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Original Paper

Using Smartwatches to Observe Changes in Activity During Recovery From Critical Illness Following COVID-19 Critical Care Admission: 1-Year, Multicenter Observational Study

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Abstract

Background: As a sequela of the COVID-19 pandemic, a large cohort of critical illness survivors have had to recover in the context of ongoing societal restrictions.

Objective: We aimed to use smartwatches (Fitbit Charge 3; Fitbit LLC) to assess changes in the step counts and heart rates of critical care survivors following hospital admission with COVID-19, use these devices within a remote multidisciplinary team (MDT) setting to support patient recovery, and report on our experiences with this.

Methods: We conducted a prospective, multicenter observational trial in 8 UK critical care units. A total of 50 participants with moderate or severe lung injury resulting from confirmed COVID-19 were recruited at discharge from critical care and given a smartwatch (Fitbit Charge 3) between April and June 2020. The data collected included step counts and daily resting heart rates. A subgroup of the overall cohort at one site—the MDT site (n=19)—had their smartwatch data used to inform a regular MDT meeting. A patient feedback questionnaire and direct feedback from the MDT were used to report our experience. Participants who did not upload smartwatch data were excluded from analysis.

Results: Of the 50 participants recruited, 35 (70%) used and uploaded data from their smartwatch during the 1-year period. At the MDT site, 74% (14/19) of smartwatch users uploaded smartwatch data, whereas 68% (21/31) of smartwatch users at the control sites uploaded smartwatch data. For the overall cohort, we recorded an increase in mean step count from 4359 (SD 3488) steps per day in the first month following discharge to 7914 (SD 4146) steps per day at 1 year ($P=.003$). The mean resting heart rate decreased from 79 (SD 7) beats per minute in the first month to 69 (SD 4) beats per minute at 1 year following discharge ($P<.001$). The MDT subgroup's mean step count increased more than that of the control group (176% increase vs 42% increase, respectively; +5474 steps vs +2181 steps, respectively; $P=.04$) over 1 year. Further, 71% (10/14) of smartwatch users at the MDT site and 48% (10/21) of those at the control sites strongly agreed that their Fitbit motivated them to recover, and 86% (12/14) and 48% (10/21), respectively, strongly agreed that they aimed to increase their activity levels over time.

Conclusions: This is the first study to use smartwatch data to report on the 1-year recovery of patients who survived a COVID-19 critical illness. This is also the first study to report on smartwatch use within a post-critical care MDT. Future work could explore the role of smartwatches as part of a randomized controlled trial to assess clinical and economic effectiveness.

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KEYWORDS

COVID-19; telemedicine; rehabilitation; critical illness; smartphone; digital health; mobile health; remote therapy; device usability

Introduction

Worldwide, the COVID-19 pandemic has resulted in a large cohort of patients presenting to critical care units with acute lung injury requiring protracted ventilatory support. In the United Kingdom alone, from March 2020 to the time of writing, a total of 44,898 patients with confirmed COVID-19 have been admitted to critical care [1].

The patients admitted to intensive care were typically male, were aged over 70 years [2], and spent on average 14 days in critical care [3]. Such patients are at significant risk of postintensive care syndrome [4,5], with studies suggesting that a constellation of physical and psychological problems are likely to persist over a protracted period [6,7].

To date, there is a lack of detailed, long-term outcome data for survivors of COVID-19 critical illness. Furthermore, rehabilitation has been challenged by social distancing, the attenuated availability of health care services, the isolation of survivors from their social support groups, restricted interventions involving face-to-face treatment, and the closure of rehabilitation settings in the community.

Smartwatch use has been rapidly growing, especially over the last 5 years [8]. Smartwatches primarily rely on the pulse wave signal derived from a photoplethysmogram [9] to estimate heart rate. There have been a large number of studies validating wrist-based heart rate measurements in diverse settings [10-14], and several studies have shown that wrist-based wearables provide useful estimates, especially those for resting and low heart rates [15,16]. Fitbit watches use patented photoplethysmogram technology (PurePulse; Fitbit LLC) [17] and have shown reasonable performance and accuracy [12-15,18]. Similarly, Fitbit-estimated, wrist-based step counts have been acceptably accurate in free-living settings, though less so when users exercise vigorously [19]. There is an emerging research base on the health care applications of smartwatches [20], including the surveillance of influenza symptoms [21], the identification of atrial fibrillation [22], chronic airway disease management [23], cardiac rehabilitation [24], and presurgical optimization [25]. In rehabilitation medicine, the use of smartwatch technology provides the

possibility of observing the recovery of patients remotely and aiding recovery via detailed, real-time data [26]. Qualitative data suggest that these devices can motivate patients to recover [27]. Although the use of smartwatch devices is evolving and increasing [20], their routine use in this way remains limited.

