of the participant for the walking tests and created some challenge for the remote evaluator due to depth perception issues. The remote evaluator recorded 3 instances of the camera freezing, which lasted less than 1 second. The angle of the laptop screen and integrated camera needed to be adjusted between some tests so that the appropriate body part could be seen. Instructions such as changing the chair orientation or distance from camera produced the correct adjustments, with instructions repeated only a couple of times by the remote evaluator. On 2 occasions, the in-person researcher, but not the telehealth researcher, noted that the participant lifted their heel during the Functional Reach Test. If the participant was further from the laptop, it was harder to hear their responses to questions. No adverse events such as pain or falls occurred during assessments. Two participants attended without their glasses and made small errors in reading the results from the Grip Strength dynamometer and the ruler on the Functional Reach Test.

Discussion

Principal Findings

Comparing telehealth to in-person assessments of strength, balance, and mobility resulted in reliability measures ranging from poor to excellent, depending on the type of assessment.

The results showed excellent reliability for Grip Strength and Functional Reach tasks; however, the reliability of mobility-focused physical outcomes assessed over telehealth, using Zoom, was poor to moderate compared to in-person assessments. Intrarater reliability for the Zoom assessments was moderate to excellent. For the Static Balance task, we could not conduct the interrater and intrarater reliability using the Bland-Altman analysis, due to a lack of data variability [21].

The interrater reliability was lower for measures that included a reaction time-dependent component, due in part to a time bias of longer times for telehealth recordings. Tests of a shorter duration were more impacted by the delay. Given the delay in some tests, caution is warranted when using traditional face-to-face assessments in a telehealth setting, and further information on the reliability and normative values of these assessments when delivered via telehealth is needed.

Comparison With Prior Work

In this study, the assessments conducted via telehealth that were performance-based rather than time-based were extremely reliable and consistent. The highest reliability tests included the Grip Strength and Functional Reach Tests with excellent interrater reliability (ICC=0.99) in a telehealth setting, compared to in-person results. This finding is consistent with previous feasibility assessments and questionnaire-based reliability assessments [22] and is not surprising, given these assessments are not subject to any time delays over telehealth [23]. Practitioners can be extremely confident in the use of these assessments via telehealth for clinical practice.

Time-based mobility measures that were reaction time dependent had less reliable results. For example, in the Timed Up and Go task, the telehealth researcher started the timer when they said “go” and stopped the timer when the participant returned to their seat. These aspects of the task could be affected by network latency and could potentially increase and add variability to the time measured by the telehealth assessor, and it may explain the longer times consistently recorded by the remote evaluator. This finding adds to data from two small studies that found longer times for Timed Up and Go, albeit of smaller magnitudes (around 0.4 seconds), in a population of people after total knee replacement [7] and heart failure [9]. In combination, these studies suggest that it is not possible to directly compare data collected in person and via Zoom for the same individual, as these values are in the same order or magnitude as the minimally important clinical difference (eg, 0.6 of a second as calculated at 0.5 SD) [24]. These differences in values between in-person and Zoom data collection reduces the ability to use population norms from face-to-face data collection in making decisions related to data collection via telehealth. For clinical populations, where the overall time to complete these assessments is longer, the impact of the small lag will be less, resulting in higher reliability.

The stability of the lag reported by the remote evaluator and whether or not it is dependent on bandwidth or other features of the technology used remains unknown. Further research to quantify lag time in remote sessions compared with in-person testing is warranted if practitioners plan to use blended models of health service delivery (eg, a mix of face-to-face and telehealth) in the future. Alternatively, to avoid the time lag issues that we identified over videoconferencing, future research

could investigate technologies that provide remote assessment without the need for timing over videoconferencing. For example, preliminary research is emerging regarding the use of mobile apps and body-worn sensor technology for walking and balance outcome measurement data in people who had a stroke [25].

Future Directions

Telehealth assessments produced moderate to excellent intrarater reliability between trials. The Timed Up and Go and walking tests all produced good intrarater reliability between telehealth trials. Clinicians who provide services only via telehealth can be confident in the reliability of these tests when delivered via telehealth. The 5-Time Sit to Stand produced moderate intrarater reliability. This reduced reliability was likely due to a learning effect as participants' second trial averaged 0.9 seconds quicker, which is consistent with previous reports [26]. Ensuring a practice trial is included before assessments would help reduce the learning effect between results in future research [27].

Strengths and Limitations

This trial has collected data using robust methods; these methods may be appropriate to use when collecting data in clinical populations; however, the results of this study cannot be generalized to those cohorts. It is a limitation that the impact of changes in the internet connection or bandwidth on latency is unknown, potentially impacting the reproducibility of these results. Other potential sources of bias that may have influenced the results include the familiarity of some participants with some of the assessment items, contamination of intrarater's second score, the difference in researchers' experiences, and the fact that we could not test the reliability over a range of scores as is more likely in clinical practice.

Recommendations

In this study, we identified considerations for practice to ensure high-quality and consistent telehealth assessments can be

completed. The bias in some measures (eg, longer times of around 1 second via telehealth) has implications for blended practice and needs to be considered when comparing real changes in functions between in-person and remotely measured assessments. Measuring network latency prior to starting the assessment may be needed to help identify and correct for telehealth time biases. Measuring walking speed remotely remains challenging. Potential improvements include using a side-on view for walking tests to reducing the impact of depth perception issues. Further to this, it should always be ensured both parties can hear appropriately. External speakers or wireless headphones could assist in minimizing communication issues when the participant is at a distance from the computer. Lastly, the camera angle should be set in a way to show a participant's full body, wherever possible.

Conclusions

We provided important information on the reliability of mobility-focused physical outcome measures and recommendations of the utility of these measures for telehealth delivery. Practitioners can be very confident in undertaking performance-based measures based on our findings. Longer timed assessments produce the best reliability compared to shorter assessments. Consequently, practitioners should favor longer timed tests and protocols that do not depend on reaction times of the participant for the most optimal and consistent results. Further research is needed with clinical populations to assess reliability of the measures included in this study, with an appropriate balance assessment for the intended population. The biases detected in reaction time-dependent tests indicate that direct comparison with face-to-face delivery and comparison to normative data collected face-to-face cannot be made. High intrarater reliability of mobility-focused physical outcome measures have been demonstrated in this study.

Acknowledgments

All authors contributed to the development of the manuscript and review of the final submission. The study was conceptualized by MLB, NAF, ER, DBS, DAC, CM, KDKA, BMS, and CE. FP and MLB undertook the data collection. KDKA and MS assisted FP with data analysis.

Data Availability

Data is available from corresponding author on reasonable request.

Conflicts of Interest

ER discloses ownership interest in Hydro Functional Pty Ltd.

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Abbreviations

ICC: intraclass correlation coefficient

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Original Paper

Assistive Robots for Patients With Amyotrophic Lateral Sclerosis: Exploratory Task-Based Evaluation Study With an Early-Stage Demonstrator

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Abstract

Background: Although robotic manipulators have great potential in promoting motor independence of people with motor impairments, only few systems are currently commercially available. In addition to technical, economic, and normative barriers, a key challenge for their distribution is the current lack of evidence regarding their usefulness, acceptance, and user-specific requirements.

Objective: Against this background, a semiautonomous robot system was developed in the research and development project, robot-assisted services for individual and resource-oriented intensive and palliative care of people with amyotrophic lateral sclerosis (ROBINA), to support people with amyotrophic lateral sclerosis (ALS) in various everyday activities.

Methods: The developed early-stage demonstrator was evaluated in a task-based laboratory study of 11 patients with ALS. On the basis of a multimethod design consisting of standardized questionnaires, open-ended questions, and observation protocols, participants were asked about its relevance to everyday life, usability, and design requirements.

Results: Most participants considered the system to provide relevant support within the test scenarios and for their everyday life. On the basis of the System Usability Scale, the overall usability of the *robot-assisted services for individual and resource-oriented intensive and palliative care of people with ALS* system was rated as excellent, with a median of 90 (IQR 75-95) points. Moreover, 3 central areas of requirements for the development of semiautonomous robotic manipulators were identified and discussed: requirements for semiautonomous human-robot collaboration, requirements for user interfaces, and requirements for the adaptation of robotic capabilities regarding everyday life.

Conclusions: Robotic manipulators can contribute to increase the autonomy of people with ALS. A key issue for future studies is how the existing ability level and the required robotic capabilities can be balanced to ensure both high user satisfaction and effective and efficient task performance.

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KEYWORDS

amyotrophic lateral sclerosis; disability; disabled; disabilities; assistive robotics; human robot interaction; robotic manipulator; semi-autonomous control; motor independence; activity of daily living; daily need; everyday activities; activities of daily living; development; usability; user design; motor impairment; physical disability; robot; assistive technology; assistive device; Europe

Introduction

Background

Amyotrophic lateral sclerosis (ALS) belongs to the group of motor neuron diseases and is a chronic degenerative disease of the motor nervous system. Recent data indicate incidence of 0.6 to 3.8 and prevalence of 4.1 to 10.5 per 100,000 persons worldwide [1-3]. The average age of onset is between 58 and 63 years [4,5], with the youngest patients being aged between 20 and 30 years [1,6]. The male-to-female ratio shows a slightly high chance for men to develop the disease [6,7]. During the course of the disease, there is progressive loss of voluntary motor function, leading up to complete paralysis [5]. Leading symptoms of the disease include progressive muscle paresis, muscle atrophy, and muscle spasticity; however, body and sensory perception are not affected. The disease initially begins in an isolated muscle region and progressively spreads from there. The continuous loss of motor function owing to the disease leads to multiple limitations in manipulative abilities related to activities of daily living (ADLs), leading to high dependence and need for support in those affected. The corresponding support network usually consists of professional and informal caregivers who share the burden of the need to provide the necessary assistance and, at the same time, respecting and promoting the independence and self-determination of those affected [8-10]. In this context, assistive technologies and devices play a prominent role in the disease management among users who are affected [11]. According to the American Assistive Technology Act of 2004, assistive technologies and devices are defined as "...any item, device, or product system, whether commercially purchased, modified, or customized, that is designed to increase, maintain, or improve the functional abilities of individuals with disabilities" [12]. Currently, various assistive technology systems are in use to compensate for the loss of body function (eg, life support devices such as ventilators and feeding tubes, environmental control devices, orthotics, transfer devices, augmentative and alternative communication devices, and mobility aids such as powered and manual wheelchairs) [11,13]. However, in general, many of these technologies are highly specialized (task-limited assistive devices), with clearly defined and often nonmanipulative functional applications. ADLs, such as picking up and placing objects independently, preparing food, eating, and drinking, or independent personal hygiene can be addressed by these systems only to a limited extent, if at all. In this context, the use of assistive robotic manipulators is expected to have great potential in promoting independence and motor self-determination among people with functional limitations. Despite a high demand for assistive robotic manipulators in the target groups, currently, only a few systems are commercially available, and only a small proportion of those affected are provided with such systems. Reasons for this include technical, economic, and normative challenges and insufficient system implementation potential into existing care processes [14]. In contrast, there is low level of empirical evidence on the perceived usefulness and acceptance of the systems by the potential user groups [15,16]. The following section provides an overview of the current state of the art.

State of the Art

Research and development on assistive robotic manipulators to assist people with functional limitations dates back to the 1960s [16,17]. The key functionality of such manipulators is to promote the user's independence by compensating for functional limitations, especially with respect to the upper limbs. Driessen [18], who refers to robotic manipulators as rehabilitation robotic devices, divides them into three categories: (1) single-task robots, (2) workstations, and (3) wheelchair-mounted manipulators. Single-task robots are specialized to perform a specific task that is implemented as a predefined operational sequence in the robot controls and, as a result, can be retrieved using very simple input devices. Examples of commercially available single-task robots include various food intake assistance systems such as My Spoon (Secom), obi (Design LLC), and Bestic (CaminoCare). These systems provide a robotic arm with a spoon (in some cases, also a special plate for portioning the meal) and a simple interaction interface, which can be extended in most cases using individually designed controls. However, the potential for promoting independence is relatively low for single-task robots owing to the high degree of specialization and the required standardization of the operational environment. In contrast, robotic lightweight arms are used as stationary workstations or as manipulation aids attached to a wheelchair. Stationary workstations allow the user to detect various objects in a predefined manipulation area and to have the robotic manipulator pick them up and position them using predefined functions. Therefore, workstation systems have high flexibility with respect to the manipulation tasks, but remain limited to a fixed location. Wheelchair-mounted manipulators form the last category. These robot arms provide 6 df (7 df including the gripper) and are characterized by very slim and lightweight design [16,18-20]. Well-known and commercially available assistive robot arms for assisting people with mobility impairment are Manus, iARM (Exact Dynamics), and JACO and MICO (Kinova). These systems also have various mounting options that allow stationary use at a table or bed [19]. In addition, studies are investigating several other existing systems from the industrial setting and various prototypes; however, they have not entered the health care market [16]. Wheelchair-mounted manipulators can be used in various settings for different manipulation tasks.

The control of the systems is performed as teleoperation via a 3-axis joystick attached to the armrest of the wheelchair. The 3 df are thereby mapped to a subset of the Cartesian arm translation and wrist rotation control. To control the 7 df (3 df for movement in 3D space, 3 df for wrist movement, and 1 df for opening and closing gripper), the user must switch between different Cartesian levels [16,20].

Teleoperation by the user without specific autonomous behavior forms a control strategy that is less expensive as the user remains in charge, which reduces the complexity of the control system. Moreover, this approach offers high level of personal safety for the operation of the systems in highly unstructured and dynamic environments and in the immediate proximity of the user. In contrast, this control strategy is associated with high cognitive and physical efforts for people with physical impairments [16,18].

Against this background, current studies are investigating novel approaches to simplify the control system. The focus is on novel user interfaces (UIs) and the different possibilities of sensor fusion techniques for semiautonomous control [18,21]. In this context, Petrich et al [16] cite approaches in which participants use gestures or eye gazes to select objects that can be approached autonomously by the robot. Other interfaces for controlling robot behavior also involve electromyography, electroencephalography, and electrocorticography. As part of a systematic review of current approaches for the use of computer vision for semiautonomous control of robotic manipulators, Bengtson et al [21] highlighted three major challenges: (1) the need for adaptive semiautonomous control schemes that allow the user some control over the entire task process, (2) the handling of arbitrary objects through approaches that rely on specific grasping points and primitive shapes instead of predefined objects, and finally, (3) the precise sensing of the environment by considering different viewpoints.

In addition to the development of novel control approaches, the identification of relevant application areas in the everyday life of users who are affected is another field of research. The goal is to determine user-specific requirements for performance parameters to develop appropriate manipulation taxonomies [17,19,22].

Robot-Assisted Services for Individual and Resource-Oriented Intensive and Palliative Care of People With ALS

Robot-assisted services for individual and resource-oriented intensive and palliative care of people with ALS (ROBINA) is a research and development project funded by the German Federal Ministry of Education and Research. The aim of the project was to develop a semiautomatic robotic manipulator that can be controlled via a multimodal UI to support people with ALS in their independence in various ADLs. Related to this, another objective of the project was to relieve professional and informal caregivers from repetitive support activities.

Objectives

This paper summarizes the results of the final evaluation of an early-stage demonstrator developed within our project. The objective of the study was to identify the specific needs, preferences, and requirements of people with ALS for the development of a semiautonomous robotic manipulator to promote autonomy and independence in ADLs.

Methods

Overview

This investigation was conducted as an exploratory task-based laboratory evaluation study. Data collection was based on a mixed methods design comprising validated and self-developed questionnaires, standardized observation protocols, and semistructured interviews. The study was designed as a task-based evaluation, and the study duration was 2 weeks.

Laboratory Study Setting

Figure 1 shows the setup for the study. It was built around a 7-axis Panda manipulator (Franka Emika) with torque sensors in its joints that enabled it to interact sensitively with the participants. Moreover, the robotic system was equipped with a 2-fingered gripper. The functional modes of the gripper included opening and closing of the 2 fingers. Rotation of the gripper to align it with the manipulation object was not possible. The control software was based on the “Robot Operating System” [23], a software framework established in robotics research for developing complex applications. It combined open-source components and custom-developed enhancements into a state machine that managed the patients’ inputs and overall control flow. The robot was controlled over the provided Franka control interface that enabled a real-time bidirectional communication. Custom-built Robot Operating System controllers used and regulated the robot’s capabilities to mimic the physical appearance of a mechanical spring. The software ran as a distributed system on 3 PCs that communicated over a shared, closed network. In total, 2 of the PCs performed computationally intensive operations with real-time communication to the robot and red, green, blue, and depth (RGB-D) camera-based object detection in a Linux-based operating system (Ubuntu Desktop 16.04 Long Term Support; Canonical Foundation, Ubuntu Community). The software for control via the patient’s sensors ran on a tablet with Windows operating system. It was implemented as a locally communicating application for modern internet browsers and accessed via control units by the patients. These control units comprised a variety of input devices to best cover each participant’s capabilities, such as joysticks that were directly operated in the hand or attached to a gooseneck mount, a head control system (Smart Nav Natural Point), and an eye control system (Alea Technologies gmbh) that offered control when only eye gaze was available.

Figure 1. Evaluation setup of the robot-assisted services for individual and resource-oriented intensive and palliative care of people with amyotrophic lateral sclerosis system.



All inputs were mapped to a mouse pointer, with which the patients navigated the menus of the browser-based graphical user input (GUI) and controlled the robot. Different task scenarios (refer to the following section) were implemented as movement sequences that the participants could execute, pause,

reset, and customize to their needs by adjusting the parameters of the workflow (Figures 1-3). The system supported partial autonomy, such as face and lip detection during drinking and visual-based grasping of objects from a tabletop.

Figure 2. Graphical user interface for the scratching scenario, with customizable settings.

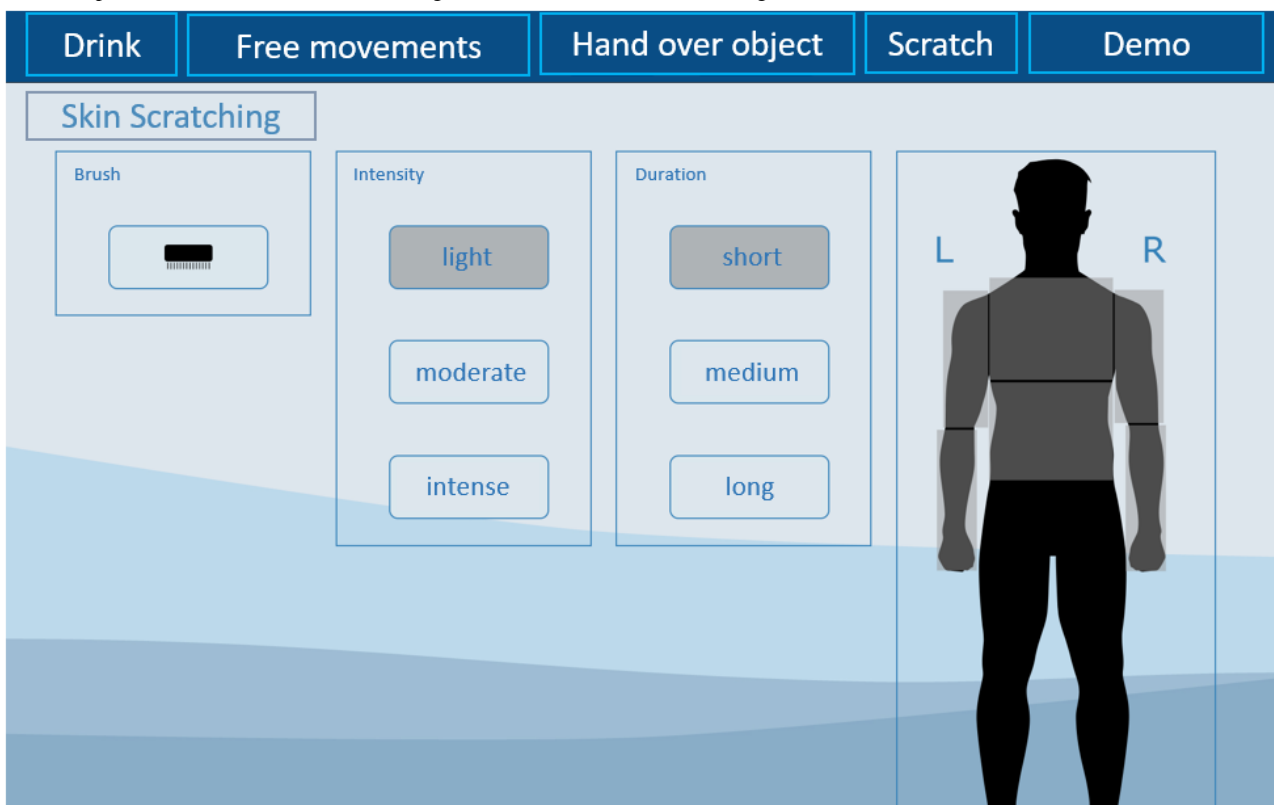
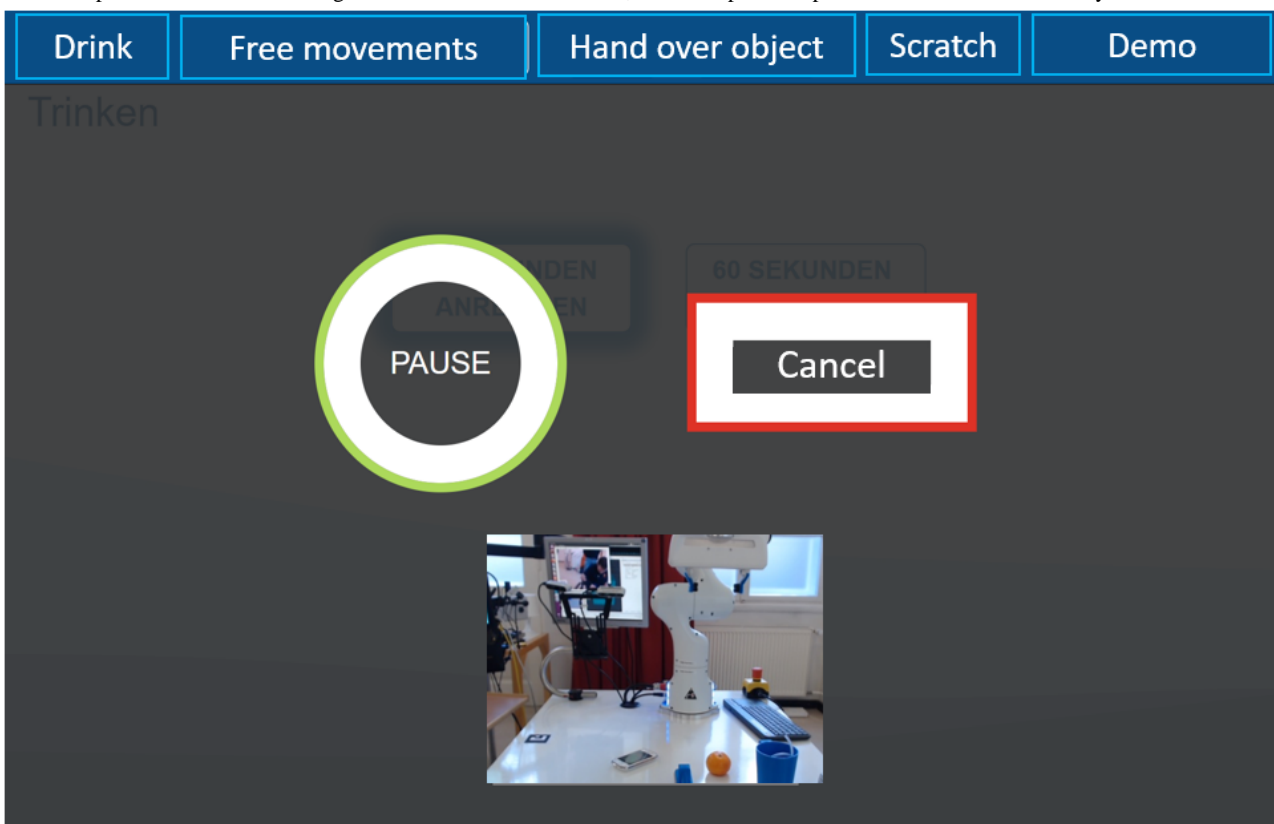


Figure 3. Graphical user interface during the execution of a robot action, with the options to pause or cancel the execution by the user themselves.



Evaluation Tasks

The different task scenarios for the evaluation are described in the following sections.

Serve a Drink

The robot system serves a cup with a silicone straw. After selecting the requested function via the UI, the robotic manipulator grips the cup autonomously with its 2-fingered

gripper. The movement to the user's mouth is determined from the calculated pose for the center of the mouth in relation to the tip of the straw. The robot autonomously leads the cup up to 10 cm from the mouth of the participant, by using visual mouth tracking. To drink, the participant must actively move their head toward the straw.

Hand Over a Mobile Phone

The study participant initiates the *hand over of a mobile phone* by clicking on the corresponding icon on the UI. Then, the robot system picks up and places the mobile phone autonomously in a predefined transfer zone. The phone is in a predefined pickup area, and the robot grasps the mobile phone autonomously with its end effector. It tracks the phone via visual object recognition.

Skin Scratching

The participant initiates the task by choosing the duration and intensity of scratching and the type of brush (Figure 2). The robot arm autonomously picks up the brush and then slowly approaches the human forearm. The forearm of the participant rests on an arm padding, which serves the robot system as position recognition. The robot sensors continuously check the contact between the brush and the human arm to adjust the robot movement in case of limb position changes. If contact is interrupted, time limit is exceeded, or execution is stopped by the user, the robot stops scratching, places the brush back on the table, and returns to its standby position.

Free Manipulation

In this task, the study participant can move the robot arm freely in a defined area and manipulate objects. For a standardized assessment of the task, the participants were asked to stack cubes on top of each other. The participant controlled all movements of the robot systems by clicking six direction levels (left, right, up, down, backward, and forward) and opening and closing the gripper on the UI.

Participants' Safety

Owing to the early-stage demonstrator status of the ROBINA system, risk analysis was conducted, defining necessary measures for participants' safety. Principal measures included conducting the evaluation under laboratory conditions and technical supervision by specially trained staff. Furthermore, except for the *scratching* scenario, the robotic arm could not reach the study participant at any time. In addition, formal and informal caregivers of the participants were included in the study to assist in the monitoring of their well-being and general condition. Moreover, a familiarization phase for the ROBINA system and evaluation task was conducted at the beginning. Another safety measure was a "Pause/Cancel" button on the UI, with which the participants could interrupt each scenario at any time. In addition, the correct execution was monitored by specially trained staff and could be interrupted by them immediately. All materials used were checked for sharp edges or damages, and participants were required to wear safety goggles throughout the testing procedure.

Ethics Approval

The ethics committee of the Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and

Humboldt-Universität zu Berlin approved the study (EA2/145/19). Moreover, the study was registered with the German Clinical Trials Register (DRKS00016554).

Study Population

Participants were recruited by the Geriatrics Research Group over a period of 4 weeks. The following were the inclusion criteria for the study: participants were aged ≥ 18 years and had clinically diagnosed ALS. To investigate the functional limitations that influence the operation of the ROBINA system, we used the ALS functional rating scale (ALS-FRS) [24], limited to the two questionnaire dimensions on limitations in speech and finger function.

In total, 11 individuals with clinically diagnosed ALS participated in the study. Of the 11 participants, 8 (73%) were male and 3 (27%) were female. The mean age was 57.1 (SD 5.9; range 51-70) years. In total, 73% (8/11) of the participants had their arms affected (arm paresis, tetraparesis, or similar conditions). Regarding the ALS-FRS dimension regarding speech, of the 11 participants, 4 (36%) participants showed no limitations, 5 (45%) showed mild to medium limitations, and 1 (9%) had lost the ability to speak. Regarding functional limitations of the fingers, of the 11 participants, 1 (9%) participant stated that they have no limitations, 6 (55%) mentioned mild to medium limitations, and 4 (36%) have severe limitation (ie, they were not able to press keys on a keyboard).

Study Procedure

Participants were contacted first via telephone and informed about the purpose and procedure of the study. After providing formal consent, they were invited to the research facility of the Geriatric Research Group.

As a first step, sociodemographic data and subdomains of ALS-FRS-Extended were recorded. Then, the most appropriate control device for operating the research demonstrator was selected with the assistance of an experienced project partner and set up according to the participant's needs (eg, head control, eye control, joystick, PC mouse, or ball mouse). In the second step, familiarization with the system and test scenarios was conducted. In this context, the experimental setup and procedure of the single scenarios, UI, robot actions, and required safety measures were presented. In addition, a functional demonstration of the system was performed to familiarize the users with the system.

Subsequently, the task-based evaluation phase was conducted, in which the study participants tested and evaluated each of the scenarios presented in the previous sections. During the execution, a standardized observation protocol was used to record the system and user errors and spontaneous expressions of the participants (think aloud). In addition, after each task, participants were asked to rate the system using a self-developed, standardized, and validated questionnaire (refer to the following sections).

Quantitative Evaluation

On the basis of a self-developed questionnaire, participants in the task-based intervention section of the study were asked to rate the categories of relevance to everyday life, usability, and

feeling of safety during task execution for each scenario on a 5-point Likert scale. Another item about the preference for human support over robotic support comprised 3 response

categories. The questions asked under each category are shown in [Table 1](#).

Table 1. Self-developed questionnaire to evaluate the robot-assisted services for individual and resource-oriented intensive and palliative care of people with amyotrophic lateral sclerosis system regarding usability.

Categories and questions	Response categories
Relevance to everyday life	
How relevant do you think the scenario is to your current everyday life?	1=very relevant to 5=not relevant
Usability	
How do you rate the operability with the control unit you use?	1=very easy to 5=very difficult
How did you feel about the speed of movement of the robotic manipulator?	1=very fast to 5=very slow
How did you feel about being [e.g., served a drink or scratched] by a robotic manipulator?	1=very comfortable to 5=very unpleasant
Feeling of safety during task execution	
How safe did you feel during the execution of actions in the...scenario?	1=very safe to 5=very unsafe
Preference for human assistance	
In the current scenario, would you prefer the assistance of a human to that of the robotic manipulator?	1=yes, 2=no, and 3=do not know

The general evaluation of the ROBINA system was based on the System Usability Scale (SUS) [25], which is a simple and technology-independent instrument for assessing the subjectively perceived usability of a technical system. The SUS comprises 10 items that are answered on a 5-point Likert scale. The answers of the users are transformed according to a recoding table and then summed up (percentile interpretation). The

possible score ranges from 0 to 100 points, whereby a score of 68 is required as a benchmark for at least good usability. A score of 100 corresponds to perfect usability.

In addition to SUS, a self-developed questionnaire was used to determine user perception in the following categories: feelings of anxiety during use, system size, and design of the graphical UI ([Table 2](#)).

Table 2. Self-developed questionnaire to evaluate the robot-assisted services for individual and resource-oriented intensive and palliative care of people with amyotrophic lateral sclerosis system regarding user perception.

Categories and questions	Response categories
Feeling of anxiety	
Have you been afraid during the testing of the robotic manipulator?	1=great fear, 2=little fear, and 3=no fear
System size	
How did you feel about the size of the robot manipulator?	1=too big, 2=appropriate, and 3=too small
Design of the graphical user interface	
How did you like the design of the graphical user interface?	1=very good to 4=very poor
How well could the elements be recognized on the graphical user interface?	1=very good to 4=very poor
How well did the robot performance meet your expectations towards task description in the graphical user interface?	1=very good to 4=very poor

Qualitative Evaluation

To gain deep insight into the subjective perception and evaluation of the ROBINA system, qualitative data were collected in 2 ways. First, from open-ended questions—regarding task-based evaluation, the participants were asked to state their preference for human or robotic assistance. In addition, they were asked about the aspects of each scenario that they like the most and those that they do not like at all. In the general evaluation, the participants were asked an open-ended question about the suggestions they had for improving the UI. Second, qualitative data were collected using observation protocols. As part of a think-aloud protocol,

participants' spontaneous expressions during testing were recorded; human and technical errors were also recorded.

Analysis

Quantitative data were analyzed descriptively using SPSS (version 28.0; IBM Corp) for Windows. Results are presented as medians, IQRs, and minimums and maximums as most of our data had an ordinal scale level or did not have a Gaussian normal distribution. Owing to the exploratory nature of our laboratory study, hypotheses and significance tests were not performed.

Qualitative results obtained from open-ended questions and observation protocols were analyzed using systematic structuring

content analysis, according to Mayring [26]. Considering the targeted study objective, the analysis included the paraphrasing of content-relevant text passages in the different materials. On this basis, the targeted level of abstraction was determined, and the paraphrases were generalized under that level. Subsequently, the first reduction of paraphrases with the same meaning was conducted through selection. In a further reduction step, paraphrases were pooled and integrated at the targeted abstraction level. To ensure data quality, these analysis steps were conducted by 2 trained researchers, who have experience with qualitative studies. The analysis steps of paraphrasing, generalization, and reduction were performed using Excel (version 2016; Microsoft).

Results

As mentioned in the previous section, the experimental setup included various input devices to best meet the abilities of each

participant. The following input devices were used to control the ROBINA system via the GUI within the four scenarios: eye control (1/11, 9%), normal PC mouse (3/11, 27%), ball mouse with switch (1/11, 9%), head control (5/11, 45%), and wheelchair joystick (1/11, 9%).

Task-Based Evaluation

In the following section, the results of the task-based evaluation of the ROBINA system are presented. In this context, the relevance of the evaluation scenario for the everyday life of the participants who are affected, usability (including ease of use of the control unit, speed of semiautonomous robotic movement, and subjective perception of the robotic support), feeling of safety, and preference for human support over robotic support are described. For better illustration of the results, they are also presented graphically (Figures 4-7). Finally, the presentation of each scenario ends with the participants' assessments obtained from the open-ended questions.

Figure 4. Aggregated presentation of the response distributions in the categories' relevance of the evaluation scenario (serve a drink) to everyday life, usability, feeling of safety during semiautonomous robotic behavior, and preference for human assistance over robotic assistance.

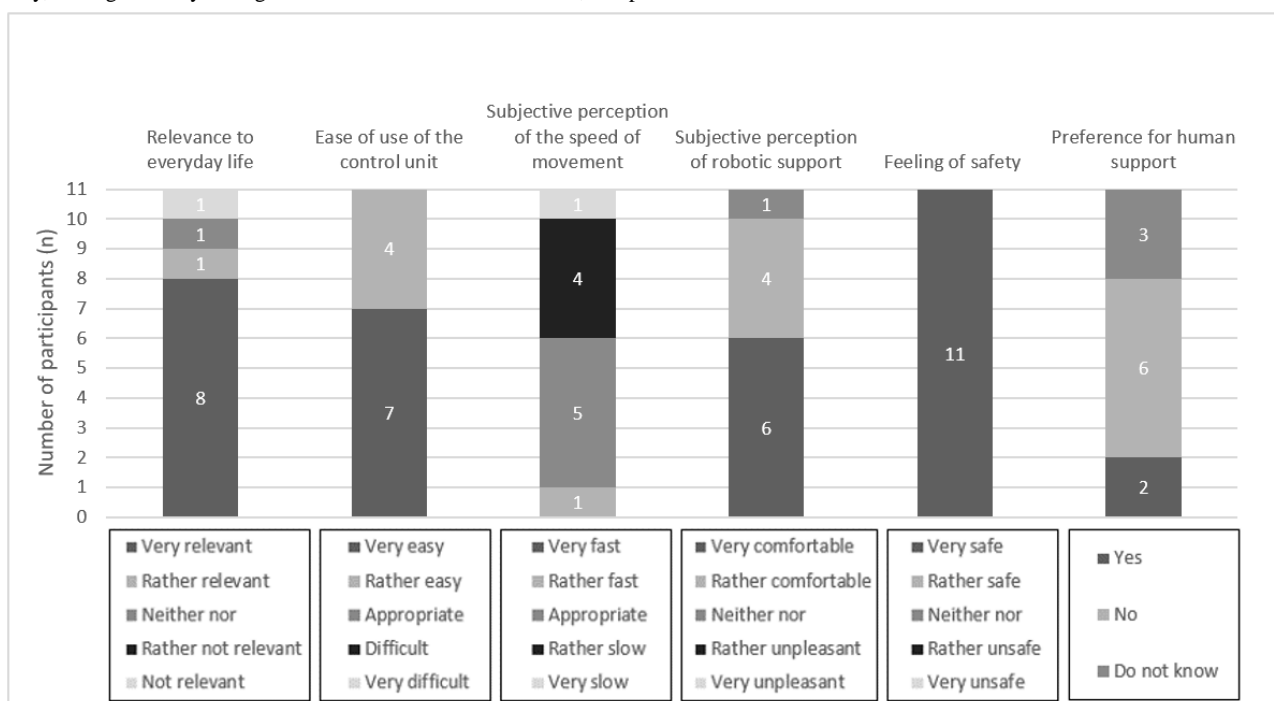


Figure 5. Aggregated presentation of the response distributions in the categories' relevance of the evaluation scenario (hand over a mobile phone) to everyday life, usability, feeling of safety during semiautonomous robotic behavior, and preference for human assistance over robotic assistance.

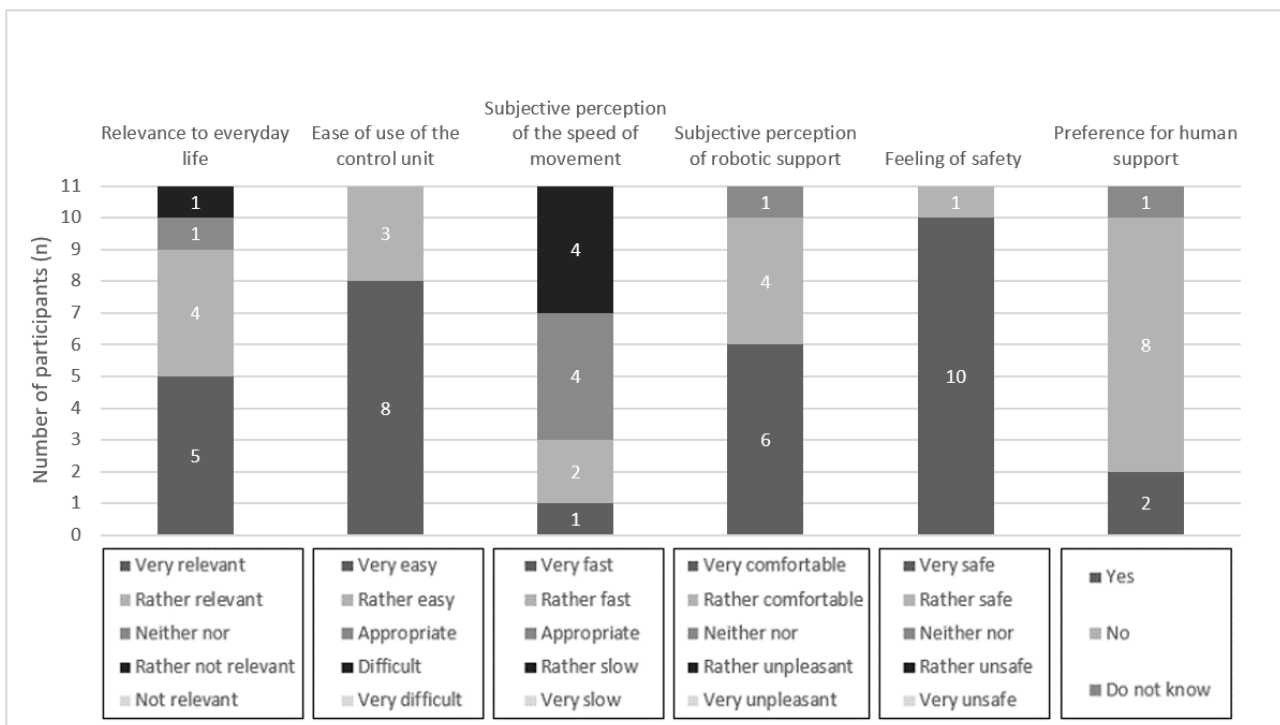


Figure 6. Aggregated presentation of the response distributions in the categories' relevance of the evaluation scenario (scratching) to everyday life, usability, feeling of safety during semiautonomous robotic behavior, and preference for human assistance over robotic assistance.

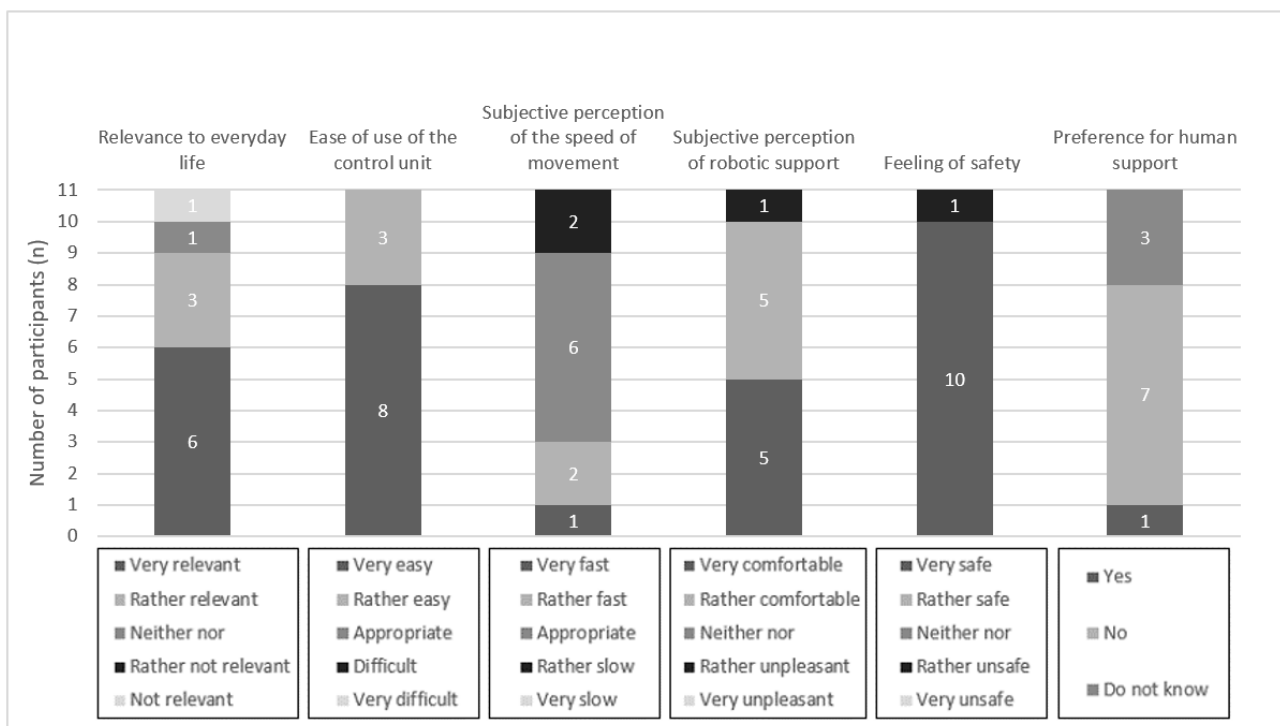
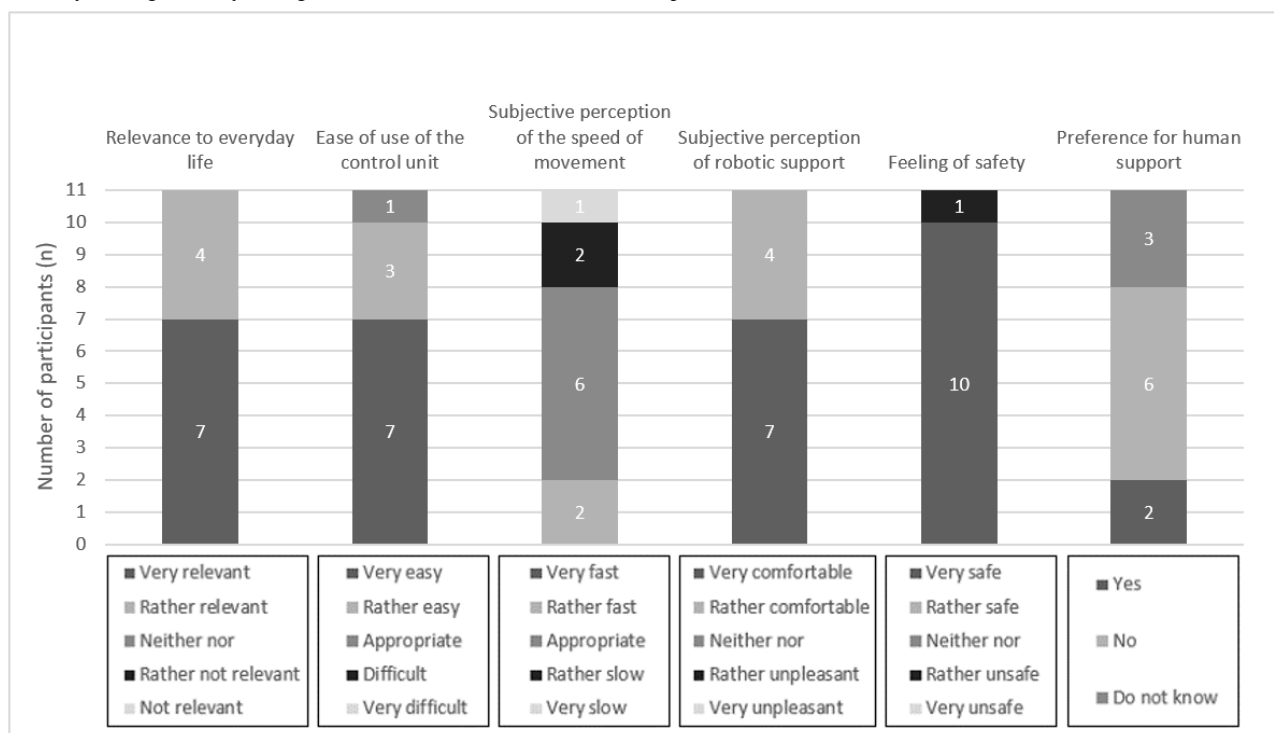


Figure 7. Aggregated presentation of the response distributions in the categories' relevance of the evaluation scenario (free movement) to everyday life, usability, feeling of safety during semiautonomous robotic behavior, and preference for human assistance over robotic assistance.



Most participants (9/11, 82%) rated the relevance of the *serve a drink* scenario for everyday life as very or rather relevant. Only 9% (1/11) of the participants rated this scenario as not relevant for everyday life. Regarding usability, all participants (11/11, 100%) rated the ease of use of the control unit as very easy or rather easy. The movement speed of the robot was rated as appropriate by 45% (5/11) of the participants. In contrast, 45% (5/11) of the participants rated it as rather slow or very slow. A participant perceived the movement speed to be rather fast. The subjective perception of the robotic support in this scenario was rated as very comfortable or rather comfortable by most participants (10/11, 91%). A participant perceived it to be neither pleasant nor unpleasant.

Furthermore, all participants (11/11, 100%) stated that they felt very safe while performing the semiautonomous robotic behaviors.

Finally, for the *serve a drink* scenario, 18% (2/11) of the participants indicated that they would prefer human assistance. In contrast, more than half of the participants (6/11, 55%) indicated that they would not prefer human assistance. Of the 11 participants, 3 (27%) participants could not provide a preference.

As part of the qualitative evaluation, the participants were asked about the aspects of the *serve a drink* scenario that they particularly liked or disliked. In particular, the participants appreciated the precise and fast reactions and the smooth motion. Moreover, the semiautonomous actions were mentioned positively. However, at the same time, participants preferred to fully control the system as long as they were physically and cognitively able to do so. In the event of a physical or cognitive decrease, for example, owing to fatigue, participants preferred the system to take over control and act autonomously. Offering

a drink to the mouth was found to be pleasant and a great relief. The size of the system, which makes it unsuitable for home use, was critically highlighted. In addition, a respondent criticized the system for taking different paths to pick up and serve the cup. In another case, the cup was served in a slightly skewed position; thus, the risk of spilling liquid was criticized. In 3 cases, the system collided with the surrounding devices when returning to the starting position (twice with the tablet and once with a wheelchair control), which caused irritation among the participants. Of the 11 participants, 2 (18%) participants noted the incompleteness of the scenario, as a third person was required to fill the cup and bring it into the robot's interaction field.

A key requirement that emerged from the *serve a drink* scenario was the reliability of the robot's actions in an unstructured environment and when manipulating objects. In this context, a participant stated that the robot needed to know its interaction radius. For reliable object manipulation, the system should also be able to recognize the material of the objects and grasp them with appropriate force. A third finger was suggested to increase the reliability of grasping.

The *hand over a mobile phone* scenario was rated as very relevant or rather relevant for their everyday lives by most respondents (9/11, 82%). A participant rated it as neither relevant nor irrelevant, and another participant rated it as rather not relevant.

Regarding the 3 questions on the usability of the ROBINA system in this scenario, the ease of use of the control unit was rated as very easy or rather easy by all participants (11/11, 100%). The evaluation of the speed of movement showed a differentiated image. Of the 11 participants, 3 (27%) participants rated it as very fast or rather fast and 4 (36%) other participants

rated the movement speed as adequate. Similarly, 36% (4/11) of the participants rated the speed of movement as rather slow. Finally, the robotic assistance was rated as very comfortable or rather comfortable by most respondents (10/11, 91%). A participant perceived it as neither pleasant nor unpleasant.

Regarding participants' feeling of safety during the semiautonomous task execution, all participants indicated that they felt very safe or rather safe (11/11, 100%).

Similar to the *serve a drink* scenario, 18% (2/11) of the respondents indicated a preference for human assistance. In contrast, 73% (8/11) of the participants did not prefer human assistance over robot assistance. A participant could not report a preference.

Regarding qualitative evaluation, the transfer of objects into the interaction field of the individuals who are affected, careful pickup of the mobile phone, and fast and precise motion sequence over large distances were described as positive. In general, the task was described as being "close to reality." However, in a few cases, the phone was dropped rather than carefully put down during the delivery. In addition, participants emphasized that the scenario was only suitable for people who can still pick up and operate a phone independently.

In summary, 3 key requirements were mentioned: first, direct transfer of the mobile phone to the user or into an appropriate holder; second, connection of the mobile phone control to the robot or wheelchair control (to operate it); and third, safety function that prevents the robotic system from dropping an object during the transfer.

In total, 82% (9/11) of the participants rated the *scratching* scenario as very relevant or rather relevant for their everyday life. Of the 11 participants, 1 (9%) participant each rated it as neither relevant nor irrelevant.

The ease of use of the control unit was rated as very easy or rather easy by all participants (11/11, 100%). In the *scratching* scenario, the evaluation of the speed of movement varied. Of the 11 participants, 3 (27%) participants found the speed to be very fast or rather fast, approximately half of the participants (n=6, 55%) rated it as appropriate, and 2 (18%) participants felt the speed was rather slow. Robotic assistance was rated as very comfortable or rather comfortable by most respondents (10/11, 91%). A participant perceived it as rather unpleasant.

Most participants (10/11, 91%) felt very safe during the semiautonomous task execution. A participant rated the feeling of safety as rather unsafe.

Preference for human assistance over that provided by the robot was not expressed by most participants in the *scratching* scenario (7/11, 64%). However, a participant indicated preference for human assistance. In total, 27% (3/11) of the participants were not able to provide a preference.

In the qualitative evaluation of the *scratching* scenario, a participant particularly liked the quick satisfaction of solving an acute problem and the increase in privacy and independence. Moreover, participants perceived the scratching as pleasant, however, depending on the brush and skin type. Similarly, the degree of scratching duration and intensity explicitly

corresponded to the ideas of the users, as did the possibility to adjust them. In contrast, a participant questioned the practicality of the task, particularly in the facial area. Another user was unsure how the system localized the area to be scratched. Uncertainty among participants occurred in cases where the system picked up the brush, skewed with the 2-finger grippers. In these cases, participants expressed concern about injury to the skin. The requirements for the correct positioning of the participant in relation to the ROBINA system were also viewed critically, because although this was plausible for safety reasons, it could not be implemented in everyday life independently by patients with ALS and limited mobility. In this respect, dependence on other people will remain. It was further critically stated that the positioning of the participant in relation to the system results in an irregular scratching movement, and therefore, the intensity varies over the distance of the scratching movement. Finally, the lack of a separate start button in the GUI was criticized, as it was not clear to the participants how the scenario can be started once the parameters had been selected.

As requirements for further development in this scenario, the possibility of the exact determination of the location of the itch instead of the vague selection of whole-body regions was highlighted. Another requirement was a clearly defined button to start the scenario. Finally, some participants wished for better adaptation of the scratching movements and the brush to the body shape.

All participants (11/11, 100%) rated the relevance of the *free movement* scenario as very relevant or rather relevant for their everyday life.

Regarding usability, the ease of use of the control unit was rated by most participants (10/11, 91%) as very simple or rather simple. A participant evaluated it as adequate. The speed of movement was also considered differently in this scenario. Of the 11 participants, 2 (18%) participants perceived it as rather fast, more than half of the participants (n=6, 55%) found it to be adequate, and 3 (27%) participants rated it as rather slow or very slow. The robotic support was rated as very pleasant or rather pleasant by all participants (11/11, 100%).

The subjective feeling of safety during the robotic executions was rated as very safe by 91% (10/11) of the participants. A participant reported to have felt rather unsafe.

For this scenario, of the 11 participants, 2 (18%) participants preferred human support, 6 (55%) other participants did not prefer human assistance to that provided by the robot, and 3 (27%) participants could not indicate a preference.

In the qualitative evaluation of the *free movement* scenario, the perceived independence from human assistance was highlighted. A participant mentioned that he would prefer care assistant to the system. However, if verbal communication was no longer possible for him, this task would be of great importance. In addition, both the precise movement control (ability to choose between small and large movements) and the sensitivity of the ROBINA system were positively highlighted. Critically, in this scenario, it was emphasized that the movement speed could not be adjusted. Furthermore, regarding the use of head control, it

was emphasized that holding the head position and the many micromovements to trigger robot movements were strenuous. Another point of criticism was the nonuniformity of the robot's movements, which did not follow a straight line.

As requirements for further development, several users wished for stepless control. For movements over long distances, a context menu that will allow speed control via sliders was suggested. Alternatively, movements over long distances can depend on the duration of pressing a corresponding button on the graphical UI.

Across the scenarios, 36% (4/11) of the participants described a potential for the promotion of independence and autonomy by the system. In total, 18% (2/11) of the participants had no preference for human or robotic support. Another 18% (2/11) of the participants stated that they will only use robotic assistance as long as it did not lead to the total replacement of their caregivers. A participant felt more comfortable with humans. This participant stated that they will use robotic assistance if their physical functionalities were very limited or if no other person was present to provide support. Apart from that, the respondent perceived the robot as a burden relief for his relatives.

General Evaluation

Following the task-based evaluation, the participants were asked to provide a general evaluation of the system.