This study aimed to (1) use smartwatches (Fitbit Charge 3; Fitbit LLC) to monitor changes in the step counts and heart rates of a cohort of participants who survived an admission to critical care during the first wave of the COVID-19 pandemic (April to June 2020) and (2) explore the use of these devices within a rehabilitation setting and report on our experiences with this.

Methods

Ethics Approval

Ethical approval was granted by Health Research Authority and Health and Care Research Wales (Yorkshire & The Humber – Bradford Leeds Research Ethics Committee reference number: 20/YH/0157 IRAS 280041).

Recruitment

Study Design and Setting

We conducted a prospective, multicenter observational trial in UK critical care units. The original protocol for this study was published previously [28].

Participants

A total of 50 participants were recruited from 8 UK hospitals in South East England (Figure 1). Adult participants who required invasive positive pressure ventilation or noninvasive ventilation and experienced at least moderate lung injury, which was defined as an arterial oxygen partial pressure to fractional inspired oxygen ratio of ≤ 26.6 kPa [29], as a result of confirmed COVID-19 were recruited. The exclusion criteria were few and primarily included the lack of a device that was able to host the Fitbit app. The sample size was determined at study inception based on feedback from medical teams in critical care units and based on the current size of their caseloads that met the inclusion criteria and were in line with other feasibility studies of a similar nature [24-27,30].

Figure 1. Recruitment sites for COVID-OR. "MDT Site" indicates participants who receive remote monthly support from the multidisciplinary team based on their smartwatch data. All other sites are control sites. COVID-OR: Coronavirus Disease-Observation of Recovery; MDT: multidisciplinary team; NHS: National Health Service.



Smartwatch Data

At each site, participants were approached at or shortly after discharge from higher dependency care between April and June 2020. Participants were recruited by a physiotherapist or critical care physician. Each site had a local research team for recruiting participants and setting up the smartwatches. Participants were assigned an anonymized study reference ID number, which was used for all data collection procedures. Demographic data were collected for each participant. For the purposes of sample characterization, further data were collected regarding the comorbidities and treatments received during participants' critical care admission (including the severity of lung injury, the length of stay, and the respiratory support and other organ support received).

Fitbit Charge 3 watches were given to each patient and linked to their anonymized study reference ID numbers. Data were synced to the Fitbit app and then periodically downloaded to a central study database. Participants were asked to wear their smartwatch for as long as they felt able and to ideally aim to use the smartwatch continuously. Participants were given a contact number for a member of the research team that they could use to obtain help for using their smartwatch.

The smartwatch data extracted included daily step count and daily resting heart rate in beats per minute, which was defined as the lowest mean heart rate recorded during a period of inactivity of at least 30 minutes [31]. Further descriptions of the methods via which these smartwatches collect these data are included in [Multimedia Appendix 1](#).

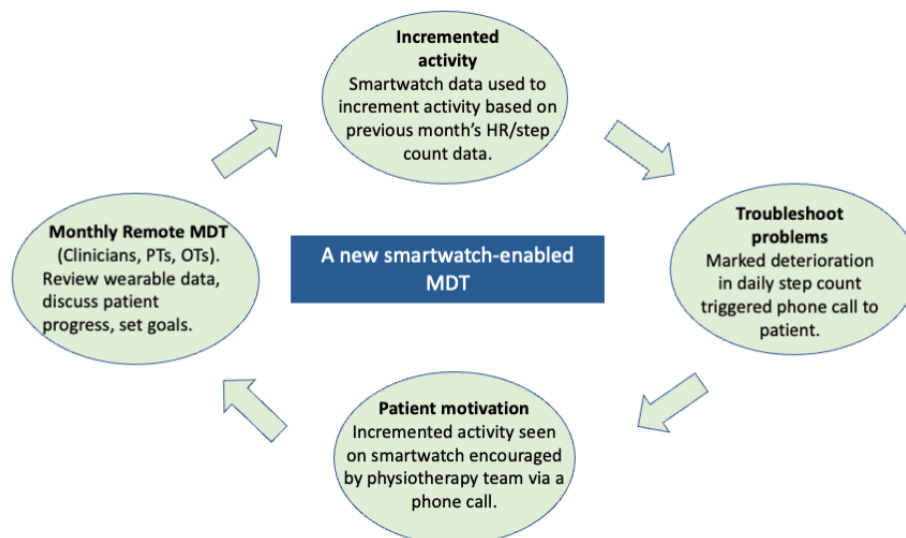
Smartwatch Usability and Use Within the Multidisciplinary Team