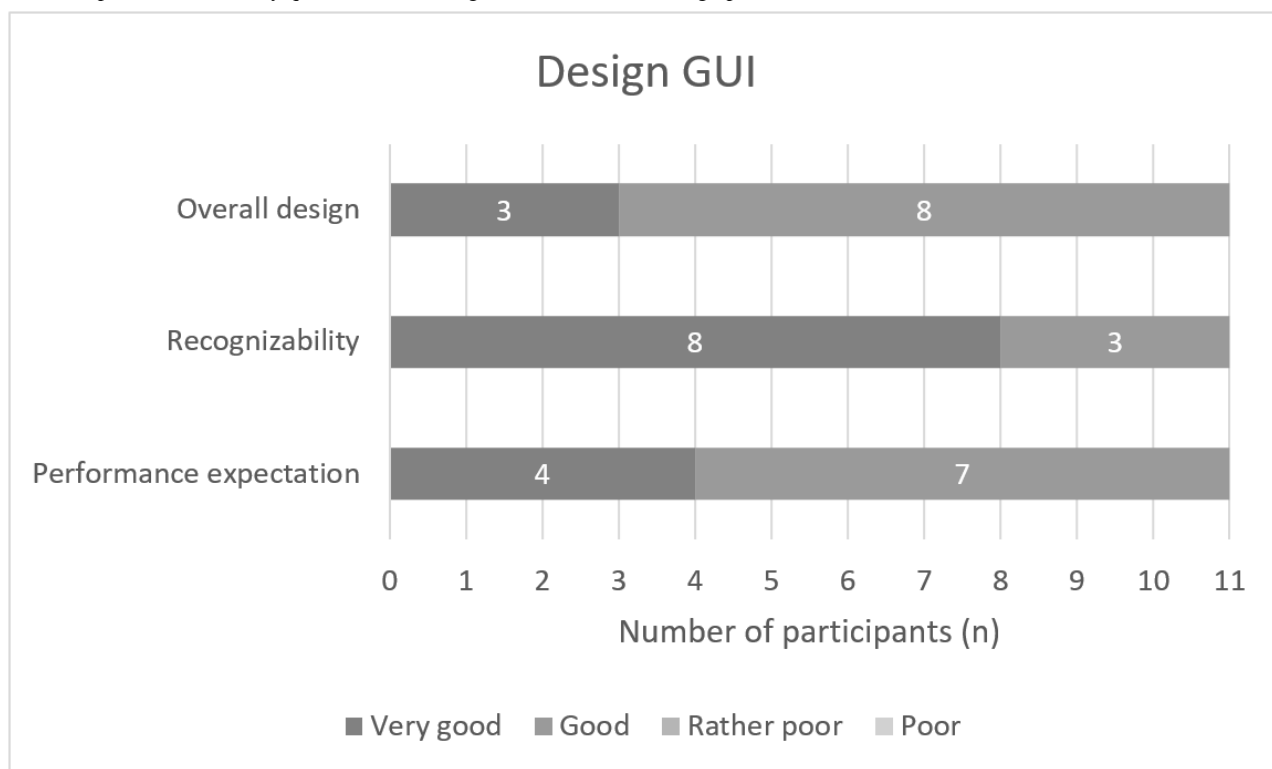
The overall usability of the ROBINA system was measured using SUS. On average, the ROBINA system was rated with median of 90 (mean 86.1; IQR 75-95; minimum 70; maximum 97.5) points, and thus, ranked in the upper range of "excellent" or grade A [27].

In addition, based on a self-developed questionnaire, participants were asked questions about the perceived fear while using the ROBINA system, the system's size, and the design of the graphical UI.

For the task-based use of the ROBINA system, all participants (11/11, 100%) indicated that they had not felt any anxiety.

Regarding the size, 64% (7/11) of the participants felt that the ROBINA system was very large and 36% (4/11) of the participants felt it was appropriate.

Another focus was the general evaluation of the graphical UI. This was generally assessed as good (8/11, 73%) or very good (3/11, 27%) by most participants. Regarding the visualization of the various functions in the graphical UI, 73% (8/11) of the participants stated that these were very well recognizable. In total, 27% (3/11) of the participants rated it as good. In addition, 64% (7/11) of the participants indicated that the representations for semiautonomous execution by the ROBINA system on the graphical UI met their expectations for robot performance well. Overall, 36% (4/11) of the participants indicated that the actual executions met these expectations very well. [Figure 8](#) presents a graphical overview of the participants' evaluations. Within the qualitative evaluations of the graphical UI, the participants were asked to provide detailed suggestions for improvement. According to the participants, 3D symbols should be displayed to better clarify the robot's control directions. The font should be more legible (ie, large and thick) and contrasting to the background. Contrast and brightness should be adjusted for operation in the dark. In general, some settings such as color and contrast should be customizable. When using the head control, there was a risk that the user would unconsciously trigger a function without looking at the screen. In 2 cases, the participants actively approached the study staff about this concern, and in another case, there was actually an unconscious cancellation of the running task after the participant had averted his gaze from the tablet to the real task execution. In total, 18% (2/11) of the participants recommended an area within the control design of the GUI into which the user can look without fear of triggering something unconsciously. In the *free movements* task, users were in favor of revising the navigation label or making it more intuitive by using a suitable color concept. Furthermore, the live image of the robot's position with respect to the manipulation object in the graphical UI was hardly used. Instead, the participants observed the process in the real study setup. The participants explained that this was because of the small size of the live image in the graphical UI, which did not show the entire interaction space of the robot. Another reason was that spatial perception of the interaction area via the 2D live image was severely limited ([Figure 3](#)).

Figure 8. Responses to the survey questions about the general evaluation of the graphical user interface (GUI).

Discussion

Principal Findings

This study aimed to investigate the key requirements and needs of people with ALS for the use of a semiautonomous robotic manipulator for supporting ADLs. For this purpose, four exemplary activities (*serve a drink, hand over a mobile phone, scratching, and free movement*) were evaluated in an explorative and task-based laboratory study with 11 individuals from the target group. The study was based on a multimethod approach comprising quantitative and qualitative methods.

Regarding the quantitative part, the use of a robotic manipulator was considered to be relevant in the investigated exemplary scenarios. Most participants evaluated the operation of the system as easy and the semiautonomous robotic actions as pleasant. At the same time, most participants felt safe during the semiautonomous robot actions. Differences existed, especially regarding the execution speed of the semiautonomous robot actions and the preference for human assistance over robotic support.

The qualitative analysis of the open-ended questions about the application and the observation and think-aloud protocols provided a deep insight into the user-centered assessments and development requirements. These findings can be summarized into 3 requirement areas.

The first area concerns the role and design of semiautonomous robot actions. In general, the investigated semiautonomous robot capabilities were evaluated positively. The precise and dynamic motion sequences and the careful picking up of objects were particularly highlighted. However, at the same time, errors such as irregular motion paths, collision with equipment in the

environment, and inaccurate pickup of objects became evident. Against this background, precise and reliable execution of semiautonomous robot motions and object manipulations and environmental and object recognition capabilities were key development requirements. Another central result concerns the execution speed, which should be customizable according to the user's abilities. Generally, the participants desire a largely self-responsible control of the robotic manipulator. In contrast, semiautonomous robotic actions should be applied when the user's physical abilities decline during the day (eg, owing to fatigue) or owing to the progressive course of the disease.

Another area of requirements concerns the control unit. Regarding the different input devices for operating the robot arm (such as head control, mouse control, and joystick), the use of head control was perceived as strenuous for the user in the scenarios with increased input requirements. As the input device used corresponded to the physical abilities that were still available, there is great demand for the design of a UI for those affected, who can no longer use their extremities for operation. Regarding the graphical UI, an increasing number of input options requires attention to design a differentiated display for better distinction of the corresponding robotic abilities.

Finally, the last area covers the requirements for the adaptation of robotic capabilities regarding the everyday life of the target group. According to the participants, the use of a robotic manipulator will enhance their independence, autonomy, and privacy in everyday life. However, at the same time, the current state of development of the test scenarios will still make the user dependent on human assistance. Consequently, the developed robot capabilities focused only on specific subareas of the respective everyday activity and require various preliminary activities that neither the user himself nor with use

of the robot can implement independently. Finally, regarding promoting autonomy and independence, it was also emphasized that the use of robotic systems should not lead to the replacement of human assistance.

Comparison With Previous Studies

In the following sections, our findings will be discussed in comparison with previous studies. We will focus on the three central requirement areas identified through the qualitative analysis: requirements for semiautonomous human-robot collaboration, requirements for UI, and requirements for the adaptation of robotic capabilities regarding the everyday life of the target group.

Requirements for Semiautonomous Human-Robot Collaboration

Regarding using semiautonomous robotic manipulators to compensate for functional limitations, 3 characteristics are of particular importance: design of the control model, handling of objects, and execution speed.

In their scoping review of recent studies on using computer vision for semiautonomous control of assistive robotic manipulators, Bengtson et al [21] found that most of the studies focused on rather fixed schemes for semiautonomous control, which are based on predefined roles for the user and the system. An advantage of this distinct distribution of role models was that the user is relieved of challenging control processes and that the accountability of responsibilities between the user and the system is simplified. However, according to the authors, a disadvantage was that the user has only limited access to autonomous processes, which in turn can have a negative impact on the user experience. As a solution to this problem, the authors suggested an adaptive semiautonomous control approach that continuously involves the user in this process. With this arbitration of control, the robot control can be more strongly adapted to the user's capabilities and thus achieve a high degree of individualization of the human-robot collaboration.

A similar conclusion was reached by Kim et al [28]. On the basis of a vision-based 6 df UCF-MANUS, the authors conducted a comparative study of two different control models (supervised autonomous operation vs manual or Cartesian operation) with the target group of individuals with traumatic spinal cord injury. The evaluation was conducted over 1 to 2 hours weekly, over a period of 3 weeks. Interestingly, both groups had comparable task completion times at the end of the study, which the authors attributed to the learning effects in the manual operating group. In addition, the authors found that the results from the autonomous operation mode showed significant reduction in the number of clicks and task completion time. At the same time, participant satisfaction did not increase. The authors concluded that participants wanted to perform the appropriate tasks independently with the robotic system. Another key finding of the study was that participants who tested both control modes required an adaptive control system that allowed them to switch between the 2 control modes as needed.

As our results have shown, another challenge of semiautonomous control models is the precise and safe object manipulation. Overall, 2 aspects are of importance here. First,

the identification and localization of an object, and second, the precise and safe grasping. Regarding the first aspect, different approaches are already available, such as proximity-based approaches or the detection of an object by a sensor (such as laser pointer, eye-tracking, or electroencephalography) [21,28,29]. Regarding the second aspect of the grasping process, different approaches are currently under review, which are based either on predefined objects or specific shapes. As these approaches deal with simplified assumptions about an object, a major challenge involves the manipulation of arbitrary objects. Bengtson et al [21] considered a solution to this problem using approaches that focus either on the recognition of suitable grasping points or the decomposition of the object into different shapes. Another approach is to involve the user in identifying and marking such grasping points for the system or teach the system to grasp different shapes of everyday objects independently. Finally, another solution to improve the manipulation properties is to adapt the gripper by using at least three fingers or use specific adapters for specific objects [22,28].

The third main challenge is regarding the execution speed of robotic actions. Various studies have shown that semiautonomous control models have led to significant improvement in both success rate and execution time of tasks compared with commercially available Cartesian control models. At the same time, in accordance with our results, some studies also show that target groups desire high execution speeds [15,28]. Thus, the user-centered adaptation of movement speed can be interpreted as an essential factor for user experience. However, at the same time, this represents an essential parameter for ensuring safe human-robot collaboration. Therefore, a potential solution to this issue can be a gradual expansion of the performance level of the robotic manipulator linked to specific operating skills. This should consider both positive adaptation to the system and potential limitations of use owing to the course of the disease. Particularly considering the progressive physical decline, it currently remains unclear to what extent the users are able to perform such system configurations on their own responsibility. Thus, to support the users in their daily use of such robotic systems, an appropriate adjustment of the system configuration, especially regarding the speed of movement, should be supervised by qualified experts.

UI Requirements

In addition to the requirements for semiautonomous human-robot collaboration, our results show that the UI is also essential for effective and efficient use of a robotic manipulator. Currently, commercially available UIs mostly rely on teleoperation via a 3-axis joystick. The 3 df are thereby mapped to a subset of the Cartesian arm translation and wrist rotation control. To control the 7 df, the user must switch between different Cartesian levels [20]. Thus, grasping an object using a robotic manipulator is transformed into a multitude of distinct movements that require frequent switching between and within different Cartesian levels. For people with functional limitations of the upper extremities, this can result in high physical and mental stress.

In this context, Chung et al [30] investigated the performance of a tablet-based UI versus a conventional joystick control in a comparative pilot study with 8 participants with upper extremity impairments using a JACO (Kinova) robotic manipulator. The use of the touch screen UI resulted in high execution speeds and low task completion times compared with the conventional control form; however, no equal distribution of UI users was realized within the study. In addition, the participants rated the touch screen UI as simple and less stressful. The authors attribute this result to the low user errors owing to the better visual-spatial assignment, low mode changes, and low physical strain compared with conventional operation using joystick and shift key.

Graphical UIs provide a promising approach as they allow to present different control levels simultaneously, and thus make them more easily accessible. Moreover, they provide a wide range of visualization opportunities to make the control characteristics more comprehensible. At the same time, most of the tablet-based UIs offer the possibility to connect additional input devices such as head or eye control. Sunny et al [31] also followed such an approach. The authors investigated the usability of a control system consisting of an eye-gaze interface and a tablet-based graphical UI for a wheelchair-mounted xArm 6 from UFactory in different manipulation tasks. A total of 10 healthy participants were included in the study. Although this is not a representative sample for the addressed target group of people with disabilities, high success rate could be achieved in the manipulation tasks. The participants highlighted the large buttons of the graphical UI as a key feature of usability in the design of the control system.

Requirements for Everyday Use

Consistent with the current state of the art on assistive robots, the results of our study demonstrate that a major challenge lies in the identification and classification of relevant task domains and associated motion and performance parameters. A key task here is to develop a taxonomy that balances robotic capabilities with health care requirements and user-centered needs.

In this context, research and development of assistive robots often refer to the International Classification of Functioning, Disability, and Health (ICF) [16,17]. The ICF is a standardized and international classification system for describing a person's functional health status, disability, social impairment, and relevant environmental factors. For this purpose, the ICF is divided into two parts, each with 2 components: first, functioning and disability (components: body functions and structures, activities, and participation) and second, contextual factors (components: environmental factors and person-related factors). Each component is divided into different domains, which in turn are composed of different categories that form the units of the classification.

Thus, the ICF provides a standardized framework for classifying health-related functional limitations or requirements in the performance of ADLs and social participation. For robotic research and development, the ICF classification provides an important approach for identifying and developing functional parameters for robotic assistance and evaluating their performance. However, at the same time, the ICF does not

provide a basis for identifying all tasks or making conclusions about their relevance and frequency in the everyday life of the individuals concerned. Therefore, more advanced approaches for the identification of relevant assistive activities and functional parameters are needed. Petrich et al [16] proposed such an approach. In their study, the authors investigated different lifelogging databases to determine both the frequency of ADL tasks in daily life and short-term arm and hand movements during domestic tasks.

Furthermore, in the process of prioritizing ADLs for robotic support, it is essential to consider the perspectives of third parties in the caring network. These parties play a crucial role because they form a secondary user group that will be involved in facilitating and supporting the use of assistive robots by the primary target group of people with functional limitations. Therefore, the consideration of their needs plays an essential role in acceptance and long-term use; however, the rating of ADL tasks varies between those parties [17].

Limitations

The generalizability of the study results is subject to several limitations, which are discussed in this section. Owing to the small sample size, the results should be considered as indicative of future studies. In addition, several influencing factors were derived from the experimental and exploratory study design. The first factor is the safety measures taken owing to the early stage of technical development of the study demonstrator. Some of our findings suggest that these measures had an impact on the user evaluations (*scratching* scenario). In addition, the fact that we used a stationary robot from the industrial environment can be considered as another influencing factor (robot size). Current systems, such as the Kinova or Exact Dynamics systems, can be mounted on the user's wheelchair and are characterized by a slim and lightweight design. Owing to the explorative pilot nature of the study, various influencing variables such as learning effect, novelty effect, and Hawthorne effect cannot be excluded. In this context, the study duration of 1 visit per participant should be mentioned as a particular factor. Therefore, the results presented in this paper need to be evaluated through further studies with field trials.

Conclusions

Assistive robots are expected to have great potential in supporting and promoting the autonomy and independence of people with functional impairments in various ADLs. To achieve effective and efficient compensation of disease-related functional losses, high demands are imposed on user-friendly system design. In this context, this study investigated and discussed the requirements and needs of people with ALS for the development of a semiautonomous robotic manipulator for everyday life support. We identified 3 key requirement areas that should be pursued as foci of user-centered development in future research and development projects, consistent with previous studies. An essential prerequisite for development is the active and continuous involvement of the target group in the control processes. Therefore, a promising approach consists of adaptive semiautonomous control systems that enable the user to be involved in the autonomous decision-making and operational processes. A key question to be addressed is how

to effectively mediate between the user's skill level and the technical challenges in motion planning and object and environment recognition for efficient task accomplishment. Another focus of development is the UI. Owing to physical limitations, conventional input devices can be a high mental and physical burden in everyday life. Tablet-based graphical UIs can provide great relief in this regard, by simplifying access

to various robot functions and making robot behavior more predictable and comprehensible through the use of diverse visualization options. Finally, there is a strong need to develop a specific taxonomy for assistive robots that provides a standardized assessment of task parameters, efficiency, and performance to serve as a comparative standard in research and development.

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Conflicts of Interest

None declared.

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Abbreviations

ADL: activities of daily living

ALS: amyotrophic lateral sclerosis

ALS-FRS: amyotrophic lateral sclerosis functional rating scale

GUI: graphical user input

ICF: International Classification of Functioning, Disability, and Health

RGB-D: red, green, blue, and depth

ROBINA: robot-assisted services for individual and resource-oriented intensive and palliative care of people with amyotrophic lateral sclerosis

SUS: System Usability Scale

UI: user interface

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Original Paper

Use of a Social Robot (LOVOT) for Persons With Dementia: Exploratory Study

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Abstract

Background: Approximately 50 million people worldwide are living with dementia. Social robots have been developed and tested to determine whether they improve the quality of life for persons with dementia. A new mobile social robot called LOVOT has artificial intelligence and sensor technologies built in. LOVOT, which is manufactured in Japan, has not yet been tested for use by persons with dementia.

Objective: This study aimed to explore how the social robot LOVOT interacts with persons with dementia and how health care professionals experience working with LOVOT in their interaction with persons with dementia.

Methods: The study was carried out at 3 nursing homes in Denmark, all with specialized units for persons with dementia. The interaction between the persons with dementia and LOVOT was tested in both individual sessions for 4 weeks and group sessions for 12 weeks. A total of 42 persons were included in the study, of which 12 were allocated to the individual sessions. A triangulation of data collection techniques was used: the World Health Organization-5 questionnaire, face scale, participant observation, and semistructured focus group interviews with health care professionals (n=3).

Results: There were no clinically significant changes in the well-being of the persons with dementia followed in the individual or group interaction sessions over time. The results from the face scale showed that in both the individual and group sessions, persons with dementia tended to express more positive facial expressions after the sessions. Findings on how persons with dementia experienced their interaction with LOVOT can be stated in terms of the following themes: LOVOT opens up communication and interaction; provides entertainment; creates a breathing space; is accepted and creates joy; induces feelings of care; can create an overstimulation of feelings; is not accepted; is perceived as an animal; is perceived as being nondemanding; and prevents touch deprivation. Findings regarding the health care professionals' experiences using LOVOT were as follows: the artificial behavior seems natural; and it is a communication tool that can stimulate, create feelings of security, and open up communication. Our findings indicate that the social robot is a tool that can be used in interactions with persons with dementia.

Conclusions: The LOVOT robot is the next generation of social robots with advanced artificial intelligence. The vast majority of persons with dementia accepted the social robot LOVOT. LOVOT had positive effects, opened up communication, and facilitated interpersonal interaction. Although LOVOT did not create noticeable effects on social well-being, it gave individual persons a respite from everyday life. Some residents were overstimulated by emotions after interacting with LOVOT. Health care professionals accepted the social robot and view LOVOT as a new tool in the work with persons with dementia.

KEYWORDS

dementia; social robots; artificial intelligence; health care professionals; health care; persons with dementia

Introduction

Approximately 50 million people worldwide are living with dementia [1]. Dementia causes deterioration in memory and mental skills such as speech. Living with dementia in everyday life can affect the person's mood, causing apathy, depression, and anxiety [1,2]. Dementia is a progressive disease, such that persons with a severe degree of dementia must live in nursing facilities that specialize in dementia care. With an increasing prevalence of dementia, health care professionals are being challenged to provide quality care and give optimum attention to persons living with dementia. New technological innovations, such as social robots, have been developed and tested to assess whether they could improve the quality of life for persons living with dementia [3]. Social robots are designed to interact with humans to increase social interaction and improve well-being [4]. Góngora Alonso et al [5] have elaborated a 4-way classification of social robots: pet robots, humanoid robots, telepresence robots, and socially assistive robots (SAR). Examples of currently deployed social robots are PARO (robot seal), Aibo (robot dog), NeCoRo (robot cat), and CuDDler (robot teddy bear) [6].

A review by Góngora Alonos et al [5] concluded that the use of social robots for persons with dementia helped provide security and reduce stress. A systematic review of the use of social robots in mental health and well-being found that SAR are used largely with persons with dementia. However, these are only pilot studies, and there are limitations in the methods applied [3].

A review by Ghafurian et al [7] showed that social robots for the care of persons with dementia have received the most attention in the literature in the context of therapy or for increasing engagement, whereas robots designed for assisting with daily activities or providing health guidance received relatively limited attention. PARO was the most commonly used robot in dementia care studies [7]. A review of the use of PARO for persons with dementia has identified benefits such

as improved mood, improved social engagement, and reduced negative emotions [8]. PARO's ability to positively influence mood is indicated by the person with dementia becoming more active and relaxed and smiling. In addition, PARO has been shown to improve both verbal and visual engagement in social interactions. Factors that inhibited the use of PARO were the cost of the robot, increased workload for health care professionals working with the robot, infection concerns, and stigma and ethical issues related to a social robot in dementia care [6].

Despite the potential benefits of social robots for persons with dementia, the use of social robots currently faces several challenges. The current evidence base assessing the benefits of social robots for persons with dementia is still at an early stage, with relatively few studies. In addition, many of the existing study methods are characterized by short-term intervention durations and only a few subjects enrolled in the trials [5,9]. Furthermore, a lack of acceptance or outright resistance to social robots among older persons or those living with dementia has also been identified. This resistance may be explained by the fact that the robots studied so far have had limited social and auditory abilities; as such, they were unable to respond to any emotion or react to persons with dementia, nor were they fully aware of the social context [7,10,11].

Some of these deficiencies have been alleviated by the development of a new mobile social robot called LOVOT, which is manufactured in Japan. LOVOT possesses artificial intelligence and sophisticated sensor technologies. LOVOT has its own personality that develops over time with the purpose of creating joy in the user or patient [12]. Until our study, LOVOT had not yet been tested among persons with dementia. [Figure 1](#) shows a photo of 2 LOVOT robots.

This study aims to explore (1) how the social robot LOVOT interacts with persons with dementia who are living in nursing homes in Denmark; and (2) how health care professionals experience working with LOVOT in their everyday interaction with persons with dementia.

Figure 1. LOVOT as a social robot (reproduced from Groove X [12], with permission from Groove X).



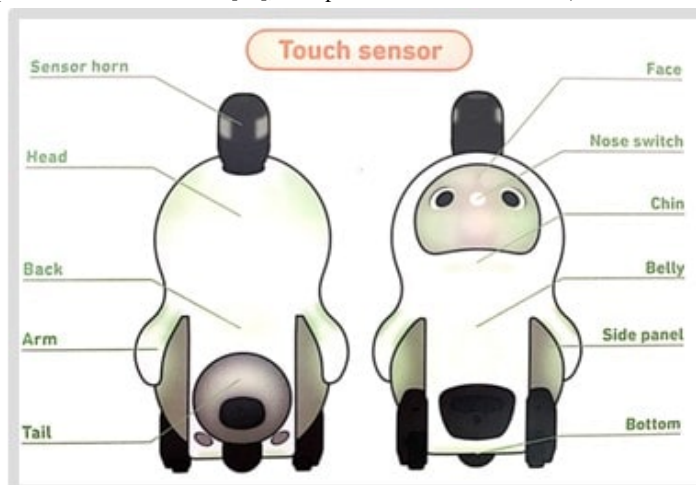
Methods

LOVOT Specifications

The social robot LOVOT was developed by the Groove X company. LOVOT weighs 4.2 kg and has a width of 28 cm, a height of 43 cm, and a depth of 26 cm. LOVOT is built with artificial intelligence, which makes it move in real time and act like a human being. LOVOT uses multiple sensors all over its body, including touch and distance sensors. The touch sensors are used to make LOVOT recognize stimulations on the body and can be warm or cold; it can even “fall asleep” when a person is stimulating the sensors. Distance sensors are used to determine the distance to objects, which makes it possible for LOVOT to move around without colliding with objects or walls [12]. The anatomy of LOVOT can be seen in Figure 2 and Multimedia Appendix 1. LOVOT was designed with a block-shaped “horn” on top of the head, as shown in Figure 2.

The horn can be used to turn LOVOT on and off. The horn includes a 360-degree thermal camera, which is used to determine humans from objects. The horn can also determine the direction of sounds and voices. LOVOT is implemented with 3 wheels, which can be enabled whenever LOVOT wants to move. LOVOT can be active for 40 minutes, after which it will need to return to its charging nest for a 20-minute charge. LOVOT can normally find and connect with the nest itself, although sometimes it needs help locating the nest. LOVOTs are designed with different personalities. For example, it can be programmed to be shy or outgoing in its personality. The personality can change over time as it gets more familiar with its user. Groove X has also developed an app that can be used in collaboration with each LOVOT. The app enables LOVOT to access the internet. LOVOT can use the internet to navigate over distances. LOVOT can take pictures of faces and use facial recognition as part of its artificial intelligence. In this study, LOVOT was not connected to the internet due to the European General Data Protection Regulation [13] and to avoid data being stored on a foreign server at Groove X in Japan [12].

Figure 2. Anatomy of LOVOT (reproduced from Groove X [12], with permission from Groove X).



Ethical Considerations

The North Denmark Region Committee on Health Research Ethics was contacted to ensure that the project would be approved by the Ethical Committee. As the project did not include a new treatment approach and because the social robot LOVOT was not a medical device, the project did not require approval by the Ethical Committee (according to mail correspondence on September 23, 2019). Nevertheless, we have followed the Helsinki Declaration. Some persons with dementia were capable of signing the informed consent themselves, but the majority of the older persons had their guardian (spouse, daughter, or son) sign the informed consent form on behalf of the person with dementia. A data sharing agreement has been signed between the parties of the project.

Context and Intervention of the Study

The study took place at 3 nursing homes in Denmark, all with specialized units for persons with dementia. The nursing homes were located in the Danish Municipalities of Aalborg, Viborg, and Skive.

The interaction between the persons with dementia and LOVOT was tested in both individual and group sessions. Individual interaction sessions between the person with dementia and the LOVOT robot took place over a 4-week period. The aim of the interaction sessions was to facilitate the activities of daily living (eg, eating and getting out of bed), companionship, health guidance (eg, receiving vaccinations), and individual engagement (eg, receiving visits from a relative) between the person with dementia and LOVOT. The individual sessions were facilitated by a health care professional and included approximately two 20- to 30-minute sessions with LOVOT per week. Group sessions, where a group of 4 to 6 persons interacted with 2 robots, were held over a 12-week period. The aim of these sessions was to facilitate communication and interaction between the persons and LOVOTs. Each of the 3 participating nursing homes established 2 groups. The group sessions, facilitated by a health care professional, lasted from 30 to 45 minutes and were held twice a week.

Participants and Recruitment

The participants in the study were recruited based on the inclusion and exclusion criteria listed in Textbox 1.

Participants enrolled in the study were diagnosed with dementia prior to the study and before they moved into the specialized nursing homes for persons with dementia. In Denmark, persons are diagnosed with dementia at the geriatric ward of a hospital and in collaboration with the person’s own general practitioner via memory test, blood samples, computer tomography scan of the brain, and the assessment of the person’s daily functioning in everyday life. The researchers were not involved in this assessment process.

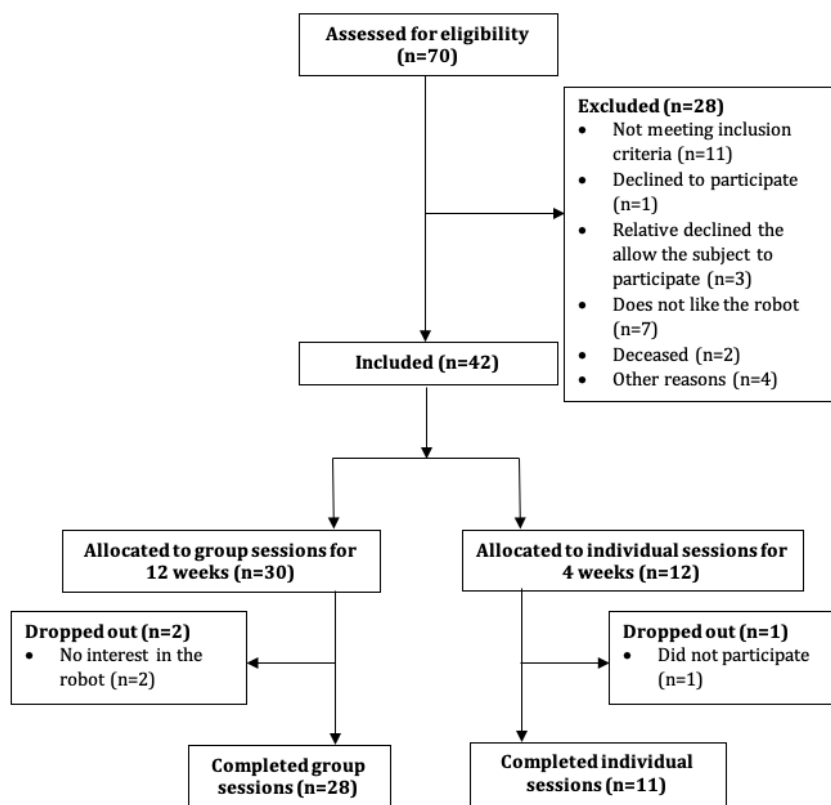
Before recruiting the persons for the LOVOT study, we conducted meetings in the specialized nursing homes with persons with dementia, their relatives, and health care professionals. The aim of the meetings was to introduce LOVOT and its functions and give further information about the trial. At the meetings, participants were able to ask questions about the trial.

Figure 3 shows a CONSORT (Consolidated Standards of Reporting Trials) diagram of the included persons and number of persons completing the sessions.

Textbox 1. Inclusion and exclusion criteria for participation in the study.

<p>Inclusion criteria</p> <ul style="list-style-type: none"> • Diagnosed with mild dementia • Lives at 1 of the participating nursing homes in Aalborg, Viborg, and Skive Municipalities • Meets one or more of the following behavioral criteria: <ul style="list-style-type: none"> • Lonely • High arousal • Introverted behavior <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Refusal to participate • Diagnosed with a neurological disorder • Diagnosed with a psychiatric disorder

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) diagram of the number of older adults included in this study.



Outcome Measures and Data Collection Techniques

The outcome measures of the study were the following:

- Well-being
- Impact on the person’s mood
- Impact on the person’s behavior

- Acceptance of LOVOT
- LOVOT’s interaction with persons with dementia

Outcome measures, data collection techniques, and the time of collection for individual and group sessions are shown in [Tables 1 and 2](#). The data collection process is described below.

Table 1. Overview of outcome measures and data collection techniques for the individual sessions.

Outcome measures	Data collection techniques	Baseline	Week 1	Week 2	Week 3	Week 4
Well-being	World Health Organization-5 questionnaire	✓		✓		✓
LOVOT’s impact on the person’s mood	Face scale		✓	✓	✓	✓
LOVOT’s impact on the person’s behavior	Participant observation		✓			✓
Acceptance of LOVOT	Participant observation		✓			✓
LOVOT’s interaction with the person	Focus group interviews with health care professionals	✓				✓

Table 2. Overview of outcome measures and data collection techniques for the group sessions.

Outcome measures	Data collection techniques	Baseline	Week 1	Weeks 2-12
Well-being	World Health Organization-5 questionnaire	✓		✓ (weeks 2, 4, 6, 8, 10, and 12)
LOVOT’s impact on the person’s mood	Face scale		✓	✓ (weeks 2, 4, 6, 8, 10, and 12)
LOVOT’s impact on the person’s behavior	Participant observation		✓	✓ (weeks 4, 8, and 12)
Acceptance of LOVOT	Participant observation		✓	✓ (weeks 4, 8, and 12)
LOVOT’s interaction with the persons	Focus group interviews with health care professionals	✓		✓ (week 12)

Well-Being

The World Health Organization-5 questionnaire (WHO-5) was used to measure the well-being of the persons over the course of the test period. The questionnaire consists of 5 questions, with responses scored from 1 to 5—a higher response score indicating greater well-being. The questionnaire was administered by the health care professionals and based on their perception of the person’s well-being. Since the health care professionals knew the persons very well, they were capable of making an informed assessment. The questionnaire was administered at baseline and then every other week during the test period for both the individual and the group sessions. The data analysis was performed according to WHO guidelines [14].

Face Scale

The face scale [15] was used to measure LOVOT’s impact on the persons’ mood before and after a session. The original face scale, inspired by Wada et al [16], consists of 20 facial expressions. For our study, we selected the 7 most common expressions and set up a 7-point scoring scale, with 1 being the most positive expression and 7 being the most negative expression. The face scale was measured by the health care professionals once a week during the test period. The health care professionals knew the persons very well and were therefore capable of making an informed assessment. The data analysis was performed according to guidelines described by Lorish and Maisiak [15].

Participant Observations

During the sessions, the health care professionals carried out observations [17] of the person’s behavior when interacting with LOVOT. We designed an observational guide [15] that focused on observations such as nonverbal behavior, interaction, and communication of the persons in their interaction with LOVOT. The health care professionals had received training in carrying out and recording their observations. By using the health care professionals as observers instead of outside researchers, we eliminated the risk that we would attract the person’s attention during their interaction with the robot. In addition, COVID-19 restrictions prevented researchers from entering the nursing homes. The observations were documented in a text file and analyzed by researchers using NVivo qualitative data analysis software (version 12.0; QSR International).

Semistructured Focus Group Interviews

The 3 semistructured focus group interviews, inspired by Brinkmann and Kvale [18], were conducted with the health care professionals at each nursing home. The first interview was a baseline interview, which was to obtain knowledge about each person’s life history and dementia. The collection of data from each person included their age, gender, work history, family information, life history, and dementia symptoms. After the test period, we conducted the second, follow-up interview. The aim of the second interview was to explore how each person with dementia had interacted with LOVOT. Each interview lasted 60 to 90 minutes and was tape-recorded and transcribed. The

interviews were coded using NVivo software and analyzed in steps inspired by Brinkmann and Kvale [18].

Data Analysis

The quantitative data, collected using the face scale and WHO-5, were analyzed by calculating the median and IQR for the data from the individual and group sessions. The 5 questions from the WHO-5 were summarized and multiplied by 4 to generate a range of values between 0 and 100, with a score of 0 indicating the worst possible well-being and a score of 100 indicating the best possible well-being for the older person. A clinically significant change in the WHO-5 score is assessed if we recorded a change of at least 10%, corresponding to 10 points in WHO-5. Data are presented in graphs, showing the median and IQR. The interviews and observational notes were analyzed

using NVivo software, in steps inspired by Brinkmann and Kvale [18].

Results

Baseline Data

A total of 42 persons with dementia were included in the study, of which 30 were allocated to the group sessions and 12 to the individual sessions. The sociodemographic and clinical characteristics of the participants in the individual and group sessions at baseline are shown in Table 3. We use either the number of persons and percentage or the median and IQR for the different parameters.

In Figure 4, the results from the individual sessions using the WHO-5 questionnaire are presented. In Figure 5, the results from groups sessions over a 12-week test period are presented.

Table 3. Characteristics of the persons at baseline.

Characteristic	Individual sessions (n=12)	Group sessions (n=30)
Gender, n (%)		
Male	1 (8)	8 (27)
Female	11 (92)	22 (73)
Age (year), median (IQR)	83 (67-92)	84 (66-96)
Years at nursing home, median (IQR)	1.75 (0.5-4)	1.9 (0.08-5)
Years with dementia, median (IQR)	2 (0.5-10)	3,5 (0.25-10)
Have children, n (%)	10 (83)	27 (90)
Type of dementia, n (%)		
Alzheimer disease	8 (67)	12 (40)
Other	4 (33)	18 (60)

Figure 4. Results from individual sessions using the WHO-5 questionnaire. WHO: World Health Organization.

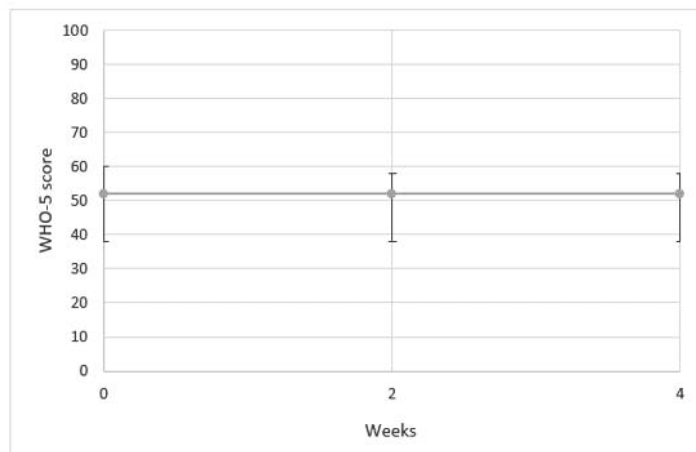
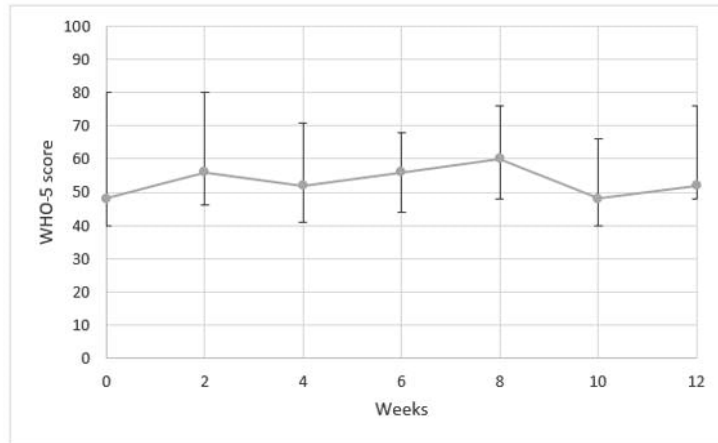


Figure 5. Results from the WHO-5 questionnaire for the group sessions over the 12-week test period. WHO: World Health Organization.



Impact on Mood

Figure 6 presents the results attained from the face scale for the individual sessions. A higher score expresses a more negative face expression. Therefore, based on the median score illustrated in Figure 6, there is a trend toward more negative facial

expressions before the LOVOT sessions than after the LOVOT sessions were completed.

Figure 7 presents the results attained from the face scale for the group sessions. Based on the median score illustrated in Figure 7, there is a trend toward more negative facial expression prior to undertaking the LOVOT sessions than after the LOVOT sessions were completed.

Figure 6. Results from individual sessions using the face scale.

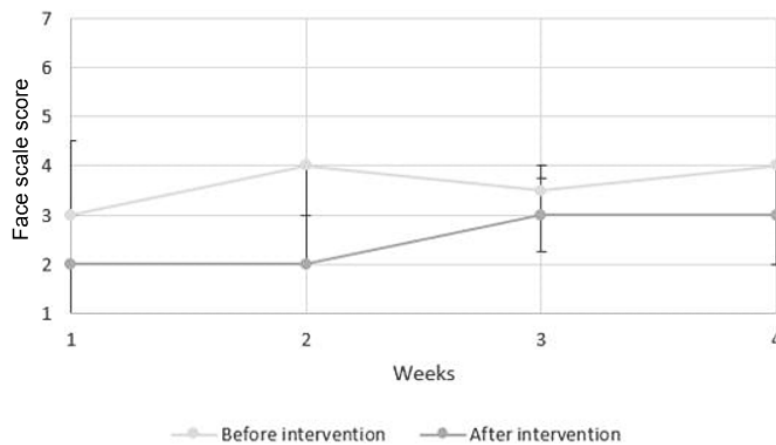
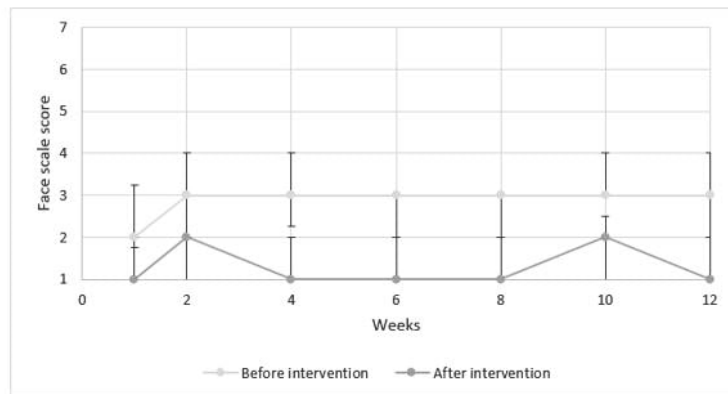


Figure 7. Results from group sessions using face scale.



Qualitative Findings

Focus Group Interviews

Tables 4 and 5 present findings on how the persons and health care professionals responded to LOVOT and the effect of LOVOT on the persons with dementia. These findings are based

on the follow-up focus group interviews with the health care professionals and the professionals' own observations at each session. In the following sections, the findings from the focus group interviews are supplemented with illustrative quotations taken from the focus group interviews. We consider these quotations to be representative of our findings.

Table 4. Findings on the experiences of how the persons experienced the interaction with LOVOT along with quotations from focus groups (FGs) with health care professionals from the nursing homes.

Theme/category	Illustrative quotation
Diverts and is calming	<ul style="list-style-type: none"> “This weekend, he also had a period where he wanted to go home, and during the shift change, I used LOVOT to calm him down.” (FG 1)
Opens up communication and interaction	<ul style="list-style-type: none"> “When LOVOT is there, she smiles and is happy. She speaks more with the other [older] persons. She’s someone who doesn’t say much.” (FG 1)
Provides entertainment	<ul style="list-style-type: none"> “They are fun to watch, both individually and together.” (FG 1)
Creates a breathing space	<ul style="list-style-type: none"> “LOVOT has given her a boost, a breathing space, where there is just something positive in her everyday life.” (FG 1)
Is accepted and creates feelings of happiness	<ul style="list-style-type: none"> “When she got LOVOT up in her hand, she started crying because she was so happy...it evoked feelings of happiness. She was moved to tears, absolutely.” (FG 1)
Induces feelings of care	<ul style="list-style-type: none"> “She has stepped into a mother role. She was one of the first ones we noticed who started treating it like a child. She sits and rocks it...She sits and rocks her leg just like you do with an infant or at least a little baby. She really just wants to sit with it and then just have that feeling.” (FG 2)
Can create an overstimulation of feelings	<ul style="list-style-type: none"> “He was quickly taken away because he reacted violently after being with LOVOT.” (FG 2)
Is not accepted	<ul style="list-style-type: none"> “She was not really able to relate to LOVOT. She has had other things in mind. She cannot find peace with it. She can just look at it and say, ‘Yes,’ but she has something else going on. So it has not had any positive effect on her either.” (FG 2)
Is perceived as an animal	<ul style="list-style-type: none"> “But she clearly sees it as something animal, because she is very fond of dogs, so she almost claps her hands when they come.” (FG 1)
Is perceived as being nondemanding	<ul style="list-style-type: none"> “But she has also always talked to it as if it were a person who was with her and has meant a lot. I don’t know whether a person with dementia can relate more to such a thing compared to us humans, because we demand something, I don’t know if they have that feeling. Because LOVOT demands nothing, [like] a dog, other than to be petted. The rest of us always demand something.” (FG 3)
Prevents “skin hunger”	<ul style="list-style-type: none"> “But we talked a little about touch deprivation...She sat with [LOVOT] on the sofa, where it sat up next to her, and she sat like that and cuddled it. She has received the warmth from LOVOT and the sounds. It can stimulate something in relation to skin hunger when she does not have much contact and touch with others.” (FG 2)

Table 5. Findings on how the health care professionals experienced using LOVOT along with quotations from focus groups (FGs) with health care professionals from the nursing homes.

Theme/category	Illustrative quotation
Artificial behavior appears natural	<ul style="list-style-type: none"> “LOVOT’s behavior seems natural, even though we know it is artificial intelligence, the robots have different personalities.” (FGs 1, 2, and 3)
Communication tool that can stimulate, create feelings of security, and facilitate communication	<ul style="list-style-type: none"> “We think that LOVOT is a good tool for creating space for collaboration with residents with dementia.” (FGs 1 and 2) “Relatives have also been very positive about what LOVOT is doing to her. Her daughter has also been to a session and seen what it does to her. Her eyes lit up so completely, and she smiled and became happy. And she spoke to [LOVOT] as if it were a child. She knows it’s a robot.” (FG 2)
LOVOT is user-friendly and fun	<ul style="list-style-type: none"> “It is user-friendly and easy to operate, but it’s difficult for a person with dementia.” (FGs 1, 2, and 3)

Persons With Dementia and Their Interaction With LOVOT

The health care professionals described LOVOT as having an entertaining and calming effect on the persons with dementia. LOVOT has also influenced the persons to communicate and interact more with each other and the staff. The health care professionals stated that LOVOT provided a degree of entertainment value for the persons. It was further described how the interaction with LOVOT allowed the person to have a breathing space and relax. According to the health care professionals, some of the persons accepted LOVOT, and it evoked positive feelings, even joy. LOVOT also evoked feelings of care for the persons, where some of the persons treated LOVOT as if it were a child. Being together with LOVOT was at times even overstimulating for some of the older persons. Not all the participants in the study accepted LOVOT. Some of the persons with dementia thought that LOVOT was simply nonsense, whereas others found the robot difficult to relate to or interact with. The staff also described how some of the persons perceived LOVOT as an animal and interacted with LOVOT as they might with an animal, such as snapping at it or calling LOVOT to get its attention. The health care professionals further described how this acceptance and promotion of positive feelings could be due to the residents' perceiving LOVOT as not demanding anything other than being petted. The ability to touch and hug LOVOT has been shown to help prevent touch deprivation in some of the persons who might not have much physical contact with others.

Health Care Professionals' Experience With LOVOT

The health care professionals described how LOVOT's artificial behavior seemed natural. The health care professionals described LOVOT as an effective tool for communication between the staff and persons with dementia, in that it can create feelings of security and facilitate communication. LOVOT was described as user-friendly and fun, but the health care professionals stated that LOVOT could also be a burden on some of the residents.

Discussion

Principal Findings

Our results showed that there were no clinically significant changes in the well-being of the persons with dementia who participated in the individual or group sessions with the LOVOT robot. Results from the face scale showed that in both the individual and group sessions, the persons with dementia tended to express more positive facial expressions after the session with LOVOT. In other words, interacting with LOVOT made them happier. The effect on mood varied throughout the test period, however. The results indicated that LOVOT may have a positive impact on the current mood of the person with dementia, but this is not a sustained effect over time. Findings on how persons with dementia experienced their interaction with LOVOT can be summarized in terms of the following: the robot has an amusing or calming effect; facilitates more open communication and interaction; has some entertainment value; creates a breathing space; is accepted and creates a degree of happiness or good feeling; creates feelings of care; can even create an overstimulation of feelings at times; may not be

accepted by all residents; can be perceived as an animal; is perceived as being nondemanding; and prevents touch deprivation. We emphasize that LOVOT was not intended as, nor did it prove to be, an effective tool for each person with dementia.

Findings on the health care professionals' experiences using LOVOT indicated that they found that its artificial behavior seems natural; that LOVOT is viewed as a communication tool that can stimulate, create feelings of security, and facilitate communication; and that LOVOT is viewed as user-friendly, fun, and a positive tool. The health care professionals found that the social robot, as a new tool in their "care toolbox," can be used in interactions with persons with dementia. The professionals expressed no ethical dilemmas regarding the use of the robot.

In our study, we did not identify any significant changes in the well-being of persons with dementia during the period when they had interactions with the social robot. We think that the persons did not have sufficient time for interactions with LOVOT in the individual and group sessions, such that insufficient time for adjustment might explain the lack of any identified changes in their well-being.

The finding that LOVOT can have a positive impact on the person's current mood is consistent with the results of other studies that have examined the effects of social robots on persons with dementia. Wada et al [16] also used the face scales to evaluate the influence of the robot seal PARO on the mood of the persons, studying their interaction over a 3-month period. Wada et al [16] found that the face scale score was lower after the session than before the start of the session. A systematic literature review by Kang et al [19] describes a study that examined persons' facial expressions during group sessions with PARO over a 6-week period. Here, significant positive changes were noted: following their interactions with PARO, the persons were smiling more and happier. Both these studies are limited by their low sample size of the persons, but they nevertheless support the findings of LOVOT's positive impact on the persons' momentary mood.

The LOVOT robot is the next generation of social robots with advanced artificial intelligence. The LOVOT has not previously been tested in any clinical settings outside of Japan. The social robot LOVOT is still under development and can be categorized as the most advanced SAR at the moment internationally. We have not identified other studies that have documented these findings, as this is the first study that tests LOVOT interacting with persons with dementia. However, studies of other, less advanced social robots interacting with persons with dementia found that social robots can provide positive outcomes; they can improve social engagement, such as facilitating more communication and promoting positive mood [6-8]. We found that LOVOT was able to open up communication and enhance the expression of feelings, laughter, and feelings of care due to LOVOT's advanced ability to respond and interact with human beings in a humanlike way. LOVOT's state-of-the-art artificial intelligence gave it a certain advantage here. A systematic review and meta-analysis of randomized controlled studies by Pu et al [20] found that social robots appeared to reduce agitation

and anxiety and enhance the quality of life for older adults, but the studies were not statistically significant. A narrative review by Pu et al [20] indicated that social robots can improve engagement, enhance interaction, reduce loneliness, and reduce stress indicators.

We found that LOVOT could create an overstimulation of feelings for persons with dementia. Participant-observation notes showed that some persons were either crying or became extremely extroverted in their behavior. Robinson et al [10] have found that some persons with dementia may find that the behavior of some social robots provokes anxiety. A systematic review by Hung et al [8] on the use on PARO in care settings found that PARO could cause negative emotional responses, including fearfulness, anger, and agitation. In their review, Hung et al [8] question whether past negative experiences with animals could have influenced whether the person “likes” or “dislikes” a social robot. Further research is needed to explore this variable.

Some persons with dementia in our study did not accept the LOVOT. Our consort diagram shows that 7 persons out of the 70 accessed for eligibility did not like the robot, equivalent to 10% of our sample. As social robots are new to dementia care, it is understandable that not everyone in the older generation would be comfortable accepting the LOVOT. The range of attitudes about social robots is also confirmed by other studies [5,6,20].

Health care professionals felt that LOVOT’s artificial behavior seemed natural in its interactions with the persons with dementia, and overall, they found LOVOT to be an effective tool for communication and interaction for persons with dementia. The review by Hung et al [8] found that the use of social robots in dementia care can lead to perceptions that care has become infantilizing and dehumanizing. However, this aspect was not found in our study. One may question if this perception is due to the appearance of LOVOT and its potential to interact with persons with dementia. This issue needs to be explored further in future international studies. Abdi et al [6], in a scoping review on the use of SAR in care for older persons, identified several potential roles that the SAR could have—as affective therapy, cognitive training, social facilitator, companionship, and physiological therapy. Ghafurian et al [7] have emphasized the need for more robust research, in an international context, to fully assess the value of SAR in care for older persons. As social robots become more advanced, with

artificial intelligence, there is a need for further, comprehensive testing of social robots within care for older persons and to develop a range of data collection techniques that can effectively assess the efficacy of social robots and identify the ethical issues connected with using social robots with persons living with dementia.

Limitations

The target group for this trial was older persons with dementia who live in nursing homes. A limitation of the study is the gender distribution, as our sample had only 9 men among the 42 subjects. Another limitation is the fact that we were not able to interview the residents directly about their condition but had to rely on observations and data from health care staff. We have instead used a triangulation of data collection techniques to explore how the persons with dementia in our study (and the health care staff) experienced their encounter with LOVOT. However, it was the health care professionals who filled out the questionnaires about the residents. This had an advantage because the staff had intimate knowledge of each resident. Another limitation is that we have not incorporated the perspectives of the residents’ relatives in this study, which could have enriched our data regarding the use of SAR in dementia care for older persons. We are aware that this is a pilot study, and there will be a need to conduct studies with LOVOT using a longer duration period and on a larger scale to fully explore LOVOT’s potential and limitations for persons with dementia.

Conclusions

The LOVOT robot is the next generation of social robots with advanced artificial intelligence. The vast majority of persons with dementia accepted the social robot LOVOT. LOVOT had positive effects, opened up communication, and facilitated interpersonal interaction. Although LOVOT did not create noticeable effects on social well-being, it gave individual persons a respite from everyday life. Some residents were overstimulated by emotions after interacting with LOVOT. Health care professionals accepted the social robot and view the LOVOT as a new tool in the work with persons with dementia. As social robots become more advanced, with artificial intelligence, there is a need for testing the advanced social robots within care for older persons and to develop a new toolbox that can fully assess the value of the social robots for persons with dementia in the health care sector.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Visualization of LOVOT's anatomy (reproduced from Groove X [12], with permission from Groove X).

[PNG File , 227 KB - rehab_v9i3e36505_app1.png]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials

SAR: socially assistive robots

WHO-5: World Health Organization-5 questionnaire

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Original Paper

A Mixed Reality Cognitive Orthosis to Support Older Adults in Achieving Their Daily Living Activities: Focus Group Study With Clinical Experts

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Abstract

Background: Mixed reality is an emerging technology that allows us to *blend* virtual objects into the actual user's environment. This can be realized using head-mounted displays. Many recent studies have suggested the possibility of using this technology to support cognition in people with neurodegenerative disorders (NDs). However, most studies have explored improvements in cognition rather than in independence and safety during the accomplishment of daily living activities. Therefore, it is crucial to document the possibility of using mixed reality to support the independence of older adults in their daily lives.

Objective: This study is part of a larger user-centered study of a cognitive orthosis using pure mixed reality to support the independence of people living with NDs. This study aimed to explore (the difficulties encountered by older adults with NDs in their daily life to ensure that pure mixed reality meets their needs, (the most effective interventions with this population to determine what types of assistance should be provided by pure mixed reality technology, how the pure mixed reality technology should provide assistance to promote aging in place, and the main facilitators of and barriers to the use of this technology.

Methods: We conducted a descriptive, qualitative study. A total of 5 focus groups were completed with occupational therapists who had expertise in the disease and its functional impacts (N=29) to gather information. Each focus group met once for a 1-hour period. All sessions were held over a 3-month period. A semistructured interview guide was used. All group interviews were audiotaped with the consent of each participant to facilitate the data analysis. We conducted inductive qualitative analysis in four stages using a thematic analysis approach: full transcription of the audio recordings, first-order coding of the transcribed data, second-order coding from the first-order code list, and data reduction and matrix development.

Results: The results suggested that the main difficulties encountered by this population were in remembering to complete tasks, initiating the tasks, and planning the tasks. Several interventions are used to improve the independence of this population, such as prevention, simplification or facilitation, adaptation, and compensation. The use of pure mixed reality in older adults with NDs to promote independence and safety at home is promising and may respond to several clinical functions identified by the participants. Finally, pure mixed reality has good potential for use in this population and involves certain facilitators and obstacles, such as resources, technical aspects, and social considerations.

Conclusions: The cognitive orthosis that will be developed in light of this study will act as a proof of concept for the possibility of supporting people with NDs using pure mixed reality.

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KEYWORDS

cognitive orthosis; mixed reality; older adults; daily activities; qualitative study; focus group; mobile phone; smartphone

Introduction

According to the World Health Organization [1], in 2050, approximately 24% of the world population will comprise older adults compared with 14% in 2015. The aging of the population has led to an increase in the presence of neurodegenerative disorders (NDs), such as Alzheimer disease (AD) or mild cognitive impairments (MCIs), which has resulted in several challenges for this population and for society in general. Indeed, NDs have an important impact on the health care system, as it has been documented that 11% of people aged ≥ 65 years are living with an ND in Canada [2]. NDs rank fourth in the burden of disease, which is constantly increasing among caregivers and in the health care systems [3].

A way of reducing the burden on caregivers and on the health care system is to support aging in place by promoting home care through assistive technologies (ATs), comprising assistive, adaptive, and rehabilitative devices used to improve functioning and quality of life for people with disabilities or the population of older adults [4-7]. This would also support older adults' desire to remain in their homes and thus live independently in the community for as long as possible [8]. To live independently in the community, a person must be able to perform basic activities of daily living (BADL), such as washing oneself and eating, as well as instrumental activities of daily living (IADL), such as managing finances, preparing meals, and taking medication. These activities are crucial for aging in place and maintaining the ability to live independently at home [9-11].

To assist in performing IADL, the AT should be able to spontaneously provide help to the person, including warning them of dangerous situations [12]. Such AT is called *intelligent AT*, which encompasses technologies that are able to capture and interpret the context in which the person is situated when

performing an activity so that it requires the least amount of interaction and input from them [4,13,14]. To guide the development of such ATs and maximize their adoption by users, the *zero-effort technology* (ZET) principles have been proposed [12]. These principles involve designing technologies that (1) fit into the person's environment and real-world setting, (2) compensate for the difficulties experienced by the person and match their residual capacities, (3) use intuitive interfaces, (4) reduce the caregiver burden, (5) protect the person's privacy and allow a sense of control, and (6) allow for adaptation and customization according to the person's preferences. Technologies that adhere to these principles involve minimal interaction with the user, allowing the user to focus on completing the task instead of on how to use the technology. In addition, it has been suggested that such technology presents better acceptability for people with moderate to severe cognitive impairments, such as older adults with NDs [15].

Pure mixed reality realized with a head-mounted display (HMD; Figure 1) can, from a theoretical point of view, meet the ZET principles and has the potential to support older adults with cognitive deficits during their BADL and IADL. Pure mixed reality encompasses technologies that allow us to *blend* virtual objects in the actual user's environment [16]. This is different from augmented reality (AR), in which holograms are overlaid onto the user's environment [16]. To do so, the device uses various embedded sensors and computational capabilities to interpret the environment and understand the user's context. This will allow the technology to intervene at any time and add virtual assistance to the environment without having to physically modify it. For example, the HMD can be used to scan the surroundings to detect where the user is in the home and what the user is doing. The HMD can also scan the surroundings to detect and recognize objects and provide assistance.

Figure 1. The head-mounted display.



Only a few devices can currently realize pure mixed reality, the most advanced of which is the Microsoft HoloLens 2 [17,18]. One of the reasons for selecting an HMD rather than a mobile device such as a smartphone is that an HMD is, by definition, worn. It can continuously capture the environment, in contrast to a smartphone, which is carried. HMD will also always display the virtual information in front of the user's eyes, in contrast to

a smartphone, which needs to be pointed in the right direction. For these reasons, the use of an HMD can realize pure mixed reality efficiently and from a theoretical point of view, meeting the ZET principles.

To the best of our knowledge, the study of this technology to support older adults with NDs in achieving their daily activities

is just beginning [13,14]. However, some researchers such as Blattgerste et al [13] are suggesting that their use in technologies to support older adults will increase because of the advantages it offers, such as providing audio and/or visual assistance and various possibilities for interactions (audio, gestures, and gaze). It is also expected that this technology will become more available in the years to come when prices will drop [13], and new designs will make HMD more usable and more versatile. To date, there has been positive reception from participants in studies conducted with HMD (based on AR and pure mixed reality) [13,19,20].

However, the types of difficulties for which older adults with NDs would require pure mixed reality assistance have not yet been documented in the literature. It is important to document these difficulties to be able to develop a prototype of an HMD based on the needs of the targeted population. Furthermore, it has not yet been specified in the literature how an HMD prototype can provide assistance to support the independence and safety of this population in BADL and IADL. Indeed, considering the limited literature on the subject, we need to understand what role the HMD could play in assisting this population and when to use such technology. It has been documented that the noncompatibility of technological advances with the needs of older adults is a major obstacle to their use and implementation; therefore, it is important to document their needs from the perspective of experts involved with this population, such as occupational therapists (OTs), to design a version that can later be tested with this population [21]. OTs are clinicians' experts who have the knowledge and skills to assess older adults with NDs and provide appropriate ATs [22].

The objectives of this study were to document, from the experts' perspective, (1) the main difficulties encountered by older adults with NDs in their daily life to ensure that the pure mixed reality meets their needs, (2) the most effective interventions for this population to determine what types of assistance should be given by the pure mixed reality technology, (3) how the mixed reality headset should provide assistance to respond to clinical purposes of promoting safety and independence at home, and (4) the main facilitators of and barriers to the use of this technology among this population to develop a version ready for laboratory testing.

Methods

The Research Design

This study is part of a larger user-centered design project on the design of a cognitive orthosis using pure mixed reality to support the independence of people living with NDs. Such an approach generally comprises four steps: exploration, ideation, generation, and evaluation [23,24]. This study reports the exploration phase, which aims to better understand users' needs, motivations, and attitudes [22].

As various methods can be used to conduct the exploration phase [24], we selected a *descriptive inductive qualitative research design* to document the main difficulties of older adults

with NDs and how assistance can be provided with pure mixed reality [25]. We collected the data through focus groups with OTs and experienced stakeholders to document their perspectives on an example of a mixed reality headset [20]. It has been documented that focus groups are relevant and appropriate for obtaining a detailed portrait of a phenomenon for which little literature exists [26]. The focus group method is particularly appropriate in this context to document the perspective of experts about the potential of using our first prototype to generate ideas because of group synergy [24].

Participants and Recruitment Process

Invitations were sent to several OTs working in various clinical settings in specialized psychogeriatrics and experienced stakeholders of a local Alzheimer association. OTs are health professionals entitled to assess the needs of people living with cognitive impairments, determine the types of interventions that can ensure safety and increase their independence in IADL, and anticipate facilitators and obstacles to the use of new technologies, such as intelligent AT [27]. Experienced stakeholders, such as those involved in associations dedicated to older adults with NDs, are closely involved in the daily life and real environment of the person and are, therefore, able to specify the main difficulties encountered by this population, as well as predict effective interventions that work with older adults in their natural environment. The inclusion criterion was participants with at least 3 years of experience in involvement with older adults with NDs. There were no exclusion criteria for this study. Participants were divided into groups of 3 to 6 in accordance with the guidelines for this method [26].

Ethics Approval

The Research Ethics Board of the Aging-Neuroimaging Research Ethics Committee of the *Centre (Intégré Universitaire de Santé et Services Sociaux—Centre-Sud-de-l'île-de-Montréal)* approved the project (CER VN 19-20-28). The participants provided written and informed consent to participate in the study.

Data Collection

Each focus group met once for 1 hour, and all sessions were held over a 3-month period. A semistructured interview guide was used (Textbox 1). Participants were asked to discuss three topics related to (1) the difficulties of older adults with NDs in everyday activities, (2) the effective interventions used to support the independence and safety of this population during meal preparation, and (3) their perspectives on the relevance of using the mixed reality headset with this population. A video describing the different features of the mixed reality headset was presented between topics 2 and 3. A member of the team (AY) acted as a facilitator and was responsible for asking questions and guiding discussions. Another member (GS) acted as an observer, took notes, and validated the discussion content with the group at the end of the discussion on each topic. All group interviews were audiotaped with the consent of each participant to facilitate the data analysis.

Textbox 1. Questions used to guide focus group discussions.

- “In your experience, what are the main challenges faced by people in the early stages of neurodegenerative disorders in their daily activities at home?”
- “What are the main interventions you use with this clientele?”
- Presentation of a short video of the current version of our prototype and explanation of the parameters of use available to support the person during daily activities:
 - “How can our prototype be useful to support the daily living of this clientele?”
 - “Following the presentation of our prototype, do you think that such a tool can help elderly people with neurodegenerative disorders to improve their independence in daily living? What would you change to adapt this tool to the needs of your clients? Would you use such a tool with your clients, and if no, why?”

Data Analysis

To ensure the validity of the data when using this type of method, words and facts were reported as accurately as possible following the focus group sessions, and we pursued data saturation. Data saturation is reached when there is sufficient information to replicate the study and when the ability to obtain additional new information has been attained so that further coding is no longer achievable. We attempted to remain close to our data, the words used, and the events described by recording the sessions and transcribing the entire verbatim [25]. We conducted inductive qualitative analysis in four stages using a thematic analysis approach [28]: (1) full transcription of the audio recordings, (2) first-order coding of transcribed data, (3) second-order coding from the first-order code list, and (4) data reduction and matrix development. To validate the data analysis, the lead author (AY) performed the coding. A list of codes was validated by an OT (PS) and a researcher from the team (NB) until a consensual integrated code list was obtained. The coding aimed to assign labels (codes) to relevant units of meaning, such as words, sentences, or paragraphs. After first-order coding,

second-order codes were used to condense the data into different categories, which were then condensed into different major themes (third-order codes). Once the 2-step coding was completed, conceptual grouping matrices based on the major themes were developed to reduce the set of codes to a format that was more manageable and easier to conceptualize. All themes and matrices were validated by PS and NB.

Results

Overview

To obtain data saturation, a total of 24 OTs from different clinical settings, including a psychogeriatric-intensive functional rehabilitation unit, long-term care, day hospital, home support, and day center (n=10, 42% of OTs had >10 years of experience; n=14, 58% had 3-10 years of experience in geriatrics) were recruited, as well as 6 experienced stakeholders from a recognized Alzheimer association. They participated in a total of 5 focus groups. [Table 1](#) presents the participant characteristics for each focus group session.

Table 1. Table of characteristics of participants.

Focus group and participant ID	Role	Gender	Clinical setting involvement
Group 1			
P1	Occupational therapist	Female	<ul style="list-style-type: none"> Intensive functional rehabilitation unit
P2	Occupational therapist	Female	<ul style="list-style-type: none"> Day hospital
P3	Occupational therapist	Male	<ul style="list-style-type: none"> Intensive functional rehabilitation unit
P4	Occupational therapist	Female	<ul style="list-style-type: none"> Day hospital Geriatric evaluation clinic
Group 2			
P1	Occupational therapist	Female	<ul style="list-style-type: none"> Intensive functional rehabilitation unit Geriatric evaluation clinic
P2	Occupational therapist	Male	<ul style="list-style-type: none"> Day center
P3	Occupational therapist	Female	<ul style="list-style-type: none"> Intensive functional rehabilitation unit Home support
P4	Occupational therapist	Female	<ul style="list-style-type: none"> Long-term care Day center
Group 3			
P1	Occupational therapist	Female	<ul style="list-style-type: none"> Long-term care Day hospital
P2	Occupational therapist	Female	<ul style="list-style-type: none"> Day hospital
P3	Occupational therapist	Female	<ul style="list-style-type: none"> Intensive functional rehabilitation unit
P4	Occupational therapist	Female	<ul style="list-style-type: none"> Home support Geriatric evaluation clinic
Group 4			
P1	Experienced stakeholder	Female	<ul style="list-style-type: none"> Community-based association
P2	Experienced stakeholder	Female	<ul style="list-style-type: none"> Community-based association
P3	Experienced stakeholder	Female	<ul style="list-style-type: none"> Community-based association
Group 5			
P1	Experienced stakeholder	Female	<ul style="list-style-type: none"> Community-based association
P2	Experienced stakeholder	Female	<ul style="list-style-type: none"> Community-based association
P3	Experienced stakeholder	Female	<ul style="list-style-type: none"> Community-based association

Objective 1: Main Difficulties of Older Adults With NDs in Everyday Activities

Our first objective was to understand the main difficulties encountered by older adults with NDs in their daily lives to ensure that pure mixed reality meets their needs. The participants

identified the main difficulties but also specified the factors influencing these difficulties (Table 2). Factors that influence the level of disability during activity performance were disease severity, social and professional support, and characteristics of the activity (newness, structure, and complexity).

Table 2. Participation of older adults with neurodegenerative disorders in everyday activities.

Disability types	Activities					
	Eating	Moving oneself	Washing oneself	Preparing meals	Managing medication	Managing finances
Difficulty in remembering to complete tasks	✓		✓			
Difficulty in initiating the tasks			✓	✓	✓	
Difficulty in remembering where they are in a task—what parts they already completed			✓	✓	✓	
Difficulty in planning a task		✓		✓	✓	✓

Main Type of Difficulties Encountered by Older Adults With NDs

According to the participants, the main difficulties encountered by this population were *difficulty in remembering to complete tasks*, *difficulty in initiating the tasks*, *difficulty in remembering where you are in a task*, and *difficulty in planning a task*. These difficulties could manifest in different activities, such as eating, getting around, bathing, preparing a meal, managing medication, and managing finances, as shown in [Table 2](#).

For example, *difficulty in remembering to complete tasks* and *remembering where you are in a task* can occur during personal care, such as washing oneself or eating, as highlighted by 7% (2/29) of participants:

But they will start to have difficulty in washing, for example by forgetting and washing two or three times the same body part...hygiene, it is easy for them to wash a place, just a place and to forget or to think that they have already done everything. [P1, FG3, number 65]

Well, I would tend to say that everything that happens at the level of nutrition in the kitchen, they are not able...as we were saying earlier, they are no longer able to get adequate nutrition, they think they have already eaten. [P2, FG4, number 34]

According to the participants, difficulties in *initiating a task* comprise difficulty in getting into action, difficulty in thinking about doing a task, or difficulty in mobilizing without instructions or cues. Older adults with NDs can struggle to accomplish BADL, such as washing, getting dressed, or eating, as they have difficulties in thinking about what to do and putting these activities into action:

Well, lately, I've had a lot of very passive patients, because we weren't even so much doing the task, but rather "initiating" it, e.g., thinking about washing, getting dressed, eating...just thinking of doing those was a challenge... [P1, FG1, number 67]

I will also go uh it is very difficult for them at the level of putting into action to do things...without getting stimulated to do so. [P2, FG4, number 38]

According to participants, difficulties in *remembering where you are in a task* appear mostly in the repetition of some steps of a task, as the person forgets the steps already taken and gets lost in the one that they perform:

Sometimes there's repetition of tasks too. I once had a lady who was doing her hygiene at the sink, she put on the deodorant, she washed again, she put the deodorant back on and then she asked me did I put it on or not? So, it's repetition, and she forgets the steps she did previously. [P2, FG2, number 29]

And then in terms of repetition, especially, earlier I had a lady who was counting her money, an amount of money that I asked her to count for me. [P1, FG2, number 37]

In contrast, difficulties in *planning the task* comprise difficulty in preparing all the elements necessary for the proper completion of the task without assistance. For example, a participant said the following:

A lot of difficulty in terms of preparation. Sometimes you really have to prepare the material for them, otherwise, nothing gets done. [P4, FG2, number 25]

Factors Influencing Level of Difficulties

According to the participants, several factors influence the participation of older adults living with NDs in everyday activities, including *disease severity*, *social and professional support*, and *activity characteristics*. The *disease severity* influences the level of symptoms and disabilities, which has an impact on the accomplishment of activities, especially complex activities such as medication management, as presented in the following extract:

It also depends on the disease severity [...] But there could be an impact on all activities of daily living, but especially activities that are complex. [P2, FG3, number 34]

Social and professional support are other factors that influence the level of disability in older adults living with NDs. Indeed, having the support of the family and adequate professional follow-up allows the person to have better needs management and a better quality of life. For example, having a proper medical follow-up with physicians and nurses influences the management of certain conditions that have a direct impact on the person's capacities. According to a participant, an infection can have negative consequences on a person's ability to participate in everyday activities, as shown in the following extract:

I think that medication, nutrition, hydration are really important points, but I would also add that medical follow-up is very, very important to me because sometimes we know that a urinary tract infection can

lead to delirium, can increase the symptoms, hallucinations, which means that for the person, it's a hell of a thing, she loses all her bearings. Uh, that can really have a major impact on the participation in daily activities. [...] [P1, FG4, number 40]

Finally, *activity characteristics* such as newness, structure, and complexity directly influence the participation of older adults living with NDs. Indeed, new, unstructured, and complex activities such as meal preparation, financial management, appointment management, and medication management are more difficult to accomplish than routine, structured, and well-known activities. Newness is a factor that influences the level of difficulty in this population in many ways. It can involve difficulty in functioning in a completely new environment, difficulty interacting with new staff, difficulty in managing a new situation or task, and difficulty in having adequate judgment to react to an unexpected situation. In addition, this population has difficulty with activities without a specific structure, as explained in the following quote:

But they will start to have difficulty in washing without forgetting or going back to the same body part. Because the task has no structure imposed [...] e.g., hygiene, it's easy to make a place, just a place and forget or think that you have done everything. So, we'll see, so for the activities that are less structured, the difficulties will appear before. [P2, FG2, number 27]

Objective 2: Effective Interventions Used to Improve the Independence of Older Adults With NDs in Daily Activities

According to the participants, several interventions have been used to improve the independence of older adults with NDs. These interventions targeted the person's abilities and task requirements or modified the environment to optimize the person's safety, independence, and quality of life. According to the participants, these interventions had different goals, such as *preventing, facilitating, adapting, and compensating*, as shown in [Table 3](#).

Table 3. Interventions used to improve the independence of older adults with neurodegenerative disorders in everyday activities.

Objective and target	Prevention or orientation	Facilitation or simplification	Compensation	Adaptation
Environment	<ul style="list-style-type: none"> • Visiting the new environment before moving in • Personalizing the new environment before moving in • Involving the family 	<ul style="list-style-type: none"> • Providing physical assistance to initiate the activity (employee) • Having a model that acts as an example • Eliminating distractors 	<ul style="list-style-type: none"> • Caregiver doing the activity for them • Using technologies to ensure safety during the task • Using a pillbox or a dispill for medication management 	<ul style="list-style-type: none"> • Providing familiar elements • Highlighting essential information
Person	<ul style="list-style-type: none"> • Providing guidance 	<ul style="list-style-type: none"> • Providing feedback to continue the task • Providing recall • Providing verbal aid when achieving the task • Graduating assistance when achieving the task 	<ul style="list-style-type: none"> • Stimulating the person to start the activity 	<ul style="list-style-type: none"> • Using a checklist • Verbalizing the steps of the task when achieving the task
Activity	<ul style="list-style-type: none"> • Providing directions and reference points 	<ul style="list-style-type: none"> • Reducing trip distances • Preferring preauthorized payments and consolidating bank accounts and automated payments • Using fewer ingredients and steps in recipes 	<ul style="list-style-type: none"> • Using preprepared meals 	<ul style="list-style-type: none"> • Using a timer to achieve meal preparation • Establishing a routine

According to the study participants, *prevention interventions* mainly comprise upstream interventions to prevent undesirable situations. For example, in the case of institutionalization or delocalization, visiting the new environment and personalizing it before moving in is a relevant intervention for preventing disorientation, as well as involving the family and providing guidance, directions, and reference points. Regarding this, a participant pointed out the following:

Someone who doesn't have any family, really, you hope that the residence in which she goes has an approach adapted to the elderly people and that...because if not, really, if she doesn't have any family to...even if it's only to personalize her room, to have her bedspread, a picture of her cat or

anything. I think to guide her on a daily basis, to reassure her, to guide her...is really important. [P3, FG1, number 108]

Facilitation and simplification interventions decrease the burden of actions by reducing the global complexity of activities. This can be accomplished by targeting the person, task, or environment. The goal of these interventions is to make the activity as simple as possible to make task accomplishment easier. For example, providing physical assistance to initiate the task or providing a model that acts as an example allowing for imitation are interventions that simplify the activity as they allow the person to skip the initiation and/or planification step of the task. For example, a participant said the following:

[...] when [they see] the attendants going to help the other clients, it is an example that is given, it saves them from doing the whole thread of planning the steps of the task and thinking about it. [P2, FG1, number 46]

Providing feedback, verbal assistance, and visual cues are also *facilitation and simplification interventions* that facilitate task accomplishment as they allow the person to reduce their cognitive burden. According to the participants, using images instead of long sentences or having a list of preprogrammed steps are effective ways of providing facilitating assistance. Regarding this, 7% (2/29) of participants highlighted the importance of such interventions:

We're going to try to simplify the task anyway. [P3, FG3, number 67]

And we're always in the spirit of making it as simple as possible. One image, let's say, no more and not too many steps. Because we know that it won't be respected if there are too many. [P1, FG3, number 68]

Adaptation interventions comprise modifying an element of the activity or the environment to allow the accomplishment of the task. According to the participants, this type of intervention differs from task simplification in that it involves adding elements and steps to the task instead of reducing it. For example, adding familiar elements or highlighting essential information in the environment, using a checklist to help planification, verbalizing the steps of the task when achieving it, using a timer to achieve some activities, or establishing a routine are effective interventions to support independence and safety according to participants. For example, a participant said the following:

I think that establishing a routine, organizing them in time and space, routine is a priority, uh, keeping them in their environment, huh, it's really reassuring, secure for them, I could see that. [P4, FG4, number 165]

Finally, according to the participants, *compensation interventions* comprise subtracting the steps of a task when

elements are already performed by external help. For example, when the caregiver performs a task for them or when they stimulate the person to start the activity, they provide assistance that subtracts the initiation step of the task. Using technologies to ensure safety or using preprepared meals are also compensation interventions as they allow the person to skip steps within the tasks. For example, using a dispill and automatic recall allows a person to skip a few steps of the medication management activity, such as planning and organizing what pills to take. The participants said the following about the technologies and safety:

I think that when it comes to cognitive impairment, there is little potential for rehabilitation as such. I think that we go more into compensatory means. Really the services, for example the lifeline, the Safecook... [P2, FG2, number 143]

The Safecook is like a box, a timer, you connect the stove to it, and you have to start the Safecook first before starting the stove. So, when you start the timer, it's sure that after half an hour, it will be turned off even if the person hasn't closed it. [P1, FG2, number 15]

Objective 3: Opportunities for Use of a Mixed Reality Cognitive Orthosis

Overview

According to the participants, the use of pure mixed reality with older adults living with NDs to promote independence and safety at home was promising. Indeed, the participants identified three main clinical functions to which the mixed reality headset could respond: *assessment*, *assistance*, and *training*. *Assessment* comprises collecting information to evaluate a person. *Assistance* comprises providing explicit or implicit guidance to support task accomplishments. *Training* comprises providing information for developing new skills and abilities. These 3 functions could be responded to via 3 principal features of the mixed reality headset, including *detection*, *information storage and provision*, and *interactive* features (Table 4).

Table 4. Opportunities for use of a mixed reality cognitive orthosis to support older adults with neurodegenerative disorders to improve their independence and safety at home.

Microsoft HoloLens functionalities	Clinical functionalities		
	Provide assessment	Provide assistance	Provide training
Detection	Location and activity detection or recognition: Microsoft HoloLens can scan surroundings to detect where the user is in the home, what the user is doing, and whether the user needs emergency help	<ul style="list-style-type: none"> Object detection or recognition: Microsoft HoloLens can scan surroundings to detect objects and provide feedback through audio and video assistance Audio assistance involves assistance in finding objects (eg, remote control) and providing information about object functions Visual assistance involves assistance in providing the name of the object to the user, the name of the person through facial recognition to help social interactions, and warning symbols when the user is near danger (eg, stairs and stove) 	N/A ^a
Information storage and provision	Task monitoring: Microsoft HoloLens can collect and store information on the user’s daily movements and activities to be collected by care providers: information on risky behaviors, information on routine, and number of omissions and errors during daily activities	<ul style="list-style-type: none"> Task support: Microsoft HoloLens can store information involved in specific daily routines and tasks to help the user perform them by providing information such as audio and video assistance Audio assistance involves assistance in providing daily reminders about upcoming appointment times and dates and in providing options (eg, dinner menu) Visual assistance involves assistance in providing pictograms of the steps of the task and a list of steps or choices 	N/A
Interactive functions	N/A	<ul style="list-style-type: none"> Task support: Microsoft HoloLens can interact with the user using visual and auditory communication to help while the user is performing the task through audio and video assistance Audio assistance involves assistance in providing verbal feedback to the person and warning them in case of error and in mentioning the steps left to achieve the task Visual assistance involves assistance in providing symbols (eg, arrows, target, timer, and yes/no) to guide the person through medication, meal preparation, and leisure activities 	Therapeutic guidance: Microsoft HoloLens can interact with the user to practice skills through guidance while the user is practicing the task, visual guidance and stimulation (eg, hemineglect), and guidance when the user is learning to use an object

^aN/A: not applicable.

Detection Features

Detection features comprise the action or process of identifying the presence of objects in the environment or the user’s position or location. This allows location and activity recognition. Related to this feature, participants identified that the mixed reality headset may assist people in finding and correctly using objects by providing audio feedback to guide them through the environment or by providing information about object functions:

let me give you a basic example...let’s say someone who cleans his house and doesn’t remember what the products are for or confuse them...someone who sometimes takes detergent to wash the floor...The Mixed Reality Headset can help him to avoid that. [P4, FG4, number 345]

Microsoft HoloLens detection features may also assist the person in finding and correctly using the objects by providing visual feedback such as an etiquette of the name of the object that appears in the virtual environment of the users. According to the participants, the mixed reality headset may also support

social interaction through facial recognition by displaying the name of the people in front of the person. It can also ensure safety by providing visual assistance such as warning symbols when the user is near danger (stairs or stove). Related to these features, participants mentioned that using a stop sign symbol would send a clear signal to the user to avoid approaching a risky element:

I would see it more naturally with the concept of “forbidden,” for example: “You don’t do that”; “You don’t use the stove”; “You don’t go to the basement”; “You don’t go outside”; “You don’t use the stove”; “You don’t go to the basement”; “You don’t go outside”...You know, the things that are harder to compensate for in everyday life and that there isn’t someone there 24 hours a day to ensure safety. [P2, FG3, number 324]

Information Storage and Provision Features

Information storage and provision features comprise accumulating information to anticipate the actions to take. For

example, according to participants, the mixed reality headset may be useful for performing task monitoring to collect and store information on the user's daily movements and activities and provide information on risky behaviors, routines, and the number of omissions and errors during daily activities. This can help in anticipating task support. Indeed, according to the participants, the mixed reality headset may be useful for storing information involved in specific daily routines and tasks to help the user perform them by providing information through audio and visual assistance. Audio assistance can be provided by providing daily reminders about upcoming appointments or by providing options and alternatives during activities (eg, dinner menu). Visual assistance can be provided through pictograms of the steps of a task or a list of steps or choices. Regarding this, a participant said the following:

Well, earlier when we were talking about the sequence, The Mixed Reality Headset can provide a visual pictogram...for example the person doesn't know what step she is in the task...so what's the next one? The visual aid could follow the steps and display a pictogram of the next one. [P1, FG3, number 378]

Interactive Features

Interactive features comprise *communicating in real time with the user to respond to the three clinical functions*: assessment, assistance, or training. For example, according to the participants, the mixed reality headset can support task accomplishment by interacting with the user in real time to help through audio and visual assistance while the user is performing the task. Related to this functionality, participants mentioned that providing verbal feedback to the user and warning them in case of an error or mentioning the steps left to achieve the task are interactive functions that may be provided by the mixed reality headset. For example, a participant said the following:

When the person uses the dispill, the device may send a vocal message like "put the dispill back on the dining table"...it will help the person find it the next day. [P1, FG1, number 234]

Providing symbols to guide the person (arrows, target, timer, and yes or no) through medication management, meal

preparation, and leisure activities is also an interactive feature of the mixed reality headset, which may be useful, according to participants. For example, participants said the following:

If they've already set the destination in advance and have a real-time GPS with arrows and things that appear and detect cars...things like that, that could be interesting. [P3, FG3, number 382]

Or for people walking around their house. So, someone who has a regular route is fine. But if sometimes when a construction gets lost, it is to wear a GPS headset so that he doesn't get lost to go back home. [...] [P2, FG3, number 382]

Indeed, integrating the GPS functions in the Mixed Reality Headset would be great. [P1, FG3, number 382]

Interactive features allow the training of a person through *therapeutic guidance* as the mixed reality headset can interact with the user to practice skills. For example, the mixed reality headset can provide guidance while the user is practicing a task or when the user is learning to use an object. According to the participants, the mixed reality headset can also provide therapeutic guidance and stimulation to train the user's visual scanning ability (eg, patients with hemineglect). Regarding this, participants underlined the following:

In the case the person doesn't think to turn his head, you can provide visual cues that stimulate...or if the person is just scanning to one side, having an arrow or a light signal may help... [P1, FG3, number 392]

Objective 4: Facilitators and Obstacles Influencing the Use of the Mixed Reality Cognitive Orthosis by Older Adults With NDs

Overall, participants perceived the mixed reality headset as a technological tool with great potential for older adults with NDs. They identified several facilitators and barriers related to (1) *resources and technical aspects*, (2) *risks and ethical and social considerations*, and (3) *individual characteristics* that may influence the use of cognitive orthosis for this population, as described in [Table 5](#).

Table 5. Facilitators and obstacles influencing the use of the mixed reality cognitive orthosis by older adults with neurodegenerative disorders to improve their independence and safety at home.

Category	Facilitators	Barriers
Resources	<ul style="list-style-type: none"> Human and professional resources Family involvement 	<ul style="list-style-type: none"> Financial resources (costs) Maintenance and professional resources
Technical aspects	<ul style="list-style-type: none"> Possibility of connecting the device to the telephone Simplicity of use 	<ul style="list-style-type: none"> Continuous wear of AR^a glasses Storage in the same place Appearance of the device not as a conventional eyewear
Ethical and social considerations	<ul style="list-style-type: none"> N/A^b 	<ul style="list-style-type: none"> Respect of privacy Social stigma
Individual characteristics	<ul style="list-style-type: none"> Ability to use and understand the usefulness of the device Presence of a need to use it Familiarity with technologies Interest in use 	<ul style="list-style-type: none"> Lack of openness to using the device Disease severity Presence of sensory deficits (auditory and visual) Difficulty in finding the device Difficulty in remembering to put on the device
Risks	<ul style="list-style-type: none"> Technical resources (technical assistance) 	<ul style="list-style-type: none"> Loss of visual, perceptual, and cognitive contact with the real environment Risk of nausea

^aAR: augmented reality.

^bN/A: not available.

Resources and Technical Aspects

In terms of resources, the involvement of the family and trained health professionals is a facilitator, as it allows for oversight of the use of the mixed reality headset. For example, 7% (2/29) of participants said the following:

And you need someone behind and all that too to facilitate the use, because there it's someone else who's going to put the cues, it's someone else who's going to know what to program, what are the activities that the person wants to do. So, there's that side too, the setting up of the necessary cues too. [P3, FG2, number 458]

And with a supervised part, a part that we come and do spot checks. [P4, FG2, number 458]

According to the participants, in terms of technical aspects, the possibility of connecting the device to the smartphone may be a facilitator as it allows more flexibility and options of use. In addition, the simplicity of use has been shown to be an important factor that may facilitate the use of the device within this population. Regarding this, a participant said the following:

No, even the use of those glasses there, it really has to be user-friendly, don't have to wonder too much about how it works. It must be very, very simple like keywords... [P3, FG2, number 54]

Nevertheless, according to the participants, the continuous wear of the AR glasses can be a burden on the person as it can add to the heaviness of daily life. Some participants proposed limiting the use of this device to a few specific IADL only; however, others suggested that in this case, the device should always be stored in the same place, as, with the omission and memory loss issues of this population, the person may forget to wear the headset or forget where it is when doing an activity

where they may need it. Regarding this, a participant said the following:

But I'm not sure, me practical, I don't know how much technology is going to evolve, but how much you can ask a person to wear this 24 hours a day for all activities [...] I think wearing it maybe for an hour, the time of the activity, but you can't expect someone to wear this all day. [P4, FG1, number 383]

Risks and Ethical and Social Considerations

The appearance of the device, which is not similar to conventional eyewear, may be an important obstacle to the use of the mixed reality headset by this population. Indeed, as social stigma is a barrier to the use of this tool, according to the participants, it would be difficult to encourage this population to wear it in its current version. In addition, participants noted ethical considerations related to the aspect of privacy as the data collected by the mixed reality headset concerns the daily life of the person being assisted, who may feel watched. Regarding this, a participant said the following:

Yeah, because there's an ethical issue behind that. There's a question of privacy, of dignity, of the person as well, so they would have to be in, able to accept that their caregiver sees them uh, you know, at all times in their daily life. With that, I think, it would be to study. [P1, FG4, number 344]

Some risks that could potentially be barriers to the optimal use of the mixed reality headset were reported by participants, including the risks of nausea, confusion, and loss of contact with the person's actual environment while wearing the mixed reality headset.

Individual Characteristics

In relation to the individual characteristics of the person, several factors that can facilitate the use of the mixed reality headset were reported by the participants, such as being able to learn how to use the device, understanding its usefulness, and presenting the need to use it. Other factors such as familiarity with the technologies and interest in using them were shown to be important in facilitating the use of the mixed reality headset. In this regard, one of the participants said the following:

I think in several years, because we're so exposed to technology and that kind of gadgetry, that if you start now, after I don't know 10-15 years, I don't know what your hope for timeline is, but more and more in we're going to use it so it's going to become mainstream for us. [P1, FG1, number 438]

Participants identified several barriers related to the characteristics of the person, such as the severity of the disability, which can have a significant impact on the person's ability to use the tool. In addition, according to the participants, this population would be more likely to have sensory deficits, such as difficulties with sight or hearing, which could make it difficult to assist with daily activities using the mixed reality headset. This would also be the case for cognitive deficits; for example, if the person has difficulty finding the device or remembering its location, this can make it more difficult to use the mixed reality headset optimally. Regarding this, a participant said the following:

Just don't be like me and not able to find your glasses! [laughs]. Because it's a bad start if you need your glasses to find your glasses. [P1, FG1, number 409]

Discussion

Principal Findings

The purpose of this study was to describe clinicians' and experts' perspectives on the potential of pure mixed reality to support independence and ensure the safety of older adults with NDs in daily life. More specifically, we aimed to document (1) the main difficulties encountered by older adults with NDs in their daily life to ensure that the pure mixed reality meets their needs, (2) the most effective interventions with this population to determine the types of assistance that should be given by the pure mixed reality technology, (3) how the mixed reality headset should provide assistance to respond to clinical purposes of promoting safety and independence at home, and (4) the main facilitators of and barriers to the use of this technology among this population to develop a version ready for laboratory testing. The results suggested the following: (1) the main difficulties encountered by this population are in remembering to complete tasks, initiating the tasks, remembering where they are in a task, and in planning the task; (2) several interventions are used to improve the independence of this population, such as prevention, simplification or facilitation, adaptation, and compensation interventions; (3) the use of pure mixed reality with older adults with NDs to promote independence and safety at home is promising and may respond to 3 clinical functions identified by the participants, including assessment, assistance, and training; and (4) pure mixed reality has good potential for use

with this population, with certain facilitators and obstacles, such as resources and technical aspects, risks, ethical and social considerations, and individual characteristics.

Comparison With Prior Work

Regarding the type of difficulties encountered (objective 1), our study showed that this population faced many challenges in the accomplishment of BADL and IADL, such as *eating, moving oneself, washing oneself, preparing meals, managing medication, and managing finances*. The main difficulties that this population may face in these activities are difficulties in *remembering to complete tasks, initiating the tasks, remembering where they are in a task* (what parts are already completed), and *planning the task*. Difficulties in initiating and planning are part of executive functions, which have been documented as one of the main cognitive functions affecting the dementia continuum [29-31]. Impairment in executive functions puts the person at risk of errors when faced with unexpected situations and when making an appropriate decision, which potentially affects independence and safety. In general, difficulties in remembering are part of the memory components documented to be affected in this population [32]. Memory impairments can affect learning abilities and a person's daily life from simple tasks (bathing and/or moving oneself) to more complex tasks (managing finances and/or preparing meals) [22]. Memory and executive function impairments in this population are highly documented in the literature [33-37], and our results confirm the evidence. According to the participants, these difficulties would require specific assistance from the pure mixed reality technology to optimize independence and safety at home. Moreover, according to our results, many factors may influence the severity of difficulties in conducting these activities, such as disease severity, presence of social and professional support, and activity characteristics. *Disease severity* and *activity complexity* were shown to be determinant factors in the severity of difficulties that affect independence in IADL and BADL. Indeed, in the earlier stages of the ND continuum, such as MCI or early stages of AD, the difficulties are more inconspicuous, appearing only at the level of very complex activities that require the coordination of several steps. Furthermore, along the continuum, the difficulties are more visible and present in basic activities [38]. In short, pure mixed reality could be useful in the early stages of the disease to overcome memory- and executive function-associated difficulties encountered in the most complex activities of daily life, such as preparing meals and managing medication and finances.

The second objective of this study was to document the effective interventions that work with this population to determine the types of assistance that should be provided by pure mixed reality technology. Our study showed that according to the participants, clinical interventions can be effective when they target the person, activity, and/or environment, which is in accordance with models of occupational rehabilitation [39,40]. According to the participants, effective interventions aim to meet four main objectives: prevention, simplification or facilitation, adaptation, and compensation. Prevention interventions mainly comprise upstream interventions to specifically prevent undesirable situations, such as falling, getting lost, or causing a fire. In the

literature, the prevention interventions described are generally aimed at delaying the onset of dementia and cognitive decline or reducing their incidences, such as promoting healthy lifestyle habits and providing education, intellectual stimulation, or early screening [41]. Nevertheless, our results focused on clinical practice in rehabilitation, as we mainly involved rehabilitation experts—OTs (24/29, 83%) and experienced stakeholders (6/29, 21%); thus, in our study, prevention interventions aimed to improve the person's independence and safety and maintain their residual capacities, such as providing guidance, directions, and reference points to help the person prevent undesirable situations such as getting lost in a new environment. Several studies have shown that the use of this type of intervention allows a person to be more independent in their environment. For example, Spector et al [42] used a reality orientation board that displayed both personal and orientation information to provide some form of continuity for older adults with AD, which has been shown to be effective in preventing the risk of getting lost in the environment and in time. Simplification or facilitation interventions decrease the burden of actions by reducing the global *complexity* of activities. For example, according to participants, providing a model that acts as an example is a *facilitation* intervention that can make it easier to accomplish some activities, especially complex activities such as meal preparation. Few interventions of this type have been documented in the literature to support independence in IADL. Rousseau and Métivier [43] proposed an intervention based on *imitation* for emotional management. Adaptation and compensation interventions, as described in our study, such as using a pillbox or a dispill for medication management, highlighting essential information, stimulating the person to start the activity, using a checklist, verbalizing the steps of the task when achieving the task, or establishing a routine, are interventions that are widely documented in the literature as effective in optimizing independence and safety of older adults with NDs in their BADL and IADL [44-46]. Finally, the interventions proposed by the participants allow a better understanding of what types of assistance would meet the needs identified for this population, which would help computer scientists to better design features of HMD intended to help older adults with NDs accomplish BADL and IADL.

Our third objective was to determine the functions of the mixed reality headset that would be useful in assisting with the difficulties experienced by this population. Our study suggests that according to the participants, the detection, information storage or provision, and interactive features of a mixed reality headset can serve three main clinical functions: assessment, assistance, and training. In *assessment*, the mixed reality headset can detect or recognize the location and activity of the user and monitor them to provide data to clinicians about performance in daily activities. The use of sensor technologies has been shown to be promising in documenting the daily lives of older adults with dementia [47,48]. It has even been suggested that these technologies could be used to screen for NDs such as MCI or early AD [47]. More specifically, according to the participants, the mixed reality headset would be useful to document information on risky behaviors, routines of the person, and the number of omissions and errors during daily activities without the need for increased user interaction, which is

particularly relevant to ZET principles [4,12,14]. Assistance was the clinical function that participants identified as the most useful for the mixed reality headset. Indeed, the mixed reality headset can scan surroundings to detect objects and provide assistance through visual and audio feedback to help the person accomplish their daily tasks. The mixed reality headset can also store information involved in specific daily routines and tasks to help the user perform them by providing audio and visual information such as daily reminders, options, instructions, pictograms, and a list of steps before the task or by interacting with the user during the task. These types of assistance have previously been documented in several other Assistive Technology Center design studies [49,50]; however, their use with older adults with NDs has limitations related to the nature of the proposed technology, as it often does not respect the ZET principles [12].

Finally, our last objective was to document the facilitators of and barriers to the use of the mixed reality headset among older adults living with cognitive impairments. Our study suggests that the mixed reality headset has good potential, with certain facilitators and barriers. Financial costs and maintenance resources were identified as the main barriers to the use of pure mixed reality. The affordability of technology is often identified by clinicians when discussing the use of technology with this population [21,51]. However, the use and early introduction of technology could delay the institutionalization of older adults with NDs for up to 8 months, when the technology is efficient and adapted to the person's needs [52,53]. Thus, from a long-term perspective, it can be argued that the use of pure mixed reality at a more mature stage could support functional independence and, therefore, aging in place, as well as optimizing health care costs [52,54].

In terms of individual characteristics, some barriers to the optimal use of the mixed reality headset were reported by participants, including the risks of nausea, confusion, and loss of contact with the person's actual environment while wearing the headset. However, it has been documented that there is little to no *virtual reality sickness* in mixed reality or AR as there is no loss of contact with the real world; thus, it would be important to better inform people about this type of technology for optimized future adoption [55]. Social stigma may also be a barrier to the use of the mixed reality headset according to the participants, as it could be difficult to encourage this population to wear it in its current version. Considering the increasing technological advances in the domain, it will be possible to consider more conventional eyeglasses in the future [56]. In contrast, in earlier studies, the simplicity of use has been suggested to be an important factor that may facilitate the use of the mixed reality headset within this population, which reinforces the need to conduct usability testing in the future to document how to adapt and make the use of the device simpler, as required by the ZET principles [4,12,14,57]. In addition, other factors documented in our study, such as familiarity with the technologies and interest in using them, are shown to be important in facilitating the use of the mixed reality headset [21]. These factors are indeed part of the Technology Acceptance Model, which is a key model for understanding predictors of human behavior toward potential acceptance or

rejection of the technology [58]. Considering the growing increase in technology use by older adults [51,59,60], it is possible to predict that the mixed reality headset will be democratized and implemented as an AT for home support services in the future.

However, we acknowledge that the current development of mixed reality headsets has several limitations that could prevent the democratization of such technology to people with cognitive disorders and, more widely, to the general public for several years [13]. Despite positive preliminary studies, the high weight of this device might affect the user's experience [13,61,62]. Moreover, immersion is not optimal because of the small field of view of the screens [13]. The high price of the device is also an obstacle to its mass adoption [13]. The design of 3D graphical user interfaces and interactions is also important and should be carefully considered [63]. The literature suggests paying attention to the specific needs of older people with cognitive disorders during the design process because of their cognitive, perceptual, or physical limitations [13,64-68], which is supported by the conclusions of this study. For example, it is suggested to limit cognitive overload by limiting possible options [66], and the size of icons should be large enough as small targets might be difficult to reach [68].

If these issues are addressed, mixed reality could have several benefits, as well as limitations, because of their nature compared with other AT. In contrast to smart environments, mixed reality headsets do not require any modifications to the user's environment. In contrast, the user is required to wear the device to receive assistance. This might be inappropriate in certain situations, for instance, in the case of night wandering [69]. In contrast to smart environments, which are stationary, mixed reality headsets can deliver assistance at any time and place. However, they cannot act directly on the user's environment, for example, to prevent the evolution of a dangerous situation. Embedded technologies, such as the Cognitive Orthosis for Cooking, can turn off power to the stove if unsafe use by a person with a cognitive disorder is detected [70,71]. The mixed reality headset will also not be able to monitor the user's health, in contrast to body sensors or some smart environments [66].

Smartphones are popular devices that offer an alternative to delivering AR or mixed reality apart from headsets [13]. This technology is inexpensive and socially accepted [13]. However, smartphones offer less mobility than a headset, as the user needs to hold them with one hand and point the device in the direction where the assistance will be located in the space [72]. A mixed reality headset provides assistance in front of the user, allowing the user to keep their hands free [72]. Headsets also offer a more immersive experience [72]. Finally, projectors can be used to free the user from wearing a device and to use both hands [13]. However, in most cases, projectors are stationary [13] and, consequently, cannot offer assistance at any time or place.

Future Directions

Several future research paths can be suggested to continue advancing knowledge about the potential of mixed reality with individuals with NDs. First, observational studies can be undertaken to refine the users' requirements based on the directions proposed by health care professionals. Second, ZET

mixed reality headset prototypes could be developed to be useful for the target population by following a user-centered design approach. In particular, optimal interactions and graphical user interfaces should be explored. Regular usability testing with users should also be undertaken to maximize the usefulness of the prototype. Third, specific mixed reality ZET principles could be developed for this population by completing the already existing guidelines [65]. Fourth, coupling mixed reality headsets with both sensors to monitor the user's health and smart environments to manage critical situations could be explored. Finally, evaluating whether those results can be transposed to other populations, such as people with traumatic brain injuries or children with neurocognitive development disorders, could help in generalizing the applicability of mixed reality to other populations in need of ATs.

Strengths and Limitations

This study had some limitations. First, >75% of our participants were female, which may represent a gender issue. However, this reflects a reality in health care settings where women represent most health care professionals to which our participants belonged. Second, participants were recruited from clinical settings within a single city, which may limit the generalizability of the results. However, our focus groups were homogenous [73], as recommended by qualitative research guides, as all participants were OTs or experienced stakeholders from diverse settings in psychogeriatrics. This diversity allowed for in-depth documentation of our assumptions regarding the functional profiles of older adults with NDs across the continuum of care. Third, data saturation was noted as early as in the fourth focus group, reinforcing the credibility of the results obtained from the analysis. Finally, this study does not directly document the end user perspective but instead involves them indirectly, which is a limitation to the applicability of the results currently. However, we decided to initiate the first step of the user-centered design cycle (exploration) by involving clinical experts as our rationale was that older adults living with NDs could have had difficulty answering our research questions because of a lack of abstraction abilities required to discuss an intangible topic [74,75]. It has been previously documented that the low maturity of technology is a barrier to the initial intention for use and may result in the rejection of the prototype in the future. Therefore, we took the possible obstacle into consideration when choosing our first design step [76]. Our intention was to document the needs of older adults with NDs from the perspective of experts to design a version that can later be tested by them. Our next step will be to design a prototype that meets the recommendations identified in this study (ideation and generation) and then test its usability with older adults living with NDs and their caregivers (evaluation).

Conclusions

This study aimed to describe experts' perspectives on the potential of pure mixed reality to support independence and ensure the safety of older adults living with NDs. The results suggest that a mixed reality cognitive orthosis may help older adults with NDs face difficulties in everyday activities, such as *remembering to complete tasks, initiating the tasks, remembering where they are in a task (what parts are already*

completed), and *planning the task*. Thus, the use of mixed reality cognitive orthosis in older adults living with NDs to overcome these difficulties and promote independence and safety at home is promising and may respond to several clinical functions identified by the participants, including assessment, assistance,

and training. Finally, the mixed reality headset has good potential for use with older adults with NDs, with certain facilitators and limits. Future studies should address usability testing in this population to develop a usable and implementable prototype to support aging in place.

Conflicts of Interest

None declared.

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Abbreviations

- AD:** Alzheimer disease
- AR:** augmented reality
- AT:** assistive technology
- BADL:** basic activities of daily living
- HMD:** head-mounted display
- IADL:** instrumental activities of daily living
- MCI:** mild cognitive impairment
- ND:** neurodegenerative disorder
- OT:** occupational therapist
- ZET:** zero-effort technology

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Original Paper

Detection of Low Back Physiotherapy Exercises With Inertial Sensors and Machine Learning: Algorithm Development and Validation

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Abstract

Background: Physiotherapy is a critical element in the successful conservative management of low back pain (LBP). A gold standard for quantitatively measuring physiotherapy participation is crucial to understanding physiotherapy adherence in managing recovery from LBP.

Objective: This study aimed to develop and evaluate a system with wearable inertial sensors to objectively detect the performance of unsupervised exercises for LBP comprising movement in multiple planes and sitting postures.

Methods: A quantitative classification design was used within a machine learning framework to detect exercise performance and posture in a cohort of healthy participants. A set of 8 inertial sensors were placed on the participants, and data were acquired as they performed 7 McKenzie low back exercises and 3 sitting posture positions. Engineered time series features were extracted from the data and used to train 9 models by using a 6-fold cross-validation approach, from which the best 2 models were selected for further study. In addition, a convolutional neural network was trained directly on the time series data. A feature importance analysis was performed to identify sensor locations and channels that contributed the most to the models. Finally, a subset of sensor locations and channels was included in a hyperparameter grid search to identify the optimal sensor configuration and best performing algorithms for exercise and posture classification. The final models were evaluated using the F_1 score in a 10-fold cross-validation approach.

Results: In total, 19 healthy adults with no history of LBP each completed at least one full session of exercises and postures. Random forest and XGBoost (extreme gradient boosting) models performed the best out of the initial set of 9 engineered feature models. The optimal hardware configuration was identified as a 3-sensor setup—lower back, left thigh, and right ankle sensors with acceleration, gyroscope, and magnetometer channels. The XGBoost model achieved the highest exercise (F_1 score: mean 0.94, SD 0.03) and posture (F_1 score: mean 0.90, SD 0.11) classification scores. The convolutional neural network achieved similar results with the same sensor locations, using only the accelerometer and gyroscope channels for exercise classification (F_1 score: mean 0.94, SD 0.02) and the accelerometer channel alone for posture classification (F_1 score: mean 0.88, SD 0.07).

Conclusions: This study demonstrates the potential of a 3-sensor lower body wearable solution (eg, smart pants) that can identify exercises in multiple planes and proper sitting postures, which is suitable for the treatment of LBP. This technology has the

potential to improve the effectiveness of LBP rehabilitation by facilitating quantitative feedback, early problem diagnosis, and possible remote monitoring.

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KEYWORDS

low back pain; rehabilitation; wearables; inertial measurement units; machine learning; activity recognition

Introduction

Low back pain (LBP) is a prevalent condition that affects both physical and mental health [1,2]. Postural re-education and physiotherapy aiming to reduce disc derangement and strengthening exercises are often used to treat LBP [3-5]. Specifically, the McKenzie approach is based on a patient's pain response to directional movements of the spine. The McKenzie approach has been proven to be effective and is commonly used by physiotherapists and other rehabilitation clinicians involved in the care of patients with LBP [2,3,6]. Research suggests that there is a positive correlation between adherence to rehabilitation programs (quantity and quality) and their ultimate success [4,7]. However, the quality of data (ie, derived from self-reported patient diaries) with respect to at-home rehabilitation program adherence can experience low rates of patient completion and biases [8]. A lack of a gold standard for measuring rehabilitation adherence has led to variability in the quality of measuring standards [8,9].

Image-based and wearable sensor systems have been used for assessing exercises and postures, applying methods developed within the broader field of human activity recognition (HAR) [10,11]. Image-based systems have many challenges (related to setup, line of sight, and computational requirements) that may limit their suitability for home-based rehabilitation assessment and posture monitoring [12]. Wearable sensors with inertial measurement units (IMUs) have been extensively used for HAR in diverse scenarios [13]. IMUs are easily embedded, compatible with multiple environments, and present fewer privacy concerns, suggesting a promising option for rehabilitation adherence and posture monitoring. Sensor placement, in the context of inertial sensors, has varied among HAR studies. Wang et al [14], O'Reilly et al [15], and Johnston et al [16] conducted reviews of wearable sensors used for the assessment of upper limb rehabilitation, lower limb rehabilitation, and posture, respectively. Recently, our group developed and validated a system to monitor home-based adherence to shoulder physiotherapy exercises (Smart Physiotherapy Adherence Recognition System [SPARS]) by using a single IMU (smartwatch) and state-of-the-art machine learning (ML) techniques [17-19]. However, LBP rehabilitation incorporates more complex movements than those found in the shoulder, which may not be adequately captured with a single IMU. As such, in developing a system to monitor LBP rehabilitation, it is important to determine the number of IMUs, their anatomical placement, and the data channels that best enable the classification of LBP rehabilitation exercises and posture.

The objective of this project was to develop and optimize a system to detect sitting posture and performance of LBP

exercises comprising movement in multiple planes (flexion, extension, side glide, and rotation). It was hypothesized that inertial sensor time series data collected from a multi-IMU-based wearable device arrangement analyzed with ML will be able to successfully identify the performance of rehabilitation exercises and good sitting posture focused on reducing LBP.

Methods

Study Design and Participants

This study used a quantitative classification design to optimize a system that can detect sitting posture and performance of LBP exercises in a cohort of healthy participants. IMU data collected from multiple sensors were used to test and validate a range of ML models.

Healthy participants (from a limited cohort because of COVID-19 pandemic restrictions at that time) were recruited to participate in the study. Inclusion criteria were adult individuals with no prior history of LBP and a healthy BMI. Following informed consent, basic demographic data were collected (ie, age and sex) and study-specific ID numbers were assigned to each participant.

Ethics Approval

Participants provided informed consent to participate in this study, and institutional research ethics board approval (research ethics board number: 3505; Sunnybrook Research Institute, Toronto, Ontario, Canada) was obtained.

LBP Exercise and Posture Protocol

The McKenzie exercises represent a clearly defined, effective exercise set widely used by physiotherapists and other clinicians to treat LBP [2,6]. For this study, we selected a set of exercises that are used for the treatment of disc derangement. In total, 7 specific activities based on the McKenzie framework were identified for inclusion in the study protocol (1 static lying position and 6 dynamic lumbar spine exercises), as well as 3 postural positions. In addition, patients were recorded while performing various activities of daily living (ADL) such as walking, relaxed sitting, and standing. These ADL were collected so that models could be trained to not only differentiate between individual physiotherapy exercises but also to classify physiotherapy activities distinctly from typical daily activities. As such, these heterogeneous activities were all given the same ADL label to test the models' ability to differentiate physiotherapy from other common activities as a general group. The exercise protocol incorporated flexion, extension, rotation, and side glide motions, as well as poor, good, and forced good sitting postures. The full list of exercises and postures is described in [Multimedia Appendix 1](#).

Participants were trained to perform the exercises and postures under the direct supervision of a single researcher, following a protocol designed in collaboration with a McKenzie exercise-trained physiotherapist. Dynamic exercises were performed for 6 repetitions, and static exercises and sitting postures were performed for 30 to 60 seconds while wearing the multi-IMU sensor system. ADL activity data were collected for 3 to 5 minutes for each participant.

Multisensor System

A wireless multi-IMU system was developed and used to collect inertial data during LBP rehabilitation for input to a classification model. The system comprised eight IMU devices (Metamotion C; MbiEntlab) [20] placed in the following anatomical locations: (1) wrist, (2) left shoulder, (3) right shoulder, (4) upper back, (5) lower back, (6) left thigh, (7) right ankle, and (8) right ear. IMU locations are described in more detail in Figure S1 and the *IMU Locations* section in [Multimedia Appendix 1](#).

The following five sensor data types, referred to here as *sensor channels*, were recorded from the IMU architecture (14 signal channels for each device, resulting in 112 channels):

1. Raw proper acceleration from the accelerometer (x, y, z), sampled at 25 Hz
2. Raw angular velocity data from the gyroscope (x, y, z), sampled at 25 Hz
3. Raw magnetic field strength from the magnetometer (x, y, z), sampled at 25 Hz
4. Quaternions from the on-board sensor fusion algorithm (w, x, y, z), sampled at 50 Hz

5. Pressure data from the barometer, sampled at 13 Hz

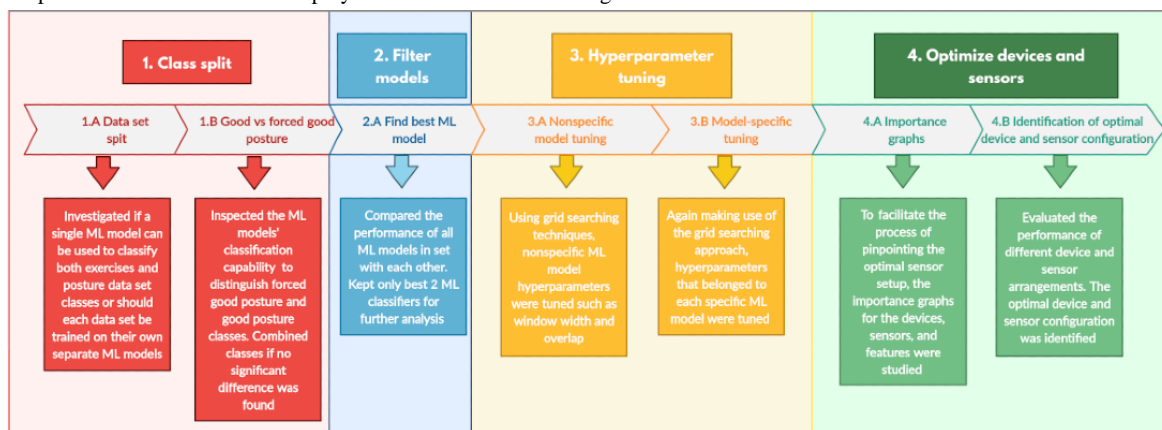
Data Acquisition and Software

The SPARS software platform developed by our laboratory was extended to enable data acquisition from multiple IMUs [14-16]. To prevent sensor drift and accumulated magnetic interference, accelerometer, gyroscope, and magnetometer sensor channels were calibrated on a weekly basis according to the manufacturer’s instructions. IMUs were secured to each participant by using Velcro straps and adherent tabs, with 1 IMU integrated into a 3D printed earbud. Participants also donned a cap, a USB hub, and Bluetooth dongles. Data files were manually labeled by the supervising researcher, with the participant number and exercise class immediately after each exercise recorded. These labels served as the ground truth for subsequent classification tasks.

Data Analysis

The flow of the data analysis is outlined in [Figure 1](#). The data collected using the SPARS-LBP system was used to determine the optimal placement of inertial sensors required to detect and classify LBP exercises and postures. This was accomplished by training a set of ML models to classify exercise data based on the full set of IMU sensor locations. A feature importance analysis was then performed to determine which IMUs and sensor channels contributed the most to model performance. Finally, a grid search was performed across a set of IMUs and channels, which contributed the most to the model performance. This was used to determine the optimal IMU locations, sensor channels, and model for a scalable SPARS-LBP system.

Figure 1. ML analysis flow. (1) Class split: to determine whether posture and exercise classification tasks require distinct classifiers and whether posture-forced good/posture good can be combined into a single class. (2) Filter models: identification of the 2 ML models with the highest performance from the classifier set. (3) Hyperparameter tuning: optimization of preprocessing parameters and model-specific hyperparameters. (4) Optimization of sensor channels and inertial measurement unit combinations: performing grid search over sensor channels and inertial measurement unit combinations, in addition to practical considerations for deployment. ML: machine learning.



Data Preprocessing

Raw accelerometer, gyroscope, magnetometer, and pressure data were taken directly from MbiEntlab sensors for use in the training pipeline. These channels were also Kalman filtered and used to calculate the 4-axis quaternions channel with a proprietary MbiEntlab algorithm. Filtering was applied to the quaternions channel by using the Bosch sensor fusion algorithm. This processing occurred during data acquisition.

The accelerometer, gyroscope, magnetometer, pressure, and quaternion channels were resampled to 25 Hz and segmented using a sliding window of a width of 5 seconds (125 samples), with 0 segment overlap. This segment length was chosen to be slightly longer than an average exercise repetition. The total number of segments after preprocessing was 7838 (5815/7838, 74.19% for exercise data, and 2024/7838, 25.82% for posture data).

Feature Extraction and Scaling

Following segmentation, 23 statistical and time domain features (see the *Seglearn Engineered Features* section in [Multimedia Appendix 1](#)) were calculated for each channel of each time series segment, resulting in 2599 features. Segmentation and feature extraction were performed using the open-source Seglearn Python package [21]. Each feature was normalized to have 0 mean and unit variance before model training.

Initial Models and Classification Task

In order to determine the optimal classification algorithm for use in subsequent experiments, 10 classifiers were initially considered: (1) decision tree, (2) random forest (RF), (3) XGBoost (XGB), (4) k-nearest neighbors, (5) support vector machine (SVM) trained with stochastic gradient descent, (6) linear discriminant analysis, (7) Gaussian naive Bayes, (8) SVM, (9) multilayer perceptron neural network, and (10) convolutional neural network (CNN).

Models 1 to 9 were trained on engineered features by using default settings from scikit-learn [22]. The CNN was trained directly on time series segments. The CNN comprised 3 convolutional layers with 128, 256, and 128 channels, respectively, followed by global average pooling, L2 normalization, and a fully connected layer. The CNN was trained for 100 epochs using the Adam optimizer, categorical cross-entropy loss, and a learning rate of 0.001. Initially, each model was trained with a 6-fold cross-validation approach on the entire data set, grouping folds based on participant. This ensured that recordings from the same participant were not present in both the train and test folds. A 6-fold cross-validation approach was chosen rather than a leave one participant out cross-validation approach because of the limited computational resources and time available to train 10 models. The class-weighted F_1 score was used as the evaluation metric for all classification tasks.

Models were trained to perform three classification tasks: (1) classifying all exercises and postures (11-class output), (2) classifying only exercises (8-class output), and (3) classifying only posture (3-class output). The performance of the engineered features models (models 1-9) was evaluated. The 2 classifiers with the highest accuracies, lowest variance, and other supporting considerations (such as processing speed) were selected for further evaluation. In addition, the CNN model was considered for further optimization because of its previous success in classifying shoulder exercises [23].

Feature Importance Evaluation

To determine the optimal combination of IMU locations and sensor channels for activity classification, the importance of engineered features was computed for the 2 selected pretrained engineered feature models. This was used to inform the selection of a subset of sensors and features for hyperparameter tuning. The following two methods of feature importance computation were explored: Gini importance (a measure of the number of branches learned from each feature in tree-based models [24]) and permutation feature importance (an approach where input features are randomly permuted and the change in model performance is measured [25]). The permutation approach is

resilient to numerical feature inflation and training set dependence, which are found in Gini importance [24]. Features were then grouped by IMU location and sensor channel to determine the relative importance of each IMU and sensor channel.

Hyperparameter Tuning and Sensor Selection

A grid search of model-specific and preprocessing hyperparameters was conducted, again using 6-fold cross-validation, grouping folds based on participant. The following preprocessing hyperparameters were included in the grid search because of their pronounced impact on time series features:

- Window width: Each exercise took approximately 5 seconds to complete, providing a maximum logical limit for the window. The lower limit was chosen as 0.5 seconds as smaller windows would not possess sufficient context.
- Window overlap: Overlap boundaries (overlap percentage between 2 consecutive window segments) were chosen to be 0%, representing no overlap at all and a maximum overlap of 60%. This parameter can also be considered a data augmentation parameter, where a higher overlap value results in more copies of similar segments.

The following model-specific hyperparameters were also considered. A full list of the model-specific hyperparameter space searched is available in Table S2 in [Multimedia Appendix 1](#).

- RF: maximum features, minimum samples leaf, minimum samples split, and n estimators
- XGBoost: maximum depth, colsample bytree, gamma, learning rate, maximum depth, minimum child weight, and n estimators
- CNN: learning rate

IMU sensor channel combinations informed by the feature importance analysis were also included in the grid search. Owing to computational constraints, a smaller set of sensor channel combinations was chosen based on results from the engineered feature-based model grid search and used in a grid search for the CNN. This approach is similar to an embedded feature selection method. Finally, optimal configurations of the IMU locations and sensor channels were selected, considering supporting factors such as practicality and scalability as a future wearable system. The RF, XGBoost, and CNN models with optimized hyperparameters and input channels and IMU locations were retrained using a more rigorous 10-fold cross-validation approach, once again grouping folds based on the participant to prevent data leakage.

Results

Study Design and Participants

In total, 19 participants were recruited into the study, of whom 12 (63%) were male and 7 (37%) were female. Although specific height data for each patient were not recorded, all participants were within the healthy BMI range. Demographic data for the participants recruited for the study are displayed in [Table 1](#).

Table 1. Demographic data collected for the participants recruited for the study (N=19).^a

Characteristic	Participants
Age (years), mean (SD)	32 (12)
Body weight (kg), mean (SD)	76 (16)
Sex, n (%)	
Male	12 (63)
Female	7 (37)

^aAll participants had a healthy BMI and had no history of low back pain.

Initial Models and Classification Task

Engineered feature models trained on a single classification task, combining exercise and posture activities using a 6-fold cross-validation strategy, did not perform as well as models separated into exercise classification (7 classes and ADL) and posture classification (3 classes). For 3-class posture classification, models were found to have a poor ability to distinguish between posture-forced good and good posture, suggesting little difference between the 2 postures. As a result, the good posture and posture-forced good groups were combined. The independent exercise (8 classes) and binary posture classifications were used for subsequent experiments.

The 10 models described in the methods were trained with default hyperparameters using a 6-fold cross-validation approach separately for exercise and posture data sets. The top 3 engineered feature models (shown in Table 2) with respect to average F_1 score for exercise and posture classification were found to be RF, XGBoost, and SVM (0.85, 0.85, and 0.81 for exercise and 0.89, 0.89, and 0.88 for posture, respectively). However, the SVM was found to have a greater SD in the exercise set (0.12). As such, RF and XGBoost were identified as the models with the best performance for both exercise (0.85, SD 0.04) and posture (0.89, SD 0.07) classification problems.

Table 2. Initial averages and SDs of class-weighted F_1 scores across 6-fold cross-validation for all 9 engineered feature-based models with default settings.^a

Classifier	Exercise classification F_1 score (weighted average), mean (SD)	Posture classification F_1 score (weighted average), mean (SD)
Decision tree	0.76 (0.04)	0.81 (0.08)
Random forest	0.85 (0.04) ^b	0.89 (0.08) ^b
XGBoost	0.85 (0.04) ^b	0.89 (0.07) ^b
K-nearest neighbors	0.79 (0.04)	0.81 (0.11)
Stochastic gradient descent	0.83 (0.07)	0.76 (0.17)
Linear discriminant analysis	0.77 (0.11)	0.59 (0.09)
Gaussian naive Bayes	0.65 (0.09)	0.72 (0.14)
Support vector machine	0.81 (0.12)	0.88 (0.09)
Multilayer perceptron neural network	0.81 (0.14)	0.76 (0.18)

^aBoth exercise and posture classification tasks are shown, with all models using all sensor channels and inertial measurement unit locations as input.

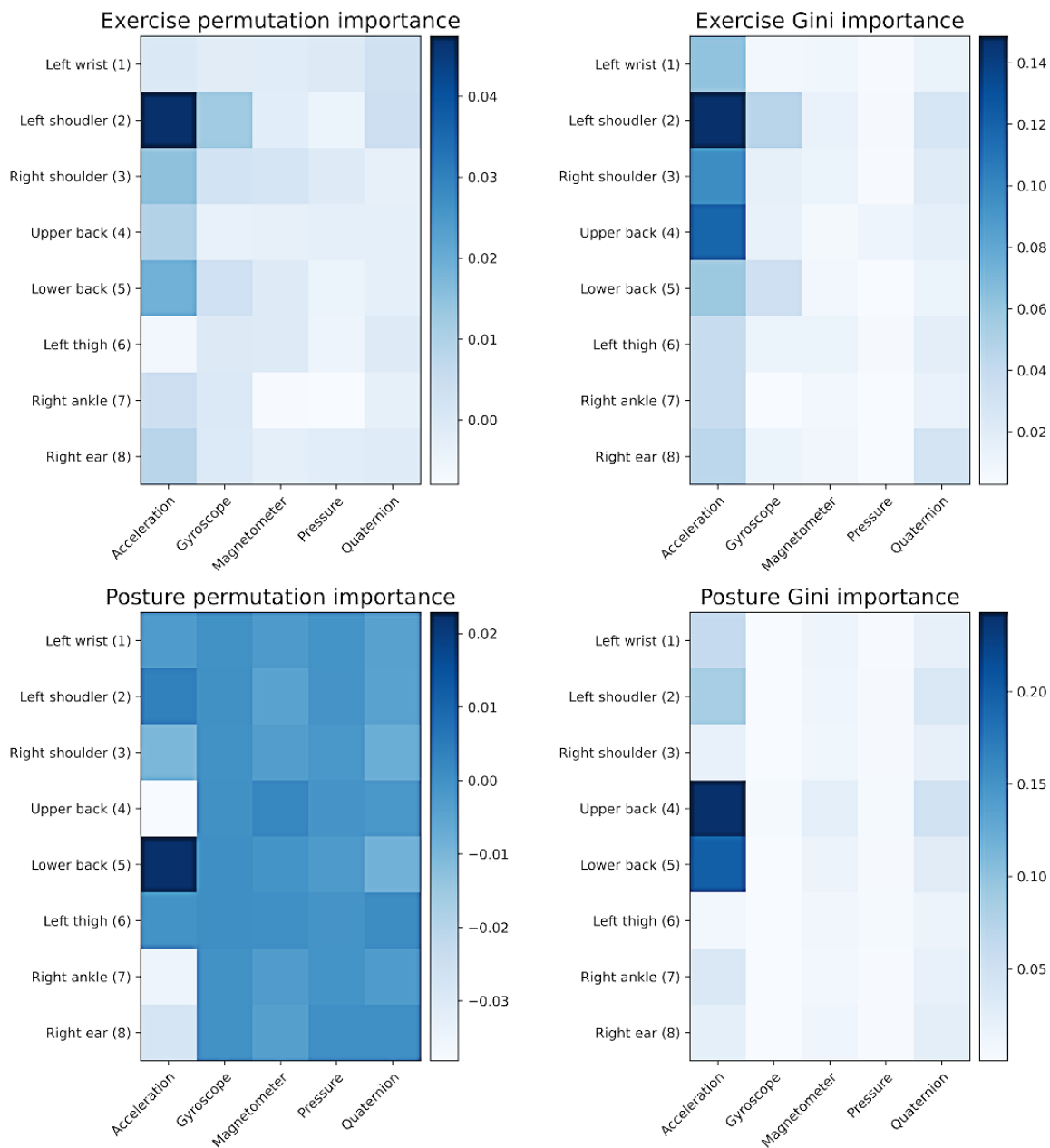
^bTop classifiers.

Feature Importance Evaluation

The XGBoost and RF models trained via 6-fold cross-validation to classify exercise and posture were used to compute the importance of input features. Inherent model importance (Gini importance and gain importance) and permutation importance for each of the input features were calculated (summarized in Figure 2 for the RF model). The importance of input features was then grouped based on IMU and sensor channel. Inherent model importance identified 5 (lower back), 6 (left thigh), and

7 (right ankle) as the most important devices; accelerometer and quaternions as the most important sensors; and mean, absolute energy, and absolute sum as the most important features. The permutation importance revealed that devices 7, 6, and 5 (reverse order compared with the Gini/Gain technique) had the highest importance; accelerometer and gyroscope had the highest importance among sensors; and minimum, absolute energy, and maximum had the top features contributing to classification performance. These findings were similar for the RF and XGBoost models.

Figure 2. Average feature importance across 6-fold cross-validation for inertial measurement unit locations (y-axis) and sensor channels (x-axis). Larger values (darker blue) represent features of relatively high importance to the model. The permutation (left column) and Gini (right column) feature importances from the exercise random forest model are displayed in the top row, whereas the permutation and Gini importances for the posture random forest model are displayed in the bottom row. Importance values shown in the figure were computed by taking the sum across subchannels (eg, x, y, and z channels of acceleration) and engineered features for each subchannel. The resulting values represent the total feature importance for a given inertial measurement unit and channel combination (eg, “acceleration” and “upper back”), which were arranged in the grid shown here.



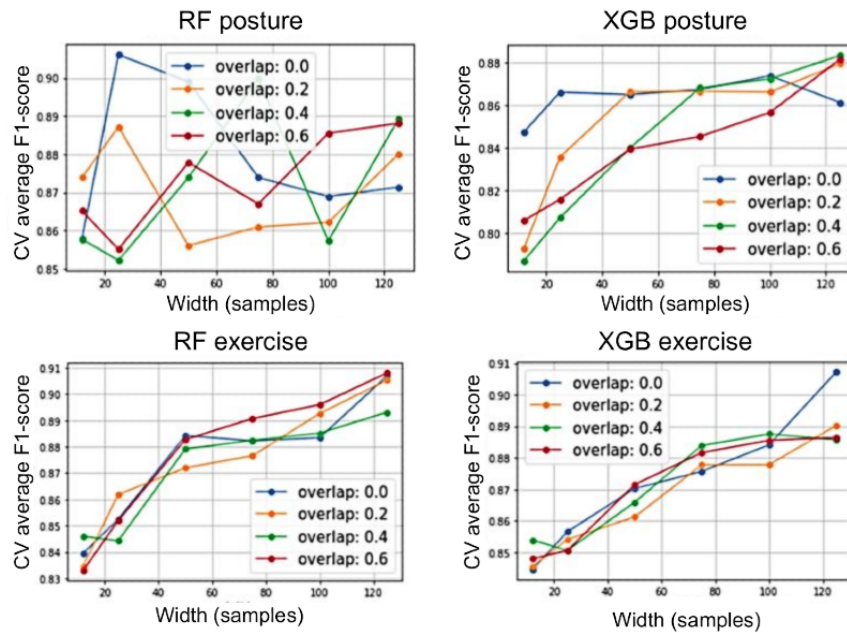
Hyperparameter Tuning and Sensor Selection

A grid search was conducted to identify the optimal model-specific hyperparameters and the optimal IMU sensor configuration. The results from the feature importance analysis were used to inform the selection of a subset of IMU sensor configurations for input to the hyperparameter grid search.

The grid search results of the window width and window overlap parameters for both the exercise and posture classifications sets are displayed in Figure 3. Larger window width resulted in higher exercise classification performance in both engineered feature models and the CNN. Width had little impact on the

performance of posture classification. Window overlap did not affect model performance for either classification task in the engineered feature models. A larger window overlap led to a small improvement in CNN exercise classification performance. Larger window widths were explored in the CNN grid search; however, the maximum window width was constrained by the length of recordings and, thus, was limited to 300 (12 seconds). On the basis of these findings, an optimal window width of 5 seconds and an overlap value of 0 were used for subsequent analyses with RF and XGBoost models, whereas a width of 300 and overlap of 50 samples (6% of the window) were used for the CNN.

Figure 3. Hyperparameter grid search considering window width and overlap for the exercise (top row) and posture (bottom row) classification tasks for the RF (left) and XGBoost (right) models. Window width is shown to have a positive impact on performance for the exercise models, whereas no improvement is seen with overlap. Clear effectiveness is not demonstrated for the posture models with respect to window width or overlap. CV: cross-validation; RF: random forest; XGB: XGBoost.



Following the grid search conducted across model-specific hyperparameters, the performance of the engineered models did not show any significant improvements. F_1 scores varied within $+0.02$ and -0.02 of the default hyperparameter results. As such, default RF- and XGBoost-specific hyperparameters were used for further analysis. The CNN performance was found to improve with a larger learning rate (0.66, SD 0.04 for learning rate=0.0001; 0.77, SD 0.050 for learning rate=0.01), with other hyperparameters held constant.

Finally, a set of IMU and sensor channel combinations, informed by the feature importance results, were included in the grid search for the RF and XGBoost models. The sensor channels evaluated using a 6-fold cross-validation approach, along with their corresponding performance scores, are displayed in Figure 4. The combination of accelerometer, gyroscope, and magnetometer sensors produced the best F_1 scores of 0.95 (SD 0.03) and 0.91 (SD 0.11) for the exercise (RF model) and posture (RF model) data sets, respectively. The IMU combinations that were included in the grid search for the RF and XGBoost models are displayed in Figure 5. Using all available IMUs produced the highest performance. Limiting the number of sensors to 3 IMUs, the lower back (5), left thigh (6), and right ankle (7) locations yielded the best performance for both exercise (F_1 score 0.94, SD 0.04) and posture (F_1 score 0.90, SD 0.11) using the XGBoost model. Confusion

matrices for the final optimized IMU (5, 6, and 7) and sensor (accelerometer, gyroscope, and magnetometer) setup for RF and XGBoost models, trained with 10-fold cross-validation grouped based on participants, are provided in Figure S2 in Multimedia Appendix 1.

Following the results showing that the low back, thigh, and ankle sensors performed optimally for exercise and posture classification with engineered feature models, a smaller subset of IMU combinations was tested with the CNN (Figure 6). A grid search was performed over the set of single IMUs in addition to the set of 2-IMU combinations, which could form a lower extremity garment (eg, pants or shorts). Furthermore, 3- and 4-IMU combinations that could form a lower extremity garment with a watch were examined. In the CNN grid search, the full set of IMUs provided the best performance (exercise F_1 score 0.96, SD 0.01; posture F_1 score 0.91, SD 0.03). The 3 best IMU systems for exercise were again 5, 6, and 7 (F_1 score 0.94, SD 0.03 for exercise; F_1 score 0.88, SD 0.07 for posture). The accelerometer and gyroscope proved to be the optimal sensor channel combination for the CNN for exercise classification, whereas only the accelerometer provided optimal performance for posture. Confusion matrices for the final optimized configurations for the CNN model, trained with 10-fold cross-validation, are also provided in Figure S2 in Multimedia Appendix 1.

Figure 4. Results of the grid search across a set of sensor channel combinations for the RF and XGBoost models for exercise and posture classification. All IMUs were used for this test. Results are reported as the mean (SD) of the F1 score across 6-fold cross-validation for each sensor channel combination. The highlighted row represents the optimized sensor channels for both exercise and posture classification. RF: random forest; XG: XGBoost.

	Sensor channel					Exercise		Posture	
	Acceleration	Gyroscope	Magnetometer	Quaternions	Pressure	RF	XG	RF	XG
1 sensor	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.94 (0.03)	0.91 (0.05)	0.88 (0.17)	0.90 (0.11)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.84 (0.06)	0.88 (0.06)	0.79 (0.08)	0.84 (0.08)
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.70 (0.14)	0.75 (0.14)	0.56 (0.20)	0.55 (0.19)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.76 (0.10)	0.75 (0.12)	0.86 (0.12)	0.85 (0.16)
2 sensors	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.40 (NA)	0.53 (0.06)	0.64 (0.08)	0.65 (0.07)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.95 (0.03)	0.92 (0.06)	0.87 (0.15)	0.91 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.93 (0.04)	0.90 (0.07)	0.90 (0.10)	0.91 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.88 (0.08)	0.88 (0.09)	0.90 (0.11)	0.91 (0.11)
3 sensors	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.91 (0.04)	0.92 (0.05)	0.88 (0.13)	0.90 (0.11)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.83 (0.08)	0.80 (0.11)	0.86 (0.13)	0.85 (0.14)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.79 (0.14)	0.80 (0.12)	0.81 (0.14)	0.80 (0.14)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.81 (0.09)	0.84 (0.10)	0.86 (0.13)	0.84 (0.16)
4 sensors	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.95 (0.03)	0.91 (0.06)	0.90 (0.10)	0.91 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.90 (0.08)	0.89 (0.09)	0.88 (0.13)	0.90 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.91 (0.04)	0.92 (0.05)	0.92 (0.13)	0.90 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.89 (0.07)	0.88 (0.09)	0.91 (0.10)	0.91 (0.11)
5 sensors	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.91 (0.07)	0.92 (0.06)	0.91 (0.10)	0.91 (0.11)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.90 (0.06)	0.89 (0.09)	0.90 (0.10)	0.90 (0.11)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.84 (0.13)	0.82 (0.13)	0.79 (0.14)	0.85 (0.12)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.83 (0.14)	0.87 (0.12)	0.69 (0.15)	0.67 (0.11)
4 sensors	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.86 (0.06)	0.85 (0.10)	0.87 (0.14)	0.87 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.83 (0.14)	0.84 (0.12)	0.77 (0.20)	0.84 (0.13)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.92 (0.06)	0.88 (0.09)	0.90 (0.12)	0.91 (0.11)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.90 (0.06)	0.92 (0.05)	0.91 (0.11)	0.91 (0.11)
5 sensors	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.91 (0.06)	0.90 (0.08)	0.88 (0.12)	0.90 (0.10)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.91 (0.06)	0.90 (0.08)	0.88 (0.12)	0.90 (0.10)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.91 (0.07)	0.89 (0.09)	0.88 (0.12)	0.90 (0.10)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.84 (0.13)	0.86 (0.12)	0.83 (0.16)	0.87 (0.09)
8 IMUs	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.91 (0.06)	0.90 (0.08)	0.89 (0.11)	0.91 (0.11)

Figure 5. Results of the grid search across a set of IMU location combinations for RF and XGBoost models, classifying exercise and posture. All models were trained with the accelerometer, gyroscope, and magnetometer sensor channels. Results are reported as the mean (SD) of the F1 scores across 6-fold cross-validation for each IMU combination. The highlighted row represents the optimized sensor locations using 3 IMUs for both exercise and posture classification. Note that the bottom row containing all 8 IMUs is equivalent to the highlighted row in Figure 4. IMU: inertial measurement unit; RF: random forest; XG: XGBoost.

	IMU location								Exercise		Posture	
	Left wrist (1)	Left shoulder (2)	Right shoulder (3)	Upper back (4)	Lower back (5)	Left thigh (6)	Right ankle (7)	Right ear (8)	RF	XG	RF	XG
1 IMU	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.66 (0.07)	0.73 (0.07)	0.71 (0.15)	0.74 (0.12)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.63 (0.08)	0.74 (0.09)	0.72 (0.20)	0.73 (0.16)
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.63 (0.10)	0.74 (0.12)	0.51 (0.16)	0.48 (0.17)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.71 (0.07)	0.83 (0.07)	0.86 (0.11)	0.87 (0.10)
2 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.85 (0.04)	0.89 (0.08)	0.64 (0.30)	0.63 (0.25)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.76 (0.08)	0.84 (0.06)	0.83 (0.18)	0.84 (0.17)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.58 (0.07)	0.75 (0.11)	0.59 (0.17)	0.60 (0.17)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.75 (0.05)	0.79 (0.06)	0.75 (0.19)	0.73 (0.17)
3 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.82 (0.05)	0.87 (0.06)	0.86 (0.10)	0.86 (0.20)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.90 (0.06)	0.90 (0.06)	0.73 (0.22)	0.67 (0.21)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.74 (0.09)	0.80 (0.09)	0.70 (0.17)	0.71 (0.14)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.65 (0.11)	0.77 (0.11)	0.74 (0.19)	0.75 (0.19)
4 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.75 (0.06)	0.83 (0.06)	0.81 (0.17)	0.83 (0.17)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.64 (0.06)	0.76 (0.10)	0.70 (0.24)	0.70 (0.22)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.74 (0.06)	0.83 (0.09)	0.84 (0.10)	0.83 (0.10)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.66 (0.08)	0.78 (0.15)	0.57 (0.18)	0.55 (0.17)
5 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.87 (0.05)	0.91 (0.04)	0.82 (0.11)	0.82 (0.14)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.74 (0.06)	0.85 (0.08)	0.87 (0.11)	0.86 (0.11)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.89 (0.05)	0.93 (0.06)	0.82 (0.25)	0.82 (0.22)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.76 (0.06)	0.81 (0.07)	0.74 (0.19)	0.78 (0.15)
6 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.82 (0.06)	0.86 (0.06)	0.81 (0.17)	0.80 (0.16)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.75 (0.06)	0.80 (0.08)	0.76 (0.20)	0.75 (0.18)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.90 (0.07)	0.92 (0.04)	0.81 (0.11)	0.82 (0.14)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.89 (0.06)	0.90 (0.07)	0.75 (0.21)	0.70 (0.20)
7 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.87 (0.06)	0.88 (0.07)	0.80 (0.20)	0.78 (0.15)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.76 (0.06)	0.83 (0.10)	0.82 (0.12)	0.84 (0.15)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.88 (0.04)	0.88 (0.06)	0.89 (0.12)	0.91 (0.11)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.93 (0.04)	0.94 (0.03)	0.83 (0.20)	0.82 (0.24)
8 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.88 (0.07)	0.91 (0.05)	0.82 (0.11)	0.81 (0.12)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.92 (0.03)	0.94 (0.04)	0.90 (0.11)	0.90 (0.11)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.91 (0.06)	0.92 (0.09)	0.85 (0.20)	0.83 (0.21)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.83 (0.06)	0.86 (0.07)	0.81 (0.16)	0.80 (0.16)

Figure 6. Results of the grid search across a subset of IMU locations and channel combinations for the CNN classifier. All models were trained with a segment width of 300, sampling rate of 25 Hz (total segment width of 12 seconds), overlap of 50, and learning rate of 0.001. These CNN grid search results used acceleration and gyroscope sensor channels for exercise classification and only the acceleration channel for posture classification. The reported F_1 scores are the average (SD) across 6-fold cross-validation, stratified based on participant. CNN: convolutional neural network; IMU: inertial measurement unit.

	IMU location								Exercise	Posture
	Left wrist (1)	Left shoulder (2)	Right shoulder (3)	Upper back (4)	Lower back (5)	Left thigh (6)	Right ankle (7)	Right ear (8)	CNN	CNN
1 IMU	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.70 (0.06)	0.57 (0.19)
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.70 (0.07)	0.69 (0.12)
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.68 (0.05)	0.56 (0.14)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.71 (0.05)	0.57 (0.18)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.81 (0.03)	0.65 (0.15)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.86 (0.05)	0.73 (0.12)
2 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.77 (0.06)	0.74 (0.09)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.66 (0.09)	0.54 (0.13)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.90 (0.04)	0.71 (0.14)
3 IMUs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.89 (0.07)	0.80 (0.14)
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.85 (0.04)	0.75 (0.11)
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.92 (0.05)	0.80 (0.12)
4 IMUs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.94 (0.03)	0.88 (0.07)
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0.91 (0.04)	0.79 (0.12)
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.89 (0.04)	0.79 (0.15)
8 IMUs	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.94 (0.02)	0.85 (0.06)
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.96 (0.01)	0.91 (0.03)

Discussion

Principal Findings

This study demonstrated the ability of SPARS-LBP to successfully identify the performance of rehabilitation exercises and good posture based on sensor time series data collected from a multi-IMU-based wearable device arrangement. A large set of ML models were initially trained to classify exercise and posture activities by using the full set of sensors. RF and XGBoost were found to outperform 7 other engineered feature models during initial testing.

Mechanical pain of discogenic origin is perhaps the most common and treatable type of LBP. The application of McKenzie-based exercises requires extensive training by the clinicians to understand the pattern of disc derangement and directional preferences. Once the leg or buttock pain is centralized to the lumbar spine, the therapist can proceed with core strengthening exercises. We specifically chose McKenzie-based exercises as they do not address specific muscles and rather focus on the symptoms that originate from stimulation or deformation of the pain-sensitive structures by using mechanical means such as static positions or repeated end range movements.

In considering the practical deployment of the SPARS-LBP system, a reduction in the number of IMU and sensor signals was required. To this end, the relative importance of input features was computed and grouped by device and sensor for the RF model. This was performed using both the inherent Gini importance of each feature and the permutation importance. The Gini importance of a feature is determined by the number of splits in the tree originating from that feature. Therefore, it is a measure of a particular feature's importance in the training data and can be misleading when the model overfits. For this reason, the permutation importance was also considered, as this can be computed on a held-out validation set using cross-validation [25]. The permutation importance is also limited by its tendency to assign low importance to highly correlated

features. Owing to the drawbacks of each importance technique, the results of both methods were considered. This revealed that the thigh, ankle, wrist, lower back, and shoulder sensors along with the acceleration, gyroscope, and quaternion channels contributed the most to the performance of the model.

Ultimately, the ideal sensor and device combination was determined based on the grid search results and practical considerations for combining these sensors into a wearable system. An XGBoost model with 3 IMU devices placed at the lower back, thigh, and ankle, each recording accelerometer, gyroscope, and magnetometer data, was found to provide an optimal platform for exercise and posture classification. These 3 standard IMUs placed on the lower back, thigh, and ankle could ultimately be embedded into a single wearable garment (eg, pants).

The finding that the low back, thigh, and ankle sensors offered the optimal performance does not come as a surprise, as the low back exercises used in this study involve a variety of movements in the lower body. In particular, all the exercises and postures cause a displacement in the low back, which was found to have high importance in both the feature importance analysis and grid search. Interestingly, the sensors on the upper body (ear, shoulder, and wrist) offered relatively little improvement in performance. However, this result supports the future development of a single lower extremity garment.

We also found that the CNN had a comparable performance with the XGBoost model for exercise classification with these 3 device locations using accelerometer and gyroscope channels. The CNN was limited by the fact that longer segment widths of between 250 and 300 (10-12 seconds) were required for optimal exercise classification performance. This could present challenges in clinical settings where patients cannot perform exercises for more than a few seconds because of pain or other factors. However, for posture classification, the CNN's best performance was achieved using just the acceleration sensor of all devices (F_1 score 0.91, SD 0.03), and segment width did not seem to relate to performance. This is likely because of the

stationary nature of the posture data, as the recording was performed once participants had already moved into position.

Comparison With Prior Work

Although varied IMU setups have been studied for exercise classification (as in the study by Rodriguez et al [26]), none of them have explored simultaneous posture and exercise detection [27-31]. Some studies focused on lower limb rehabilitation exercises [15], whereas others focused only on postural classification [16]. Studies that focused on lower extremity rehabilitation found that the thigh, shin, and foot were useful sensor locations [15,32,33]. For posture experiments, sensor locations such as the lower back, upper back/sternum, feet, and thigh were used successfully [16]. These device locations described for exercise and posture studies coincide with our current findings, except for the upper back/sternum. Most studies that included the upper back/sternum as an IMU location used dynamic angle measurements to model their system in which they were used in relation to another device (usually a lower back IMU) or to an absolute starting position. These dynamic experiments also acquired data as participants repositioned themselves from a bad posture to a good posture, yielding time-varying fluctuations in the data. Using this approach, their algorithms would just need to learn the oscillations that occur in the upper back/sternum IMU when the posture changes to classify the data. By contrast, the postural data set collected in this study was static, where 1 good posture instance had the patient staying stationary for the whole period of the recording, with no time variation, limiting the importance of the upper back sensor (IMU 4) in the current algorithm.

Strengths and Limitations

The performance of ML algorithms is generally dependent on the size of the available training data sets. Owing to COVID-19 pandemic restrictions, the recruitment of study participants and the resultant data set were limited. Participants were limited in the number of exercises and repetitions to avoid fatigue and prolonged session time. As such, the exercises used in this study represent a subset of all McKenzie exercise variations. Additional exercises may be explored to incorporate a larger exercise set, which will widen the scope and applicability of SPARS-LBP. This small data set resulted in greater interfold variability in cross-validation, particularly when larger segment widths were used, resulting in fewer training and validation samples. A second limitation is that feature selection was not used in the initial pipeline to select classifiers. This has the potential to penalize some classifiers (eg, k-nearest neighbors) and lead to overfitting. Third, this study demonstrated that the use of this technology is feasible, and the results are accurate; however, only healthy participants (without LBP and with healthy BMI) were included, and only correct execution of the LBP exercises was performed. Future work is needed to determine whether the optimized SPARS-LBP system can similarly classify exercises performed by those whose motion may be compromised and also consider the impact of age, sex, and BMI in relation to ML classification. A fourth limitation of the study was the restriction of monitoring devices to IMUs only. Testing a wider range of sensor technologies, such as

electromyography or video data, could add to the robustness and accuracy of the classifications. However, there are challenges to the acquisition, synchronization, and analysis of multiple data streams, and the consideration of additional data sources is outside the scope of this study.

Future Directions

As the use of wearable devices and artificial intelligence technology is expanding to facilitate web-based care, it is critical to explore the utility and accuracy of these devices in the musculoskeletal field. Validating the performance of the SPARS-LBP system with individuals prescribed McKenzie exercises for acute and chronic LBP is essential to see whether they generalize appropriately for these specific target populations. Essential to a clinical study is a simple IMU data acquisition system, such as a garment, incorporating the low back, thigh, and ankle IMU sensors. Similar to our ongoing work in the shoulder, this would allow elucidation of the relationship between participation and outcome (including functional assessment and patient-reported outcome measures). This would ultimately help guide future research into the effectiveness of physiotherapy programs and is key to understanding the relationships among exercise, posture, and clinical outcomes in individuals with LBP. App development may enable remote monitoring of participation/adherence by both patients and providers. This could allow for early identification of barriers to recovery while ensuring safe and effective management.

This work is also an important first step toward building effective tools to assess the quantity and quality of physiotherapy exercises. In particular, CNNs trained to classify physiotherapy exercises may be used to generate quantitative performance metrics based on generating embeddings for exercises performed in the clinic and at home by the same patient. Passing both recordings through the convolutional layers of the CNN, the distances between pairs of embeddings could then be used as a metric for the similarity between 2 exercises. Computing the similarity of a supervised exercise to an unsupervised exercise of the same class (performed at home) could give the patient and their clinician valuable feedback on the quality of unsupervised exercise performance.

Conclusions

This study evaluated a large set of IMU devices (8) and sensors (5) during the performance of LBP exercises and sitting postures. The best performance was found using an optimized configuration of 3 IMUs (lower back, thigh, and ankle), with sensors limited to the accelerometer, gyroscope, and magnetometer. This device arrangement can be easily integrated into a wearable garment (pants) with a more efficient, simple, and clinically viable data acquisition system. No significant differences in performance of the 3 IMU systems were observed using the XGBoost, RF, and CNN models. This proof-of-concept study motivates further development of SPARS-LBP as a monitoring system that can help track participation and assist with the early identification of problems encountered in the performance of LBP exercise and correct posture, ultimately enhancing the effectiveness of at-home rehabilitation delivery.

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Data Availability

Data preprocessing and engineered feature extraction were performed with the Seglearn package [33]. The Python code used to create the convolutional neural network is also available [35]. The raw inertial measurement unit data can be found in the repository cited [36].

Conflicts of Interest

DB is a cofounder and holds equity in Halterix Corporation, a digital physiotherapy company. CA works part-time for Halterix. MH and CW hold equity in Halterix.

Multimedia Appendix 1

Supplementary material containing detailed descriptions of the exercises, specific anatomic locations of the inertial measurement units (IMUs), the full list of model-specific hyperparameters included in the grid searches, and the confusion matrices of the optimized models.

[DOCX File, 9010 KB - [rehab_v9i3e38689_app1.docx](#)]

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Abbreviations

- ADL:** activities of daily living
- CNN:** convolutional neural network
- HAR:** human activity recognition
- IMU:** inertial measurement unit

LBP: low back pain
ML: machine learning
RF: random forest
SPARS: Smart Physiotherapy Adherence Recognition System
SVM: support vector machine
XGB: XGBoost

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Original Paper

Automated Assessment of Balance Rehabilitation Exercises With a Data-Driven Scoring Model: Algorithm Development and Validation Study

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Abstract

Background: Balance rehabilitation programs represent the most common treatments for balance disorders. Nonetheless, lack of resources and lack of highly expert physiotherapists are barriers for patients to undergo individualized rehabilitation sessions. Therefore, balance rehabilitation programs are often transferred to the home environment, with a considerable risk of the patient misperforming the exercises or failing to follow the program at all. Holobalance is a persuasive coaching system with the capacity to offer full-scale rehabilitation services at home. Holobalance involves several modules, from rehabilitation program management to augmented reality coach presentation.

Objective: The aim of this study was to design, implement, test, and evaluate a scoring model for the accurate assessment of balance rehabilitation exercises, based on data-driven techniques.

Methods: The data-driven scoring module is based on an extensive data set (approximately 1300 rehabilitation exercise sessions) collected during the Holobalance pilot study. It can be used as a training and testing data set for training machine learning (ML) models, which can infer the scoring components of all physical rehabilitation exercises. In that direction, for creating the data set, 2 independent experts monitored (in the clinic) 19 patients performing 1313 balance rehabilitation exercises and scored their performance based on a predefined scoring rubric. On the collected data, preprocessing, data cleansing, and normalization techniques were applied before deploying feature selection techniques. Finally, a wide set of ML algorithms, like random forests and neural networks, were used to identify the most suitable model for each scoring component.

Results: The results of the trained model improved the performance of the scoring module in terms of more accurate assessment of a performed exercise, when compared with a rule-based scoring model deployed at an early phase of the system (k-statistic

value of 15.9% for sitting exercises, 20.8% for standing exercises, and 26.8% for walking exercises). Finally, the resulting performance of the model resembled the threshold of the interobserver variability, enabling trustworthy usage of the scoring module in the closed-loop chain of the Holobalance coaching system.

Conclusions: The proposed set of ML models can effectively score the balance rehabilitation exercises of the Holobalance system. The models had similar accuracy in terms of Cohen kappa analysis, with interobserver variability, enabling the scoring module to infer the score of an exercise based on the collected signals from sensing devices. More specifically, for sitting exercises, the scoring model had high classification accuracy, ranging from 0.86 to 0.90. Similarly, for standing exercises, the classification accuracy ranged from 0.85 to 0.92, while for walking exercises, it ranged from 0.81 to 0.90.

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KEYWORDS

balance rehabilitation exercises; scoring model; exercise evaluation; persuasive coaching system

Introduction

Balance rehabilitation is essential evidence-based treatment for patients with balance disorders, especially when they are at risk of falls [1]. However, it is not feasible or economically affordable to provide patients with in-hospital sessions involving a dedicated clinician for all rehabilitation sessions required [2]. Physiotherapy health services are provided in hospitals or outpatient clinics, with assessment sessions conducted in-person by clinicians, followed by unsupervised rehabilitation sessions in the patients' homes (eg, Otago Exercise Program [3]). Research groups and published reports have shown that more than 90% of all treatments are home based [4]. According to these procedures, patients are asked to report their daily activities related to the instructed exercises and actions at home. Actual progress evaluation is performed during visits to the physician [5]. Low patient motivation and adherence to the appropriate rehabilitation exercise programs have been reported, and these consequently prolong treatment times and impose higher health care costs [6]. While various factors have been identified that contribute to low compliance, lack of continuous feedback is an important factor, and accurate monitoring of patient exercises by medical professionals in a home environment is considered essential [7,8].

A typical home-based rehabilitation exercise program (with no digital tools integrated) is based on a handbook of instructions and directions about the frequency, intensity, and correct performance of physiotherapy exercises [8]. Yet, such programs do not always ensure the full recovery of patients, as compliance rates are low [9]. In turn, activity recognition and evaluation have received increasing attention in the fields of machine learning (ML) and computer vision. Especially during the COVID-19 outbreak, the need for enhancing typical home-based rehabilitation programs with sensing devices and virtual reality interaction has substantially increased [10].

Activity recognition approaches use sensing devices to collect appropriate signals and infer the performed activity. Sensing devices vary in complexity and cost, and include video sensors, inertial measurement units, and pressure sensors. Motion analysis based on video signals explores various representations, like skeleton extraction and space-time volume. While many visual techniques have been used in recent decades, large

differences in anatomy, human occlusion, and changes in perspectives often limit the capacity of the proposed models to correctly assess the performance of an exercise. Sensing technology (apart from video) has made significant progress during the last decade, especially with low-power devices, wireless communication, high computational capacity, and data processing [11]. Wearable sensors can be integrated in clothes, strips, mobile devices, and smartwatches [12]. It is important to mention that the assessment of balance rehabilitation exercises requires accurate identification of specific movements and kinematics during the execution of the exercise (eg, head movement speed and direction, and chest flexion).

In contrast to the pure recognition of an activity, in rehabilitation programs especially, the evaluation of exercise execution is of paramount importance. This is especially significant for recovery, as it demonstrates whether the patient can perform the prescribed process [13]. During the last few years, several approaches for exercise evaluation have been proposed. In a previous study [14], a smart sensor-based rehabilitation exercise recognition and evaluation system using a deep learning framework was proposed. The main limitation was data synchronization from several sensors related to activity recognition. In similar approaches, the collected data include noise and vary when different people perform the same activity [15]. Furthermore, a state probability transition is proposed to show the transition likelihoods among states to capture the hidden states of sensory data. To test rehabilitation activities, a special matrix has been introduced, and the learned classifier has been used to identify the best features of every class at various levels. The scoring functions are given for the (0-1) range of the output values tested. To train the proposed deep neural networks in rehabilitation, the resulting movement quality scores have been used [16].

A previous study [17] proposed the hidden semi-Markov model for the assessment of rehabilitation exercises. The method extracts clinically related motion features from an RGB-D camera's skeleton and proposes an abstract representation of the subject. The effectiveness of the proposed solution has been assessed by analyzing the correlation between both a clinical evaluation and dynamic time-warping algorithms. Additionally, a previous study [18] proposed the multi-path convolutional neural network (CNN) for the recognition of rehabilitation exercises. The results of the classification accuracy in the

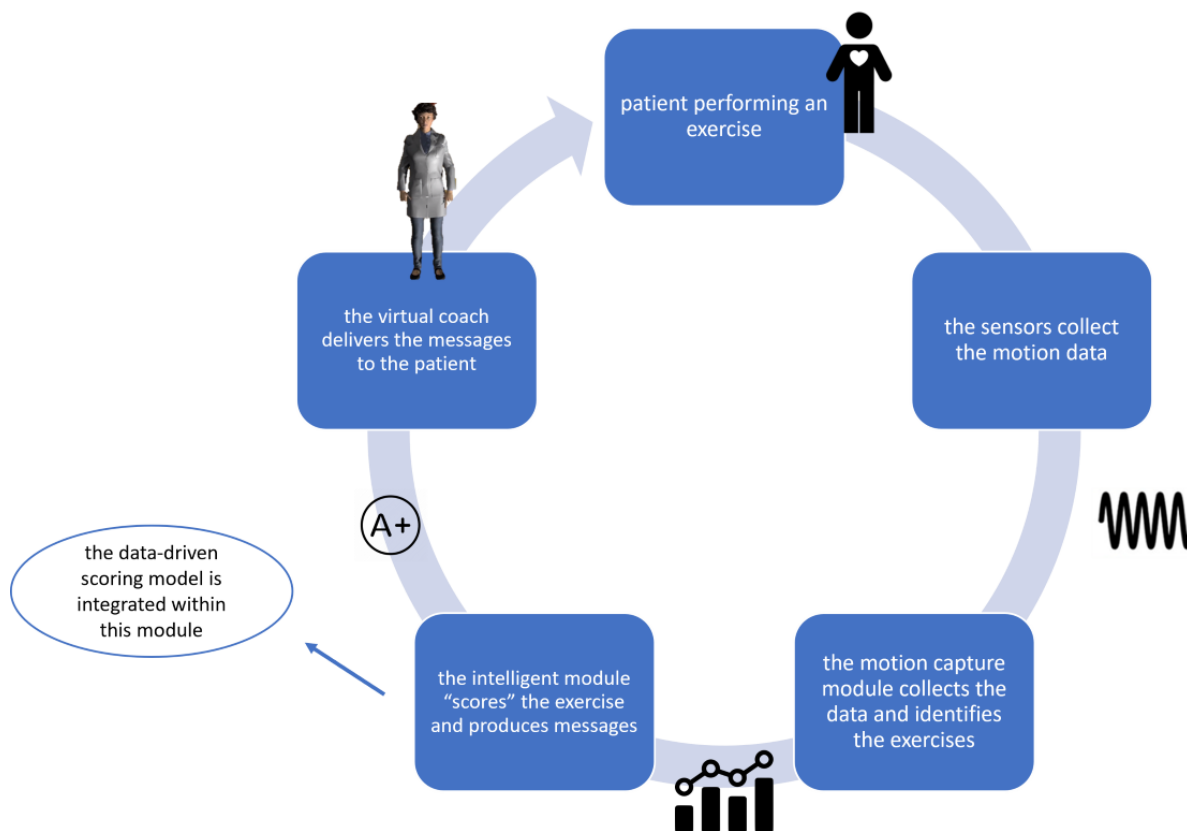
relative experiments showed that a multi-path CNN is highly efficient for sensor data acquisition. In another study [19], a deep learning-based framework for rehabilitation exercise assessment was introduced. The main modules of the system were the calculation of metrics for the quantity of motion output, the scoring of performance assessment functions for numerical motion quality ratings, and deep neural network models for quality regression of input motion through supervised learning. A previous survey [20] suggested sensor-based activity recognition by deep learning. More specifically, the survey [20] presented the recent progress in sensor-based recognition in a deep learning model, where the authors summarized the current literature (deep models and sensory techniques). Finally, a previous paper [21] assessed physical activity recognition and monitoring using Internet of Things and presented a systematic review of existing studies.

The recent development of deep learning allows high-level automated feature extraction to achieve promising performance in numerous areas [22]. Deep learning approaches for sensor-based activity recognition have been widely adopted. Further, deep learning can greatly reduce the strain on features

and can acquire much higher and meaningful features by training a neural end-to-end network. Furthermore, the deep network structure facilitates uncontrolled and incremental learning. However, compared with supervised learning approaches, deep learning models require a substantially large amount of data, which are, in general, not available in the physiotherapy domain. Thus, bearing in mind the individualities of the physiotherapy exercises, feature engineering is mandatory for each specific exercise.

In our previous work [23], we have proposed a framework for managing a balance physiotherapy program at home. This framework (Figure 1), which has been designed and developed within the Holobalance project, comprises a holographic virtual coach, presented to the patient through an augmented reality system, a motion sensing platform, and a smart engine, which assesses in real time the exercise performance. Details on the overall architecture of the system can be found elsewhere [24,25]. The technology supporting the virtual coach augmented reality module is described in several studies (eg, [26]), where information regarding augmented reality systems in rehabilitation systems can be found.

Figure 1. Virtual coaching closed-loop interaction. The proposed model is integrated into the “intelligent” module of the virtual coaching system.



The aim of this study was to design, implement, test, and evaluate a scoring model for the accurate assessment of balance rehabilitation exercises, based on data-driven techniques. More specifically, this work presents an improved model for the offline scoring function, which is not based on the knowledge-based model that was used previously [23], but is based on a data-driven model with the capacity to predict with higher accuracy the score of a performed exercise. As it is of paramount importance for a closed-loop persuasive system to

correctly evaluate the performance of an exercise, the proposed scoring model is expected to provide more robust and reliable feedback to the overall system’s reasoning engine.

Methods

Ethics Approval

This study has received institutional ethics approvals in Germany/Freiburg (reference: 265/2019) and Greece/Athens (reference: 9769/24-6-2019).

Study Design

A pilot study with 20 participants was conducted with the aim to collect the appropriate data set to develop the scoring model. After 1 dropout, 19 patients followed an 8-week balance rehabilitation program, according to the protocol described previously [27] at 2 pilot sites. Participants were elderly individuals who had experienced at least one fall during the last year. They were all informed about the context of the study and volunteered to participate, after providing their written consent regarding the willingness to use the Holobalance system in the

clinic and to have their data recorded and used for research purposes.

While the Holobalance system is designed for home use, it was installed in a clinic setup to test safety and to collect the necessary data. After recruitment of the patients, functional and cognitive assessments were performed based on the Mini-Balance Evaluation Systems Test (MINIBEST), Functional Gait Assessment (FGA), Falls Efficacy Scale International (FES-I), Montreal Cognitive Assessment (MoCA), World Health Organization Disability Assessment Schedule (WHODAS), and Activities-Specific Balance Confidence Scale (ABC), as per the clinical study protocol [27]. It is important to mention that while both the FES-I and ABC attempt to infer similar information about the patient, their outputs are not fully correlated [28]. Demographic data as well as the distribution of the tests are presented in Table 1. According to FGA results, the population of this study had mild cognitive impairment [1].

Table 1. Study participant details.

Variable	Pilot site		Total value
	Athens	Freiburg	
Participants, n	14	5	19
Age (years), median (IQR)	64.5 (15.5)	72.0 (4.0)	68.0 (11.0)
Height (cm), median (IQR)	157.5 (11.8)	170.0 (2.0)	160.0 (16.5)
Weight (kg), median (IQR)	67.0 (21.5)	69.0 (8.0)	69.0 (21.0)
Male gender, %	7.14	40.00	15.79
Mini-Balance Evaluation Systems Test score (range ^a 0-28), median (IQR)	21.5 (6.0)	21.0 (1.0)	21.0 (5.5)
Functional Gait Assessment score (range ^a 0-30), median (IQR)	21.0 (5.0)	22.0 (3.0)	21.0 (5.5)
Falls Efficacy Scale International score (range ^a 16-64), median (IQR)	27.5 (9.25)	19.0 (8.0)	27.0 (8.5)
Montreal Cognitive Assessment score (range ^a 0-30), median (IQR)	25.5 (3.75)	27.0 (4.0)	26.0 (4.0)
World Health Organization Disability Assessment Schedule score (range ^a 100-0), median (IQR)	23.0 (24.5)	17.0 (21.0)	17.0 (22.0)
Activities-Specific Balance Confidence Scale score (range ^a 0-100), median (IQR)	76.9 (20.3)	87.5 (15.0)	82.5 (19.9)

^aFor the score range a-b, "a" represents no disability and "b" represents the highest disability.

Data Set

The participants, following the balance rehabilitation program prescribed by their physicians, performed a set of exercises during 16 sessions (2 sessions per week). During each session, a set of exercises was performed according to the program. The number of exercises per session varied from 3 to 8. Participants were instructed to execute the exercises at a self-paced rate (frequency and velocity of the movements) that would make them feel comfortable, avoiding any symptoms. As the sessions progressed, the aim of the program was to increase these metrics.

The performed exercises (with the relative progression levels for each exercise), which are described in a previous paper [27], were grouped into 9 classes, according to the kinematic characteristics of each exercise. The rehabilitation protocol

included 3 types of exercises (sitting exercises, standing exercises, and walking exercises). More specifically, there were 3 sitting exercises with 3 progression levels (in terms of intensity and complexity), 4 standing exercises with 4 progression levels, and 3 walking exercises with 3 progression levels (Table 2). The exercises were designed under the rationale of progressiveness of difficulty, including both simple and complex tasks, aiming for head-eye-hand coordination through multisensory rehabilitation exercises. As reported previously [29], the system is acceptable by end users and is feasible for use in hospital and home environments.

The data set was collected from April 2020 to June 2021. In total, 1313 exercises were recorded. Table 3 summarizes the collected annotated exercises.

Table 2. Description of the available rehabilitation exercises offered within the Holobalance intervention protocol (adapted from Liston et al [27], which is published under Creative Commons Attribution 4.0 International License [30]).

Exercise type	Exercise description
Sitting 1: Yaw	Perform head rotations of 30 degrees in the yaw plane (ie, left-right) while sitting, aiming at enhancing gaze stability.
Sitting 2: Pitch	Perform head rotations of 30 degrees in the pitch plane (ie, up-down) while sitting, aiming at enhancing gaze stability and improving common vestibular symptoms such as dizziness, swimminess, and light-headedness.
Sitting 3: Bend over	Bend as if to pick up an object off the floor from the sitting position and return to the upright position, aiming at improving functional activities of daily living (ADL) tasks and mitigating vestibular symptoms if provoked through practice.
Standing 1: Maintain balance	Maintain balance while standing up and remain in the proper position, aiming at improving postural alignment and standing ability with a smaller base of support.
Standing 2: Maintain balance on foam	Maintain balance as in standing exercise 1 while standing on a cushion and remain in the proper position, aiming at promoting sensory reweighting.
Standing 3: Bend over and reach up	Bend over bringing the chin to the chest, return the head to the normal upright position on coming up, and reach up while slightly tilting the head back, aiming at improving functional ADL tasks and dizziness.
Standing 4: Turn	On site, turn to face the opposite direction (ie, 180° turn), aiming at improving functional ADL tasks and dizziness.
Walking 1: Walk to horizon	Walk across the room (back and forth) in a straight path while looking at the horizon, aiming at promoting a normal gait pattern. Minimum space of 2 meters.
Walking 2: Walk & yaw	Walk across the room (back and forth) in a straight path while turning the head left and right, aiming at improving gaze stability while walking and functional ADL walking tasks. Minimum space of 2 meters. Yaw movement as in sitting exercise 1.
Walking 3: Walk & pitch/V-shape	Walk across the room (back and forth) in a straight path while turning the head up and down, and with V-shaped movement, aiming at improving gaze stability while walking and functional ADL walking tasks. Minimum space of 2 meters. Yaw and pitch movements as in sitting exercises 1 and 2.

Table 3. Exercises according to the type and progression level (N=1313).

Exercise type	Value, n	Exercise progression
Sitting exercise	514	
Sitting exercises 1 and 2	347	All progression levels
Sitting exercise 3	167	All progression levels
Standing exercise	530	
Standing exercises 1 and 2	312	All progression levels
Standing exercise 3	97	Progression levels 0 and 1 included 46; progression level 2 included 19; progression level 3 included 32
Standing exercise 4	121	All progression levels
Walking exercise	269	
Walking exercise 1	87	All progression levels
Walking exercises 2 and 3	182	All progression levels

During the execution of the exercises, a physiotherapist monitored the patient and scored patient performance using a scoring rubric that included 4 components (frequency, amplitude, velocity, and symmetry) for the sitting and standing exercises and an additional component (gait quality) for the walking exercises. For exercises with complex kinematic characteristics, additional components were considered in the scoring. For example, if an exercise included movement of the head and walking, rubric components for head movement and for gait quality were included in the scoring process.

More specifically, for sitting exercises, frequency referred to the number of head rotations (eg, in the yaw plane for sitting exercise 1) per second, while amplitude referred to the degree

of head turn from the upfront position to the extreme points of the movement. Additionally, velocity referred to the number of seconds a patient needed to perform a movement. This metric differs from frequency, as patients usually paused for some seconds between exercise movements, especially for complex ones like sitting exercise 3.

For each component, a score from 0 to 3 was given, with a score of 0 representing the noncompletion of the exercise. On top of the rubric components, a total score for each exercise was calculated a posteriori as the average of all components (N) of an exercise.



The proposed scoring model infers the score for all the involved components of an exercise, as well as the total score, which is mainly required to provide input to adjacent modules of the persuasive coaching system.

All patients undertook training sessions to get familiarized with the system. In addition, the session physiotherapists provided specific instructions for the correct execution of the exercises to the patients, in terms of timing and kinesiology. As described previously [23], these instructions were used to create the knowledge-based scoring model of the system.

A subset of the data set described in Table 3 was annotated by 2 physiotherapists, who monitored the patients during the execution of the exercises. More specifically, 38 sessions from 4 patients, which included 90 sitting exercises, 78 standing exercises, and 59 walking exercises, were scored by 2 independent evaluators to assess the interobserver variability of the annotation process. This resulted in 665 annotated scores for the different components of the scoring rubric.

Metrics and Analytics

As presented previously [23], based on a set of sensing devices (Figure 2), the system collected temporal signals and processed

them by extracting specific kinematic metrics, which were translated to exercise analytics. These analytics, along with the knowledge-based scoring model presented previously [23], were used as features in the ML models used to constitute the scoring model. Table 4 summarizes the extracted features, which were used as inputs for the ML models. The build prototype of the home-based system, including all the sensing devices, the head-mounted display, and the processing unit, costs approximately €4800 (US \$4850) (Figure 2).

The knowledge-based exercise score model (kb_score), mentioned in Table 4, refers to a rule-based model that attempts to assess the performance of an exercise based on the values of the captured motion analytics. More specifically, a group of experts established the acceptable range for each of the motion analytics (eg, 30 degrees for the head movement in sitting exercise 1). Based on these ranges, the knowledge-based model calculates the proportion of time a patient performs within these ranges, as well as how close the patient comes to the optimal range, and outputs the final kb_score. For assessing balance, sway, and stability, posture and trunk_sway metrics (Table 4) have been used.

Figure 2. The Holobalance system. (A) Sensor positioning in the Holobalance system. (B) Devices of the Holobalance system. IMU: inertial measurement unit.



Table 4. Input features for training the machine learning models.

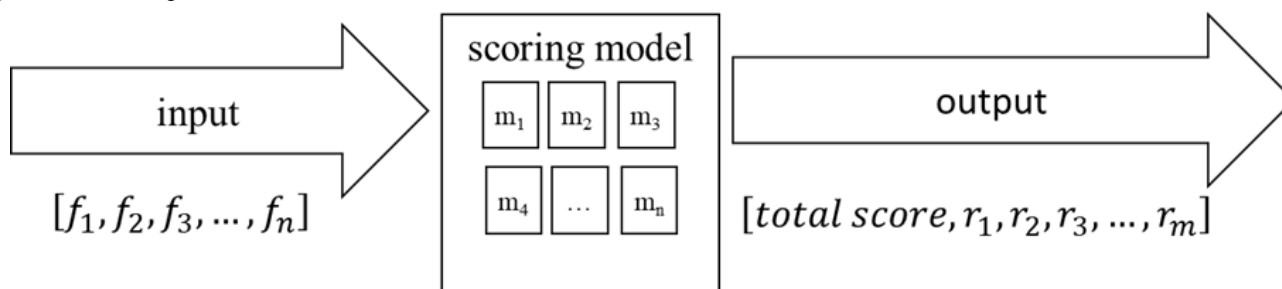
Feature	Description
kb_score	Knowledge-based exercise score as proposed previously [27]
head_movement_speed	Number of head rotations per second (mean and standard deviation) in the yaw and pitch planes
head_movement_range	Range of head rotations (mean and standard deviation) in the yaw and pitch planes
posture	Angle of the torso (sitting and standing)
trunk_sway	Mean and standard deviation of trunk sway
gait_parameters	Center of pressure on both feet (mean distance covered by the center of pressure and standard deviation per gait cycle); double support time (mean value and standard deviation per gait cycle); single support time (mean value and standard deviation per gait cycle); step duration (mean value and standard deviation per gait cycle); stride duration (mean value and standard deviation per gait cycle); cadence (mean value and standard deviation per gait cycle)

Scoring Model

The proposed data-driven exercise scoring model uses as inputs the analytics described in Table 4 and outputs a scoring vector for each exercise, as presented in Figure 3. More specifically, f_i refers to the features that describe the motion and movement of a patient during the performance of an exercise, while r_i refers

to each one of the evaluation components (frequency, amplitude, velocity, and symmetry), as expressed in each different exercise. Finally, *total score* refers to an overall assessment of the exercise. As the importance of the input features varies for the different exercise categories (Table 3), a separate model for each one of these groups of exercises and progressions has been developed and incorporated in the final scoring model.

Figure 3. The scoring model.



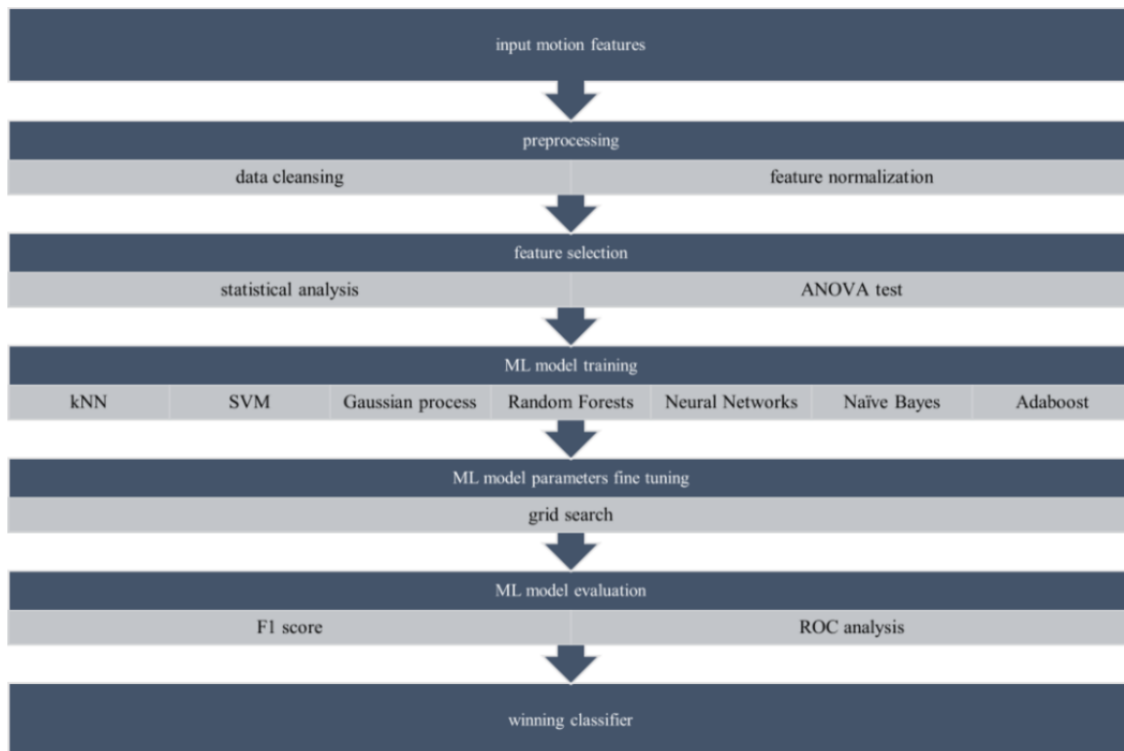
Aiming to identify the most relevant ML model for each rubric component (and for the total score), a set of ML models was assessed for each one of the components. The considered models were k-nearest neighbors (kNN) [31], support vector machines (SVMs) [32] (with both lineal and radial basis function), Gaussian process [33], random forests [34], neural networks [22], naïve Bayes [35], and AdaBoost [36]. These specific models were selected as they have been used in a wide set of similar data-driven problems [37].

For standing exercise 3, it was required to consider different models for different progressions owing to different kinematic characteristics in its progressions. This resulted in relatively small data sets for these cases. For this, the SMOTE (synthetic minority oversampling technique) algorithm [38] was used to

oversample the collected instances in order to obtain the necessary data to train the ML models.

The approach followed during the training of the ML models is summarized in Figure 4. More specifically, the first step was to identify data inconsistencies, like missing values, and remove them from the data set. Afterwards, min-max feature normalization was applied, aiming to improve the training process of the ML models. The next step involved an iterative process of training different ML models and evaluating them. For each model, an intermediate step for fine-tuning each parameter was applied, mainly using the grid search approach. Finally, the winning classifier for each model was selected, based on F1-score and receiver operating characteristic analysis results.

Figure 4. Machine learning (ML) model training approach. kNN: k-nearest neighbors; ROC: receiver operating characteristic; SVM: support vector machine.



Deployment Details: Integration

The winning classifiers were implemented under Python 3.8, using the scikit-learn 0.24 library. As soon as the system identifies the performed exercise, the appropriate classifier is invoked and the score of the exercise is inferred. This is now part of the Holobalance system, which is currently under evaluation.

Results

Overview

Within this section, the results of the training and evaluation of the ML models for each component of the scoring rubric are presented. All models were evaluated by applying a 10-fold cross-validation process and assessing the macro-average accuracy of the models. The training and testing data sets for each fold were created under an 80/20 ratio.

Interobserver Variability

As already mentioned earlier, almost 17.3% of the recorded exercises were scored by 2 observers to assess the interobserver

variability of the annotation process. The results of this procedure are presented in [Table 5](#). The selected evaluation metric is Cohen kappa coefficient [39], which is calculated as follows:

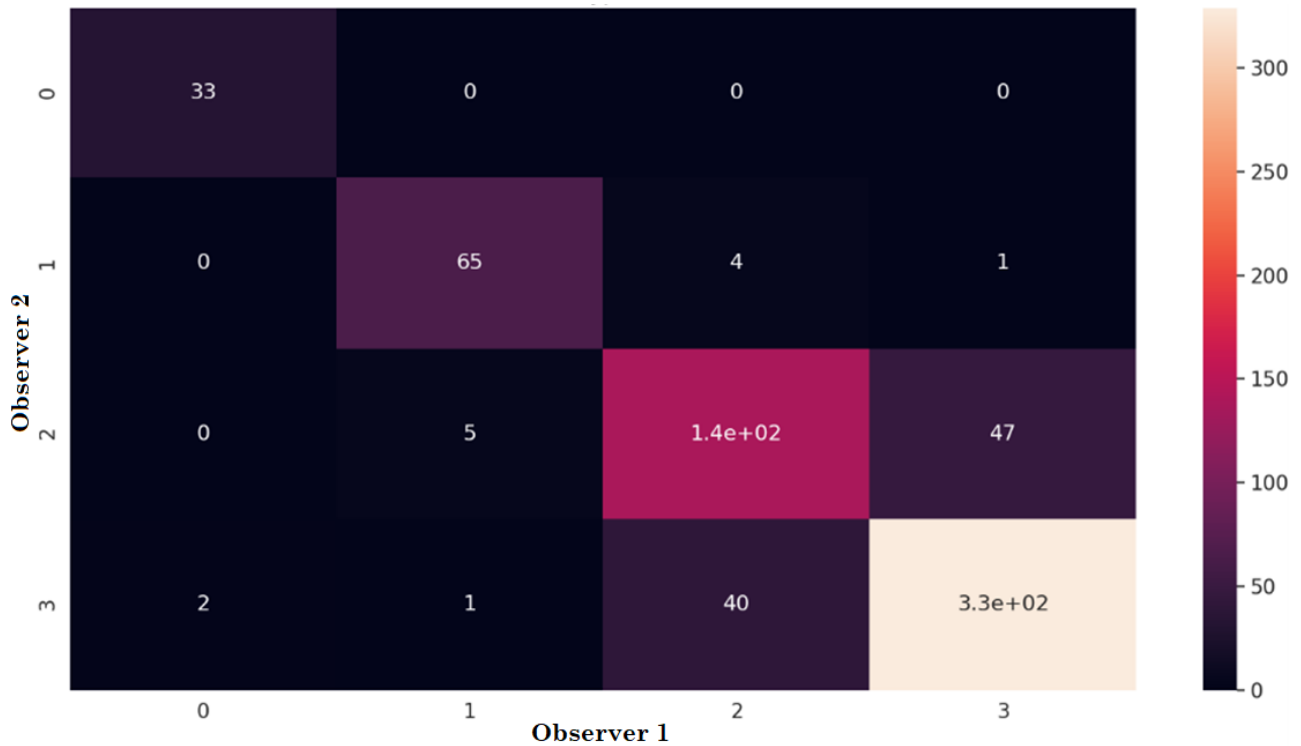
$$k = \frac{\text{Pr}(a) - \text{Pr}(e)}{1 - \text{Pr}(e)}$$

where $\text{Pr}(a)$ is the relative observed agreement among raters and $\text{Pr}(e)$ is the hypothetical probability of chance agreement, using the observed data to calculate the probability of each observer randomly seeing each category. If the raters are in complete agreement, then $k=1$. If there is no agreement between the raters other than what would be expected by chance (as given by $\text{Pr}(e)$), then $k=0$.

From a previous study [40], it can be concluded that the agreement of the observers was “good,” allowing the use of the collected data set to train reliable ML models. [Figure 5](#) presents the confusion matrix of the annotation process (please see [Multimedia Appendix 1](#) for more details).

Table 5. Results of interobserver variability per exercise type.

Exercise type	k statistic
All exercises	0.75
Sitting exercises	0.68
Standing exercises	0.79
Walking exercises	0.75

Figure 5. Confusion matrix. All types of exercises (N=665) in the annotation process of 2 observers.

Classification Results of Each Model

As mentioned earlier, an ML model for each component of the scoring rubric was trained and evaluated. The results are presented in [Table 6](#), where the macro-average accuracy has been provided, along with the winning classifier for each model. The results below present a set of 40 trained classifiers, which finally constitute the system's scoring model. More detailed results for the classification models are presented in [Multimedia Appendix 1](#).

For the sitting and standing exercises, it can be observed that the Gaussian process is the most relevant classifier, most probably because the number of features was lower compared with that for the walking exercises. Additionally, the low number of input features was correlated with higher accuracy results, which was expected. Thus, the accuracy for sitting exercises 1 and 2 was almost 90%, while that for walking exercises 2 and 3 dropped to slightly higher than 80% ([Table 6](#)). Finally, for the total score, the random forest classifier outperformed the rest of the models for 2 exercise subgroups, while kNN and linear SVM outperformed for 1 subgroup.

Table 6. Macro accuracy results of the winning classifiers for each of the considered models.

Exercise type	Macro accuracy/winning classifier						
	Total score	Component 1	Component 2	Component 3	Component 4	Component 5	Component 6
Sitting 1 and sitting 2	0.90/Gaussian process	0.88/Gaussian process	0.90/kNN ^a	0.89/Gaussian process	N/A ^b	N/A	N/A
Sitting 3	0.87/Gaussian process	0.86/Neural network	0.91/Gaussian process	N/A	N/A	N/A	N/A
Standing 1 and standing 2	0.85/Gaussian process	0.83/Gaussian process	0.86/Gaussian process	N/A	N/A	N/A	N/A
Standing 3 (progressions 0-1)	0.91/kNN	0.91/Gaussian process	0.92/Gaussian process	0.89/kNN	0.90/Random forest	N/A	N/A
Standing 3 (progression 2)	0.87/SVM ^c (linear)	0.89/Gaussian process	0.90/Naïve Bayes	0.88/Random forest	0.91/kNN	N/A	N/A
Standing 3 (progression 3)	0.91/Random forest	0.90/AdaBoost	0.88/Neural network	0.86/kNN	0.89/kNN	N/A	N/A
Standing 4	0.92/Gaussian process	0.86/Gaussian process	0.88/Gaussian process	0.80/kNN	N/A	N/A	N/A
Walking 1	0.90/Random forest	0.81/Gaussian process	0.85/Random forest	0.92/Random forest	N/A	N/A	N/A
Walking 2 and walking 3	0.81/kNN	0.74/kNN	0.75/SVM (linear)	0.78/SVM (RBF ^d)	0.71/kNN	0.75/SVM (RBF)	0.75/kNN

^akNN: k-nearest neighbors.

^bN/A: not applicable.

^cSVM: support vector machine.

^dRBF: radial basis function.

Overall Results: k-Statistic Analysis

Table 7 presents the overall results of the classification models for each individual exercise and the progression levels. In the same table, comparisons of interobserver variability, and the variability among observer 1 and the trained ML models are provided, which were performed on the testing data sets of each model. In addition, the previously used knowledge-based model [23] was compared with the annotations of the first observer.

Based on the results, the proposed framework's performance was similar to interobserver variability, thus constituting a reliable model for automated scoring of balance physiotherapy exercises. More specifically, the variability for the sitting exercises was almost identical, while there was a drop of 0.02

for the standing exercises. Finally, for the walking exercises, the decrease in the k-statistic was 0.04, which was justified due to the increased complexity of the relative exercises and the increased input features for the classification problems in these specific exercises.

When compared with the knowledge-based scoring model, the improvement in the agreement was substantial (15.9% for sitting exercises, 20.8% for standing exercises, and 26.8% for walking exercises for the k-statistic). This improvement enables the system to effectively deduce the performance of the patient, and thus, the system can not only correctly inform the clinician about the patient's status, but also enable them to design/choose correctly future rehabilitation programs.

Table 7. Overall classification accuracy and k-statistic analysis.

Exercise type	Total score (model)	k statistic (interobserver variability)	k statistic (observer 1 – ML ^a model)	k statistic (observer 1 – knowledge-based model)
Sitting		0.68	0.69	0.58
Sitting exercises 1 and 2	0.90 (Gaussian process)			
Sitting exercise 3	0.86 (Gaussian process)			
Standing		0.79	0.77	0.61
Standing exercises 1 and 2	0.853 (Gaussian process)			
Standing exercise 3 (progression level 0-1)	0.912 (kNN ^b)			
Standing exercise 3 (progression level 2)	0.8736 (SVM ^c linear)			
Standing exercise 3 (progression level 3)	0.905 (random forest)			
Standing exercise 4	0.918 (Gaussian process)			
Walking		0.75	0.71	0.52
Walking exercise 1	0.899 (random forest)			
Walking exercises 2 and 3	0.813 (kNN)			

^aML: machine learning.

^bkNN: k-nearest neighbors.

^cSVM: support vector machine.

Discussion

Principal Findings

The proposed set of ML models can effectively score the balance rehabilitation exercises of the Holobalance system. The models had similar accuracy in terms of Cohen kappa analysis, with interobserver variability, enabling the scoring module to infer the score of an exercise based on the collected signals from sensing devices. More specifically, for the sitting exercises, the scoring model had high classification accuracy, ranging from 0.86 to 0.90. Similarly, for the standing exercises, the classification accuracy ranged from 0.85 to 0.92, while for the walking exercises, it ranged from 0.81 to 0.90. From the obtained results, we observed that the lowest classification accuracies were related to the most complex exercises, in terms of required movements. While this result was anticipated, it is interesting that the same exercises also presented the highest interobserver variability, revealing that objectively scoring a complicated exercise is not a trivial task, even for expert physiotherapists. This is clearly reflected by the k-statistic analysis for almost all different exercise types. It is also important to mention that most of the misclassifications involved classes 2 and 3, meaning that poor performance (classes 0 and 1) and adequate performance (classes 2 and 3) can be assessed more accurately, by both the experts and the scoring model.

Comparison With Prior Work

The first version of the scoring module was built upon medical knowledge extracted by a group of experts [27]. The main drawback of this model was that it could not capture all possible states of a patient during the execution of a balance rehabilitation exercise. Thus, it failed in various situations to correctly grade the patient. The proposed data-driven model significantly

improves the accuracy for the performed exercises, increasing the k-statistic by 0.11 for sitting exercises, 0.16 for standing exercises, and 0.19 for walking exercises. It was noticeable that a more complex exercise was associated with higher improvement.

Strengths

The novelty of this work can be summarized in 2 main remarks. First, an annotated data set of sensor signals during the performance of about 1300 exercise sessions from 19 patients, along with the scoring of the exercises from an expert, was created. To the best of our knowledge, no such data set has been reported in the literature. Second, a scoring module, which includes several ML-supervised learning models, was developed and tested. The results clearly indicate that the proposed model appears to have similar predicting capacity considering the interobserver variability of experts who annotated the ground-truth data set.

Within the context of the Holobalance system, the capacity of the scoring module obviously enables correct exercise assessment in a rehabilitation program, as a physician can monitor the performance and progress of a patient and adopt the program accordingly. This assessment has a 2-fold advantage. First, the physiotherapist managing the patient is properly informed about the performance of the patient; thus, the next rehabilitation phases are designed based on objective information, which avoids the bias of self-reported results. Second, the virtual coach interaction with the patient is based on accurate scores, which facilitates realistic interaction with the system. More specifically, the exercise progression module is based on the scores produced by the scoring module to correctly assess whether a patient should progress to the next level of an exercise. As discussed earlier, each exercise is administered at different levels in terms of difficulty, speed,

and repetitions. Hence, the high accuracy of the scoring module enables the proper function of the exercise progression module. Additionally, the scoring module can be used for “red flagging” patients with very low performance and adherence early, thus allowing the physiotherapist to alter the rehabilitation approach. These aspects have a direct impact on the safe and effective execution of rehabilitation programs in home environments.

It is also important to stress that compared with other scoring models (eg, [41] and [42]), the output of the proposed model assesses not the recognition of the performed exercise but the quality of the performance of the exercise, a crucial aspect in the assessment of a rehabilitation program. By providing a high-accuracy exercise assessment model, as the one presented, virtual coaching systems can be equipped with the capacity to interact with patients using personalized context, thus enriching user experience.

Besides the value of a reliable scoring module within a persuasive coaching system like Holobalance, this module can be used independently as a separate module in clinical practice. One of the most important uses is objective baseline assessment of a patient, as it can support clinicians in objectively evaluating the baseline of a patient when performing an exercise during the first clinic visit. Additionally, the analysis for building the scoring module, especially the feature statistics analysis, can contribute to the design of new balance rehabilitation exercises targeting mainly the metrics that appear to have an important contribution to the score of an exercise, while eliminating aspects and kinematics related to metrics of low importance to the model. Furthermore, the scoring module can support patients who require long-term monitoring, especially those with

degenerative neurological conditions, such as ataxia or dementia, which require long-term rehabilitation and monitoring for maintenance purposes. Moreover, a reliable scoring and assessment module can facilitate the education of novice physiotherapists and physicians, enabling them to better understand the needs of different clinical populations. Finally, within the research context, the sensor-based information from this model could be used as a biomarker to monitor populations of interest over the long term (such as older adults or patients with cognitive impairments) for the early prediction of the risk of falls and early prediction of cognitive decline.

Limitations

Regarding the limitations of the proposed model, a major drawback is that the model requires knowledge of the type of exercise to assess the score for the exercise. In other words, the proposed scoring model does not have the capacity to recognize the exercise, limiting its usage to only rehabilitation programs with predefined exercise sets. Additionally, the size of the collected data set did not allow us to test deep learning models, which might show higher classification accuracies.

Future Directions

Regarding the future directions related to the scoring model, we anticipate to incorporate motion recognition algorithms, enabling the module to infer which exercise is performed. This will allow the module to support free-program exercise sessions. Finally, deploying the module to more sites will allow us to extend the exercise data set, which will provide wider validation to the proposed solution and help in the use of deep learning models, if the volume of data is adequate.

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Data Availability

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

Conflicts of Interest

None declared.

Multimedia Appendix 1

Additional study results.

[DOCX File, 873 KB - [rehab_v9i3e37229_app1.docx](#)]

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Abbreviations

- ABC:** Activities-Specific Balance Confidence Scale
CNN: convolutional neural network
FES-I: Falls Efficacy Scale International
FGA: Functional Gait Assessment
kNN: k-nearest neighbors
ML: machine learning
SVM: support vector machine

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Original Paper

mHealth Apps for Musculoskeletal Rehabilitation: Systematic Search in App Stores and Content Analysis

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Abstract

Background: The number of mobile health (mHealth) apps released for musculoskeletal (MSK) injury treatment and self-management with home exercise programs (HEPs) has risen rapidly in recent years as digital health interventions are explored and researched in more detail. As this number grows, it is becoming increasingly difficult for users to navigate the market and select the most appropriate app for their use case. It is also unclear what features the developers of these apps are harnessing to support patient self-management and how they fit into clinical care pathways.

Objective: The objective of this study was to scope the current market of mHealth apps for MSK rehabilitation and to report on their features, claims, evidence base, and functionalities.

Methods: A cross-sectional study of apps for MSK rehabilitation was performed across the iTunes App Store and Google Play Store. Four search terms were used, namely, physiotherapy rehabilitation, physical therapy rehabilitation, rehabilitation exercise, and therapeutic exercise to identify apps, which were then cross-referenced against set selection criteria by 4 reviewers. Each reviewer, where possible, downloaded the app and accessed supplementary literature available on the product to assist in data extraction.

Results: A total of 1322 apps were identified. After applying the inclusion and exclusion criteria and removing duplicates, 144 apps were included in the study. Over half (n=81, 56.3%) of the included apps had been released within the past 3 years. Three quarters (n=107, 74.3%) of the apps made no reference to evidence supporting the design or efficacy of the app, with only 11.1% (n=16) providing direct citations to research. Most of the apps did utilize exercise pictures (n=138, 95.8%) or videos (n=97, 67.4%); however, comparatively few harnessed additional features to encourage engagement and support self-management, such as an adherence log (n=66, 45.8%), communication portal (n=32, 22.2%), patient-reported outcome capture (n=36, 25%), or direct feedback (n=57, 39.6%). Of note and concern, many of these apps prescribed generic exercises (n=93, 64.6%) in the absence of individualized input to the user, with few providing specific patient education (n=43, 34%) and safety advice or disclaimers (n=38, 26.4%).

Conclusions: The cohort of apps included in this study contained a large heterogeneity of features, so it is difficult for users to identify the most appropriate or effective app. Many apps are missing the opportunity to offer key features that could promote exercise adherence and encourage self-management in MSK rehabilitation. Furthermore, very few developers currently offering products on the market are providing evidence to support the design and efficacy of their technologies.

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KEYWORDS

mHealth; musculoskeletal rehabilitation; app; home exercise program; home exercise; telehealth; mobile health; connected health

Introduction

An injury to the musculoskeletal (MSK) system involves damage to 1 or more components of the locomotor system and its associated tissues. These injuries account for the greatest proportion of noncancer persistent pain conditions [1]. The World Health Organization (WHO) estimates that between 20% and 33% of people across the world live with a painful MSK condition, and it is the highest contributor to global disability, with low back pain the single leading cause of disability worldwide [1,2]. The burden of MSK conditions on societal and personal well-being is escalating, resulting in a reduction of quality of life, mental well-being, and function [3]. Additionally, MSK conditions account for 25% of overall costs of illness globally, placing a significant burden on health care resources [4]. Exercise as treatment for MSK conditions is widely accepted [5], with clinical guidelines advocating the promotion of physical activity and the use of exercise programs [6,7].

The prescription of home exercise programs (HEPs) encourages patients to take responsibility and self-manage their condition to mitigate limitations in physical function, a hallmark consequence of MSK conditions [8]. Adherence is considered an important prerequisite for the success of HEPs and has a direct link to improved patient outcomes [9]. However, in a study by Bassett et al [10], nonadherence to HEPs was estimated to be as high as 50%. Therefore, solutions to improve adherence and support self-management are required to optimize the efficacy of MSK treatment [11,12]. It has been suggested that mobile apps and connected health technologies can incorporate design features to maximize adherence, encourage self-management, and bridge the gap between the clinic and home [11,13].

Mobile health (mHealth) is defined by the WHO Global Observatory for eHealth as a “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” [14]. The current capabilities and ubiquity of mobile devices make them a valuable tool for improving the delivery of health care services and providing scalable, low-cost interventions [15]. Today, 3.8 billion people worldwide own a smartphone [16], posing an opportunity for health care providers to make health care accessible to a large proportion of the population [17,18]. With this rise in accessibility of mHealth comes a surge in the choices of apps, with at least 318,000 health apps available worldwide [19]. Other areas of health, including diabetes and hypertension management, have reported promising results in favor of the use of apps for improving several clinical, behavioral, knowledge, and psychosocial outcomes [20,21]. With the mHealth app market growing exponentially, the employment of such apps in various clinical contexts correlates with this growth. Clinicians in both cardiac and neurorehabilitation/palliative care adopting mHealth apps into their practices have reported similar, clinically relevant successful outcomes [22,23].

One clear use case that mHealth affords health care professionals is the opportunity to provide interactive and engaging access to self-management programs for MSK rehabilitation,

incorporating features such as goal setting, coaching, remote monitoring, and exercise tracking [11,24]. Therefore, these systems have the potential to increase self-efficacy, optimize quality of life, and reduce the burden of MSK conditions [25,26]. However, caution must be taken with this opportunity, as there is a need for better standardization and regulation of mHealth apps to ensure proper integration and identification of beneficial and safe apps [27,28]. With over 200 health apps being added to the iOS and Google Play app stores each day [17], the integrity, in terms of quality and safety, of mHealth apps is questionable. Despite the iTunes App Store and Google Play Store categorizing apps (health, well-being), searches on the stores yield millions of results of indeterminate quality [29,30], making the search and selection of health care apps challenging for clinicians and patients alike [31]. There is a large body of qualitative research looking at the potential of mHealth to improve adherence and the role that digital technology can play in exercise rehabilitation [32,33]. However, research examining the current state of mHealth apps for exercise rehabilitation is limited. A recent systematic review found that approximately one-third of the 102 studies included evaluated the clinical efficacy of an intervention, with the remainder assessing the functionality of the app or patient engagement with the app [34]. To our knowledge, there has been no research to date exploring the overall scope of the market.

Given the exponential rise in mHealth apps and the limited research into their effectiveness and acceptance, the aim of this study was to investigate the current state of the mHealth app market targeted at assisting patients with MSK exercise rehabilitation. Recent innovations in health care provision can help improve the delivery and efficacy of physiotherapy to this cohort of patients [35]. The aim of this paper is to scope the current market of mHealth apps for MSK rehabilitation and describe which features exercise rehabilitation apps currently offer, document the accessibility of the app, and explore the evidence supporting each individual app.

Methods

Study Design

A cross-sectional study of MSK rehabilitation apps was performed to identify apps from 2 major smartphone app stores: iTunes App Store and Google Play Store, which together represent 98.9% of the smartphone app market share [36]. Building on the approach by Giunti et al [27], a systematic search strategy was developed that attempted to identify all relevant apps, followed by a synthesis of the characteristics of the apps.

Setting

On October 28, 2020, 4 reviewers searched both stores from the Republic of Ireland using 4 different search terms: “physiotherapy rehabilitation,” “physical therapy rehabilitation,” “rehabilitation exercise,” and “therapeutic exercise.” The iTunes App Store is a digital distribution platform developed and maintained by Apple Inc for mobile apps on iOS with 1.96 million apps available [16]. Google Play store (originally the Android Market) serves as the official app store for the Android operating system and contains over 2.86 million apps [16].

Selection Criteria

Apps were included if they were available in English, focused on exercise interventions for MSK injuries or general MSK physiotherapy rehabilitation, and were available for use on

smartphone devices. Apps that were determined to be general well-being/fitness apps without reference to physiotherapy or rehabilitation were excluded. A full list of inclusion and exclusion criteria can be found in [Textbox 1](#).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria
<ul style="list-style-type: none"> Title or description makes reference to musculoskeletal (MSK) physiotherapy/physical therapy rehabilitation Title or description makes reference to exercise interventions for specific or general MSK conditions Patient-centered app Includes exercise prescription
Exclusion criteria
<ul style="list-style-type: none"> Title or description does not make reference to MSK physiotherapy/physical therapy rehabilitation Title or description does not make reference to exercise interventions for specific or general MSK conditions Description is not written in English Duplicates from the same store Clinician-focused app Women's health apps such as pelvic floor center apps General fitness apps with no mention of physiotherapy/physical therapy or MSK conditions

After the search was completed, the resultant apps were screened by 1 of 4 reviewers (authors SR, NNC, SOH, and DC) for eligibility against the inclusion and exclusion criteria. A small random sample (5%) was independently reviewed by 2 reviewers who evaluated the eligibility of the apps against the selection criteria. To assess the clarity of the selection criteria, interrater reliability was assessed using Cohen kappa coefficient. If any conflicts or disagreements arose, the app in question was discussed between the 4 reviewers until they came to an agreement. In line with common practice, different versions of the same app (basic/premium, iOS/Android) were included separately due to version capabilities or store submission processes [37]. A cohort of identical apps from the same developer was classed as "white labeled" by the authors, with the underlying app being identical but branded for different health care providers. During selection, this cohort was represented by 1 randomly selected app per developer from each store.

Data Extraction

All apps included for data extraction were split evenly between the 4 reviewers. The data were extracted from the app description on the stores, screenshots on the stores, and the app website (link provided on app stores). Data extracted on the apps included year of release, developer, charging models, targeted body part, features, and evidence. If information on

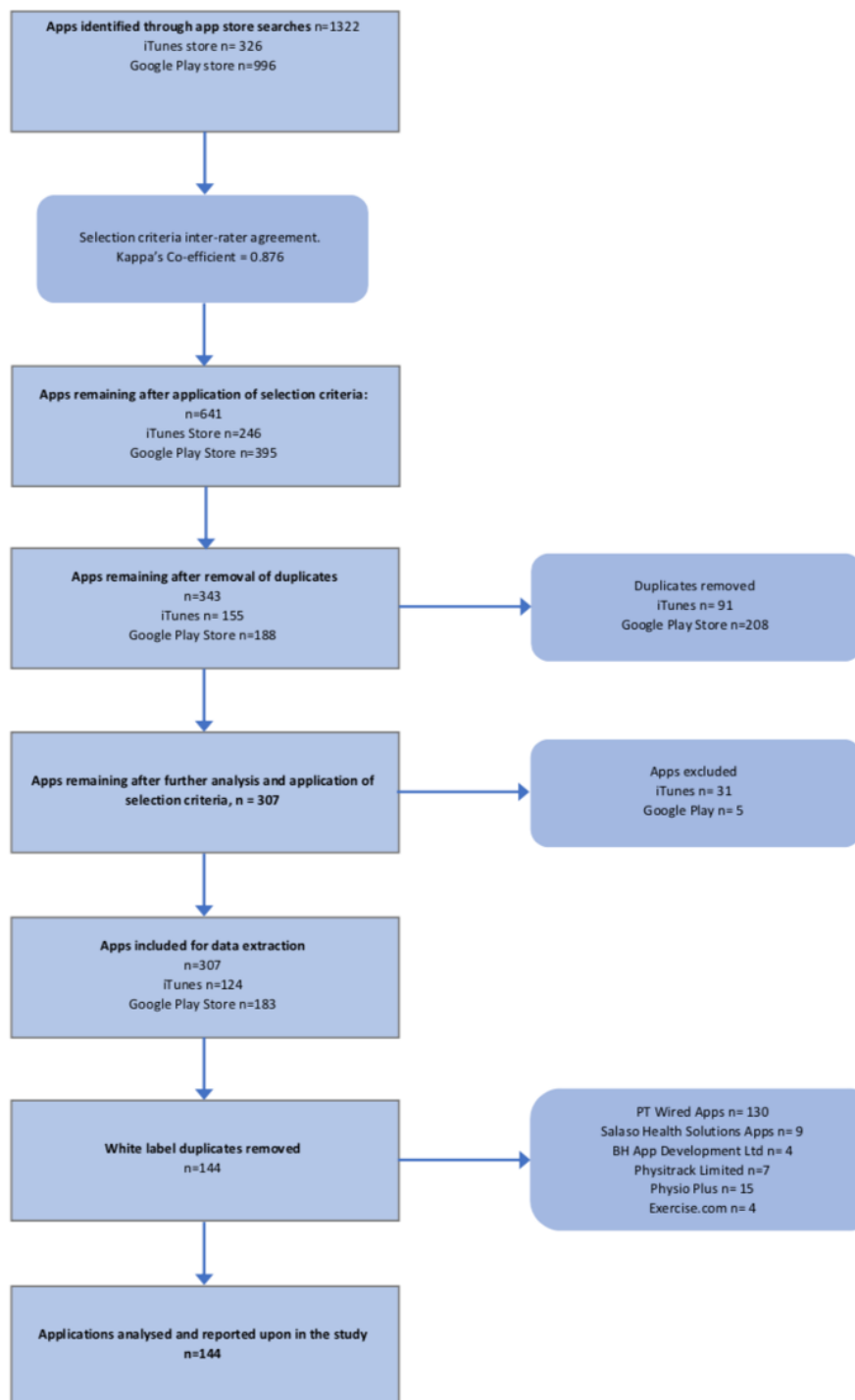
the app features was unavailable or unclear in the description, screenshots, and website, the app was downloaded to decipher the remaining features. If a reviewer was unsure of any data, a discussion was held between the 4 reviewers until a resolution was reached. A list of parameters that were used for data extraction and a description of each is included in [Multimedia Appendix 1](#).

Results

App Selection

A total of 1322 apps (326 iTunes App Store and 996 Google Play Store) were identified using the described search strategy. After screening, a total of 641 apps (246 from iTunes App Store and 395 from Google Play Store) met the inclusion/exclusion criteria. Duplicates were then removed, bringing the total to 343 apps. During data extraction from the apps and their associated websites, a further 36 apps were excluded because further investigation revealed that they did not meet the selection criteria. White-label app duplicates were then removed, resulting in a total of 144 apps for data analysis (40 from iTunes App Store and 104 from Google Play Store). Interrater reliability on data screening was tested by calculating the kappa coefficient, resulting in a value of 0.876. [Figure 1](#) presents the flowchart of the app selection process.

Figure 1. Study Flow.



App Analysis Results

General Characteristics of Included Apps

The content analysis of the included apps is shown in Table 1. Despite the existence of both app stores since 2008, the past 5 years account for 84% of all app releases, with a notable increase between 2017 and 2019.

The predominant revenue model was a fully cost-free business-to-consumer approach (n=53, 36.8%), with revenue

presumably derived from advertising and marketing. A further 23.6%

(n=34) of apps were free to download but offered in-app purchases. This included paying for additional exercises, exercise progression, or other features such as exercise logging. Many other developers (n=43, 29.9%) have pursued a business-to-business model whereby clinics pay for the platform and then provide it in their service to patients.

Table 1. Results of review of apps for musculoskeletal rehabilitation (N=144).

Characteristics	Value, n (%)
Year of app release	
2006	3 (2.1)
2008	3 (2.1)
2012	2 (1.4)
2013	2 (1.4)
2014	13 (9.0)
2015	8 (5.6)
2016	16 (11.1)
2017	16 (11.1)
2018	23 (16.0)
2019	32 (22.2)
2020	26 (18.1)
Charging model type	
Free to download and no in-app purchase	52 (36.8)
Clinic charged	42 (29.9)
Free to download with in-app purchase	33 (23.6)
Download charge for patient	10 (6.9)
Multiple	3 (2.1)
Unable to determine	4 (2.7)
Evidence base	
No research highlighted	107 (74.3)
References provided to relevant research	16 (11.1)
Evidence based claims but no reference	21 (14.6)
Method of exercise prescription	
Generic	93 (64.6)
Tailored to user requirements	44 (30.6)
Both	7 (4.7)
Targeted body part	
Shoulder	6 (4.2)
Neck and shoulder	2 (1.4)
Neck	5 (3.5)
Knee and hip	2 (1.4)
Knee and back	1 (0.1)
Knee	21 (14.6)
Hand and wrist	1 (0.1)
Hand	3 (2.1)
Back and neck	2 (1.4)
Back and knee	1 (0.1)
Back and hip	1 (0.1)
Back and core	1 (0.1)
Back	18 (12.5)
Ankle	2 (1.4)

Characteristics	Value, n (%)
Tailored	73 (50.7)
Presence of design enhancing features	
Pictures	138 (95.8)
Videos	97 (67.4)
Self-reported log	66 (45.8)
Adherence reminders	49 (34.0)
Patient-reported outcomes	
Standardized instruments	21 (14.6)
Response to targeted questions	2 (1.4)
Present—unable to determine method	1 (0.1)
Free text	1 (0.1)
Multiple	11 (7.6)
None	108 (75.0)
Communication features	
Video conferencing	6 (4.2)
Two-way messaging	8 (5.6)
Robotic messaging	1 (0.1)
Messaging—unable to differentiate	2 (1.4)
Instant messaging	4 (2.8)
Multiple sources	11 (7.6)
None	112 (77.8)
Feedback to patients	
Automated	5 (3.5)
Progress tracking	25 (17.4)
Gamification	5 (3.5)
Direct feedback from physiotherapist	5 (3.5)
Multiple	17 (11.8)
None	87 (60.4)
Clinical specificity	
Clinic-specific	18 (19.4)
Public access	116 (80.6)

Almost three quarters (n=107, 74.3%) of apps made no reference to research or an evidence base for their interventions, nor did they make scientific claims about their apps. Meanwhile, 11.1% (n=16) of the apps did provide research evidence to support the clinical relevance of their platform, marketing claims, or features of the app. The remaining 14.6% (n = 21) of apps made evidence-based claims but failed to reference or supply links to the relevant research.

The majority (n=116, 80.6%) of apps were available to the general population, with the remainder being restricted to a specific clinic and requiring patients to log in to access the features available. Table S1 in [Multimedia Appendix 2](#) shows the general characteristics of the apps.

Prevalence of Exercise Prescription and Assistance Features

Most (n=93, 64.6%) of the apps used automated exercise prescription to generate a generic HEP, while only 30.6% (n=44) of the apps prescribed exercises selected by a health care professional to the patient post assessment ([Table 1](#)). The remaining 4.7% (n=7) utilized both methods of exercise prescription. Just under half (71/144, 49.3%) of the apps only targeted the rehabilitation of a specific body part. The knee (n=21, 14.6%) was the most commonly featured body part, followed by the back (n=18, 12.5%) and shoulder (n=6, 4.2%). The remainder (n=73, 50.7%) of the apps did not target a specific body part or tailor the HEP to the specific needs of the individual patient.

Over two-thirds ($n=97$, 67.4%) of the apps included videos to illustrate the exercise and assist with technique, while the vast majority ($n=138$, 95.8%) incorporated static pictures in their HEPs. Less than half ($n=66$, 45.8%) of the apps utilized a self-reported exercise log, although adherence reminders were more frequently used, featuring in 66.7% ($n=96$) of the apps (Table 1). Table S1 in [Multimedia Appendix 2](#) shows the exercise prescriptions and assistance features of the apps.

Prevalence of Communication and Feedback Features

Only 25% ($n=36$) of the apps offered patient-reported outcome (PRO) features supporting self or remote monitoring. Even fewer ($n=32$, 22.2%) had any direct personalized communication feature. Less than half (39.6%, $n=57$) included a feature for feedback from the app to the patient. Only 34% ($n=49$) contained patient education on their app, with fewer ($n=38$, 26.4%) featuring any safety advice or warnings.

In the apps containing PROs, standardized instruments like a visual analogue scale or a Likert scale ($n=21$, 14.6%) were the most common. Only 1.4% ($n=2$) included specific questions for the patient to respond to, and 0.7% ($n=1$) included free-text boxes for the patients. Meanwhile, 7.6% ($n=11$) used more than 1 of these features. It was not possible to determine whether PRO features were used in 0.7% ($n=1$) of the included apps.

The most common (5.6%, $n=8$) communication feature was 2-way text messaging between health care professionals and patients (Table 1), followed by video conferencing ($n=6$, 4.2%), instant messaging ($n=4$, 2.8%), and robotic automated messages ($n=1$ 0.7%). More than 1 type of communication feature was seen in 7.6% ($n=11$) of the apps. In 1.4% ($n=2$) of the apps, it was not possible to identify which communication features were present or if there were any at all.

Of the apps that did include a feature to enable feedback to the patient, progress tracking was the most prevalent ($n=25$, 17.4%). This is where the patient could track the exercises or workouts they had completed on a calendar. Gamification was utilized in 3.5% ($n=5$) of the apps, where awards or badges were given. The same percentage of apps supplied direct feedback on progress from the health care provider and included automated feedback, meaning they would receive feedback on their progress through automated messages or emails. Overall, 11.8% ($n=17$) of the apps included 1 or more of the above feedback-supporting features. Table S2 in [Multimedia Appendix 2](#) shows the additional features of the apps.

Discussion

Principal Findings

The sheer volume of mHealth apps available for exercise rehabilitation proves the popularity and prospects of technology in physical medicine. Yet, the acceptance of mHealth apps into routine clinical practice lags behind [38], as clinicians struggle to identify and select appropriate evidence-based apps. This study is the first to complete an in-depth analysis of exercise rehabilitation apps to help elucidate the state of the mHealth app market and investigate the relevance, design, and accessibility of the apps currently available in the iTunes and Google app stores. Despite the prevalence of these apps, many

fail to offer individualized HEPs or harness design features available in mHealth systems to encourage self-management and adherence [11,39]. Going forward, app developers should focus on the inclusion of features that can be specific and customized to the end user for the capabilities of mHealth to be capitalized upon in rehabilitative medicine.

This study reveals a lack of evidence supporting the use of these apps, with only 11.1% ($n=16$) providing supporting research in their marketing material. Perhaps most concerning is the 14.6% ($n=21$) of apps that make claims relating to being evidence based but fail to cite any research; the absence of accessible evidence in any of the marketing material makes it difficult to appraise each offering. This might explain why most physiotherapists report only using apps for administrative purposes and not routinely recommending them to support patients' HEPs in MSK rehabilitation [40]. Health care professionals must feel confident in the evidence base supporting the app to enhance their clinical judgement in their app selection and encourage adoption [41]. The National Institute for Health and Care Excellence (NICE), in collaboration with the National Health Service (NHS) in the United Kingdom, recently published an Evidence Standards Framework for digital and care technologies [42]. This framework contains a comprehensive list of evidence criteria required for such technologies to be adopted into the UK health system, including both minimum and best practice standards. Such frameworks create an awareness among developers, clinicians, and end users of the various types of evidence required for the effective development and implementation of technology in health care.

Communication is a cornerstone of the patient-physiotherapist relationship; a discrepancy in this alliance is a decisive indicator of nonadherence to HEPs, with poor physician communication increasing the risk of nonadherence by up to 19% [43]. Digital health technologies have a variety of communication methods to employ, from telehealth consultations (offered by only 6 of the included apps) to real-time messaging platforms, such as SMS text messaging, emails, or instant messaging (15 apps). The incorporation of such features may encourage the uptake of mHealth apps by clinicians and deviate patients from the more generic "back pain" or "shoulder pain" apps that provide automated programs in the absence of clinician input. The findings from this study are consistent with other research, as physiotherapists expressed concerns about app quality, patient safety, and knowledge base of mHealth apps [38]. A good HEP considers the individual it aims to help, which is fundamental to positively impacting adherence [44]. The literature makes a clear stance in favor of frequent and clear 2-way communication between the therapist and the patient [45], yet less than a quarter of the apps included in this study facilitated communication between the therapist and the patient.

Facilitating 2-way feedback (patient to clinician and clinician to patient), although challenging, is key to ensure that the clinician is readily equipped with data that can improve clinical decision making [11]. Consumer adoption of digital technology presents an opportunity to continuously capture feedback from patients through clinically approved PROs [46]. A variety of PROs, including standardized instruments, have been developed and validated to use as part of patient management [47], and

such features improve communication and enhance clinical decision making [48]. Standardized PROs were featured in less than 15% (n=21) of the apps in this study, something that potentially contradicts the purpose of these “patient-centered” apps. Equally, the delivery of feedback to patients provides an opportunity for the therapist to reassure and educate the patient. The information a patient receives and the beliefs they hold about their condition influence their decision making and thus their adherence [49]. App developers may potentially be adopting the rationale that the inclusion of communication and feedback features may raise concerns regarding patient data security and privacy, with unencrypted communication and third-party data hosting common in general apps in the Google Play Store [50]. Numerous studies have identified the increasing amount of sensitive data handled by mHealth apps as new developments in the industry emerge [51], and this poses challenges to developers and regulators alike.

The idea of using an app in exercise rehabilitation is not to replace the therapist but rather to be seen as a facilitator [52]. mHealth apps have the capacity to send adherence reminders and notifications directly to the device, but the results of this study indicate that this is an area that developers are slow to take advantage of, with just over one-third of the apps featuring adherence reminders. Technology has the potential to affect the outcomes of HEPs by improving the accuracy, adherence, and quality of exercises performed by the patient through multimedia versions of a program (pictures and videos). The inclusion of pictures in a HEP is common in clinical practice [53], although providing patients with videos is slightly more difficult without the use of an app. Remarkably, one-third of the apps failed to incorporate videos into their HEPs [54]. The significant absence of these features, which have shown to increase levels of patient adherence [55], is an area we identified as an underutilization of the resources offered by mHealth apps.

Health care apps have become an industry in themselves for developers, investors, and health care professionals alike [56]. The findings in this study suggest that for these apps to be used in routine MSK practice, greater efforts need to be made by app developers to engage with academic research and stakeholders. Both health care providers and organizations have quality and validity concerns when it comes to choosing an app to recommend [57]. The absence of features proven to enhance adherence to HEPs, along with no real-time clinician input, leads to the information provided on these apps remaining static [27]. The findings in this study are consistent with those of apps to improve a patient's adherence to medications, with the majority lacking desirable features and considered to be of low quality [58]. There is a wide selection of tools to assess the quality of health-related websites; however, the same cannot be said when it comes to assessing and evaluating mHealth apps [57]. The Mobile App Rating Scale (MARS) is a tool for classifying and assessing the quality of mobile health apps. Further work should look at developing similar tools with a specific relevance to certain areas of health care such as rehabilitation [59]. It would be beneficial for future work to offer stakeholders an informative repository evaluating mHealth apps.

It was beyond the scope of this study to obtain access to the cohort of apps requiring payment to download or private subscriptions. In such cases, data extraction was completed via the app store through analysis of the available screenshots and developer websites. Where evidence of a feature could not be found using this method, it was stated that the feature was absent for this app. As highlighted by Giunti et al [27], while it is possible that an app's features may only be disclosed to registered app users, this seems unlikely to be a common occurrence as the app store's description and screenshots serve as major selling points to potential users.

Only apps available in the Republic of Ireland were included in this study. Hence, it is possible that there exists a cohort of eligible apps that have not been included due to geographical limitations. We also decided to exclude white labeled apps. Apps were considered to be white labeled if they were identified as identically structured apps provided by a single developer to multiple different companies. Given that the only discrepancy identified was in accessibility (customers must be linked to the specific private practice or company selling the app to gain access), we felt that the inclusion of such apps would provide a less relevant data set with heavily skewed results. These limitations aside, the data set reported upon reflects the most accurate depiction of the currently available apps for MSK rehabilitation across the 2 major app stores.

It is not surprising that as the capabilities of technology in health care grow, the number of apps coming onto the mHealth app market correlates. Just under 85% (n=122) of the apps that met the inclusion criteria were released into the respective app stores from 2015. The change in outpatient service delivery from traditional face-to-face patient contact to remote management has accelerated rapidly in response to the COVID-19 pandemic [60]. This shift toward technology was reflected in our findings, with 18% (26 apps) of the apps coming to the market in 2020. The pandemic has provided an opportunity for clinicians to embrace innovation and redesign their services to enhance their efficacy beyond the immediate crisis [61-63]. With the rapid proliferation of apps being brought to the market, the findings of this review highlight an opportunity is not being embraced to its full extent. Further research is required to investigate which digital health care features have a meaningful effect on adherence to HEPs. A framework to guide clinician and patient selection of mHealth apps in MSK rehabilitation could help navigate through the overwhelming number of apps available in the respective stores.

Conclusions

This study analyzed a large number of MSK rehabilitation apps available to consumers. Most of the apps were designed to provide HEPs and empower patients with the aim of improving adherence to HEPs and bridging the gap between the clinic and home. With the emerging capabilities and developments of mHealth, the use of apps in clinical practice is becoming more widely accepted. However, this study identified several missed opportunities by app developers to offer key features that promote adherence and self-management. There was a significant absence of properly cited sourced material or references in the apps included in this study. With the

capabilities of mHealth underutilized in physical medicine, this review raises questions about the efficacy and quality of MSK rehabilitation apps, indicating that the current ecosystem of mHealth apps available do not lend well to evidence-based clinical practice. The paucity of evidence in this field reiterates

the need for high-quality research and presents an opportunity to all stakeholders involved to develop and enhance these patient-facing apps to further bridge the gap between the clinic and the home.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Featured descriptors.

[[DOCX File , 17 KB - rehab_v9i3e34355_app1.docx](#)]

Multimedia Appendix 2

Additional features.

[[DOCX File , 16 KB - rehab_v9i3e34355_app2.docx](#)]

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Abbreviations

HEP: home exercise program

MARS: Mobile App Rating Scale

mHealth: mobile health

MSK: musculoskeletal

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

PRO: patient-reported outcome

WHO: World Health Organization

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Review

Real-Time Telerehabilitation in Older Adults With Musculoskeletal Conditions: Systematic Review and Meta-analysis

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Abstract

Background: Real-time telerehabilitation (TR) is a new strategy for delivering rehabilitation interventions to older adults with musculoskeletal conditions, to provide continuity to conventional services and mitigate travel-related barriers.

Objective: We aimed to examine the effectiveness of treatment delivered via real-time TR services compared to conventional services among older adults with musculoskeletal conditions, in terms of physical performance, treatment adherence, and cost-effectiveness.

Methods: A literature search of randomized controlled trials (RCTs) published from January 2000 to April 2022 was conducted in six online databases: Cochrane Library, PubMed (ie, MEDLINE), PEDro, ClinicalKey, EBSCO, and ProQuest. The main eligibility criterion for articles was the use of real-time TR among older adults with musculoskeletal conditions to improve physical performance. Two reviewers screened 2108 abstracts and found 10 studies (n=851) that met the eligibility criteria. Quality assessment was based on version 2 of Cochrane's risk-of-bias tool for RCTs, in order to assess the methodological quality of the selected articles. Results were pooled for meta-analyses, based on the primary outcome measures, and were reported as standardized mean differences (SMDs) with 95% CIs. A fixed model was used, and subgroup analysis was performed to check for possible factors influencing TR's effectiveness based on different treatments, controls, and outcome measures.

Results: The search and screening process identified 10 papers that collectively reported on three musculoskeletal conditions in older adults and three types of TR programs. Aggregate results suggested that real-time TR, compared to conventional treatment, was more effective at improving physical performance regarding balance (SMD 0.63, 95% CI 0.36-0.9; $I^2=58.5\%$). TR was slightly better than usual care at improving range of motion (SMD 0.28, 95% CI 0.1-0.46; $I^2=0\%$) and muscle strength (SMD 0.76, 95% CI 0.32-1.2; $I^2=59.60\%$), with moderate to large effects. Subgroup analyses suggested that real-time TR had medium to large effects favoring the use of smartphones or tablets (SMD 0.92, 95% CI 0.56-1.29; $I^2=45.8\%$), whereas the use of personal computers (SMD 0.25, 95% CI -0.16 to 0.66; $I^2=0\%$) had no effect on improving balance and was comparable to conventional treatment.

Conclusions: We found that real-time TR improved physical performance in older adults with musculoskeletal conditions, with an effectiveness level equal to that of conventional face-to-face treatment. Therefore, real-time TR services may constitute an alternative strategy for the delivery of rehabilitation services to older adults with musculoskeletal conditions to improve their physical performance. We also observed that the ideal device for delivering TR is the smartphone. Results suggested that the use of smartphones for TR is driven by ease of use among older adults. We encourage future studies in areas related to rehabilitation in older adults, in addition to examination of physical performance outcomes, to gain additional knowledge about comprehensive care.

Trial Registration: PROSPERO CRD42021287289; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=287289

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KEYWORDS

telerehabilitation; internet-based intervention; older adults; physical performance; physical therapy

Introduction

Telerehabilitation (TR) was introduced to modify rehabilitation services that can be delivered to patients through interventions. It is currently used to increase the effectiveness of long-term treatment. There are various ways of receiving these interventions; technology helps in facilitating two-way communication via phone, video conferencing, and chat and health care apps. TR interventions have resulted in clinical outcomes being similar to or better than face-to-face (FTF) treatments; they are also in high compliance with home programs [1-4]. Previous systematic reviews evaluated TR for people with different health conditions in terms of feasibility, efficacy, and costs. The reviews supported the effectiveness of TR as an alternative to FTF interventions [5-8].

Musculoskeletal conditions affect 25% of the world's population and are the leading cause of pain and disability [9]. This study defines musculoskeletal conditions as any diagnosed primary musculoskeletal condition, including those requiring operations. These disorders are more common among older adults [6], and their prevalence ranges from 5% to 74%, depending on the particular musculoskeletal disease. Older adults have been defined as people 60 years of age or above [10]. From a health care perspective, there is an increasing demand for health care among the older adult population; as such, health care providers recognize this burden on the health care system and have increased their awareness of the health and disability of this population. Consequently, there is a need for better rehabilitation services to address the current magnitude and impact of musculoskeletal conditions, as the number of patients grows.

It has been found that older adults who closely follow physiotherapy recommendations experience better treatment outcomes [11]. However, many older adult patients with geographical isolation or who lack local service availability continue to experience restrictions in appropriate and timely care as a result of increases in cost and wait times for orthopedic health services, as well as poor access to these services [12-14]. Older adults typically also have low adherence to home exercise programs [15]. This leads to a need for real-time interventions through, for example, the use of phone calls or video conferencing to deliver exercise information without a need to meet physiotherapists at the clinic. An increased awareness and understanding of different learning styles [16,17] and the emergence of new technologies have created opportunities for real-time TR instructions to be provided through a wider variety of formats; this could promote better adherence and, ultimately, better functional outcomes.

Recently, there have been many studies on the effectiveness of TR in the management of health conditions, such as stroke [18,19], chronic obstructive pulmonary disease (COPD) [20,21], and heart disease [22,23]. However, those studies rarely explored the management of musculoskeletal conditions among older adults through TR. This became a hindrance to the implementation of TR as another way to deliver health care services. Previous systematic reviews about musculoskeletal conditions in older adults [6,24,25] examined studies with different conclusions. The aim of this systematic review was to (1) determine whether older adults with musculoskeletal conditions can improve physical performance via real-time TR and whether the results are effective compared with conventional services and (2) compare adherence to and cost-effectiveness of real-time TR with that of conventional treatments.

Methods

We systematically conducted and reported results of our review in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [26]. This review was registered at PROSPERO (International prospective register of systematic reviews; CRD42021287289).

Search Strategy

An electronic literature search was conducted on April 10, 2022, in six online databases: Cochrane Library, PubMed (ie, MEDLINE), PEDro, ClinicalKey, EBSCO, and ProQuest. The literature search was limited to articles written in English and Thai languages that were published from January 1, 2000, to the date of the search. Studies in other languages were not compiled. We used a search strategy that combines Medical Subject Headings with free keywords and connected them with Boolean conjunctions (ie, OR and AND). Keywords included “real-time telerehabilitation,” “real-time internet-based,” and “remote exercise.” The search strategy and keywords were developed through discussion and peer review between two authors (NJ and PS); keywords included specific search terms related to research objectives. Details of the search strategy and keywords are given in [Multimedia Appendix 1](#).

Eligibility Criteria

In this systematic review, we included only randomized controlled trials (RCTs) that studied the effects of real-time TR interventions on the physical performance of older adults with musculoskeletal conditions. The specific eligibility criteria used for selecting studies were established; these were based on the PICO (population, intervention, comparison, and outcome) framework ([Table 1](#) [27]).

Table 1. Eligibility criteria for inclusion of articles in the study.

Criterion type	Inclusion criteria	Exclusion criteria
Study design	Randomized controlled trials	<ul style="list-style-type: none"> • Systematic reviews • Case studies • Cross-sectional studies
Population	Community-dwelling older adults with musculoskeletal conditions, aged 60 years and over, receiving exercise interventions for health conditions	<ul style="list-style-type: none"> • People not actively seeking or accessing health care • Services targeting recipients of health promotion measures, screening, and so on
Intervention	Physical therapy exercise instructions provided using real-time TR ^a ; definition of real-time TR was quoted from a previous study [27] describing the interventions as follows: provided by means of any kind of technological device allowing for health care professional–patient interaction online, provided by health care professionals or caregivers through remote supervision, and including at least one specific intervention targeted to rehabilitation (eg, teletraining, TR, telehealth, and internet based)	<ul style="list-style-type: none"> • General information not tailored or selected specifically for individual patients • Telemedicine using multimedia approaches, with an intention for patient action or behavior change
Comparison	Comparators included either usual physical therapy rehabilitation interventions, which were provided in person in a hospital or institution setting; educational interventions; or no specific interventions	N/A ^b
Outcome	Any kind of physical function or motor performance outcome (eg, mobility, balance, strength, and walking), adherence outcome (eg, complete rate), or cost-effectiveness outcome	<ul style="list-style-type: none"> • Clinician outcomes • Service-level outcomes • Questionnaire results • Self-report results

^aTR: telerehabilitation.

^bN/A: not applicable; the comparison criterion type did not have any exclusion criteria.

Study Selection

In a standardized blinded manner, two authors (NJ and PS) independently identified potentially relevant papers and performed eligibility assessments. This process was divided into two phases. First, titles and abstracts were screened independently by two reviewers (NJ and PS). They assessed the relevance of each article and rated each one as definitely relevant, possibly relevant, or not relevant. Second, they screened the full text of the articles that had been judged in the first phase as definitely relevant or possibly relevant, and they made a final judgement on the articles as relevant or not relevant. In both phases, disagreement between the two reviewers was resolved through discussion until consensus was reached or through consultation with a third reviewer (SK). To assess the degree of agreement between authors, we calculated κ statistics for both phases. As part of our calculations, categories of definitely relevant and possibly relevant in the first phase were merged into the category definitely or possibly relevant. $P < .05$ was considered statistically significant.

Data Extraction

Extracted information for each article in this study included authors, publication year, study setting (ie, country or region), sample characteristics (eg, age, gender, and medical conditions), duration of study, description of interventions for both control and experimental groups (eg, information and communications technology [ICT] devices and platforms, intervention formula, presence or absence of in-person intervention during TR, compared intervention, and effects), outcome data from both processes (eg, intervention completion rate, reasons for

withdrawal from the intervention, and adverse events during the intervention), and patient outcomes (eg, impairment, activities, and participation). Data extraction was completed by one reviewer (NJ) and checked for accuracy by the second reviewer (PS).

Quality Assessment

Risk of bias was assessed using version 2 of Cochrane's risk-of-bias tool (RoB 2) for randomized trials [28]. Two reviewers (NJ and PS) assessed all five domains independently. The domains are as follows: (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in measurement of the outcome, and (5) bias in selection of the reported result. Each domain contains several signaling questions for assigning one of three risk-of-bias levels to each domain: low risk of bias, some concerns, or high risk of bias. These assessments allow the assessor to judge the overall risk of bias in each trial. Lower-quality articles were not excluded from the meta-analysis.

Statistical Analysis

Continuous data are presented as the mean difference or standardized mean difference (SMD) with 95% CI, whereas dichotomous data are presented as the risk ratio with 95% CI. If the studies did not adjust for clustering, we attempted to adjust their standard errors using the methods described in the Cochrane Handbook for Systematic Reviews of Interventions [29].

The I^2 test was used to identify heterogeneity: homogeneity was set at $I^2 < 50\%$. The data were pooled by a fixed-effects model if eligible studies were included. In addition, Forest plots for the meta-analysis were conducted if more than 2 eligible RCTs were included. We conducted a sensitivity meta-analysis that was restricted to recently published (ie, in 2000 or later) RCTs with an overall low risk of bias (ie, low risk of bias in all 10 criteria). Otherwise, $I^2 > 50\%$ was regarded as having substantial heterogeneity. Under such situations, a fixed model was used, and subgroup analysis was conducted to check for any possible reasons that could have caused substantial heterogeneity based on the different treatments, controls, and outcome measurements. After subgroup analysis, if the heterogeneity was still significant, a narrative summary was presented instead of pooled data and a meta-analysis.

Additionally, sensitivity analyses were also performed to check the robustness of the pooled results, depending on the different methodological qualities, and the statistical models.

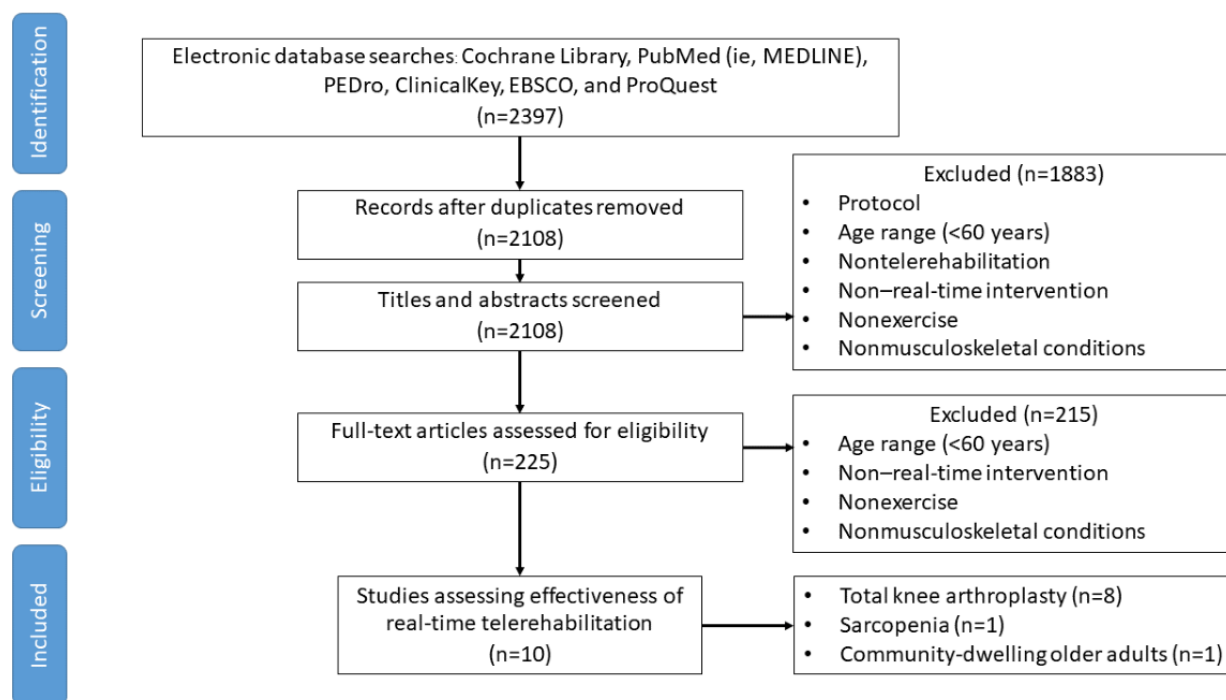
Furthermore, funnel plots were created, and the Begger test was carried out to identify any reporting biases if a sufficient number of eligible studies were included in the study.

Results

Study Selection

The study selection process is shown in [Figure 1](#). This was carried out through a literature search and identification of 2395 articles without duplication. The screening categorized 225 of the articles as being definitely relevant or potentially relevant, whereas the remainder were not considered relevant in the first phase. After screening the full text of 225 articles in the second phase, the reviewers found that 10 studies were eligible for inclusion in this systematic review. κ statistics for judgement in the first and second phases were 0.619 ($P < .001$) and 0.667 ($P < .001$), respectively. All conflicts regarding the judgments were reconciled through negotiations between the authors.

Figure 1. Flow of studies through the review.



Characteristics of the Studies

The 10 eligible RCTs are summarized in [Table 2](#) [30-39]. All studies were conducted in South Korea, Canada, Portugal, the United States, and Australia. The participants' health conditions, sample sizes, and sex ratios varied widely across the studies. Health conditions included patients with pre- and postoperative total knee arthroplasty (TKA) or total hip arthroplasty as well as community-dwelling older adults with sarcopenia. The total sample size was 851 participants, of which 351 (41.2%) were males. The ICT devices used in real-time TR were smartphones and personal computers. Out of 10 studies, 7 (70%) had developed a specific platform to administer their real-time TR; 2 (20%) used Skype, a free telecommunications app; and 1 (10%) used video conferencing.

The main components of the real-time TR interventions from the 10 studies included exercise regimens that varied across the studies: resistance exercise, combination resistance and range of motion (ROM) exercise, ROM exercise, and balance program exercise. Out of 10 studies, 2 (20%) included an educational intervention about self-management during real-time TR.

The interventions that were compared in the studies included in-clinic physical therapy, home visit rehabilitation, home exercise programs, education for general health, and nutrition. Because of the heterogeneity in the study characteristics, it was not appropriate to carry out a meta-analysis. Thus, a narrative analysis of the 7 eligible studies was conducted.

Table 2. Characteristics of the 10 eligible randomized controlled trials.

Author, year	Population		Intervention			Outcome report
	Size, n	Mean age (years)	Device	Platform	Type of intervention	
An et al, 2021 [30]	36	70.51	Smartphone	Video conferencing	Preoperative rehabilitation of TKA ^a	<ul style="list-style-type: none"> • Quadriceps strength • ROM^b of knee flexion • Timed Up and Go test
Doiron-Cadrin et al, 2020 [31]	34	65.97	Smartphone or tablet	Skype	Preoperative rehabilitation of TKA or THA ^c	<ul style="list-style-type: none"> • Timed Up and Go test • Stair test
Fernando et al, 2018 [32]	59	68.65	Smartphone or tablet	Specially developed platform	Postoperative rehabilitation of TKA	<ul style="list-style-type: none"> • ROM of knee flexion • Timed Up and Go test
Hong et al, 2017 [33]	23	81.85	Personal computer	Skype	Resistance and balance exercises	<ul style="list-style-type: none"> • Timed Up and Go test • Chair stand test
Prvu Bettger et al, 2020 [34]	287	65.25	Personal computer	Specially developed platform	Postoperative rehabilitation of TKA	<ul style="list-style-type: none"> • Total cost • ROM of knee flexion
Russell et al, 2003 [35]	21	67	Personal computer	Specially developed platform	Postoperative rehabilitation of TKA	<ul style="list-style-type: none"> • ROM of knee flexion • Timed Up and Go test • Knee extensor strength
Russell et al, 2011 [36]	65	67.9	Personal computer	Specially developed platform	Postoperative rehabilitation of TKA	<ul style="list-style-type: none"> • ROM of knee flexion • Timed Up and Go test • Knee extensor strength
Sparrow et al, 2011 [37]	100	71	Personal computer	Specially developed platform	Resistance exercise program	<ul style="list-style-type: none"> • Knee extensor strength • Single-leg stance
Tousignant et al, 2011 [38]	41	66	Personal computer	Specially developed platform	Postoperative rehabilitation of TKA	<ul style="list-style-type: none"> • ROM of knee flexion • Berg Balance Scale • 30-second chair stand test
Tousignant et al, 2015 [39]	197	66	Personal computer	Specially developed platform	Postoperative rehabilitation of TKA	<ul style="list-style-type: none"> • Total cost • Cost per time

^aTKA: total knee arthroplasty.

^bROM: range of motion.

^cTHA: total hip arthroplasty.

Risk-of-Bias Assessment

The results of the risk-of-bias assessment, based on the RoB 2, are summarized in Figure 2. The risk of bias in 1 study was high, 5 studies had some concerns, and 4 studies were categorized as having a low risk of bias. Regarding the risk of bias caused by the randomization process (domain 1), 4 studies used a nonconcealment approach, and the baseline characteristics were different between groups because they may

have had some selection bias. Thus, regarding domain 1, most studies were assessed as having a risk of bias of some concern. The risk of bias due to deviations from intended interventions (domain 2) was judged to be low in 7 studies, which were assessed as having a risk of bias of some concern. Regarding the risk of bias due to missing outcome data (domain 3), outcome measurement (domain 4), and selection of the reported results (domain 5), all studies were judged as having a low risk of bias.

Figure 2. Summary of the the risk-of-bias assessment. A red circle with a minus sign indicates a high risk of bias, a yellow circle with a question mark indicates there are some concerns, and a green circle with a plus sign indicates a low risk of bias.

Author, year	Overall	Randomization process	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results
An et al, 2021 [30]	+	+	+	+	+	+
Doiron-Cadrin et al, 2020 [31]	+	+	+	+	+	+
Fernando et al, 2018 [32]	+	+	+	+	+	+
Hong et al, 2017 [33]	-	?	?	+	+	+
Prvu Bettger et al, 2020 [34]	?	+	?	+	+	+
Russell et al, 2003 [35]	+	+	+	+	+	+
Russell et al, 2011 [36]	?	?	+	+	+	+
Sparrow et al, 2011 [37]	?	?	+	+	+	+
Tousignant et al, 2011 [38]	?	+	?	+	+	+
Tousignant et al, 2015 [39]	?	?	+	+	+	+

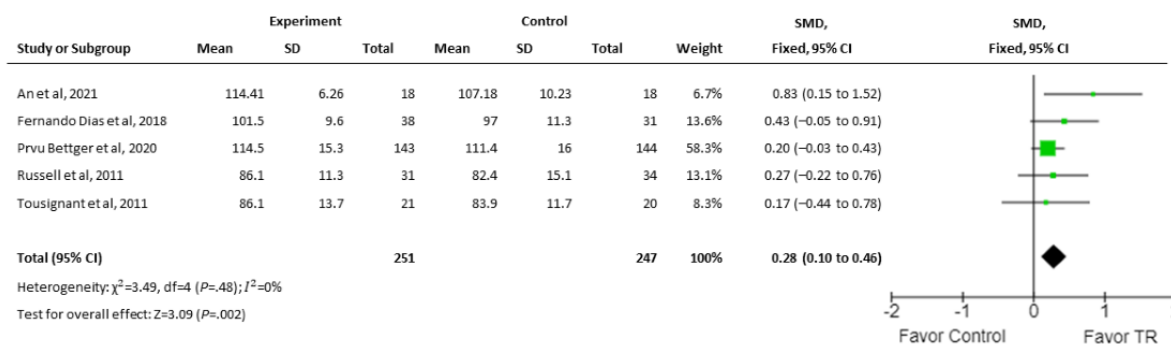
Effects of Real-Time Telerehabilitation

Range of Motion

The ROM of knee flexion was assessed in only 5 trials, as their primary outcomes were able to be pooled [30,32,34,36,38].

Data from only 498 participants were able to be pooled due to insufficient data in the ROM of knee flexion. Aggregate results showed a small effect in favor of real-time TR as compared to conventional service (SMD 0.28, 95% CI 0.1-0.46; $I^2=0\%$; Figure 3).

Figure 3. Meta-analysis comparing the effect of real-time telerehabilitation on range of motion of knee flexion following interventions for all conditions. SMD: standardized mean difference; TR: telerehabilitation.



Subgroup analyses were conducted for specific musculoskeletal conditions and type of TR medium (ie, personal computer, smartphone, tablet, and platform). For rehabilitation of postoperative TKA, the pooled results of 4 trials [32,34,36,38] suggested that TR interventions were less favorable (SMD 0.24, 95% CI 0.06-0.42; $I^2=0\%$); while 3 RCTs had a risk of bias of some concern [34,36,38], they did not favor real-time TR for the improvement of ROM of knee flexion following postoperative TKA (SMD 0.21, 95% CI 0.01-0.4; $I^2=0\%$).

Muscle Strength

Data from 3 trials assessing muscle strength as a primary outcome were able to be pooled. One trial used knee extensor strength [30], whereas 2 trials presented physical function data in the form of lower-limb strength from the sit-to-stand test [33] or the stair test [31]. Aggregate results of substantial statistical heterogeneity suggested that real-time TR had more moderate to large effects favoring the TR intervention as compared to usual care (SMD 0.76, 95% CI 0.32-1.2; $I^2=59.60\%$).

Regarding the intervention medium of real-time TR, 2 trials [30,32] that used smartphones or tablets showed a moderate effect favoring TR (SMD 0.56, 95% CI 0.18-0.95; $I^2=0\%$), whereas 3 studies that used personal computers with specific software [34,36,38] yielded a small effect in favor of TR (SMD 0.21, 95% CI 0.01-0.4; $I^2=0\%$).

Balance

In total, 5 trials assessed balance using the Timed Up and Go (TUG) test as a primary outcome. Data from only 216 participants were able to be pooled due to insufficient data. Aggregate results showed a moderate effect that favored real-time TR for the improvement of TUG test results (SMD

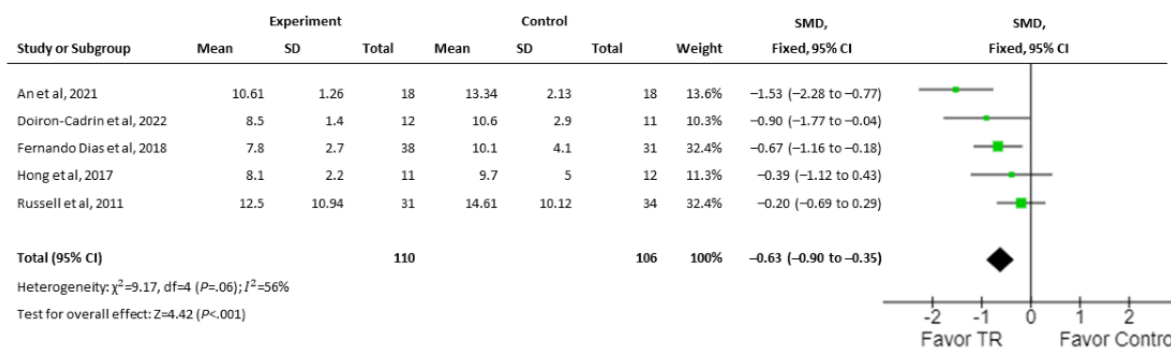
0.63, 95% CI 0.36-0.9; $I^2=58.5\%$; Figure 4) [30-33,36]. Meanwhile, 3 RCTs with a low risk of bias [30-32] had large effects that favored real-time TR (SMD 0.92, 95% CI 0.56-1.29; $I^2=45.8\%$).

Subgroup analyses further suggested that real-time TR interventions with medium to large effects favoring smartphones or tablets (SMD 0.92, 95% CI 0.56-1.29; $I^2=45.8\%$) [30-32] or

personal computers (SMD 0.25, 95% CI -0.16 to 0.66; $I^2=0\%$) [33,36] have an equal effect on improvement of balance.

Finally, results from 4 trials that examined rehabilitation following preoperative TKA [30,31] or postoperative TKA (SMD 0.43, 95% CI 0.09-0.77; $I^2=45.4\%$) [32,36] specifically showed that TR was more favorable than usual rehabilitation care.

Figure 4. Meta-analysis comparing the effect of real-time telerehabilitation on balance following interventions for all conditions. SMD: standardized mean difference; TR: telerehabilitation.



Feasibility and Acceptance of Real-Time Telerehabilitation

Completion rates, reasons for withdrawal, and adverse events are shown in Table S1 in Multimedia Appendix 2. Completion rates were reported in all studies: mean 91.09% (SD 5.77%; range 85%-100%) in the experimental group and 94.89% (SD 5.18%; range 83.3%-100%) in the control group. Most studies described the reasons for withdrawal, including dropout, lack of follow-up, and hospitalization as a result of other diseases. However, these reasons were not described clearly in all studies. In total, 3 studies [31,32,37] reported that adverse events occurred during real-time TR, whereas the other 7 studies did not specifically describe adverse events.

Only 2 studies reported cost-effectiveness analysis, which evaluated the total costs of rehabilitation in older adults with osteoarthritis of the knee in the postoperative phase. Total costs of real-time TR (mean US \$1502.98, SD \$278.98) and usual care (mean US \$3006.89, SD \$1519.89) had moderate effects favoring real-time TR (SMD 0.69, 95% CI 0.51-0.88; $I^2=0\%$).

Potential Contributing Factors to Feasibility

We summarized the data from factors potentially contributing to safety and feasibility based on treatments via video conference, as seen in Table S1 in Multimedia Appendix 2. For safety measures in 2 studies [33,37] in which community-dwelling older adults were recruited, data regarding the rate of perceived exertion were collected from a tolerance exercise program; the 2 studies also used the patients' own records of pain, falls, and readmission to hospitals. Patients were accompanied by a caregiver when giving reports during the postoperative TKA treatment period. Finally, we found that 6 studies set minimum internet speeds ranging from 18 kbps to 10 Mbps, whereas 4 studies did not report this information.

Discussion

Principal Findings

The main finding of this study was that, following noninferiority analysis, one particular treatment is not inferior to the current standard treatment for a particular health condition [40]. Post hoc noninferiority analysis was undertaken to compare results between cohorts from the examined interventions when sufficient data were found for subgroup analyses. Results of the noninferiority analysis supports a conclusion that physiotherapy exercises for the TKA population via real-time TR is equivalent and not inferior to FTF care.

This study is the first systematic review that focuses on real-time TR services using phone calls or video conferencing for home-based exercising to improve physical performance and adherence to treatment in older adults with musculoskeletal conditions. These results showed that TR had similar or better effects, as compared to usual care, on older adults' physical performance, including balancing ability, strength, and ROM. Furthermore, when compared to conventional care, small to moderate, but significant ($P<.001$), effects could be seen in favor of real-time TR, suggesting that real-time TR is superior to conventional services with respect to physical performance. Subgroup meta-analyses in this review showed small statistical heterogeneity across the studies due to trials that used smartphones or tablets ($I^2=0\%$). However, in those studies that only provided real-time TR treatment via personal computer or videoconferencing software, real-time TR still produced favorable outcomes, albeit to a small extent, as compared to FTF care following the intervention ($I^2=0\%$). Regardless of the musculoskeletal condition or by which medium the real-time TR was delivered, improvements in balance were also seen to be comparable between cohorts.

The primary findings in this review were similar to those of previous systematic reviews that reported positive benefits in

patients following TKA [8], cardiac disease [3,41], and COPD [42] among community-dwelling older adults [43]. Articles from a systematic review and meta-analysis [8] on TR for TKA reported strong positive effects from a TR program (mean difference 1.14, 95% CI -0.61 to 2.89; $I^2=0\%$) and improvement in active knee flexion status that were similar to those among patients with improving health conditions in the conventional therapy group. TR seems to be a practical alternative to conventional FTF rehabilitation therapy in patients who underwent TKA. Similarly, a previous systematic review [6] aimed to examine TR for musculoskeletal conditions and evaluated the effectiveness of TR as compared to usual care in improving physical function and disability; a moderate effect was observed in favor of TR (SMD 0.45, 95% CI 0.20-0.70; $I^2=56\%$). In this review, only the selected primary outcome measures were pooled to estimate the effects of treatment interventions, in which the TUG test served as a validated assessment tool that was simple, quick, and able to be applied in a short time to measure physical performance in a TKA population. Therefore, improvement in physical function has been added to the growing body of evidence for the efficacy of real-time TR in older adults with musculoskeletal conditions.

In our review of adherence data across the selected studies, the intervention completion rate was available in all of them, with adherence reported to be 91% (range 85%-100%) in the experimental group. This figure is comparable with previously reported completion rates of real-time TR among older adults with COPD in Australia (95%) [44], those with hemiplegia in China (96%) [45], those with heart failure in Australia (95%) [46], and those suffering from peripheral artery disease in the United States (85%) [47]. However, a direct comparison of findings between studies is difficult due to discrepancies across the countries, participants' conditions, and intervention regimens. Our findings imply that real-time TR interventions might constitute an acceptable rehabilitation strategy for older adults.

In contrast, there was less emphasis on other reporting regarding adherence, such as specific reasons for withdrawal from interventions and adverse events during interventions. In-depth interviews in a previous study [48] described specific reasons for withdrawal from their TR service among older adults, such as "one person withdrew because of the need to train at the local center" and "one person withdrew [from] the program after finding the technology too difficult to use the computer and IT platform." These descriptions allow readers the opportunity to vary programs in order to simulate adherence or to design a program and judge the appropriateness of the intervention in order to make it more feasible for their clinical practice or research project. Future studies documenting this relevant information can improve real-time TR services.

Comparison to Prior Work

Although the effectiveness of real-time TR among older adults with musculoskeletal conditions is apparent, findings from this review still need to be supported by additional studies. Thus, the interpretation of our findings require careful consideration. The poor methodological quality and heterogeneity in telehealth-related studies were also reported in previous

systematic reviews [1,27,41,49]. A previous systematic review [43] insisted that there is a critical need for high-quality studies investigating the impact of TR interventions in older adults. Consequently, it is crucial that these issues be taken into consideration when further studies are conducted.

Potential Future Directions

This study showed that the technologies used during real-time TR interventions varied across the included studies. In the examined studies, we observed variations in the health conditions of older adults, various kinds of technologies being used, and specific trends.

First, we observed that an app's ease of use was important during real-time TR services among older adults with a health condition. Previous studies [50,51] found that interactive app use during individual interviews helped identify content for creating a prototype before designing a mobile health (mHealth) app. Thus, mHealth apps that are used for TR focus on user characteristics.

Second, health care providers are able to motivate and increase the self-confidence of older adults during real-time TR services. Previous studies that conducted in-depth interviews with patients found that motivational techniques, including giving feedback to patients regarding exercise during the intervention, were important for helping patients improve [52,53]. If a physiotherapist cannot give older adult patients clear and sufficient advice regarding their health conditions in order to improve their physical performance, the patients could lose their self-confidence and treatments could become ineffective. On the other hand, effective communication can enhance participants' confidence and ensure positive outcomes from the treatment programs.

Finally, based on our findings, there was a moderate effect with a significant difference (SMD 0.69, 95% CI 0.51-0.88; $I^2=0\%$) on cost-effectiveness as a result of real-time TR as compared to usual care. It is reasonable to believe that the costs of real-time TR interventions can be lower than those incurred from conventional treatments with FTF communication between physiotherapists and patients [34,39]. The cost-effectiveness measure is an important factor for the treatment of patients, and it can vary depending on patients' conditions during real-time TR interventions.

Limitations

There were four limitations in our study. First, we had limited access to research databases and articles in different languages, preventing us from reviewing some research studies. Other research databases, such as Embase and ScienceDirect, were not used due to accessibility issues. Moreover, our review did not cover articles written in other languages. This selection bias may seriously have impacted our results and must be acknowledged when interpreting them.

Second, the focus of our review was limited to the outcome measures of physical performance and intervention adherence. Furthermore, other subjective outcome measures, such as pain scales, activities of daily living, quality of life, and feasibility indexes, should also be evaluated in future studies.

Third, caution was taken when we made conclusions about the overall effects of the management of musculoskeletal conditions. Because almost all of the trials examined interventions that followed common orthopedic surgery procedures in areas where access to conventional FTF interventions are limited, TR is an alternative treatment that could provide patients with sufficient availability of health care services.

Finally, as mentioned earlier, the number of selected studies with a low risk of bias was small, so real-time TR interventions must have high-quality methodologies to ensure that their effectiveness and results can be generalized to various treatments at clinics.

Conclusions

This study showed that there is strong evidence to conclude that TR-based physiotherapy interventions are effective in improving physical performance among older adults with musculoskeletal conditions; in addition, treatment outcomes from TR can be as successful as those from conventional FTF treatment. This is the first systematic review that evaluated the effects of real-time TR in older adults with musculoskeletal conditions; our results indicated that real-time TR services can potentially constitute an alternative strategy for the delivery of rehabilitation services in patients with musculoskeletal conditions. Future rigorous clinical trials are warranted in order to formally establish the efficacy of TR in the management of specific musculoskeletal conditions.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy.

[[PDF File \(Adobe PDF File\), 94 KB - rehab_v9i3e36028_app1.pdf](#)]

Multimedia Appendix 2

Summary of completion rates, reasons for withdrawal, and adverse events in the included studies.

[[PDF File \(Adobe PDF File\), 115 KB - rehab_v9i3e36028_app2.pdf](#)]

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Abbreviations

COPD: chronic obstructive pulmonary disease

FTF: face-to-face

ICT: information and communications technology

mHealth: mobile health

PICO: population, intervention, comparison, and outcome

PROSPERO: International prospective register of systematic reviews

RCT: randomized controlled trial

RoB 2: version 2 of Cochrane's risk-of-bias tool

ROM: range of motion

SMD: standardized mean difference

TKA: total knee arthroplasty

TR: telerehabilitation

TUG: Timed Up and Go

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Original Paper

Lessons Learned From Clinicians and Stroke Survivors About Using Telerehabilitation Combined With Exergames: Multiple Case Study

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Abstract

Background: In Canada, stroke survivors have difficulty accessing community-based rehabilitation services because of a lack of resources. VirTele, a personalized remote rehabilitation program combining virtual reality exergames and telerehabilitation, was developed to provide stroke survivors an opportunity to pursue rehabilitation of their chronic upper extremity (UE) deficits at home while receiving ongoing follow-up from a clinician.

Objective: We aimed to identify the behavioral and motivational techniques used by clinicians during the VirTele intervention, explore the indicators of empowerment among stroke survivors, and investigate the determinants of VirTele use among stroke survivors and clinicians.

Methods: This multiple case study involved 3 stroke survivors with chronic UE deficits and their respective clinicians (physiotherapists) who participated in the VirTele intervention, a 2-month remote rehabilitation intervention that uses nonimmersive virtual reality exergames and telerehabilitation aimed at improving UE deficits in stroke survivors. Study participants had autonomous access to Jintronix exergames and were asked to use them for 30 minutes, 5 times a week. The VirTele intervention included 1-hour videoconference sessions with a clinician 1 to 3 times a week, during which the clinician engaged in motivational interviewing, supervised the stroke survivors' use of the exergames, and monitored their use of the affected UE through activities of daily living. Semidirected interviews were conducted with the clinicians and stroke survivors 4 to 5 weeks after the end of the VirTele intervention. All interviews were audiorecorded and transcribed verbatim. An abductive thematic analysis was conducted to generate new ideas through a dynamic interaction between data and theory.

Results: Three stroke survivors (n=2, 67%, women and n=1, 33%, man), with a mean age of 58.8 (SD 19.4) years, and 2 physiotherapists participated in the study. Five major determinants of VirTele use emerged from the qualitative analyses, namely technology performance (usefulness and perception of exergames), effort (ease of use), family support (encouragement), facilitators (considerations of the stroke survivors' safety as well as trust and understanding of instructions), and challenges (miscommunication and exergame limits). During the VirTele intervention, both clinicians used motivational and behavioral techniques to support

autonomy, competence, and connectivity. All these attributes were reflected as empowerment indicators in the stroke survivors. Lessons learned from using telerehabilitation combined with exergames are provided, which will be relevant to other researchers and contexts.

Conclusions: This multiple case study provides a first glimpse into the impact that motivational interviewing can have on adherence to exergames and changes in behavior in the use of the affected UE in stroke survivors. Lessons learned regarding the supportive role caregivers play and the new responsibilities clinicians have when using the VirTele intervention may inform the use of exergames via telerehabilitation. These lessons will also serve as a model to guide the implementation of similar interventions.

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KEYWORDS

stroke; rehabilitation; virtual reality; video games; telerehabilitation; upper extremity; motivation

Introduction

Background

In Canada, stroke survivors have difficulty accessing community-based rehabilitation services because of a lack of resources [1]. Evidence indicates that there is potential for recovery, even several years after stroke [1,2]. However, rehabilitation services are generally provided in the acute and postacute stages [1]. A common long-term consequence of stroke is hemiparesis, or weakness on one side of the body, leading to loss of upper extremity (UE) motor function with a significant long-term impact on everyday activities [3]. Given the chronic nature of stroke, it is essential to develop interventions that provide community-dwelling stroke survivors opportunities for further personalized training.

Telerehabilitation and virtual reality technologies could play an important role in providing novel rehabilitation approaches to optimize stroke recovery in the chronic phases, as suggested by Canadian stroke guidelines [1]. More specifically, telerehabilitation can be used to increase accessibility to rehabilitation programs and follow-up for persons no longer receiving rehabilitation (or discharged from intensive rehabilitation), whereas virtual reality technologies, which involve engaging activities for practice, can provide the intensity needed for optimal recovery. Moreover, behavioral and motivational techniques [4] could be used with these technologies to empower stroke survivors to continue exercising and using their affected UE in everyday activities (eg, brushing their hair, getting dressed, and eating). A few studies have examined the combined use of telerehabilitation and virtual reality technologies in stroke survivors [5-7]. These studies reported an improvement in UE motor function and high adherence to the treatment plan, which suggests that adding a motivational component to the technology may foster gains and changes in behavior in the long term.

VirTele: Virtual Reality Combined With Telerehabilitation

VirTele, a personalized remote rehabilitation program combining virtual reality exergames and telerehabilitation, was developed to provide stroke survivors an opportunity to pursue rehabilitation of their chronic UE deficits at home while receiving ongoing follow-up from a clinician [8]. More

specifically, VirTele used Jintronix exergames [9] and the Reacts platform (Koninklijke Philips NV) [10] to provide personalized training for the UE and enable videoconference sessions with a clinician, respectively. At the time of the intervention, the Jintronix exergames included 5 types of UE games (*Space Race*, *Fish Frenzy*, *Pop Clap*, *Apple Picking*, and *Kitchen Cleanup*) performed in a sitting position. The performance of the affected UE (score, percentage of compensation, and number of repetitions) and the duration and number of sessions played can be accessed on the web through a clinician portal within the Jintronix system. Reacts is an internet-based audiovisual platform that can be used through a computer or mobile phone to conduct secure videoconferences and share content (images, videos, messages, etc). It enables screen sharing (viewing the participant's computer screen) to supervise in real time the stroke survivors' performance, provide direct feedback, and adjust difficulty level in collaboration with the stroke survivors, taking into account their preferences and capacities (as observed during real-time Reacts sessions and through the data available on the Jintronix web portal).

An initial study was conducted with a stroke survivor to test the VirTele technology and study protocol during the development phase of the intervention [11]. The results showed that it was feasible to use the VirTele program for remote UE rehabilitation [11]. Meaningful determinants of technology use were identified, including performance (perceived improvement in UE use during daily activities and unlimited time of exercises), effort (feeling comfortable using VirTele and experiencing only minor technical issues, which the stroke survivor could easily resolve), and social influence (positive feedback from family and friends) [11]. Preliminary efficacy results showed improvement in UE motor function, UE quality and quantity of use in activities of daily living, and quality of life [11]. Hence, there is interest in studying this technology further to explore varied experiences among more participants, including clinicians and stroke survivors.

Sustaining Gains Through Behavior Modification and Shared Decision-making

Behavior-modification strategies (eg, patient-centered counseling, action planning, and self-monitoring) have been implemented in exercise promotion interventions to enhance motivation, exercise participation, and maintenance [12-14].

As gains achieved during rehabilitation are not always maintained in the long term [15], chronic-stroke survivors may benefit from such behavior-modification strategies when they are integrated into postrehabilitation programs. These strategies could be used to empower stroke survivors to continue exercising and using their UE in everyday activities (eg, brushing their hair, getting dressed, and eating). Furthermore, there is increased recognition that programs aimed at changing behaviors should have a strong theoretical basis [16]. Self-determination theory (SDT) [17] states that human beings have a natural tendency to autonomously pursue goals or achieve healthy changes when 3 of their psychological needs are satisfied, namely autonomy (a person's ability to act according to their own values and aspirations), competence (a person's belief in their ability to achieve changes), and connectivity (a feeling of belonging) [17]. Therefore, social environments where the clinician engages in a partner relationship with the stroke survivor while supporting their autonomy (shared decision-making, choice of exergames, etc), competence (the stroke survivor's belief in their capacity to achieve their goals, etc), and connectivity (a nonjudgmental interaction) may result in greater autonomous motivation [18]. Previous studies [19,20] demonstrated that support of the 3 psychological needs predicted greater autonomous motivation, which resulted in better adherence to exercises. A recent meta-analysis of SDT-informed interventions [21] found small-to-medium effects of physical health outcomes (physical fitness and function, weight-related outcomes, blood pressure, etc) at the end of the interventions and during the follow-up period (ranging from 1 week to 30 months after the interventions). As autonomous motivation is a key element for developing maintained change, a supportive psychological needs environment should be integrated into the VirTele intervention. Thus, motivational interviewing [22], consistent with SDT, was incorporated into the VirTele program to ensure that shared decision-making and empowerment were consistently integrated into the intervention. The behavioral and motivational techniques incorporated into motivational interviewing may enhance autonomous motivation to adhere to the treatment plan and change behavior regarding UE use in activities of daily living. In addition, combining real-time videoconferencing (telerehabilitation) with virtual reality technology could allow for adequately monitored and engaging theory-based UE rehabilitation programs, which may enhance stroke survivors' empowerment and sustain gains in the long term.

Eventually, the SDT-informed VirTele intervention may not only help patients and clinicians decide together on the best treatment options but also allow clinicians to identify potential problems once the patient has reintegrated into the community. Thus, this study will also document the experiences of the stroke survivor as well as the clinician when using the VirTele program, which are key aspects for the successful eventual implementation of such interventions.

The objectives of this study were as follows:

1. Identify behavioral and motivational techniques used by clinicians during the VirTele intervention.
2. Explore indicators of empowerment among stroke survivors.

3. Investigate the determinants of VirTele use among stroke survivors and clinicians.

Methods

Study Design

This study used a multiple case design, which allows extensive data collection with varied methods across different cases [23]. This design enables the exploration of the studied phenomenon across a more varied range of characteristics compared with a single-case model [23]. The unit of analysis in this multiple case study is each stroke survivor and their respective clinician (physiotherapist) participating in the VirTele intervention. A range of experiences in terms of age, sex, familiarity with technology, and living arrangements were sought.

Context

This multiple case study is embedded into a 2-armed randomized clinical trial comparing an experimental group (receiving the VirTele intervention) with a control group (receiving standard care) in Montreal, Quebec, Canada, and registered with ClinicalTrials.gov (NCT03759106) [8].

The qualitative data were collected between June 2019 and August 2020 by the first author (DRA; who was not involved in the VirTele intervention), a PhD student under the supervision of DK and JH who had previous experience in qualitative research and stroke rehabilitation research. This multiple case study was reported according to the Standards for Reporting Qualitative Research [24].

Sampling Strategy and Participants

This study targeted the stroke survivors who were assigned to the experimental group receiving the VirTele intervention in the context of the 2-armed randomized clinical trial and who had completed the 2-month program. This group of stroke survivors was screened for eligibility before enrollment, and participants were selected based on the inclusion and exclusion criteria described in the published protocol (refer to the Participant Selection and Recruitment Strategy section) [8]. The clinicians included in the main study were physiotherapists who had experience with stroke rehabilitation. All participants had to speak French or English.

Ethical Considerations

This study received ethics approval from the research ethics board of the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (review number CRIR-1319-0218; June 28, 2018) [8]. All participants provided informed written consent before starting the VirTele intervention.

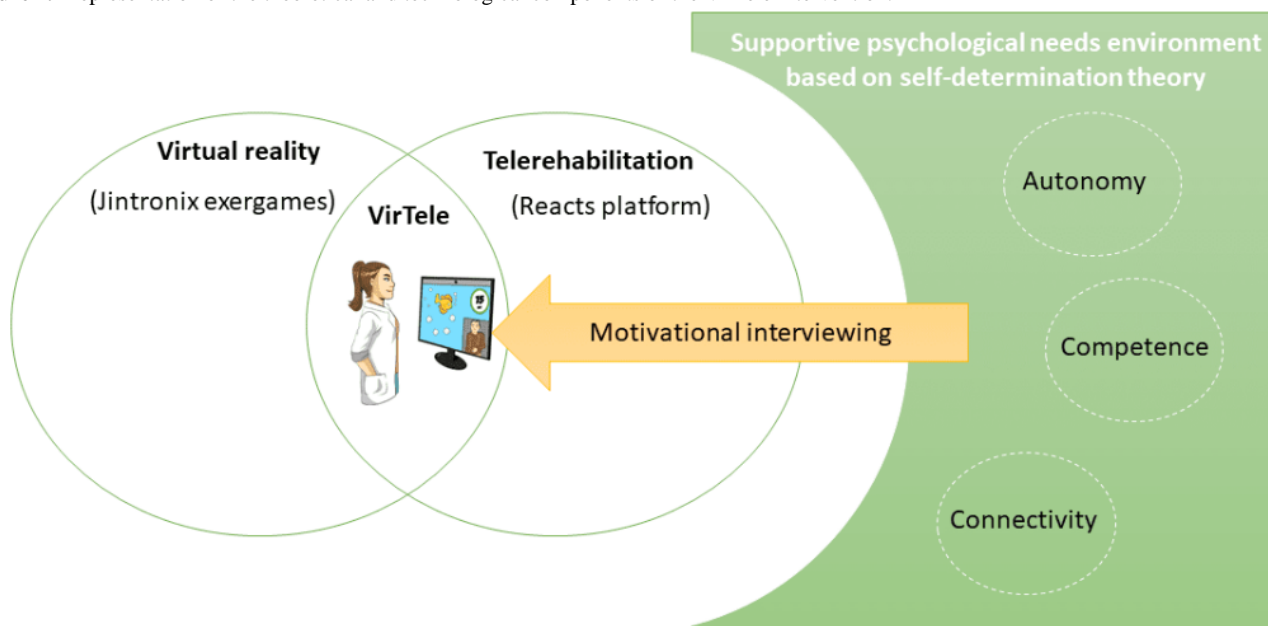
VirTele Protocol

The VirTele intervention protocol is illustrated in [Figure 1](#). The stroke survivors were invited to use Jintronix exergames for 30 minutes at least 5 times a week and conduct 1-hour videoconference sessions with a clinician, using Reacts, for a period of 2-months. The videoconference sessions took place 3 times a week for the first 2 weeks, twice a week for the next 2 weeks, and then once a week for the remaining 4 weeks [8].

The clinicians only received training to familiarize themselves with the VirTele technology (Jintronix exergames and Reacts platform) because they were already trained in motivational interviewing (including SDT concepts), an approach they had been using in their practice for >2 years before the study began. Although SDT and motivational interviewing were developed independently, a resemblance exists between them [25]. In fact, motivational interviewing techniques [4] are consistent with the 3 psychological needs of SDT [25]; for example,

motivational interviewing promotes shared decision-making (selection of treatment goals, exercises, etc), behavior change techniques (such as express advantages and disadvantages of change, goal setting, and review of goals) [26], and reflective listening (shows empathy), which emphasize autonomy, competence, and connectivity, respectively [4]. Thus, motivational interviewing, including motivational and behavioral techniques, was achieved through videoconferencing sessions conducted using the Reacts platform (Figure 1).

Figure 1. Representation of the theoretical and technological components of the VirTele intervention.



Determinants of VirTele Acceptability Among End Users

The Unified Theory of Acceptance and Use of Technology (UTAUT) [27] was used to explore the factors that may influence VirTele adoption intention and use behavior among stroke survivors and clinicians, to fulfill the third objective of this study. The UTAUT states that the intention to adopt a new technology is determined by 3 main factors: expected performance (the degree to which the technology is perceived as helpful and useful), expected effort (ease of use and complexity associated with using the technology), and social influence (positive or negative feedback that family and friends may have regarding the technology) [27]. In addition to the intention to adopt a new technology, contextual conditions (such as the ability and knowledge to use a new technology and interoperability) may facilitate the use behavior regarding the technology [27].

The UTAUT also incorporates 4 moderators—age, sex, experience, and willingness to use—that can influence technology adoption intention and use behavior [27]. In the context of this study, it is interesting to capture the expectations of users as well as their actual experiences to see whether the technology meets the needs of end users. Operational definitions of the UTAUT and concrete examples are provided in [Multimedia Appendix 1](#).

Data Collection

Triangulation was used for this multiple case study. This involved the use of various methods to collect qualitative data [28]. First, semistructured interviews (lasting from 30 minutes to 1 hour) were conducted 4 to 5 weeks after the end of the VirTele intervention with the stroke survivors and clinicians. Two interview guides were developed and tailored to the clinicians (eg, What was your role or responsibility during VirTele? Did you have any concerns when you first started using the technology?) and the stroke survivors (eg, Did you perceive any change in your arm function? Can you describe this change?) to facilitate the interview administration while allowing new ideas to emerge. Questions were structured to target the key concepts of each theory. Key UTAUT concepts were used to identify major factors that influenced the VirTele experience in the stroke survivors as well as the clinicians. For the stroke survivors, SDT concepts were used to explore the indicators of empowerment in terms of autonomy, competence, and connectivity. For the clinicians, SDT was used to identify which motivational interviewing technique was used and which need was supported (autonomy, competence, or connectivity) when interacting with the stroke survivors. The interview took place either face to face at the research center or remotely through the Reacts platform.

Second, logbooks were used by the clinicians to collect data related to technical difficulties, number of videoconference meetings, complementary activities suggested in addition to the

exergames, and motivational strategies used. Third, reflexive notes were used by the researchers to collect VirTele intervention–context-related data (technical difficulties, adverse events, etc). Demographic information about the stroke survivors was also collected. A sample size of 10 stroke survivors and 4 clinicians was targeted to diversify the experiences and enrich the data. However, only data saturation can predict the final sample size [29].

Data Analysis and Processing

Abductive thematic analysis was conducted. This type of analysis seeks to go beyond inductive and deductive reasoning [30]. By adopting this approach, researchers can generate new ideas through a dynamic interaction between data and theory [30]. First, a predetermined coding scheme was developed based on UTAUT and SDT constructs. Next, the transcript text was examined to identify which meaning unit reflected one of the predetermined codes. Codes and assemblies were frequently revised, and relevant new codes were assigned to meaning units that could not be coded or categorized within the initial scheme codes. Finally, the new codes were examined and either represented as subcategories (reflecting border concepts related to the UTAUT or SDT) or new categories of codes (enriching the corpus of existing theories).

QDA Miner (Provalis Research) [31] was used to enter the list of predetermined scheme codes and retrieve the highlighted text into meaning units, which were condensed and then coded and categorized using the scheme codes.

In each case, the stroke survivors' and clinicians' experiences with the VirTele intervention and indicators of SDT variables

were developed and examined independently and across the duos (stroke survivors and clinicians) for a within-case comparison. Next, experiences were examined among cases, using a cross-case analysis, to explore differences and similarities regarding the determinants of VirTele use and indicators of SDT variables. Underlying similarities and constant associations were then developed to form more general explanations. The analysis was conducted by 3 members of the research team (DRA, DK, and JH). The verbatim transcripts were translated from French into English for publication and verified by bilingual team members (DRA and DK).

Rigor

The principles of Lincoln and Guba [32], including confirmability, credibility, reliability, and transferability, were applied to ensure study rigor. Audit trails and verification were conducted to ensure confirmability. An external verification by members was carried out for credibility. Reliability was confirmed through verification of a portion of the data by 3 coders (DRA, DK, and JH). For transferability, reflexive notes and a detailed description of the context of the intervention were compiled. The variation in the cases may increase the robustness of the qualitative data [29].

Results

Sociodemographic Data of Stroke Survivors

Five stroke survivors were assigned to the intervention group and completed the VirTele intervention (Table 1).

Table 1. Stroke survivor sociodemographic data.

Variable	Stroke survivor ID				
	1	2	5	10	11
Age (years)	41	67	89	47	50
Sex	Female	Male	Female	Male	Male
Dominance	Right-handed	Right-handed	Right-handed	Right-handed	Ambidextrous
Year of stroke	2014	2011	2014	2010	2017
Stroke side	Right	Left	Right	Right	Right
Chedoke-McMaster stroke assessment score	Stage 3	Stage 3	Stage 5	Stage 4	Stage 4
Living arrangement	Living with family	Living with spouse	Living with daughter	Living alone	Living with spouse
Computer familiarity	Very comfortable, accessible at home, and use less than once a month	Comfortable, accessible at home, and use one or more times a week	Not comfortable, accessible at home, and never use	A little comfortable, accessible at home, and use once a week	Very comfortable, accessible at home, and use one or more times a week

However, recruitment was halted in mid-March 2020 at the onset of the COVID-19 pandemic in Canada, and all research activities were suspended from March 2020 to October 2020. Of the 5 stroke survivors allocated to the VirTele group, 1 (20%) could not be reached to conduct the interview, and 1 (20%) was excluded because he did not speak French or English fluently. Of the 3 remaining stroke survivors, 2 (67%) were women (participant ID1 and participant ID5), and 1 (33%) was a man

(participant ID11); their mean age was 58.8 (SD 19.4) years, and they varied in terms of computer familiarity, Chedoke-McMaster stroke assessment score, time since stroke, and dominance of UE. Two physiotherapists participated in administering the VirTele intervention. Participant ID11 received a 3-month VirTele intervention instead of 2 months, as was the case for participant ID1 and participant ID5, given that it was impossible to retrieve the technology material during

the COVID-19 pandemic period. We decided to give this participant the opportunity to benefit from the services offered by this technology for an additional month. For readability, each participant was given a pseudonym: participant ID1 identified as Carolina, participant ID5 identified as Helene, and participant ID11 identified as Jack.

Case Description and Comparison

A detailed case description of the 3 duos (stroke survivor and respective clinician), collected from the interviews, logbooks, and exergame portal, is provided in [Multimedia Appendix 2](#). A

summary of the techniques used by the clinicians during motivational interviewing and their impact on stroke survivor empowerment, collected from logbooks and interviews, is provided in [Table 2](#). The differences among the 3 cases are illustrated in [Multimedia Appendix 3](#). The determinants of VirTele use, as expressed by the stroke survivors and clinicians during the interviews, are presented in [Table 3](#). Although we did not reach our target sample size because of the COVID-19 pandemic, the data collected from the 5 participants allowed us to achieve a certain level of data saturation because many of the reported experiences were repeated across cases.

Table 2. Indicators of support of psychological needs and empowerment^a.

Category	Support of psychological needs by the clinician	Stroke survivor empowerment
	Technique used to change behavior ^b	Strategies specific to VirTele ^c
Autonomy		
	9.2: Allows participant to express advantages and disadvantages	Gives the participant an opportunity to talk about UE ^d use in daily activities and the difficulties encountered
	N/A ^e	Changes the difficulty parameters of the exergames according to participant preferences
	N/A	Shared decision-making
Competence		
	15.1: Verbal persuasion about capability	Answers participants' questions and helps solve problem discussed
	1.1: Goal setting	Shows the participant how to perform stretches and exercises with affected arm
	1.5: Review of goals	Demonstrates exercises in exergames
	1.1: Goal setting	Gives advices on performance during exergames
	1.4: Action planning	Celebrates small successes
	1.2: Problem-solving	Encourages participant to maintain some postures, even for a few seconds
	2.7: Feedback on behavior results (positive feedback)	N/A
	2.2: Feedback on behavior	N/A
	7.1: Prompts and cues	N/A
Connectivity		
	N/A	Has a calm way of speaking
	N/A	Establishes a trust relationship
	N/A	Uses reflective listening (expresses empathy)
	N/A	Listens and acknowledges the participant's opinion
	N/A	Is patient and enthusiastic

^aThe indicators of support of psychological needs and empowerment for each participant are provided in more detail in [Multimedia Appendix 3](#) to reflect the differences and similarities among the 3 cases.

^bThe behavior change techniques reported in the table are based on the taxonomy of Michie et al [26], who proposed 93 clustered behavior change techniques. To make it easier for the reader to find the techniques used in our study in the taxonomy of Michie et al [26], the number assigned to each technique is reported in the table.

^cA program that combines nonimmersive virtual reality exergames and telerehabilitation.

^dUE: upper extremity.

^eN/A: not applicable.

Table 3. Determinants of VirTele^a use.

Category	Subcategory of codes	
	Stroke survivors	Clinicians
Performance		
	Relative advantage	Relative advantage
	Perceived limits of exergames	Stroke survivor empowerment
	Stroke survivors' perception of exergames	Perceived limits of exergames
	Perceived change in the affected arm use	Stroke survivors' perception of exergames
	Awareness of usefulness of the technology	Perceived change in the affected arm use
	Stroke survivors' adherence to exergames	Clinician's instructions and demonstrations of exercises through technology
	Stroke survivors' experience with exergames	Clinicians are apprehensive about demonstrating exercise through technology
	N/A ^b	Clinicians' role in VirTele context
Effort		
	Managing technical issues	Managing technical issues
	Perceived ease of use of the technology	Perceived ease of use of the technology
Social influence		
	Feedback from family and friends, agreement, and assistance with the technology	N/A
	Clinician support and encouragement	N/A
Contextual facilitating conditions		
	N/A	Stroke survivor safety
	N/A	Stroke survivor capacity to understand the clinician's instructions
	N/A	Trust between clinicians and stroke survivors
	N/A	Clinicians' apprehension related to stroke survivors' trust
Contextual challenges		
	Comfort in using the technology	Miscommunication between the stroke survivor and clinician
	Internet access	N/A
	Miscommunication between the stroke survivor and clinician	N/A

^aA program that combines nonimmersive virtual reality exergames and telerehabilitation.

^bN/A: not applicable.

Determinants of VirTele Use

Differences and similarities have emerged regarding the determinants of VirTele use between the duos (stroke survivor and clinician).

Performance

Relative Advantages

In terms of relative advantages, the clinicians believed that VirTele facilitated access to rehabilitation services and that exergames and follow-up enhanced stroke survivor motivation and compliance to the rehabilitation program. A clinician felt that the feedback (scores of games and clinician feedback) and the follow-up increased stroke survivor empowerment. Neither the clinicians nor the stroke survivors expressed expectations

regarding the benefits of the VirTele program, and only apprehensions were reported.

Stroke Survivors' Perceptions of Exergames

The stroke survivors had different perceptions of the exergames (perceived either as an instrument of play or a therapeutic intervention). Helene compared the exergames with "bridge card games" and stated that she liked to win, which motivated her to continue playing during the 2-month intervention. Jack initially showed some apprehension, which diminished with practice, regarding the therapeutic value of the exergames.

Perceived Change in Use of Affected Arm

All stroke survivors demonstrated high adherence to the exergames; however, only Carolina and Helene expressed an intention to use the affected UE in daily activities, which was maintained after the end of the VirTele intervention. Jack had

expressed no intention to use the affected UE in daily activities, which was corroborated by the clinicians. Helene experienced no improvement in motor function. She reported no change in her arm function but said that she had begun to use her arm in daily activities.

Clinicians' Role in VirTele Context

From the clinicians' perspective, their main role when using VirTele can be summarized in terms of the following tasks: adjust the difficulty level of the exergames, monitor the stroke survivors' adherence to the exergames and their compliance to carrying out activities of daily living, observe the movements during the exergames, correct postures and movements, and act as coaches to motivate the stroke survivors and encourage and maintain adherence.

Instructions and Demonstration of Exercises Through Technology

With regard to demonstrating the exercises through the videoconference technology, without physical contact (hands-on demonstrations), the clinicians reported considerable apprehension, which subsided later because the stroke survivors were able to correctly comprehend the instructions. In addition, the clinicians were able to demonstrate the exercise through clear, concise, and simple instructions, which was challenging at times because of the participants' loss of attention (not listening to the instructions or sound getting cut off).

Perceived Limits of Exergames and Stroke Survivors' Experience

The clinicians pointed out some limits of the exergames that may influence technology performance, such as limited choice of exergames, which could become repetitive (significant focus on shoulder movements); limited parameters of difficulty; and insufficient rest time between sets of repetitions (users need to click the pause button manually). This feedback was provided by Jack. According to one of the clinicians, the lack of diversification in the difficulty parameters may induce a ceiling effect in terms of difficulty, which can be demotivating for the stroke survivor.

Helene and Carolina reported a problem with the avatar in some of the games (the avatar did not always follow the real movements). The clinicians believe that the avatar issues were related to not following recalibration instructions before starting the game, an important phase that allows the Kinect camera (Microsoft Corporation) to capture both arms and recalibrate the degrees of movement in each limb, enabling better control over the avatar.

Effort

With regard to effort, the clinicians as well as the stroke survivors encountered technological issues (eg, the screen froze or slowed down, and the sound or the internet connection were cut off), which caused some frustration among the stroke

survivors. The issues were managed either by the research team or the clinician (telephone support) or by the stroke survivors themselves or with the help of a family member (restarting the computer, reconnecting to the internet, etc).

All of the clinicians and stroke survivors, except Helene, found the technology intuitive and user friendly. Helene needed the help of a family member to turn on and use the VirTele intervention.

Social Influence (Only for Stroke Survivors)

Positive feedback from friends and family, after seeing or hearing about the system, encouraged the stroke survivors to start or continue using the VirTele intervention. The clinicians also played an important role in supporting (demonstration, instructions, advice, etc) and encouraging the stroke survivors to adhere to the exergames and use the affected UE in daily activities. This may have contributed to their empowerment. Further details regarding stroke survivor empowerment are provided in [Table 2](#).

Contextual Facilitators and Challenges

According to the clinicians, 3 main factors facilitated their use of the VirTele intervention: the stroke survivors' safety (the exergames were performed in a sitting position, and no adverse events occurred), the capacity of the participants to comprehend their instructions through the technology, and the trust relationship established with the stroke survivors (through shared decision-making), regarding which the clinicians were apprehensive before the intervention.

The main challenge encountered by a clinician with Jack was that the stroke survivor had been diagnosed with aphasia. This led to miscommunication between the clinician and Jack, as well as frustration for the latter. Thus, the clinician encountered difficulty in carrying out the motivational interviews and customizing the intervention according to Jack's needs because these were not well understood. Furthermore, challenges related to lack of comfort in using the technology (unfamiliarity with computers) and limited access to the internet were problems that both Helene and Jack had to deal with.

Clinicians' Recommendations Regarding the Use of the VirTele Intervention

In the clinicians' interviews, some meaning units, reflecting different recommendations related to the use of the VirTele program, were assembled. They are presented as a bulleted list in [Multimedia Appendix 4](#). Lessons can be learned from these recommendations ([Textbox 1](#)) regarding the use of telerehabilitation combined with exergames. In fact, these lessons provide relevant instructions for the use of exergames via telerehabilitation and suggest useful strategies to optimize the potential of this technology for the rehabilitation of the affected UE.

Textbox 1. Lessons learned about using telerehabilitation combined with exergames.

Lessons learned from clinicians' recommendations

- Both stroke survivors and clinicians are receptive to using the technology, despite technological limitations.
- The caregiver has a supportive role in using the technology, particularly among stroke survivors who are not familiar with IT.
- The clinicians' transition into the new roles and responsibilities may be facilitated by considerations of the stroke survivors' safety, capacity to understand the instructions, and trust.
- Aphasia may lead to frustration among stroke survivors when interacting with clinicians, but it does not affect technology use.
- The use of telerehabilitation combined with exergames may empower stroke survivors, through autonomy, competence, and connectivity, and increase frequency of use of the affected upper extremity in activities of daily living during and after the end of the VirTele intervention.

Discussion

The objectives of this multiple case study were to (1) identify behavioral and motivational techniques used by clinicians during the VirTele intervention, (2) explore indicators of empowerment among stroke survivors, and (3) investigate the determinants of VirTele use among stroke survivors and clinicians.

Principal Findings

Indicators of Empowerment and Support of Psychological Needs

The clinicians used numerous motivational interviewing strategies that helped to create supportive psychological needs environments. The stroke survivors demonstrated empowerment at different levels in term of autonomy, competence, and connectivity. This is likely to result in better management of self-care, more independence from clinicians, and increased motivation to pursue a rehabilitation program [33]. In fact, all participants used the exergames and achieved a great amount of autonomous use of the platform (the number of autonomous exergame sessions ranged from 37 to 68). More importantly, Carolina and Helene continued using their affected UE in daily activities and self-directed exercises after the end of the VirTele intervention.

Jack did not express any intention to use his UE in daily activities after the end of the VirTele program, although he used his UE in self-directed exercises during the VirTele program as per the clinician's recommendations and instructions. Jack may have been externally motivated, which means that he wanted to change only for external reasons, not because he wanted to; for example, he performed an exercise because the clinician asked him to, or he used the exergames because he knew that he was being monitored. In addition, Jack's indicators of empowerment were less developed at the connectivity and competence levels, which can be explained by the miscommunication challenge that he faced (because of his aphasia diagnosis). In fact, Jack's clinician pointed out that Jack's needs were not well understood. This made it difficult to customize the program and provide adequate support for competence and left little space for a sense of connectivity and belongingness. Therefore, the lack of participant empowerment in terms of autonomy, competence, and connectivity may reflect externally regulated motivation, rather than internal motivation, which often involves short-term changes (eg, stopping use of the UE after the end of the VirTele program).

Helene also demonstrated external motivation because she stated that she continued to use the exergames to win, not to exercise her UE, because she did not perceive any significant change with her UE. However, external motivation can be internalized and accepted to lead to effective changes [17]. At the end of the VirTele intervention, Helene reported that she had started self-directed exercises to avoid deterioration of her health condition and even started using her affected UE more frequently, which may reflect a self-regulated or self-identified motivation [17]. It is also important to note that other factors may increase autonomous motivation in stroke survivors, such as enjoyment during exergames or when improvements are perceived. This should be further examined in future studies.

Furthermore, recommendations reported by the clinicians reflecting what they learned from using VirTele were also provided, although these data were supplementary to, and not the original focus of, the study ([Multimedia Appendix 4](#)). These recommendations can be relevant to other researchers and transferable to other populations and contexts when incorporating virtual reality and telerehabilitation technologies.

Determinants of VirTele Use

Among the main determinants that were identified from the UTAUT, performance stood out as being meaningful in the 3 cases. In fact, the clinicians as well as the stroke survivors perceived relative advantages of the VirTele intervention compared with standard therapy (facilitating access to therapy and enhancing motivation) and felt comfortable interacting with each other.

The main role of the clinician during the VirTele intervention was to monitor the use of the affected UE by the stroke survivor through self-directed exergames and activities of daily living, which aims to enhance the stroke survivor's autonomy to continue using their affected UE after the end of the intervention. This is particularly relevant in the chronic stage of stroke because not all stroke survivors have access to rehabilitation services after discharge [1]. The VirTele program could be offered at the end of inpatient rehabilitation to learn how to self-manage the UE rehabilitation at home, while being closely monitored by a clinician.

The limits of the exergames, as pointed out by the clinicians and stroke survivors, may have reduced the technology performance with regard to attaining the individual stroke survivors' goals. However, it did not seem to affect the behavioral intention and use behavior regarding the technology

among the clinicians and stroke survivors. Furthermore, family members ended up playing a supportive role (managing technical difficulties, supporting technology use, and motivating the participant and encouraging VirTele use) during the VirTele program, particularly with Helene who was not familiar with computers.

Communication difficulties, such as those resulting from Jack's aphasia diagnosis, were considered the main challenge to motivational interviewing administration, which led to frustration for Jack, but did not affect technology use among the stroke survivors. Furthermore, 3 factors were identified by the clinicians as facilitators of technology use including trust, considerations for the participants' safety, and their capacity to comprehend the clinician's instructions. In addition to these factors, the previous experiences of the clinicians in motivational interviewing and their ease of use of the VirTele intervention may have facilitated the transition to their new roles and responsibilities in the VirTele context. This also suggests that the VirTele intervention may be easily transferred into actual clinical practice to offer stroke survivors opportunities for practice and to change their unhealthy behaviors.

Comparison With Prior Work

This study's results corroborate the findings in the study by Caughlin et al [34], which confirmed the supportive role of caregivers during telerehabilitation interventions (facilitating the use of the technology). The high level of adherence to the exergames and the increased use of UE in stroke survivors echo the findings of a previous systematic review [21], which found that interventions involving tailored counseling strategies such as goal setting and monitoring, motivational interviewing, and follow-up seem to be effective at promoting long-term physical activity participation after stroke. Furthermore, the use of the affected UE in self-directed exercises may result in improved motor function. At this stage of the study only the evaluations of the first few participants of the randomized clinical trial [35] were performed, and firm conclusions cannot be drawn regarding the results obtained on the sensorimotor measures. However, a trend in improvement was observed regarding motor function measured using the Fugl-Meyer Assessment [35] in Carolina and Jack as well as UE activity measured using the Motor Activity Log [35] (quality and quantity of use) in all participants. These gains were maintained 2 months after completion of the VirTele intervention [35]. The high adherence to the exercise program demonstrated by the participants could optimize the motor gains. In addition, the change in behavior with respect to the use of the UE in daily activities, as observed in Carolina and Helene, could justify the maintenance of the gains in the long term. Furthermore, it is important to note that Jack, who did not intend to use the affected UE after the end of the VirTele program, still managed to maintain long-term gains (improvements noted in the Fugl-Meyer Assessment and Motor Activity Log scores [35]), highlighting the importance of

adhering to the VirTele program and its potential to maximize gains.

In a previous study, Sit et al [36] found that stroke survivors (n=105) receiving motivational techniques similar to those in our study (encouragement, verbal persuasion, goal setting, partner relationship between the clinician and the patient, action plan, and self-management steps) significantly improved functional indices (Barthel and Lawton indices, which are scales used to assess activities of daily life performance on independent living) and self-management outcomes (medication adherence, self-monitoring of blood pressure, communication with physician, etc) compared with a control group receiving standard care. Hence, further research is needed to explore the correlation between motivational interviewing and UE motor function outcomes among stroke survivors.

Moreover, the determinants of VirTele use, identified through this study, are in part consistent with the determinants reported by other studies deploying telerehabilitation [37] and virtual reality exergames [38]. Despite the technical issues, the 3 participants were receptive to the VirTele program and continued using the system, which echoes the findings of previous studies among stroke patients and clinicians using telerehabilitation [34].

Limitations

Participants' expectations regarding the VirTele intervention before the start of the study were not documented. Therefore, it was not clear whether the intervention met the participants' expectations, which could affect technology acceptability and their compliance to the rehabilitation program. Future studies could investigate expectations before the start of the intervention to better capture end user expectations of similar interventions. Furthermore, given the small sample size, the results of this study should be interpreted with caution.

Conclusions

In conclusion, the factors predicting intention to use the VirTele intervention and use behavior among stroke survivors and clinicians include technology performance, effort, social influence, contextual facilitators, and challenges. The empowerment attained by stroke survivors is promising for the future deployment of such an intervention to encourage the use of the affected UE in activities of daily living and achieve impactful long-term improvement. The lessons learned from this study regarding the resilience of stroke survivors and adaptability of clinicians with respect to technology limitations, role of the caregiver, new responsibilities of clinicians during the VirTele intervention, impact of aphasia diagnosis, and empowerment of stroke survivors may help to guide the implementation of similar interventions. However, further studies in different contexts are needed to better understand the factors affecting intention to use such technologies and use behavior.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Operational definitions.

[[PDF File \(Adobe PDF File\), 115 KB - rehab_v9i3e31305_app1.pdf](#)]

Multimedia Appendix 2

Case description.

[[PDF File \(Adobe PDF File\), 197 KB - rehab_v9i3e31305_app2.pdf](#)]

Multimedia Appendix 3

Indicators of empowerment and support of psychological needs among the 3 cases.

[[PDF File \(Adobe PDF File\), 117 KB - rehab_v9i3e31305_app3.pdf](#)]

Multimedia Appendix 4

Clinicians' recommendations regarding using telerehabilitation combined with exergames.

[[PDF File \(Adobe PDF File\), 95 KB - rehab_v9i3e31305_app4.pdf](#)]

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Abbreviations

SDT: self-determination theory

UE: upper extremity

UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Feasibility of Virtual Reality Exercises at Home for Post–COVID-19 Condition: Cohort Study

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Abstract

Background: Between 30% to 76% of COVID-19 patients have persistent physical and mental symptoms, sometimes up to 9 months after acute COVID-19. Current rehabilitation is mostly focused on the physical symptoms, whereas experts have agreed on the need for a biopsychosocial approach. A novel approach such as virtual reality (VR) rehabilitation at home might benefit patients and therapists, especially considering the expected rush of patients with post–COVID-19 condition needing rehabilitation.

Objective: The aim of this study was to investigate the feasibility of self-administered VR exercises at home for post–COVID-19 condition.

Methods: This was a single-arm feasibility study in an outpatient care setting. Patients who needed physiotherapy because of post–COVID-19 condition were included as determined by the treating physiotherapist. Participants performed VR physical exercises at home for a period of 6 weeks and were allowed to perform VR mental exercise through applications available on the VR platform to reduce stress and anxiety and promote cognitive functioning. The main outcomes were related to feasibility (ie, duration and frequency of VR use), safety (ie, adverse events), patient satisfaction, and reasons to withdraw. Physical performance, daily activities, cognitive functioning, anxiety and depression, and the quality of life were measured before and after.

Results: In total, 48 patients were included; 1 (2%) patient did not start VR, and 7 (15%) patients withdrew, mostly due to dizziness. Almost 70% (33/47) of participants reported experiencing any adverse event during VR exercising. However, only 25% (9/36) recalled these events at the end of the intervention period. The majority (27/36, 75%) of the patients described VR as having a positive influence on their recovery, and the global satisfaction score was 67%. The average VR use was 30 minutes per session, 3–4 times a week for 3–6 weeks. The overall use of VR applications was almost equally distributed over the 3 sets of VR exercises (physical, relaxing, and cognitive). However, the use frequency of physical exercises seemed to decrease over time, whereas the use of cognitive and relaxation exercises remained stable. Physical performance and quality of life outcomes were significantly improved after 6 weeks.

Conclusions: VR physical exercises at home is feasible and safe with good acceptance in a significant percentage of patient with post–COVID-19 condition.

Trial Registration: ClinicalTrials.gov NCT04505761; <https://clinicaltrials.gov/ct2/show/NCT04505761>

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KEYWORDS

virtual reality; rehabilitation; COVID-19; long COVID; feasibility; physical function; quality of life; pandemic; multimodal virtual reality; outpatient care; physiotherapy; digital health; patient care

Introduction

The ongoing COVID-19 pandemic is leading to serious morbidity and mortality worldwide [1,2]. Studies show that 30% to 76% of COVID-19 patients have persistent symptoms, sometimes up to 9 months after acute COVID-19 [3-5]. These patients have a variety of symptoms in the physical and mental domains [6,7]. A substantial amount of post-COVID-19 patients experience limitations in daily activities and social participation in the long term [8,9]. This condition was described as “long COVID,” “Post-(acute-)COVID syndrome,” or “postacute sequelae of SARS-CoV-2 infection” and is now termed “post-COVID-19 condition” [10-12]. Patient-tailored post-COVID-19 rehabilitation is needed to recover these physical and mental functions and ultimately improve the patients’ quality of life [13,14].

Several reviews, consensus statements, and position papers concerning post-COVID-19 rehabilitation have already been put forth by professional rehabilitation organizations [13,15-18]. These experts agree on the need for an individualized program with a multimodal approach, not only aiming at restoring physical functioning, but also at reducing anxiety and depression and offering cognitive rehabilitation when needed. Virtual reality (VR) applications may be important tools in such rehabilitation, since they have the potential to address all aspects of this multimodal approach in a single solution [19]. Furthermore, they can provide health care practitioners with an easy-to-administer, tailor-made home rehabilitation solution against an impending surge of demand for post-COVID-19 rehabilitation.

VR has the ability to immerse someone into another world, which can be used to distract patients from experiencing pain, fatigue, and anxiety and may increase therapy adherence. VR is increasingly used in rehabilitation such as poststroke rehabilitation, limb rehabilitation, and the treatment of posttraumatic stress disorder [20-22]. The use of VR for the improvement of general physical condition and health is relatively new and often involves 2D “exergaming” [23,24]. Recently, VR relaxation games were used for inpatient post-COVID-19 rehabilitation, showing high patient satisfaction and benefits regarding stress reduction and cognitive functioning [25]. VR exercises for patients with post-COVID-19 condition outside of the hospital may have similar benefits. These exercises would enlarge access to rehabilitation resources in general and, more specifically, for the large group of patients with acute COVID-19 at home.

This study aimed to assess feasibility—usability, acceptability, tolerability, and safety—of 6 weeks of VR exercises at home indicated by community-based physiotherapists. Secondly, we analyzed the changes in physical and mental functions and the quality of life.

Methods

Design

This was a single-arm study to primarily assess the feasibility regarding acceptability, usability, and tolerability and, additionally, the changes in physical and mental functions and the quality of life of 6 weeks of VR exercises at home. As part of this study, a digital health design evaluation was performed, which was separately reported [26].

Ethics Approval

Ethical approval was obtained by the Research Ethics Committee of the Radboud University Medical Centre (2020-6770). The study was conducted according to the principles of the Helsinki Declaration and in accordance with Dutch guidelines, regulations, and acts (Medical Research involving Human Subjects Act) and registered at ClinicalTrials.gov (NCT04505761).

Participants and Study Setting

The study population comprised of patients with post-COVID-19 condition referred for physiotherapy to a physiotherapist in a community-based practice or outpatient rehabilitation clinic in the southeast of the Netherlands between July 2020 and February 2021. The selection criteria are listed in [Textbox 1](#). Proven COVID-19 by laboratory test was not an inclusion criterion, because a considerable number of patients with the acute disease at home were not tested in the study period. We considered an estimated duration of 3 weeks of physiotherapy as the minimum to properly investigate feasibility outcome parameters and avoid including patients with minimal or single symptoms. No sample size calculation was performed. Patients who withdrew from the study within 3 weeks were replaced to achieve a total number of 40 evaluable patients for the physical and mental functions and quality of life outcomes. Written informed consent was obtained from each participating patient. Participating physiotherapists were experienced in treating similar conditions such as Q fever and post-intensive care syndrome, and half (7/15, 47%) had completed a master’s degree in psychosomatic physiotherapy.

Textbox 1. Inclusion and exclusion criteria of patients with post–COVID-19 condition.

Inclusion criteria

- Symptoms attributable to post–COVID-19 condition
- Indication for physiotherapy for rehabilitation after COVID-19
- Considered suitable for virtual reality home exercises by the treating physiotherapist
- Estimated duration of physiotherapy of at least 3 weeks
- Aged ≥ 16 years on inclusion date
- Willing and able to comply with the study protocol
- Read and speak Dutch

Exclusion criteria

- Patient participates in another study that interferes with this study
- One or more “red flags” for exercise in patients with COVID-19 (see [Multimedia Appendix 1](#) [27])
- Severe anxiety or depression complaints
- High risk of contamination with therapy resistant microorganism, such as methicillin-resistant *Staphylococcus aureus*
- Patient has difficulties handling virtual reality in the following ways:
 - Experiencing delirium or acute confusional state
 - (A history of) dementia, seizure, or epilepsy
 - Severe hearing or visual impairment that is not corrected
 - The skin of the head or face is not intact (eg, head wounds, psoriasis, and eczema)

Intervention

The intervention consisted of 6 weeks of VR physical exercises at home with the choice by the participants to additionally perform VR mental exercises. To this end, a VR suite was composed of off-the-shelf and custom-made applications for physical (SyncVR Fit; SyncVR Medical), cognitive (Koji’s Quest; NeuroReality), and relaxation exercises (SyncVR Relax & Distract; SyncVR Medical) in collaboration with SyncVR Medical and NeuroReality. SyncVR Fit comprises several game applications, such as goalkeeping or beach squats, each with a duration of approximately 10 minutes and 3 levels in difficulty. Koji’s Quest immerses players in a virtual environment designed to engage players through increasingly more challenging brain training activities combined with a reward system that encourages daily play. SyncVR Relax & Distract offers relaxation through games, videos, and meditation. Patients received written instructions on all applications ([Multimedia Appendix 2](#)). For the VR at home exercises, all patients were loaned an Oculus Quest head-mounted display (Facebook Technologies), which can bring the user into an immersive, realistic, and multisensory environment by computer-generated visuals. Participating physiotherapists were instructed on prescribing VR use by the research team. Prescription followed the guidelines of the Royal Dutch Society for Physiotherapy for post–COVID-19 physiotherapy with the type, time, and frequency of the exercises translated into VR exercises [27]. Prescription was individualized to the needs and impairments of the patient and as determined by baseline performance tests. However, patients were instructed not to exceed 30 minutes per session to avoid “VR sickness” [28]. Per the protocol, the

prescription was meant to be adapted at follow-up contacts according to the patient’s feedback and digital VR tracking data. Due to organizational challenges and the practicality of conducting the study during the pandemic, this protocol was changed to instructing patients to choose the frequency and duration of VR use according to their preferences and needs. For safety reasons, the first few VR sessions were supervised by the physiotherapist in the office. When deemed safe, patients continued the VR exercises at home. Telerehabilitation, including remote monitoring and video consulting, was not part of the study procedure due to the workload of the physiotherapists and limited resources.

Procedure and Measurements

After informed consent, patient and disease characteristics were documented. Physical performance metrics were administered by the physiotherapists as part of usual care and collected at the start and end of the intervention period of 6 weeks. Questionnaires were completed by the patients at the same time. Postintervention questionnaires were not administered to patients who withdrew from the study within 3 weeks. During the intervention period, patients were asked to keep a diary on the frequency and duration of their VR use, which applications they used, and if they experienced any adverse events. Weekly, short, and semistructured telephone interviews were carried out to monitor adherence and solve any (technical) problems. Furthermore, a 24/7 support line was available for questions or (technical) problems, and patients were encouraged to contact it when needed.

Patient Characteristics

Patient characteristics included age, gender, the duration of symptoms, and prior hospital and intensive care unit admission for COVID-19. The duration of symptoms was defined as the number of months between the first day of COVID-19 symptoms and the first day of the VR exercises. Previous experience with digital technology was assessed, including smartphone, laptop, exergaming, smart home devices, and VR or augmented reality games. The Mentality test (Motivaction) was used to gain insight into the individuals' opinions, motivation, and behavior toward (support in) health care and susceptibility for technology [29]. The Mentality test is a questionnaire consisting of 59 items. Based on the answers, patients are categorized as "less self-sufficient," "pragmatic," or "socially critical."

Outcome Measures

Primary outcome was feasibility, as reflected by end points regarding the acceptability, usability, tolerability, and safety of VR exercises. Secondary outcomes were physical and mental functions and the quality of life.

Acceptability

The discontinuation of the VR exercises was noted as an acceptability outcome, together with the reasons for withdrawal. Patient satisfaction was measured at the end of the intervention period by the Treatment Satisfaction Questionnaire for Medication [30], modified by replacing "medication" with "intervention." Subscores were calculated for effectiveness, side effects, convenience, and global satisfaction, where 0 is extremely dissatisfied and 100 is extremely satisfied [30]. Furthermore, 2 questions were added: "If you would end up in the same situation in the future, would you want to use Virtual Reality again?" and "Would you recommend Virtual Reality to a friend or family member?"

Usability

The frequency and duration of VR use were assessed using the digital tracking feature that is incorporated in the VR intervention and a patient diary. Patients also noted technical difficulties affecting usability in the diary. The third source of usability data was the weekly semistructured telephone call and patient calls to study staff.

Tolerability and Safety

Tolerability was determined by registering adverse events in the diary through open-ended questions and the subscore "side effects" of the treatment satisfaction questionnaire. Additionally, for participants who withdrew from the study, any possible adverse events were registered. Safety was assessed by registering serious adverse events such as falls or near falls as reported by participants in the diaries or weekly telephone calls.

Physical Function

The 6-Minute Walk Test (6-MWT) was used to measure the overall physical condition of the participants [31]. When participants were not able to perform the 6-MWT, the Timed Up and Go Test (TUG) was performed [32]. Grip strength was used as an indicator of general strength [33]. The strength of the lower extremity was determined with the 30-Second Chair

to Stand Test (30-CST) [34]. When the participant was not able to perform the 30-CST, the 5-times stand test (measured in seconds) was performed. Fatigue was assessed using an 11-point Borg scale (0=no fatigue and 10=maximal fatigue) [35]. The Patient-Specific Complaints (PSC) questionnaire was used to score the patients' ability to perform 3 self-chosen daily activities [36]. The Nottingham Extended Activities of Daily Living (NEADL) score was used to measure to what degree a patient can independently perform the activities of daily living [37].

Mental Function and Quality of Life

The Hospital Anxiety and Depression Score (HADS) was used as a global measure of psychological distress. The cutoff for possible anxiety or depression disorder is 8 points [38]. The Short Form-12 (SF-12) was used to measure the health-related quality of life. Norm-based scores were calculated using the method described by Ware et al [39]. The Positive Health questionnaire was used to measure patients' feelings about their different dimensions of health: overall health, bodily functions, mental well-being, meaningfulness, quality of life, participation, and daily functioning [40]. The higher the score, the better a patient feels about his or her health. The Cognitive Failure Questionnaire (CFQ) was used to measure subjective cognitive function [41].

Data Analysis

All patients who started VR were included in the feasibility analyses. The VR applications used, as noted in the patient diaries, were categorized as physical, cognitive, or relaxing. To analyze the frequency and duration of VR use per week, patients were included when they reported having used VR at least once in the corresponding week. For analysis of (serious) adverse events, the free-text reports of participants were matched to the terminology of the Common Terminology Criteria for Adverse Events (version 5.0) and the definition of the US Food and Drug Administration for serious adverse events [42].

Only patients who used the VR exercises for 3 weeks or more and with baseline and final measurements were included in the analyses of physical and mental functions and quality of life metrics and questionnaires.

Statistical Analysis

SPSS statistical software (version 25; IBM Corp) was used for statistical analyses. Descriptive statistics were used to analyze the outcomes of usability, acceptability, tolerability, safety, physical and mental functions, and quality of life. Dependent on the distribution of the data, paired samples 2-tailed *t* test or Wilcoxon signed-rank test was used to determine changes in the functions and quality of life of post-COVID-19 VR exercises. To evaluate which patients benefitted the most from VR, we explored correlations matrices and calculated Pearson correlation coefficient for the different combinations of patient and disease characteristics, duration of VR use, and physical and mental functions and quality of life outcomes. Post hoc subgroup analyses were performed regarding the use of cognitive and relaxation exercise applications (yes/no) and their respective outcomes on the CFQ and HADS.

Results

Patient Characteristics

Between July 2020 and February 2021, 48 patients were included from 13 community-based physiotherapy practices and 1 rehabilitation clinic. In 66% (31/47) of the patients,

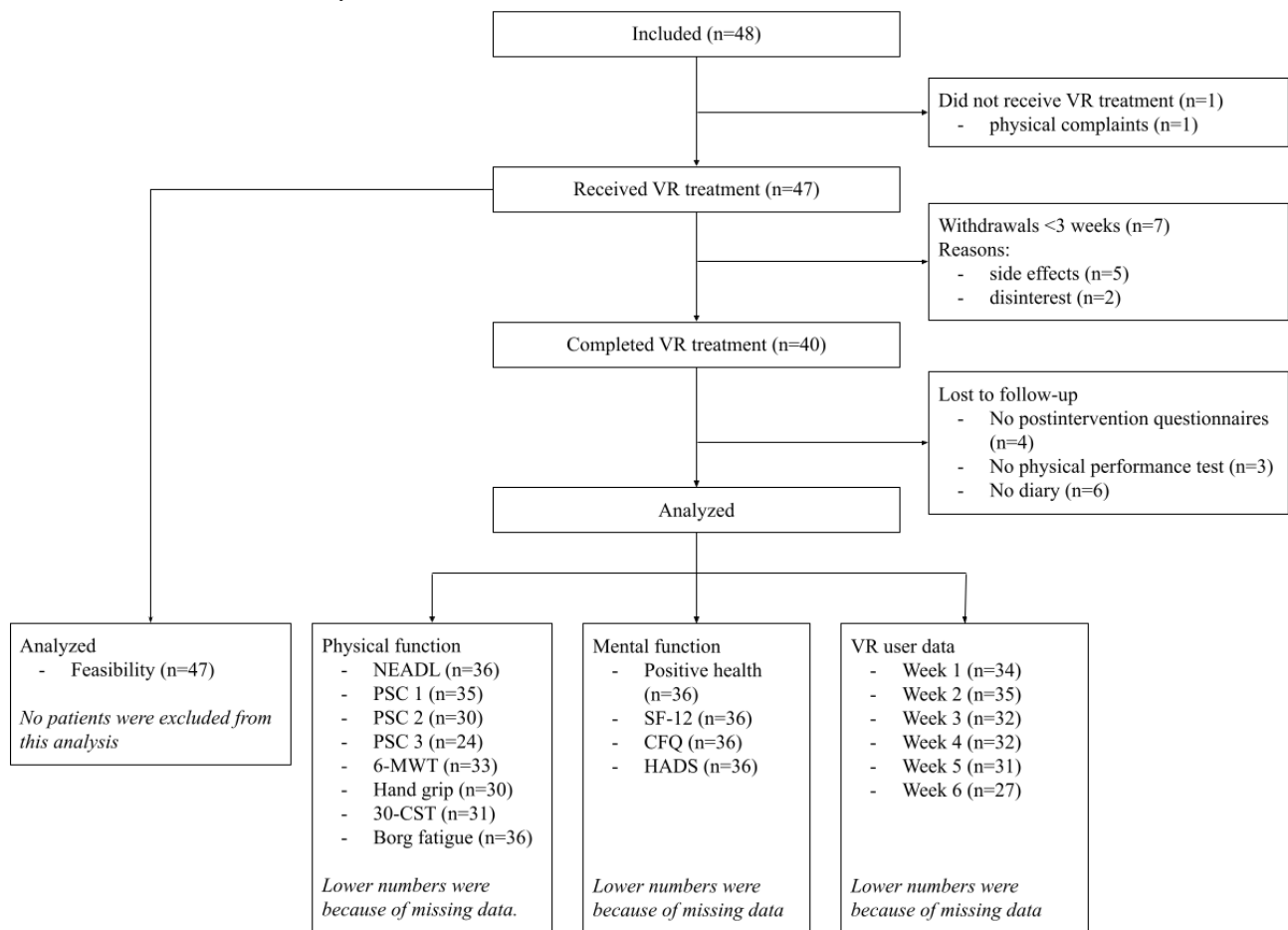
COVID-19 was confirmed by a positive polymerase chain reaction test, and the remaining 34% (16/47) had signs and symptoms corresponding with COVID-19. The median age was 54 years, and 68% (32/47) was female (Table 1). There was 1 patient who experienced an acute onset of back pain before receiving VR treatment; the remaining 47 patients were eligible for the feasibility analyses (Figure 1).

Table 1. Patient and disease characteristics of 47 patients who were evaluated for feasibility.

Characteristic	Patient (N=47)
Age (years), median (IQR; range)	54 (39-59; 21-70)
Gender, female, n (%)	32 (68)
Duration of COVID-19 symptoms (months), median (IQR; range)	7.2 (4.3-8.2; 1.2-10.1)
Hospital admission	
Patient admitted to hospital, n (%)	9 (19)
Duration of hospital admission (days), mean (range)	21 (3-114)
Missing, n (%)	4 (9)
Intensive care unit admission	
Patient admitted to hospital, n (%)	5 (11)
Duration of intensive care unit admission (days), mean (range)	10 (9-84)
Missing, n (%)	4 (9)
Mentality test, n (%)	
Less self-sufficient	11 (23)
Pragmatic	22 (47)
Socially critical	7 (15)
Missing	7 (15)
Daily experience with ≥ 3 digital technologies ^a , n (%)	41 (86)
Previous experience with virtual reality, n (%)	12 (26)

^aFor example, smartphone, tablet, laptop, internet, and television.

Figure 1. Study flowchart. 30-CST: 30-Second Chair to Stand Test; 6-MWT: 6-Minute Walk Test; CFQ: Cognitive Failure Questionnaire; HADS: Hospital Anxiety and Depression Score; NEADL: Nottingham Extended Activities of Daily Living score; PSC: Patient-Specific Complaints questionnaire; SF-12: Short Form-12; VR: virtual reality.



Outcomes

Acceptability

In total, 7 patients withdrew from the study within the first 3 weeks, 5 due to adverse events (dizziness, migraine, and blurred vision) and 2 because of lost interest. These patients were replaced according to the study protocol. Between weeks 3 and 5 in the study period, another 5 patients discontinued the VR exercises due to neck pain, dizziness, emotional processing of the post-COVID-19 condition, lost interest, and study logistics. Patients who lost interest mentioned that they found the games boring or had doubts about the value of the VR exercises.

In the weekly telephone calls, patients used mostly positive words to describe VR, such as “fun,” “motivational,” “stimulating,” “relaxing,” “valuable,” and “energizing.” Some

patients described it as “intense,” “tiring,” “confronting,” “boring,” and “energy demanding” (Figure 2). The terms “energizing” and “energy demanding” revealed a contrast between 10 patients who felt VR was too energy demanding while resuming work after sick leave and 3 patients who found the relaxation exercises energizing, especially after work. There were 3 patients who felt that VR would have benefitted them more when used early after COVID-19.

The median (range) scores of the treatment satisfaction questionnaire were 58% (33%-100%) for effectiveness, 100% (41%-100%) for side effects, 72% (33%-100%) for convenience, and 67% (33%-100%) for global satisfaction. In total, 78% (28/36) of patients would like to reuse VR in case they would need rehabilitation in the future, and 92% (33/36) of patients would recommend the VR intervention to others.

Figure 2. Word cloud of patients’ remarks regarding virtual reality exercising.



Usability

The median VR use frequency was 3 to 4.5 times a week for 95-115 minutes per week (Table 2). The duration of individual VR sessions varied between 5-165 minutes with a median duration of 30 minutes. There were large variations between individuals in the use of the applications in the different domains. Of the 643 sessions, cognitive exercises (n=257, 40%) were used somewhat less than physical exercises (n=344, 53.5%). However, the use frequency of cognitive exercises was more stable over time, whereas the use of physical exercises seemed to decrease over time (Table 3). Relaxation exercises were performed in 52.6% (n=338) of all sessions, and use remained relatively stable over time.

The 24/7 support line was primarily used by patients to report technical problems. In total, 40 technical problems were reported by 14 patients. Most problems related to the battery, which could be resolved by charging the head-mounted display or changing the batteries of the controllers. Some patients experienced difficulties with operating the applications. These problems could be remotely solved by the study staff. There were 3 head-mounted displays that needed to be replaced due to missing applications or a defective controller. Additionally, a software update during the intervention period caused considerable inaccuracy of digital tracking, and 7 patients were unable to use the VR intervention for 4-7 days.

Table 2. Frequency and duration of virtual reality use by patients who completed at least 3 weeks of virtual reality exercises.

Characteristic	Week 1 (n=34)	Week 2 (n=33)	Week 3 (n=32)	Week 4 (n=32)	Week 5 (n=31)	Week 6 (n=27)
Frequency ^a , median (IQR)	4.5 (3.0-6.0)	4.0 (2.0-6.0)	3.0 (2.0-5.0)	3.0 (2.0-5.8)	3.0 (2.0-6.0)	3.0 (2.0-5.0)
Duration ^b (min), median (IQR)	115.0 (66.3-161.3)	90.0 (45.0-170.0)	107.5 (52.5-123.8)	95.0 (60.0-165.0)	97.5 (50.0-163.8)	95.0 (63.8-150.0)

^aNumber of sessions.
^bTotal per week.

Table 3. Frequency of virtual reality use by patients who completed at least 3 weeks of virtual reality exercises divided by physical, cognitive, and relaxation exercises.

Exercise	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Overall
Physical							
Patients ^a , n/N (%)	28/34 (82.4)	25/33 (75.8)	24/32 (75)	21/32 (65.6)	18/31 (58.1)	18/27 (66.7)	31/34 (91.2)
Sessions, n/N (%)	78/643 (12.1)	65/643 (10.1)	51/643 (7.9)	58/643 (9)	51/643 (7.9)	41/643 (6.4)	344/643 (53.5)
Cognitive							
Patients ^a , n/N (%)	15/34 (44.1)	19/33 (57.6)	24/32 (75)	17/32 (53.1)	16/31 (51.6)	12/27 (44.4)	28/34 (82.4)
Sessions, n/N (%)	44/643 (6.8)	45/643 (7)	51/643 (7.9)	45/643 (7)	39/643 (6.1)	33/643 (5.1)	257/643 (40)
Relaxation							
Patients ^a , n/N (%)	20/34 (58.8)	24/33 (72.7)	23/32 (71.9)	24/32 (75)	24/31 (77.4)	23/27 (85.2)	33/34 (82.4)
Sessions, n/N (%)	56/643 (8.7)	58/643 (9)	55/643 (8.6)	54/643 (8.4)	56/643 (8.7)	59/643 (9.2)	338/643 (52.6)

^aNumber of patients that used exercises at least once in the corresponding week.

Tolerability and Safety

Of the 47 patients, 33 (70%) reported VR-related adverse events at least once in the diary or telephone interview. Most frequent adverse event was dizziness (n=21, 45%), followed by headache (n=10, 21%; Table 4). Notably, 25% (9/36) of the participants

reported adverse events in the treatment satisfaction questionnaire, taken after the VR treatment. No falls or near falls due to VR use were reported. Additionally, 2 patients reported self-measured falls in oxygen saturation when performing physical exercises for a longer period of time (over 30 minutes); these were considered serious adverse events.

Table 4. Adverse events reported at least once in diary and telephone interviews.

Adverse event	Patient (N=47), n (%)
Dizziness	21 (45)
Headache	10 (21)
Fatigue	6 (13)
Nausea	7 (15)
Noncardiac chest pain	3 (6)
Neck pain	3 (6)
Blurred vision	2 (4)
Anxiety	1 (2)
Hot flashes	1 (2)
Dry eyes	1 (2)
Dyspnea	1 (2)
Restlessness	1 (2)

Physical Function

Significant improvements were found in the 6-MWT, grip strength, 30-CST, Borg scale on fatigue, and PSC on all 3 activities (PSC 1, 2, and 3; Table 5). There were 3 patients who performed the TUG instead of the 6-MWT, with scores between 5.0 to 17.0 seconds before and 4.2 and 9.0 seconds after the intervention. Additionally, 2 patients performed the 5-times

stand test instead of the 30-CST, with before and after scores of 17.7 and 7.4 seconds and 23.9 and 13.6 seconds, respectively. Lower extremity strength was measured with a microFET dynamometer (Hoggan Scientific) in 4 participants, with before and after percentages of from 57% to 79% and from 67 to 84%, respectively. No significant changes were seen in the scores on the different domains of the NEADL.

Table 5. Physical function, mental function, and quality of life outcome measures before and 6 weeks after virtual reality exercises in patients who performed virtual reality exercises for at least 3 weeks. Patients with missing baseline or final measurements were excluded from analysis.

Measurement (range)	Before	After	Mean difference (95% CI)	P value
Positive Health (n=36)				
Total score (0-420), mean (SD)	297.5 (41.0)	307.9 (43.8)	10.4 (0.7-19.9)	.04 ^a
Bodily functions (0-70), mean (SD)	38.7 (8.4)	44.2 (10.3)	5.5 (2.9-8.0)	<.001 ^a
Mental well-being (0-70), mean (SD)	45.8 (9.1)	49.4 (9.2)	3.6 (0.9-6.2)	.01 ^a
Meaningfulness (0-70), mean (SD)	50.8 (7.8)	52.0 (8.3)	1.2 (-0.6 to 3.0)	.19 ^a
Quality of life (0-70), mean (SD)	52.3 (8.0)	53.3 (7.7)	1.0 (-0.7 to 2.6)	.25 ^a
Participation (0-70), mean (SD)	57.5 (6.9)	57.0 (6.6)	-0.5 (-2.6 to 1.6)	.63 ^a
Daily functioning (0-70), median	53.5	53.0	— ^b	.78 ^c
Short Form-12 (n=36)				
Physical (0-100), mean (SD)	34.9 (8.3)	36.4 (9.5)	1.5 (0.01-3.08)	.049 ^a
Mental (0-100), mean (SD)	44.0 (8.8)	47.5 (9.1)	3.5 (0.76-6.07)	.01 ^a
CFQ ^d (0-100; n=36), median	37.5	31.5	—	.11 ^c
HADS^e (n=36)				
Total score (0-42), mean (SD)	11.6 (5.1)	10.2 (5.6)	-1.4 (-2.8 to 0.2)	.08 ^a
No generalized anxiety disorder (0-7), n (%)	28 (78)	29 (81)	—	—
Possible generalized anxiety disorder (8-10), n (%)	5 (14)	6 (17)	—	—
Likely generalized anxiety disorder (11-21), n (%)	3 (8)	1 (3)	—	—
No major depressive episodes (0-7), n (%)	26 (72)	26 (72)	—	—
Possible major depressive episodes (7-10), n (%)	8 (22)	7 (19)	—	—
Likely major depressive episodes (11-21), n (%)	1 (3)	2 (6)	—	—
NEADL^f (n=36)				
Mobility (0-18), mean (SD)	14.0 (2.8)	14.5 (2.3)	0.5 (-0.3 to 1.4)	.22 ^a
Kitchen (0-15), median	15.0	15.0	—	.25 ^c
Domestic (0-15), median	13.0	12.0	—	.86 ^c
Leisure (0-18), mean (SD)	11.8 (4.2)	12.1 (4.3)	0.3 (-1.1 to 1.6)	.71 ^a
PSC ^g 1 (0-100; n=35), mean (SD)	71.3 (20.1)	43.9 (25.4)	-27.4 (-36.5 to -18.3)	<.001 ^{a,h}
PSC 2 (0-100; n=30), mean (SD)	64.1 (18.9)	36.8 (24.2)	-27.3 (-35.7 to -19.1)	<.001 ^{a,h}
PSC 3 (0-100; n=24), median	80.0	50.0	—	<.001 ^c
6-MWT ⁱ (m; n=33), median	462.5	522.5	—	<.001 ^{c,h}
Grip strength (kg; n=30), median	29.0	29.8	—	.01 ^{c,h}
30-CST ^j (repetitions; n=31), median	13.0	15.0	—	.02 ^{c,h}
Borg fatigue scale (0-10; n=36), median	5.0	4.0	—	.03 ^{c,h}

^aPaired samples 2-tailed *t* test.^bNot available.^cWilcoxon signed-rank test.^dCFQ: Cognitive Failure Questionnaire.^eHADS: Hospital Anxiety and Depression Scale.^fNEADL: Nottingham Extended Activities of Daily Living questionnaire.

^gPSC: Patient-Specific Complaints questionnaire.

^hClinically relevant improvement (>10%).

ⁱ6-MWT: 6-Minute Walk Test.

^j30-CST: 30-Second Chair Stand Test.

Mental Function

The scores of the Positive Health questionnaire and SF-12 were significantly increased after 6 weeks. The 1.4 point decrease of total HADS score was not significant ($P=.08$) for the total group but reached significance ($P=.01$) for the subgroup of patients who used the mental VR applications.

Cognitive failure, as measured by the CFQ, did not significantly decrease, both in the whole group and the subgroup of patients who used the cognitive exercise application Koji's Quest.

Correlations Between Patient and Disease Characteristics and Functions and Quality of Life Outcomes

A positive correlation was found between the duration of VR use and age ($r=0.57$; $P<.001$). Other patient and disease characteristics did not show any significant correlation. The duration of VR use did not correlate with physical and mental functions or quality of life outcomes.

Discussion

Principal Findings

This study demonstrates that the use of VR for physical and self-administered mental exercising at home is feasible and appreciated in about three-quarters of patients with post-COVID-19 condition. Patients spent on average over 90 minutes per week exercising in VR. The overall use of VR applications was almost equally distributed over the 3 sets of VR exercises (physical, relaxing, and cognitive), although only physical exercises were prescribed, and considerable individual variations existed. Several physical function outcomes, perceived positive health, and quality of life improved in time, whereas cognitive function seemed unaltered. The design of the study did not allow for establishing improvement as a sole benefit of VR exercises. The results show patients' need for mental rehabilitation in addition to physical rehabilitation and the potential of self-administered VR in the recovery from post-COVID-19 condition.

The main study aim was the feasibility of self-administered VR physical exercises at home. The design was chosen accordingly, which does not allow conclusions to be drawn on effectiveness in comparison with standard rehabilitation alone. This precaution mainly regards physical function, because one might doubt similar mental effects with standard home exercise instructions by physiotherapists. An effect of the natural course of recovery cannot be ruled out, although it is less likely considering the long duration of symptoms at study entry in most patients. This study was largely conducted before the availability of vaccination and in a time of social distancing and reluctance of physical encounters. This may have affected the appreciation of home VR exercising programs by patients and

physiotherapists and the acceptability and usability results in both positive and negative directions.

This practice-based study was performed in the primary care setting and included a representative group of patients with a variety of symptoms of post-COVID-19 condition and rehabilitation needs [43,44]. Physiotherapists and patients were engaged early in the study design for defining relevant VR content, inclusion criteria, and outcome measures according to the most recent rehabilitation standards. This design benefits the generalizability of the study results. However, one could question the generalizability when taking into account the selection of therapists with a holistic approach to physiotherapy and the inclusion of patients who were capable of exercising at home with VR. This selection bias may have affected the appreciation, feasibility, and other outcomes of VR exercises, particularly in the mental domain. Conceivably, physiotherapists have emphasized the importance of stress and anxiety reduction and cognitive function along with physical recovery for restoring the health-related quality of life and participation.

One-quarter of the patients discontinued VR use before study end, in which half were due to adverse events, particularly dizziness. Dizziness is a common adverse effect of VR in general. The almost 50% of patients complaining of dizziness at some point in the 6-week treatment period seems high compared to VR in other areas, such as pain management or stress therapy [45]. This finding may be explained by concomitant complaints in the context of post-COVID-19 condition, such as fatigue, balance disturbances, and "brain fog." Notably, only 25% of the patients recalled having experienced any adverse events at the end of the intervention period. This may imply that the symptoms were relatively mild. The dropout rate of 15% due to adverse events in this study was comparable to the mean dropout rate of 16% reported in a recent systematic review on factors associated with VR adverse events [28]. A potential factor affecting dizziness and nausea, both symptoms of "VR sickness," is a prolonged playing time per session and possible latency in the software of physical exercising applications [28]. Although patients were instructed not to exceed 30 minutes, a considerable number did, because they lost track of time when immersed in the virtual world, particularly when performing physical exercises. Time compression is a known phenomenon in VR, which contributes to the benefit of VR in acute pain management [46]. Some participating physiotherapists initially observed serious falls in oxygen saturation levels after a few minutes of supervised VR physical exercises, which remained unnoticed by patients. This was an important reason to continue supervised sessions in the office for a few times and urge these patients not to exceed the exercise time. The 2 occasions of oxygen saturation falls reported by patients should be considered a serious adverse event of unsupervised VR physical exercising, in particular when followed by a postexertional symptom exacerbation [47]. Prolonged exercising due to time compression prompted us to

instruct all patients to set an alarm when exercising alone at home.

We found a positive correlation between the duration of VR use and age. There may be several explanations for this result. Older patients may have been slower in using the applications than younger patients, because they are not used to navigating through the application menu or with the controllers. Older patients may be more immersed in the virtual environment and are more curious about this “new” experience, prolonging the time of VR use. Conversely, younger patients might become bored earlier, as they are used to gaming in VR [48]. Finally, attitude toward a prescribed therapy might differ between age groups, with older patients being more adherent than younger patients. Age differences in acceptance, usability, tolerability, and the effects of VR have been described in numerous papers, however, with equivocal results. Our feasibility study, with a limited group of patients, did not allow for the analysis of other individual characteristics related to VR use. From the results of the digital health design evaluation study, we demonstrated a complex interplay between patients’ beliefs and values about VR use, such as autonomy, social comfort, self-identity, privacy, and its effects on recovering from post-COVID-19 condition [26].

Between 0% to 10% of the data were missing regarding the primary outcome measures of acceptability and tolerability. However, the diaries’ data were increasingly missed over time in 15% to 32% of the patients, most likely because they forgot to answer the same questions daily, which would mean that the actual use was higher than the reported use of VR. Automated collection of data from the headset would have benefitted the accurate assessment of the type, level, frequency, and duration of VR use. However, this functionality was not made available in the software (eg, application type and level) or was hampered by technical problems (eg, Wi-Fi connection and interim updates). Function outcomes were missing in 10% to 25% of patients, possibly due to delayed evaluations and administration faults by the physiotherapists. Accordingly, we cannot rule out an overestimation of these outcomes in this study.

Comparison to Prior Work

The frequent use of mental exercise applications at the patients’ own initiative in this study underlines the needs of patients with post-COVID-19 condition for a multimodal rehabilitation approach. However, most patients were only referred for physiotherapy as a single treatment. This finding reflects the emphasis on the physical domain of rehabilitation in most studies, although guidelines include multidisciplinary rehabilitation after COVID-19 for both hospitalized and nonhospitalized patients [43,49]. Daynes et al [50] evaluated a multimodal, home-administered, post-COVID-19 rehabilitation program for feasibility; however, they did not evaluate VR. The study duration was 6 weeks with 2 supervised sessions per week. The sessions comprised of physical exercises and educationally oriented conversations regarding mental complaints. The authors reported improvements in physical and cognitive functions but not regarding anxiety and depression. A recent study exploring the feasibility of VR relaxation games found similar results to our study with high patient satisfaction and benefits regarding

mental function; however, this study concerned inpatient post-COVID-19 rehabilitation [25]. Multimodal VR has been used in poststroke rehabilitation, resulting in improved physical and cognitive functions [21,51]. The differences in domains regarding effect might be due to the design of the VR intervention. Purpose-designed VR interventions seem to be more effective [52]. When we selected the applications, little was known about post-COVID-19 condition, and therefore, we chose a broad range of existing applications.

Strengths and Limitations

The strength of this study is the comprehensive collection of feasibility and function data using a novel approach of rehabilitation for post-COVID-19 condition with VR exercises. The study was designed to allow patients a lot of autonomy in choosing exercises in both the physical and mental domains, reflecting the real needs and wishes of the patients with this condition.

This study also has limitations. First, the approach was mono-professional for a postinfectious condition with symptoms that commonly require a multiprofessional approach. Accordingly, VR exercises to improve cognitive function and reduce stress and anxiety were not prescribed in contrast to physical exercises. However, by selecting physiotherapists with a psychosomatic approach and experience in treating similar postinfectious conditions, attention given to mental recovery might have been higher compared to the average physiotherapists’ approach. A further limitation in this context is the absence of information regarding concurrent treatment by an occupational therapist and a psychologist, which may have affected mental function outcomes and the quality of life. The mono-professional approach likely made no difference for the feasibility outcomes of VR exercises. Second, the study was conducted in the first year of the pandemic with limited knowledge of the cause of symptoms and scarce evidence on post-COVID-19 rehabilitation. Despite the reference to follow the actual guidelines in the protocol, this setting may have resulted in a multiformity of physiotherapy approaches, such as different uses of physical metrics and performance measurements, different indications for self-administered VR exercises at home, and different follow-up schemes. Notably, the guidelines considered standard and not VR physical exercises. Third, the first use of the multimodal VR suite for this condition and for use at home came with several organizational, technical, and monitoring challenges. We attempted to mitigate these challenges by supporting physiotherapists and patients through distributing, disinfecting, and administrating the hardware, providing around-the-clock (technical) support and performing weekly telephone calls. Against the background of limited physiotherapy resources and social distancing, this support may have positively affected feasibility outcomes despite the strict contact protocols with the patients and physiotherapists by the research team. This support by a research team does not reflect the normal practice of physiotherapy, which reduces the relevance of the results.

Future Directions

The results of this study show that a self-administered multimodal VR intervention at home is feasible and safe. Many

rehabilitation programs for other conditions are based on the same needs, implying that VR might benefit rehabilitation in general. The deployment of VR in rehabilitation could be administered to patients with the means to recover at home; thus, patients would not have to travel to a physiotherapist or clinic multiple times a week. Physiotherapists would be able to monitor patients' progress at a distance to relieve workload. Telerehabilitation, including wearables for (vital sign) monitoring, analytic platforms with patient and provider dashboards, and video consulting equipment, is increasingly available for use to administer virtual physiotherapy [53,54]. It can be expected that over time VR technology will become more affordable and more easily accessible [55]. This trend might eventually result in a reduction of health care costs.

Regarding the ongoing pandemic, an increase of patients with post-COVID-19 condition is expected to increase demand for rehabilitation. Self-administered VR rehabilitation at home for physical and mental impairments can be a novel means to restore the functional status and well-being of patients with post-COVID-19 condition that is inclusive, adopted by

caregivers, and sustainable and moves care from hospital and practices to at home. A wide range of VR applications in different domains motivates patients to exercise, improving therapy adherence and self-efficacy. Remotely monitoring adherence and progress in recovery and accordingly adapting the treatment plan can be a safe alternative to routine, unsupervised home exercising and regular patient visits to the physiotherapists' office. Before broad implementation, it is recommended to perform controlled trials on the cost-effectiveness of VR for the rehabilitation of post-COVID-19 condition. The results of this study have provided several substantive and organizational leads to future research delineating the health, societal, and economic impact of VR use in the rehabilitation of post-COVID-19 condition.

Conclusion

We found that 6 weeks of VR physical and mental exercises at home is feasible, well accepted, and safe in patients with post-COVID-19 condition, with improvements in physical and mental functions and the health-related quality of life.

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Data Availability

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

Authors' Contributions

MS, MdV, BS, and HvG conceived the study and were responsible for study design and methodology. TG, MS, RA, and RvH executed the study and collected the data. TG and RA managed the data and performed the data and statistical analyses. All authors contributed to data interpretation and writing, reviewing, and editing the manuscript. BS and HvG supervised the whole study process, including the writing of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Red flags.

[[DOCX File , 15 KB - rehab_v9i3e36836_app1.docx](#)]

Multimedia Appendix 2

Oculus Quest instructions for patients.

[\[PDF File \(Adobe PDF File\), 10639 KB - rehab_v9i3e36836_app2.pdf \]](#)**References**

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Abbreviations

- 30-CST:** 30-Second Chair to Stand Test
- 6-MWT:** 6-Minute Walk Test
- CFQ:** Cognitive Failure Questionnaire
- HADS:** Hospital Anxiety and Depression Score
- NEADL:** Nottingham Extended Activities of Daily Living score
- PSC:** Patient-Specific Complaints questionnaire
- SF-12:** Short Form-12
- TUG:** Timed Up and Go Test
- VR:** virtual reality

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Original Paper

Return-to-Work Following Occupational Rehabilitation for Long COVID: Descriptive Cohort Study

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Abstract

Background: Emerging evidence suggests that worldwide, between 30% and 50% of those who are infected with COVID-19 experience long COVID (LC) symptoms. These symptoms create challenges with return-to-work (RTW) in a high proportion of individuals with LC. To tailor rehabilitation programs to LC sequelae and help improve RTW outcomes, more research on LC rehabilitation program outcomes is needed.

Objective: This study describes the characteristics and outcomes of workers who participated in an LC occupational rehabilitation program.

Methods: A cohort study was conducted. Descriptive variables included demographic and occupational factors as well as patient-reported outcome measures (PROMs, ie, the Fatigue Severity Scale [FSS], the Post-COVID Functional Scale [PCFS], the 36-item Short Form Health Survey [SF-36], the Pain Disability Index [PDI], the pain Visual Analogue Scale [VAS], the 9-item Patient Health Questionnaire [PHQ-9], the 7-item Generalized Anxiety Disorder Questionnaire [GAD-7], and the Diagnostic and Statistical Manual for Mental Disorders Fifth Edition [DSM-5] posttraumatic stress disorder [PTSD] checklist [PCL-5]). The main outcome variable was the RTW status at discharge. Descriptive statistics were calculated. Logistic regression examined predictors of RTW.

Results: The sample consisted of 81 workers. Most workers were female (n=52, 64%) and from health-related occupations (n=43, 53%). Only 43 (53%) individuals returned to work at program discharge, with 40 (93%) of these returning to modified duties. Although there were statistically significant improvements on the pain VAS (mean 11.1, SD 25.6, $t_{31}=2.5$, $P=.02$), the PDI (mean 9.4, SD 12.5, $t_{32}=4.3$, $P<.001$), the FSS (mean 3.9, SD 8.7, $t_{38}=2.8$, $P=.01$), the SF-36 PCS (mean 4.8, SD 8.7, $t_{38}=-3.5$, $P=.001$), the PHQ-9 (mean 3.7, SD 4.0, $t_{31}=5.2$, $P<.001$), and the GAD-7 (mean 1.8, SD 4.4, $t_{22}=1.8$, $P=.03$), there were no significant improvements in the PCFS, the overall mental component score (MCS) of the SF-36, or on the PCL-5. The availability of modified duties (odds ratio [OR] 3.38, 95% CI 1.26-9.10) and shorter time between infection and admission for rehabilitation (OR 0.99, 95% CI 0.99-1.00) predicted RTW even when controlling for age and gender.

Conclusions: Workers undergoing LC rehabilitation reported significant but modest improvements on a variety of PROMs, but only 43 (53%) returned to work. Outcomes would likely improve with increased availability of modified duties and timelier rehabilitation. Additional research is needed, including larger observational cohorts as well as randomized controlled trials to evaluate the effectiveness of LC rehabilitation.

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KEYWORDS

compensation and redress; postacute COVID-19 syndrome; long COVID; COVID-19; rehabilitation; return-to-work; health outcome; occupational health; patient-reported outcome; anxiety disorder

Introduction

Background

Emerging evidence indicates that worldwide, between 30% and 50% of those who contract COVID-19 experience long COVID (LC) symptoms (dependent on ethnicity, gender, and hospitalization status) [1]. LC is defined by the World Health Organization as postacute COVID-19 sequelae lasting at least 3 months postinfection that are not explained by any other diagnosis [2]. An international study (N=3762) analyzing the symptom makeup and severity, expected clinical course, impact on daily functioning, and return to baseline health of individuals experiencing LC found that the time to full recovery exceeded 35 weeks for most respondents (>91%) [3]. For some, the time to full recovery is much longer.

Individuals recovering from COVID-19 will increase demands for rehabilitation due to the prevalence and diversity of recognized LC sequelae [4-11]. Common LC symptoms, such as profound fatigue, breathlessness, cognitive impairment (brain fog), and muscle and joint pain, among other mental and physical health symptoms, create challenges with return-to-work (RTW) [11-13]. A systematic review (N=81 studies) found that between 29% and 47% of those employed prior to contracting COVID-19 were unable to RTW [14]. RTW with LC was found to be most limited when symptoms included fatigue and cognitive impairment [14-17]. On an individual level, challenges with RTW cause feelings of lack of control and increased levels of uncertainty about employment and finances [15]. Since the risk of LC is greater in females, they will likely be disproportionately affected by the illness's subsequent impacts on loss of employment and income [12,18]. This creates a compounding societal issue as females were already more vulnerable than males in terms of income and employment prior to the pandemic [19]. Further, individuals who intersect multiple vulnerable groups at higher risk for COVID-19 exposure (eg, ethnic minorities, new immigrants, those working in health care settings) often have less access to jobs with modifications or accommodations to promote RTW [20]. Maintaining linkages with the workplace and returning to work as soon as safely possible helps avoid the long-term health and socioeconomic consequences that accompany prolonged unemployment [21].

To optimally tailor rehabilitation programs to LC sequelae and help improve outcomes of RTW programs, more research on LC rehabilitation is needed. This is especially true of rehabilitation programs that specifically aim to promote RTW. It is also important to explore whether certain individuals with LC fare better in rehabilitation than others, as this may identify potentially modifiable lifestyle or broader contextual factors that may facilitate the tailoring of rehabilitation services, thus increasing relevance and potentially improving RTW outcomes in this population.

Objectives

This study aims to describe the characteristics and outcomes of workers participating in occupational rehabilitation through Workers' Compensation Board of Alberta's (WCB-Alberta) Millard Health post-COVID rehabilitation program. We met this aim by (1) describing the characteristics of workers who accessed the program, (2) describing and comparing program admission and discharge data to determine whether there were significant changes in rehabilitation outcomes over the course of the program, and (3) comparing baseline and RTW status at discharge to determine what factors identified through admission data, if any, best predicted RTW status.

The specific research questions (RQs) were as follows:

- RQ1: What are the descriptive characteristics of workers participating in WCB-Alberta's Millard Health post-COVID rehabilitation program?
- RQ2: Are there significant improvements in outcomes between admission and discharge from the program?
- RQ3: Are worker descriptive characteristics or health status, identifiable upon admission, predictive of RTW status at discharge from the program?

Methods

Design

A descriptive cohort study was conducted using data collected by WCB-Alberta for regular program evaluation purposes.

Ethical Considerations

This research was approved by the University of Alberta's Health Research Ethics Board (#Pro00113982).

Population

This study included data from workers participating in WCB-Alberta's Millard Health post-COVID rehabilitation program. This program was created to help workers with compensation claims due to workplace COVID-19 exposure who developed LC return to regular work duties [22]. The multidisciplinary program consists of occupational, physical, and exercise therapy along with psychology, nursing, and medical interventions, as needed. The program provides psychoeducational approaches for management of LC symptoms, guidance on pacing and energy conservation, and breathing strategies. Some activity or exercise interventions are also prescribed, as tolerated by the workers and in a manner that avoids the postexertional malaise that is common to the LC population. The programs are provided in person, through telerehabilitation (telephone or videoconference), or a combination of the 2, depending on each worker's individual context. A primary goal of the program is RTW; thus, advice about work activity, exploration of modified duties, and negotiation with employers about appropriate duties are also performed.

The data set included information about all workers who contracted COVID-19 between March 2020 and mid-May 2021. To be included in this study, workers had to be at least 18 years of age and discharged from the aforementioned rehabilitation program. Workers who had not yet been discharged from the program were excluded as their outcomes resulting from program participation were not yet known. All workers had been discharged from the program prior to early January 2022.

Data Collection Procedures

Anonymized data were extracted from provincial databases managed by WCB-Alberta Health Care Strategy. WCB-Alberta reports are electronic, and data from health care providers are automatically entered into databases. Reports are filed by health care providers at admission to, and discharge from, any WCB-Alberta program. Providers of the post-COVID rehabilitation program report on a variety of demographic, clinical, and occupational variables. Our team has previously conducted several studies using data from WCB-Alberta programs [23-26], and we worked with the same experienced team in Health Care Strategy to retrieve data for this study.

Sampling

All data points were included in descriptive statistical calculations. This allowed us to obtain a clear picture of the demographics and general outcomes of the post-COVID rehabilitation program. No sample sizes were calculated, as all workers completing the post-COVID rehabilitation program were included (ie, population based).

Measures

Independent Variables

The data set included a variety of descriptive variables, including demographic factors (eg, age, gender), occupational factors (eg, National Occupational Classification code, employment and working status, job attached status, modified work available, work abilities), treatment factors (eg, number and type of services received prior to beginning the post-COVID rehabilitation program, days between date of COVID-19 symptom onset and admission for rehabilitation, program length), and mode of treatment delivery (ie, virtual, in person, or combination). Gender was treated as a categorical variable with 3 options: male, female, and undisclosed.

Independent variables also included patient-reported outcome measures (PROMs) administered at the time of admission to the program. The PROMs included in this study were the Fatigue Severity Scale (FSS) [27], the Post-COVID Functional Scale (PCFS) [28], the 36-item Short Form Health Survey (SF-36) [29], the Pain Disability Index (PDI) [30], the pain Visual Analogue Scale (VAS) [31], the 9-item Patient Health Questionnaire (PHQ-9) [32], the 7-item Generalized Anxiety Disorder Questionnaire (GAD-7) [33], and the *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition* (DSM-5) posttraumatic stress disorder (PTSD) checklist (PCL-5) [34]. [Table 1](#) contains detailed information about each measure. Since the PROMs rely on self-reporting and completion is voluntary, there is typically a high level of missing data on these measures.

Table 1. Details about scoring of PROMs^a completed by workers in WCB-Alberta's^b Millard Health post-COVID rehabilitation program.

Survey	Measure details
FSS ^c	The FSS contains 9 numerical rating scales, with scores on each scale ranging from 1 (indicating strongly disagree) to 7 (indicating strongly agree) [27]. The 9 scales address the perceived level of disability caused by fatigue as well as how fatigue interferes with physical functioning and activities of daily living [27]. Raw scores are summed into a total score out of 63, with higher scores indicating greater impairment due to fatigue [27].
PCFS ^d	The PCFS is a 1-item question asking "how much the patient is affected in their everyday life by COVID-19" [28]. Scores range from 0 (indicating no functional limitations) to 4 (indicating severe functional limitations) [28].
SF-36 ^e	The SF-36 is a 36-item survey that includes domains related to the health-related quality of life specifically in terms of physical functioning, role limitations due to physical health, role limitations due to emotional problems, vitality (ie, energy/fatigue), emotional well-being, social functioning, pain, and general health [29]. Domains are scored, standardized [35,36], and combined into an overall PCS ^f and an MCS ^g [29].
PDI ^h	The PDI is a 7-item measure assessing the degree to which pain interferes with family and home responsibilities, recreation, social activity, occupation, sexual behavior, self-care, and activities of daily living [30]. Each item is measured on a scale from 0 (indicating no disability) to 10 (indicating the worst disability) [30]. Raw scores are summed into a total score out of 70, with higher scores indicating greater disability due to pain [30].
Pain VAS ⁱ	The pain VAS measures a patient's perceived pain intensity on a scale of 0-100, with 100 indicating the highest level of pain [31].
PHQ-9 ^j	The PHQ-9 is a 9-item measure assessing levels of depression [32]. Each item is scored from 0 (indicating not at all) to 4 (indicating nearly every day) [26]. Raw scores are summed into a total score out of 27, with higher scores indicating a higher severity of depression [32].
GAD-7 ^k	The GAD-7 is a 7-item measure assessing levels of anxiety [33]. Each item is scored from 0 (indicating not at all) to 3 (indicating nearly every day) [33]. Raw scores are summed into a total score out of 21, with higher scores indicating a higher severity of anxiety [33].
PCL-5 ^l	The PCL-5 is a 20-item measure assessing the DSM-5's ^m 20 symptoms of PTSD ⁿ [34]. Each item is scored from 0 (indicating not at all) to 4 (indicating extremely). Total scores range from 0 to 80, with higher scores indicating a higher likelihood of PTSD [34].

^aPROM: patient-reported outcome measure.

^bWCB-Alberta: Workers' Compensation Board of Alberta.

^cFSS: Fatigue Severity Scale.

^dPCFS: Post-COVID Functional Scale.

^eSF-36: 36-item Short Form Health Survey.

^fPCS: physical component score.

^gMCS: mental component score.

^hPDI: Pain Disability Index.

ⁱVAS: Visual Analogue Scale.

^jPHQ-9: 9-item Patient Health Questionnaire.

^kGAD-7: 7-item Generalized Anxiety Disorder Questionnaire.

^lPCL-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition* posttraumatic stress disorder checklist.

^mDSM-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition*.

ⁿPTSD: posttraumatic stress disorder.

Dependent Variable

The outcome variable for this study was RTW status at program discharge. RTW status was chosen as the outcome variable of interest because previous research has shown that RTW status is impacted by LC and RTW is a primary goal of the rehabilitation program [14-17]. RTW status was coded as a binary variable, with 1 indicating RTW and 0 indicating "other" ("other" indicated the worker was fit for work [FFW] but had not returned to work or that they were unable to work). We chose to collapse FFW with unable to work due to a low sample size (only 18 cases of FFW) and because those deemed FFW at discharge often have ongoing issues that prevent them from returning to their usual employment. Comparisons were made between the RTW, FFW, and unable-to-work groups on each

of the descriptive variables and PROMs. The FFW group was more similar to the unable-to-work group than the RTW group on several of the descriptive variables (ie, occupation, gender, program length, and availability of modified duties). Clinically, the FFW group was also similar to the unable-to-work group on the PDI, FSS, PHQ-9, GAD-7, and PCL-5, further justifying the collapsing of these 2 groups.

Data Analysis

Data were analyzed using SPSS Statistics version 28 (IBM Corp). To address RQ1, we calculated the mean and SDs of any interval data (eg, worker age) and the frequency of any categorical data (eg, gender or occupation).

To address RQ2, we calculated descriptive statistics for the various PROMs. We calculated the mean and SDs of interval

data and the frequency of categorical data. We performed paired-samples t tests for each variable collected upon admission to and discharge from the program to determine whether there were any significant improvements in outcomes. Wilcoxon signed-rank tests were performed if the dependent variable was not continuous (ie, the PCFS does not have a total score and therefore is an ordinal variable).

To address RQ3, logistic regression analyses were used to determine which variables (ie, worker demographics, data collected at admission), if any, were predictive of RTW status at discharge. Imputation techniques were used to address the high levels of missing data on the PROMs. We completed univariable logistic regression analyses to examine each potential prognostic factor. Due to the limited sample size, we were unable to build multivariable predictive models. However, we examined the potential confounding effects of age and gender on the significantly predictive variables. Relevant assumptions were tested.

Results

Demographics

The data set included 81 workers who had been discharged from WCB-Alberta Millard Health post-COVID program (demographics shown in Table 2). The majority were female ($n=52$, 64%), had their program delivered virtually ($n=79$, 98%), and worked in health occupations ($n=43$, 53%). The mean (SD) age was 48.9 (10.5) years, and the mean (SD) length of time between symptom onset and program admission was 165.2 (73.0) days. Prior to starting the post-COVID program, the workers most frequently visited their doctor ($n=64$, 79%) or received physiotherapy ($n=38$, 47%). Although the majority were still employed at program admission ($n=77$, 95%), only 42 (52%) had modified duties available. A small majority ($n=43$, 53%) returned to work at the time of program discharge. Of those who returned to work, 40 (93%) returned to modified duties.

Table 2. Demographics of workers (N=81) undergoing WCB-Alberta's^a Millard Health post-COVID rehabilitation program.

Variable	Value
Age (years), mean (SD)	48.9 (10.5)
Gender, n (%)	
Male	20 (25)
Female	52 (64)
Undisclosed	9 (11)
Duration (average days between symptom onset and admission), mean (SD)	165.2 (73.0)
Program length (work days), mean (SD)	49.9 (12.5)
Program delivery, n (%)	
Virtual	79 (98)
In person	0 (0)
Combination	2 (2)
Occupation category, n (%)	
Business, finance, and management	5 (6)
Health	43 (53)
Education, law, social, and community government services	10 (12)
Trades	15 (19)
Other	8 (10)
Interpreter required, n (%)	
Yes	1 (1)
No	80 (99)
Services received prior to admission, n (%)	
Physician	63 (79)
Physiotherapy	38 (47)
RTW ^b specialist	27 (33)
Psychology	26 (32)
Occupational therapy	19 (24)
Hospital admission	14 (17)
Diagnostic testing	19 (24)
Acupuncture	1 (1)
Chiropractor	1 (1)
Injections	1 (1)
No services prior to admission	8 (10)
Employed at admission, n (%)	
Yes	77 (95)
No	4 (5)
Modified duties available at admission, n (%)	
Yes	42 (52)
No	39 (48)
Work abilities (National Occupational Classification strength level) at admission, n (%)	
Limited (lifting required up to 5 kg)	56 (69)
Light (lifting required up to 10 kg)	8 (10)

Variable	Value
Medium (lifting required up to 20 kg)	3 (4)
Heavy (lifting required over 20 kg)	4 (5)
N/A ^c	10 (12)
Working at admission, n (%)	
Yes	10 (12)
No	71 (88)
Employed at discharge, n (%)	
Yes	76 (94)
No	5 (6)
Modified duties available at discharge, n (%)	
Yes	50 (62)
No	31 (38)
Discharge outcome, n (%)	
RTW	43 (53)
Other	38 (47)
RTW outcome at program discharge (N=43)	
Return to regular work duties	3 (7)
Return to modified duties	40 (93)
Work abilities (National Occupational Classification strength level) at discharge	
Limited (lifting required up to 5 kg)	41 (51)
Light (lifting required up to 10 kg)	15 (18)
Medium (lifting required up to 20 kg)	8 (10)
Heavy (lifting required over 20 kg)	14 (17)
N/A	3 (4)

^aWCB-Alberta: Workers' Compensation Board of Alberta.

^bRTW: return-to-work.

^cN/A: not applicable.

Patient-Reported Outcome Measures

There were substantial missing data on the PROMs, with 58 (72%) workers not completing at least 1 of the measures at admission or discharge. Only raw SF-36 data were available at discharge, thus preventing calculation of domain scores at admission. However, overall PCSs and MCSs for the SF-36 were logged at admission and discharge.

Table 3 outlines mean (SD) admission and discharge scores on each PROM for those with complete data. Mean (SD) scores on the FSS were quite high at admission (mean 51.3, SD 11.4), indicating moderate-to-severe levels of fatigue in the sample. Pain seemed to cause moderate disruptions in the sample, with a mean (SD) PDI score of 33.3 (15.6) out of 70. Individuals moved from moderate depression (mean 14.1, SD 5.9) to mild depression (mean 10.1, SD 5.3) between admission and discharge, respectively.

Paired-samples *t* tests were run on those with complete matched PROM data (ie, complete data at admission and discharge). Due to the substantial amount of missing PROM data, we included

all workers with complete data (the maximum number of matched pairs on any PROM in our sample was 39). Significant changes were noted on several measures (Table 4). There were statistically significant improvements on the pain VAS (mean 11.1, SD 25.6, $t_{31}=2.5$, $P=.02$), the PDI (mean 9.4, SD 12.5, $t_{32}=4.3$, $P<.001$), the FSS (mean 3.9, SD 8.7, $t_{38}=2.8$, $P=.01$), the SF-36 PCS (mean 4.8, SD 8.7, $t_{38}=-3.5$, $P=.001$), the PHQ-9 (mean 3.7, SD 4.0, $t_{31}=5.2$, $P<.001$), and the GAD-7 (mean 1.8, SD 4.4, $t_{22}=1.8$, $P=.03$). There were no significant improvements to the overall MCS measured through the SF-36 or the PCL-5 scores.

The PCFS does not have a total score, so a paired-sample *t* test could not be carried out. Instead, a Wilcoxon signed-rank test was performed (Table 5). Again, due to the substantial amount of missing PROM data, we included only workers with complete matched data ($n=38$, 47%). There was not a significant difference in PCFS scores between admission and discharge.

We conducted a missing data analysis to determine whether workers with missing data were more or less likely to RTW at

discharge. Incomplete data at admission or discharge or both on GAD-7 were significantly associated with RTW (odds ratio [OR] 0.34, 95% CI 0.13-0.87), suggesting that those with incomplete data had a lower likelihood of returning to work.

Table 3. Mean scores on PROMs^a at the time of admission and discharge from WCB-Alberta's^b Millard Health post-COVID rehabilitation program.

PROMs	Admission	Discharge
PCFS^c (out of 4)		
Score, mean (SD)	2.2 (0.8)	2.1 (1.1)
Missing, n (%)	43 (53)	55 (68)
Pain VAS^d (out of 100)		
Score, mean (SD)	48.2 (23.0)	42.0 (25.6)
Missing, n (%)	25 (31)	39 (48)
PDI^e (out of 70)		
Score, mean (SD)	33.3 (15.6)	26.8 (16.2)
Missing, n (%)	19 (23)	42 (52)
FSS^f (out of 63)		
Score, mean (SD)	51.3 (11.4)	48.3 (12.0)
Missing, n (%)	13 (16)	36 (44)
SF-36^g version 2 (all out of 100), mean (SD)		
Physical functioning	N/A ^h	32.9 (11.7)
Role physical	N/A	35.3 (7.3)
Role emotional	N/A	42.9 (6.3)
Bodily pain	N/A	29.7 (5.7)
Vitality	N/A	33.5 (10.8)
Social functioning	N/A	29.9 (12.5)
Mental health	N/A	38.4 (13.3)
General health perceptions	N/A	32.2 (15.9)
Overall PCS ⁱ	28.9 (8.5)	33.4 (9.4)
Overall MCS ^j	35.2 (11.0)	37.9 (9.0)
PHQ-9^k		
Score, mean (SD)	14.1 (5.9)	10.1 (5.3)
Missing, n (%)	39 (48)	43 (53)
GAD-7^l		
Score, mean (SD)	10.6 (5.0)	8.2 (5.2)
Missing, n (%)	39 (48)	43 (53)
PCL-5^m		
Score, mean (SD)	32.4 (15.8)	28.0 (13.2)
Missing, n (%)	50 (62)	48 (59)

^aPROM: patient-reported outcome measure.

^bWCB-Alberta: Workers' Compensation Board of Alberta.

^cPCFS: Post-COVID Functional Scale.

^dVAS: Visual Analogue Scale.

^ePDI: Pain Disability Index.

^fFSS: Fatigue Severity Scale.

^gSF-36: 36-item Short Form Health Survey.

^hN/A: not applicable.

ⁱPCS: physical component score.

^jMCS: mental component score.

^kPHQ-9: 9-item Patient Health Questionnaire.

^lGAD-7: 7-item Generalized Anxiety Disorder Questionnaire.

^mPCL-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition* posttraumatic stress disorder checklist.

Table 4. Mean differences in PROM^a scores between admission and discharge from WCB-Alberta's^b Millard Health post-COVID rehabilitation program (paired-sample *t* tests).

Variable	Differences, mean (SD)	<i>t</i> (<i>df</i>)	Two-sided <i>P</i> value
Pain VAS ^c (n=32)	11.1 (25.6)	2.5 (31)	.02
PDI ^d (n=33)	9.4 (12.5)	4.3 (32)	<.001
FSS ^e (n=39)	3.9 (8.7)	2.8 (38)	.01
Overall PCS ^f (n=39)	-4.8 (8.7)	-3.5 (38)	.001
Overall MCS ^g (n=38)	-0.7 (13.3)	-0.3 (37)	.73
PHQ-9 ^h (n=32)	3.7 (4.0)	5.2 (31)	<.001
GAD-7 ⁱ (n=32)	1.8 (4.4)	2.3 (31)	.03
PCL-5 ^j (n=23)	5.6 (3.1)	1.8 (22)	.09

^aPROM: patient-reported outcome measure.

^bWCB-Alberta: Workers' Compensation Board of Alberta.

^cVAS: Visual Analogue Scale.

^dPDI: Pain Disability Index.

^eFSS: Fatigue Severity Scale.

^fPCS: physical component score.

^gMCS: mental component score.

^hPHQ-9: 9-item Patient Health Questionnaire.

ⁱGAD-7: 7-item Generalized Anxiety Disorder Questionnaire.

^jPCL-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition* posttraumatic stress disorder checklist.

Table 5. Mean differences in PCFS^a scores between admission and discharge from WCB-Alberta's^b Millard Health post-COVID rehabilitation program (Wilcoxon signed-rank test).

Variable	Admission	Discharge	Median	Z value	Two-sided <i>P</i> value
Difference	Mean 2.2 (SD 0.8)	Mean 2.1 (SD 1.1)	Admission: 2.0 Discharge: 2.0	-0.6	.53
Missing, n (%)	43 (53)	55 (68)	N/A ^c	N/A	N/A

^aPCFS: Post-COVID Functional Scale.

^bWCB-Alberta: Workers' Compensation Board of Alberta.

^cN/A: not applicable.

Predicting Return-to-Work After Rehabilitation

Univariate associations between all potential predictors and the outcome of RTW are shown in Table 6. Three factors were significantly associated with RTW: modified duties available at admission (OR 3.20, 95% CI 1.29-7.95), days between symptom onset and program admission (OR 0.93, 95% CI 0.87-0.998), and the PHQ-9 score at admission (OR 0.87, 95% CI 0.76-0.999). Modified duties available at admission remained a significant predictor of RTW (OR 3.38, 95% CI 1.26-9.10) when controlling for age and gender. Days between symptom

onset and program admission also remained a significant predictor of RTW (OR 0.94, 95% CI 0.88-0.999). The PHQ-9 score at admission did not remain significant when controlling for age and gender, suggesting that these demographic variables have a confounding effect. There were no statistically significant or clinically important associations found between any preadmission health care use variable and future RTW status. Imputation with mean (SD), minimum, and maximum values for those with missing data on the PROMs did not result in meaningful changes to the logistic regression analyses. Therefore, we did not present imputed analyses.

Table 6. Logistic regression predicting RTW^a at time of discharge from WCB-Alberta's^b Millard Health post-COVID rehabilitation program.

Variable	OR ^c (95% CI)
Gender	
Male	1.00 (N/A ^d)
Female	1.03 (0.37-2.11)
Undisclosed	0.41 (0.08-2.91)
Age (years)	0.99 (0.95-1.04)
Job attached at admission	
No	1.00 (N/A)
Yes	3.60 (0.36-36.17)
Modified duties available at admission	
No	1.00 (N/A)
Yes	3.20 (1.29-7.95) ^e
Days between symptom onset and admission to program	0.93 (0.87-0.998) ^f
Work abilities at admission	
Heavy	1.00 (N/A)
Medium	0.17 (0.006-4.52)
Light	0.33 (0.02-4.74)
Limited	0.40 (0.04-4.05)
N/A	0.27 (0.02-3.65)
Industry	
Other	1.00 (N/A)
Business, finance, and management occupations	6.67 (0.49-91.33)
Health occupation	2.32 (0.49-10.95)
Education, law, social, and community government services	2.50 (0.37-16.89)
Trades	0.83 (0.14-4.99)
PROMs^g	
PCFS ^h (n=38), 0-1	1.00 (N/A)
PCFS (n=38), 2-3	2.57 (0.41-16.12)
Pain VAS ⁱ at admission (n=56)	1.00 (0.98-1.02)
PDJ ^j at admission (n=62)	0.97 (0.94-1.00)
FSS ^k at admission (n=68)	0.96 (0.92-1.01)
Overall PCS ^l at admission (n=39)	1.01 (0.96-1.07)
Overall MCS ^m at admission (n=38)	1.01 (0.97-1.06)
PHQ-9 ⁿ at admission (n=42)	0.87 (0.76-1.00) ^e
GAD-7 ^o at admission (n=42)	0.88 (0.77-1.02)
PCL-5 ^p at admission (n=31)	0.97 (0.94-1.03)

^aRTW: return-to-work.^bWCB-Alberta: Workers' Compensation Board of Alberta.^cOR: odds ratio.^dN/A: not applicable.^eIndicates significance at $P < .01$.

^fIndicates significance at $P < .05$.

^gPROM: patient-reported outcome measure.

^hPCFS: Post-COVID Functional Scale.

ⁱVAS: Visual Analogue Scale.

^jPDI: Pain Disability Index.

^kFSS: Fatigue Severity Scale.

^lPCS: physical component score.

^mMCS: mental component score.

ⁿPHQ-9: 9-item Patient Health Questionnaire.

^oGAD-7: 7-item Generalized Anxiety Disorder Questionnaire.

^pPCL-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition* posttraumatic stress disorder checklist.

Discussion

Principal Findings

In this cohort study of workers with LC participating in WCB-Alberta's Millard Health post-COVID rehabilitation program, many worker outcomes significantly but modestly improved between admission and discharge. However, several key functional measures did not improve (ie, the PCFS; the overall MCS, measured through the SF-36; and PTSD, measured through the PCL-5). Only a small majority of the sample returned to work (53%), and of these, 93% required modified duties. Those who identified at admission that modified duties were available in their workplace were 3.38 times as likely than those without available modified duties to RTW at program discharge, after controlling for age and gender. Workers with a longer time between symptom onset and program admission also had a lower likelihood of successful RTW.

Our study found that the presence of modified duties in the workplace at admission to LC rehabilitation results in better RTW outcomes. Although we could not find other studies quantifying the relationship between modified duties and RTW with LC, the emerging literature suggests that individuals with LC would likely have greater chances of RTW if they have access to flexible, gradual RTW plans with modified duties. For example, Wong et al [37] completed 2 focus groups (n=8) with rehabilitation counsellors and physicians providing services to individuals with LC and determined that modified work and gradual RTW plans are the most frequently used accommodations to assist individuals with LC with RTW. In a cross-sectional, mixed methods study (N=145) aimed at understanding experiences of workers with LC, Lunt et al [38] found that individuals with LC wanted workplace accommodations that included modified or reduced hours and workload as well as gradual and flexible RTW planning. Support for similar workplace accommodations was echoed in the United Kingdom's Health and Safety Executive's report on RTW after LC [39].

The importance of modified duties in LC rehabilitation is consistent with the broader field of occupational rehabilitation and work disability prevention, where modified work duties and RTW coordination are core components of rehabilitation and used to promote RTW [40]. Early intervention is another core principle of occupational rehabilitation [41] and consistent with our finding that more time between initial symptom onset and program admission leads to worse RTW outcomes.

However, to meet the clinical case definition of LC (symptoms lasting for at least 3 months after acute infection) [2], individuals with LC are often required to wait at least 3 months to access rehabilitation programs. This waiting period may in turn lead to worse RTW outcomes and therefore warrants further research to determine whether earlier educational or other rehabilitation interventions could improve RTW outcomes in people with lingering symptoms after COVID-19 infection who are not yet diagnosed with LC.

To the best of our knowledge, this is the first study examining the predictors of RTW among workers with LC, likely because of the novelty of the condition. However, previous research has examined RTW in individuals with chronic fatigue syndrome, which has been found to have an overlapping clinical presentation with LC [42]. In a longitudinal study (N=508) exploring sociodemographic, work, and clinical characteristics associated with occupational status among individuals with chronic fatigue syndrome, those who returned to work functioned better (as measured by the SF-36) and were younger [43]. Individuals who reported more fatigue (measured by the Chalder Fatigue Questionnaire) or met the criteria for anxiety and depression (measured by the Hospital Anxiety and Depression Scale) were more likely to have stopped working between baseline and follow-up [43]. These findings suggest that levels of fatigue, age, function, anxiety, and depression may be important variables to consider in future studies analyzing prognostic factors of RTW among individuals living with LC.

Limitations

The primary limitations of this study are the large amount of missing data on the PROMs and the relatively small sample size. Completion of the PROMs was voluntary for patients in the program, which explains the sizeable amount of missing data. Missing data and a modest sample size limited our ability to build multivariate models and limited conclusions that could be drawn from our results. Having incomplete data on the GAD-7 was significantly associated with worse RTW, which suggests that those with missing data had a lower likelihood of returning to work. There are also likely unmeasured factors that influence both completion of the PROMs and RTW that should be further explored. Results are, however, important for individuals with LC due to the novelty of the condition and uncertainty around optimal rehabilitation approaches.

Conclusion

Workers undergoing LC rehabilitation reported significant but modest improvements on a variety of PROMs, but only 53% of workers with LC returned to work at the time of program discharge. RTW outcomes would likely improve with increased

availability of modified duties and timelier rehabilitation. Additional research is needed, including larger observational cohorts with additional variables as well as randomized controlled trials to evaluate the effectiveness of LC rehabilitation.

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Conflicts of Interest

None declared.

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Abbreviations

DSM-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition*

FFW: fit for work

FSS: Fatigue Severity Scale

GAD-7: 7-item Generalized Anxiety Disorder Questionnaire

LC: long COVID

MCS: mental component score

PCFS: Post-COVID Functional Scale

PCL-5: *Diagnostic and Statistical Manual for Mental Disorders Fifth Edition* posttraumatic stress disorder checklist

PCS: physical component score

PDI: Pain Disability Index

PHQ-9: 9-item Patient Health Questionnaire

PROM: patient-reported outcome measure

PTSD: posttraumatic stress disorder

RQ: research question

RTW: return-to-work

SF-36: 36-item Short Form Health Survey

VAS: Visual Analogue Scale

WCB-Alberta: Workers' Compensation Board of Alberta

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Original Paper

Internet-Based Information Sharing With Families of Patients With Stroke in a Rehabilitation Hospital During the COVID-19 Pandemic: Case-Control Study

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Abstract

Background: The spread of COVID-19 has affected stroke rehabilitation. Given that inpatient visits are restricted in most institutions, alternative ways of providing information to family members are imperative. Informing families about patients' rehabilitation progress via the web may help involve families in the rehabilitation process, enhance patients' motivation to continue rehabilitation, and contribute overall to patients' improvement in activities of daily living (ADL).

Objective: We aimed to investigate the feasibility of the Internet-Based Rehabilitation Information Sharing (IRIS) intervention for families of patients with stroke at a rehabilitation hospital and examine the effect of IRIS on patients' ADL improvement.

Methods: In this case-control study, participants were inpatients at a rehabilitation hospital between March 2020 and April 2021. The intervention group (information and communication technology [ICT] group) included patients and families who requested IRIS, which consisted of a progress report on patients' rehabilitation using text, photos, and videos. Those who did not receive internet-based information were included in the non-ICT group. The control group, matched with the ICT group based on a 1:1 propensity score, was selected from the non-ICT group. The covariates for calculating the propensity score were patients' age, sex, and motor and cognitive scores on the Functional Independence Measure at admission. The main outcome was the degree of ADL improvement during hospitalization. Multiple regression analysis (forced entry method) was performed to confirm the impact of ICT use on ADL improvement. The independent variables were the presence of intervention, length of hospital stay, and number of days from onset to hospitalization.

Results: In total, 16 groups of patients and families participated in the IRIS. The mean age of patients was 78.6 (SD 7.2) and 78.6 (SD 8.2) years in the ICT and control groups, respectively. The median total Functional Independence Measure difference was 28.5 (IQR 20.3-53.0) and 11.0 (IQR 2.8-30.0) in the ICT and control groups, respectively, and the ICT group showed significant improvement in ADL function ($P=.02$). In the multiple regression analysis of the ICT and control groups, the unstandardized regression coefficient was 11.97 (95% CI 0.09-23.84) for ICT use. These results indicate that ICT use was independently and significantly associated with improvement in ADL.

Conclusions: This study examined the effect of IRIS on family members to improve ADL in patients with stroke who are hospitalized. The results showed that IRIS promotes the improvement of patients' ADL regardless of age, sex, motor and cognitive functions at admission, and the length of hospital stay.

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KEYWORDS

COVID-19; internet-based; health information; stroke; family; rehabilitation; case-control; activities of daily living; information communication technology; physical function; recovery

Introduction

Background

The spread of COVID-19 has affected medical institutions in general [1,2]. Given that inpatient visits are restricted in most institutions, communication between patients and families and between patients' families and medical workers is difficult [3]. Studies have shown that family members of patients with stroke who are hospitalized are not usually informed about the type of care provided to patients, rehabilitation progress, and functional prognosis [4-6]. Therefore, if inpatient visits are restricted, alternative ways of providing information to family members are imperative [6].

Web-based interventions are expected to improve the quality of medical services [7]. There have been increasing reports on telemedicine and telerehabilitation. Web-based medical services include video conferencing, education for patients and their families, counseling, and rehabilitation support [8]. The expected benefits of the web in medical services are efficiency, convenience, and reduced COVID-19 infection risk due to noncontact [9]. In the future, web-based interventions will continue to be developed, and a variety of intervention methods and effects will be reported. However, at present, there are no previous studies using information and communication technology (ICT) to share information with family members of patients admitted to rehabilitation hospitals.

The guidelines for adult stroke rehabilitation published by the American Heart Association/American Stroke Association [10] indicate that "Communication and coordination between a large team, including the patient and his or her families, physicians, nurses, physical and occupational therapists, speech-language pathologists [is] paramount in maximizing the effectiveness and efficiency of rehabilitation. Without communication and coordination, isolated efforts to rehabilitate the stroke survivor are unlikely to achieve their full potential." It is recommended that patient assessment in stroke rehabilitation be based on the International Classification of Functioning, Disability and Health [11]. Therefore, family information, such as family caregiving abilities and home environment, is useful for medical workers. Activities to intervene during hospitalization should be selected according to environmental factors after discharge. International Classification of Functioning, Disability and Health-based goals have been reported to increase rehabilitation efficiency [11]. With information from the family, personalized goals can be set for each patient.

Rehabilitation professionals have suspected that a patient's motivation plays an important role in determining the outcome of therapy. Motivation for rehabilitation can be conceived as an internal "personality trait" of the individual patient, a quality that is affected by social factors [12]. It was reported that among patients in rehabilitation hospitals, those who perceive higher levels of family support are more motivated to improve mobility [13]. Therefore, the patient perception of family support is an

important factor in enhancing the effectiveness of rehabilitation. However, during the COVID-19 outbreak, patients were isolated due to visitation limitations. Therefore, communication between patients and families mediated by health care providers is needed. Showing that family members care about the patient may improve their rehabilitation motivation.

Objectives

Patients' families play an important role in the rehabilitation of patients with stroke [14]. Health care providers should be more aware of the fact that a patient's family acts as a facilitator and supporter of the patient's functional improvement [15]. Therefore, interactive information sharing on rehabilitation with patients' families via the web is expected to involve families' ability to support rehabilitation, set personalized goals, motivate patients, and contribute to improving patients' activities of daily living (ADL). Thus, we aimed to investigate the feasibility of the Internet-Based Rehabilitation Information Sharing (IRIS) intervention for families of patients with stroke at a rehabilitation hospital and examine the effect of IRIS on patients' ADL improvement.

Methods

Study Design and Participants

In this case-control study, electronic medical records were retrospectively examined between March 2020 and April 2021. Participants were inpatients at a rehabilitation hospital in Hirakata City, Osaka, Japan. The inclusion criteria were being aged >60 years and having a stroke diagnosis. The exclusion criterion was having been institutionalized before stroke onset.

The study period was during a time when hospital policy restricted visiting for all patients following the spread of COVID-19 infection, making it difficult for family members to see the progress of rehabilitation. In this study, the intervention group (ICT group) included patients and families who requested internet-based information provision. Information forms placed at the reception counter of the wards were distributed to hospitalized patients, and posters were displayed in the corridors of the wards. The information sheet contained the email address of the physiotherapist in charge of the ward, and patients' families could receive internet-based information by indicating their willingness to participate in the study by sending an email to the concerned physiotherapist.

In contrast, patients and families who did not receive internet-based information were included in the non-ICT group. The non-ICT group was selected as the control group after a 1:1 propensity score matching [16] with the ICT group. The covariates for calculating the propensity score were patients' age, sex, motor score on the Functional Independence Measure (FIM) at admission, and cognitive score on the FIM. Nearest-neighbor matching was used as the matching method.

Ethics Approval

This study was approved by the Research Ethics Committee at Osaka Prefecture University (2018-118) and the Research Ethics Committee at Japan Community Health Care Organization Hoshigaoka Medical Center (IRB-HG2146). Hoshigaoka Medical Center obtained consent from all patients for the use of anonymized data from patients who are hospitalized for clinical research. Patients were also offered the opportunity to opt out, and the information was posted on the hospital’s official website.

Intervention

The intervention, named IRIS, began within 2 weeks of admission to the rehabilitation hospital, and it was maintained until discharge. For the ICT group, the therapist reported on patients’ rehabilitation progress to their families at least once every 2 weeks using videos and text and responded to questions from family members. The IRIS mainly consisted of a progress report on rehabilitation. Videos were sent to patients practicing standing and walking during physiotherapy, patients practicing ADL during occupational therapy, and patients testing their higher brain functions in speech-language pathology. The intentions and concerns of patients’ families were also included to facilitate decision-making. Videos were used to explain ways to help assist a patient. Patients’ families sent pictures of their

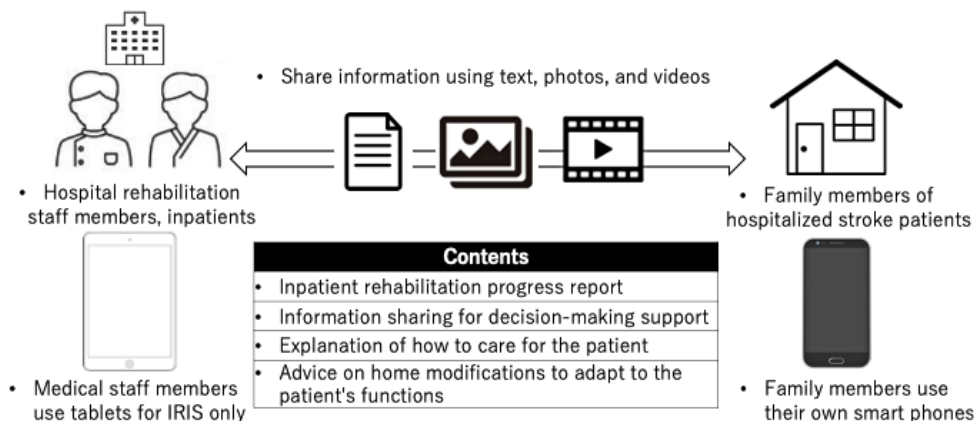
homes so that the physiotherapist in charge could suggest modifications to enable adaptation to patients’ functions. An overview of the IRIS is shown in Figure 1.

In addition, using IRIS, the medical staff interviewed the patient’s family members about the patient’s environmental factors and used these factors in setting the patient’s rehabilitation goals. For example, for a patient who lived alone during the day and had difficulty moving independently to the toilet, the patient’s family’s wishes were included when suggesting that the patient practice using a portable toilet. Additionally, in cases where the use of stairs was essential to enter the house, the need for stair climbing practice was identified and prioritized.

The information shared using IRIS between the health care provider and the patient’s family was also provided to the patient. The family learned about the patient’s rehabilitation process and informed the patient that the family expected the patient to improve. This information was used to encourage the patient’s rehabilitation motivation.

The Medical Care Station (MCS) application (Embrace Co., Ltd) was used to provide information. MCS is a security-conscious, “completely private” social networking service that shares information in a timeline format. Only authorized members can view MCS communications.

Figure 1. The overview diagram of Internet-Based Rehabilitation Information Sharing (IRIS).



Inpatient Rehabilitation

All patients received daily physical and occupational therapy, as well as speech and language therapy as needed. The total time commitment was a maximum of 3 hours per day. The program was determined by each in-charge therapist after evaluating the patient. The hospital held a face-to-face conference approximately 1 month after admission, and the medical staff informed patients’ families about the rehabilitation progress during their hospital stay.

Main Outcome

The main outcome was the degree of ADL improvement during hospitalization. The total FIM scores at the time of admission and discharge were evaluated by the occupational therapist in charge, and the difference between the 2 scores was defined as ADL improvement. In addition, data on patients’ age, sex, discharge destination, hospital stay, and the number of days

from onset to hospitalization were obtained from the medical records.

Characteristics of the Patient’s Family

In the ICT group, patient family information, including age, sex, relationship with the patient (spouse or child), and occupation, were obtained from the MCS.

Statistical Analysis

For univariate comparisons, the χ^2 test, uncorrelated 2-tailed *t* test, and Mann-Whitney *U* test were used. Multiple regression analysis (forced entry method) was performed to confirm the impact of ICT use on ADL improvement. In the analysis of the ICT and control groups, the independent variables were the presence of intervention, length of hospital stay, and number of days from onset to hospitalization.

Results

Control Group Selection

A total of 131 participants met the inclusion criteria during the study period. The patient results are presented in Table 1. In total, 16 groups of patients and families participated in the IRIS. The median (IQR) total FIM score on admission was 37.0 (28.8-79.3) in the ICT group and 75.0 (55.0-97.0) in the non-ICT

group, and patients who received IRIS reported significantly lower independence in ADL on admission ($P=.004$). In addition, 16 control participants were selected from the non-ICT group and matched to the ICT group using age, sex, motor FIM score at admission, and cognitive FIM score at admission as covariates (Figure 2). The total FIM score at admission for the control group was 40.5 (IQR 22.8-81.8), which was not significantly different from that of the ICT group ($P=.90$).

Table 1. Comparison of ICT and control groups by matching. P values are all based on comparisons with the ICT group.

Variable	ICT ^a group (n=16)	Control group (n=16)	P value	Non-ICT group (n=115)	P value
Age (years), mean (SD)	78.6 (7.2)	78.6 (8.2)	.96 ^b	77.3 (8.2)	.53 ^b
Sex, female, n (%)	6 (37.5)	5 (31.2)	>.99 ^c	50 (43.5)	.79 ^c
Type of stroke, n (%)			.45 ^c		.81 ^c
Ischemic	10 (62.5)	7 (43.8)		79 (68.7)	
Hemorrhagic	5 (31.2)	6 (37.5)		32 (27.8)	
Subarachnoid hemorrhage	1 (6.2)	3 (18.8)		4 (3.5)	
Discharge destination, home, n (%)	10 (62.5)	8 (50)	.72 ^c	85 (73.9)	.38 ^c
Length of hospital stay (days), mean (SD)	95.3 (37.4)	70.6 (33.5)	.06 ^b	66.0 (37.3)	.004 ^b
Onset to hospitalization (days), mean (SD)	31.4 (17.5)	30.9 (15.3)	.93 ^b	27.7 (15.7)	.38 ^b
Total FIM^d score (out of 126), median (IQR)					
Admission	37.0 (28.8-79.3)	40.5 (22.8-81.8)	.90 ^e	75.0 (55.0-97.0)	.004 ^e
Discharge	81.0 (60.3-105.0)	62.5 (29.5-109.5)	.21 ^e	105.0 (78.0-119.0)	.03 ^e
Difference	28.5 (20.3-53.0)	11.0 (2.8-30.0)	.02 ^e	22.0 (10.0-31.0)	.02 ^e
Motor FIM score (out of 91), median (IQR)					
Admission	21.5 (13.0-51.3)	20.5 (13.0-53.0)	.90 ^e	51.0 (31.0-66.0)	.003 ^e
Discharge	64.0 (38.8-76.3)	42.5 (16.0-80.0)	.14 ^e	79.0 (54.0-87.0)	.06 ^e
Difference	24.0 (17.0-46.0)	10.5 (3.0-25.8)	.03 ^e	20.0 (9.0-27.0)	.048 ^e
Cognitive FIM score (out of 31), median (IQR)					
Admission	19.0 (12.3-26.5)	20.0 (9.3-28.5)	.93 ^e	26.0 (20.0-32.0)	.01 ^e
Discharge	22.0 (16.3-29.0)	21.0 (11.3-30.0)	.78 ^e	28.0 (21.0-33.0)	.02 ^e
Difference	2.0 (0.0-5.0)	0.0 (0.0-1.8)	.29 ^e	0.0 (0.0-3.0)	.28 ^e

^aICT: information and communication technology.

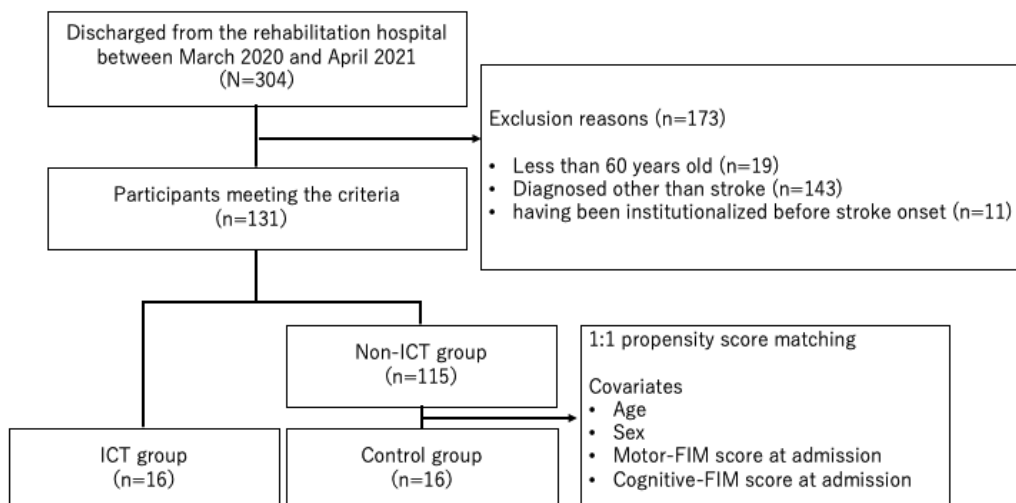
^bUnpaired 2-tailed t test.

^c χ^2 test.

^dFIM: Functional Independence Measure.

^eMann-Whitney U test.

Figure 2. Flow of the study participants. FIM: Functional Independence Measure; ICT: information and communication technology.



Main Outcome

The mean age of the patients was 78.6 (SD 7.2) and 78.6 (SD 8.2) years in the ICT and control groups, respectively. The median total FIM difference, which was the main outcome, was 28.5 (IQR 20.3-53.0) and 11.0 (IQR 2.8-30.0) in the ICT and control groups, respectively, and the ICT group showed significant improvement in ADL function ($P=.02$). The mean number of days from onset to hospitalization was 31.4 (SD 17.5) and 30.9 (SD 15.3) days for the ICT and control groups, respectively, which was not significantly different ($P=.93$). The

length of hospital stay—95.3 (SD 37.4) and 70.6 (SD 33.5) days for the ICT and control groups, respectively—showed a trend toward a longer hospital stay, but this result was not statistically significant ($P=.06$).

In the multiple regression analysis of the ICT and control groups, the unstandardized regression coefficients were 11.97 (95% CI 0.09-23.84) for ICT use, 0.19 (95% CI 0.03-0.36) for the length of hospital stay, and -0.37 (95% CI -0.72 to -0.02) for the number of days from onset to hospitalization. These results indicate that ICT use was independently and significantly associated with ADL improvement (see Table 2).

Table 2. Factors associated with activities of daily living improvement. Multiple regression analysis (forced imputation method) was used, with the dependent variable being the total Functional Independence Measure difference ($R^2=0.420$). The number of participants is the sum of those in the ICT^a and control groups ($n=32$).

Factor	B	β	95% CI	P value
Group (1: ICT group)	11.97	0.32	0.094-23.840	.048
Length of hospital stay (days)	0.19	0.37	0.031-0.356	.02
Onset to hospitalization (days)	-0.37	-0.31	-0.719 to -0.018	.04

^aICT: information and communication technology.

Characteristics of the Patient’s Family

Information on the 16 family members in the ICT group is as follows. The 16 family members of the ICT group included 2 (12%) spouses (aged 64 and 74 years; both were female) and

14 (88%) children (6 sons and 8 daughters). There were 2 (12%) children in their 30s, 7 (44%) in their 40s, and 5 (31%) in their 50s (Table 3). Additionally, 13 (81%) family members were working.

No adverse events, such as information leakage, were reported.

Table 3. Families' characteristics in the information and communication technology group.

Characteristic	Family member (n=16), n (%)
Age (years)	
30-39	2 (12)
40-49	7 (44)
50-59	5 (31)
60-69	1 (6)
70-79	1 (6)
Employment status	
Working	13 (81)
Not working	3 (19)

Discussion

Principal Findings

This study examined the effect of IRIS on family members to improve the ADL of patients with stroke who are hospitalized. The results showed that IRIS promoted patients' ADL improvement regardless of age, sex, motor and cognitive function at admission, or the length of hospital stay.

Comparison to Prior Work

In a previous study, a 4-day consecutive empowerment program for family members of patients with stroke who are hospitalized showed an improvement trend in patients at 2 weeks (during hospitalization) and significant improvement in patients' ADL at 2 months (after discharge) compared to that of the control group [17]. Therefore, interventions for family members of patients with stroke who are hospitalized may indirectly improve the patients' ADL. During the study period, inpatient visits were restricted to prevent the spread of COVID-19, so the control group families may have been less well informed than usual [18]. Therefore, we believe that the IRIS is an effective way to provide information, encourage the involvement of patients' families in the rehabilitation process, and improve the effectiveness of the rehabilitation program.

In the Cochrane Database, there is some very low-quality evidence that goal setting may improve some outcomes for adults receiving rehabilitation for an acquired disability [19]. Personalized care planning leads to improvements in certain indicators of physical and psychological health status [20]. By obtaining more information on environmental factors from the patient's family, IRIS was able to set personalized and appropriate goals, which may have contributed to improved patient functioning.

Living alone has been reported to be the strongest predictor of poststroke depression [21]. Living alone has also been reported to be a factor that leads to worse outcomes in inpatient rehabilitation after stroke. Furthermore, it was reported that the outcome of inpatient rehabilitation was better for those who lived with their children than for those who lived only with their spouses. This result was not due to differences in the time from stroke onset to hospital arrival [22], which may indicate that functional recovery was more effective in rehabilitation for

patients with cohabiting family members than those living alone, who were less likely to have recovery expectations from their family members. There is evidence that information improves patient and caregiver knowledge about stroke and reduces patient depression scores [23]. Additionally, feeling strongly supported by family members has been reported to improve motivation to exercise [24]. It is possible that communicating the patient's family's recovery expectations to the patient through the IRIS program may have improved the patient's motivation for rehabilitation and promoted ADL improvement.

Strokes often occur around the age of 70-80 years [25], and children of patients with stroke are often aged 40-50 years. Many family members support patients while working, but their busy schedules may make it difficult to both work and support the patients [26]. Moreover, documents related to inpatient care are difficult to understand and may stress patients' families. The web, however, makes it possible to share videos and thereby transmit information that is visually easy to understand. Patients' families do not need to worry about the time of the day when checking or sending information. Furthermore, the system can be used as a measure to restrict inpatient visits to prevent the spread of COVID-19. In the future, information sharing between hospital staff and patients' families using the web will likely become more common.

Strengths and Limitations

This study is the first to examine IRIS for family members of patients with stroke who are hospitalized to improve patients' ADL. Despite the importance of these findings, this study had a few limitations. First, this study was not a randomized controlled trial. Since we were not involved in the allocation process, we were unable to eliminate the effects of selection bias and unmeasured confounders. Family members of patients who want to share information via the web may be more likely to be proactive in supporting patients. Previous studies have reported that factors associated with ADL improvement in patients with stroke who are hospitalized include patients' age [27], sex [28], and motor and cognitive functions at the time of admission [29]. In this study, patients' age, sex, and motor function and cognitive function at admission were used as covariates for propensity score matching and selecting a control group. We also used the length of stay, which is an indicator of the degree of the rehabilitation provided, as a covariate in the

multiple regression analysis. Therefore, although this study was not a randomized controlled trial, we believe that we statistically adjusted for the confounders as much as possible. Second, limited information on patients' families was collected. In the future, we plan to investigate family members' understanding of patients, satisfaction with inpatient care, and psychological anxiety. Third, we were unable to evaluate patients' motivation for rehabilitation. It is unclear whether sharing information with patients' families via the web affects patients' motivation. Fourth, the study was conducted at a single institution, and the sample size was small. Therefore, it is necessary to conduct a

large-scale study to verify the generalizability of the study findings.

Future Research Directions

Considering the difficulty of providing information for patients' families due to inpatient visitation restrictions owing to COVID-19, we believe that the IRIS has a reasonable demand. Additionally, patients' families' responses to the IRIS were positive, and no adverse events were reported. Thus, it would be useful to continue implementing the IRIS to disseminate vital patient-related information to patients' families.

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Data Availability

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

Conflicts of Interest

None declared.

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Abbreviations

- ADL:** activities of daily living
- FIM:** Functional Independence Measure
- ICT:** information and communication technology
- IRIS:** Internet-Based Rehabilitation Information Sharing
- MCS:** Medical Care Station

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