At one site, which was called the *MDT site* ([Figure 1](#)), targeted multidisciplinary team (MDT) meetings (including critical care doctors, physiotherapists, occupational therapists, and a nurse) were held monthly for a subset of the overall cohort. These patients had their individual smartwatch data interrogated and reviewed by the MDT each month, and the physiotherapy team used these meetings to determine future exercise plans and rehabilitation goals. A member of the MDT contacted the patients before and after the meetings to inform the MDT about patients. Afterward, feedback was provided to patients with identified issues, and adaptations to rehabilitation plans were agreed on by patients and the MDT ([Figure 2](#)). Feedback from members of the MDT was used to assess the feasibility of incorporating smartwatch devices into the post-critical care rehabilitation MDT.

At all other sites (control sites), usual follow-up care was provided without feedback based on the smartwatch data and without MDT intervention.

One-year follow-up visits were completed by a member of the research or physiotherapy team at each site. These were primarily completed via face-to-face or telephone appointments. A patient feedback questionnaire ([Multimedia Appendix 2](#)) was completed at this point, and a review of perceptions on using the smartwatches was conducted to assess usability.

Figure 2. The smartwatch-enabled MDT model. HR: heart rate; MDT: multidisciplinary team; OT: occupational therapist; PT: physiotherapist.



Adherence

Smartwatch use was defined as participants using their watch for a minimum of 1 month. A month was included for analysis if there were over 10 days of data for that month. A data set was considered complete at 1 year if there were data for every month of the year. Patients were considered adherent if they used their smartwatch for any month and were excluded from analysis when there were no data uploaded for any month. Participants were included for comparative analysis at 1 year if data for month 1 and month 12 were present.

Statistical Analysis

All data were analyzed using R (version 4.0.5; R Foundation for Statistical Computing), and raw data were collected in Microsoft Excel.

P values were calculated to determine statistical significance, and actual values were included in analyses unless *P* was $<.001$. Data were tested for normality via Shapiro-Wilk testing, and significance was tested by using a 2-tailed Student *t* test.

Patient and Public Involvement

Feedback based on patients' experiences with the recovery from critical illness was incorporated via patient research champions to inform the design of this study. The COVID-OR (Coronavirus

Disease-Observation of Recovery) study steering group had 2 previous patients on the panel that helped to tailor this study to patients' preferences, and the steering group will help disseminate the results via a patient network of critical care survivors.

Results

Sample Characterization

The participants who were recruited across sites in South East England totaled 50. The smartwatch users who were included for analysis totaled 35 participants (MDT site: $n=14$; control sites: $n=21$).

For the full cohort, the mean age was 57 (SD 10) years (Table 1), 74% (26/35) of participants were of White ethnicity, and 54% (19/35) had at least 1 comorbidity. The mean length of critical care stay was 18 (SD 16) days, and the mean length of hospital stay was 30 (SD 20) days. There were no statistically significant differences in age ($P=.22$), comorbidities ($P=.35$), and the length of critical care stay ($P=.37$) or hospital stay ($P=.46$) between the MDT and control groups. Similarly, there were no statistically significant demographic differences between smartwatch users ($n=35$) and nonusers ($n=15$; Multimedia Appendix 3).

Table 1. Demographic comparison of multidisciplinary team (MDT) site-supported participants and control site-supported (all other sites) participants.

Characteristic	MDT site participants (n=14)	Control site participants (n=21)
Age (years), mean (range)	61 (49-73)	57 (35-77)
Ethnicity, n		
White (English, Irish, and any other White background)	9	17
Asian and Asian British (Indian, Pakistani, Bangladeshi, Chinese, and any other Asian background)	4	3
Black, African, Caribbean, and Black British (any other Black, African, or Caribbean background)	1	1
ICD-10^a comorbidities, n		
None	7	9
Hypertension	4	7
Asthma	3	5
Admission weight (kg), mean (range)	84 (53-106)	96 (65-150)
Length of stay (days), mean (range)		
Intensive care unit	17 (5-36)	21 (6-67)
Hospital	28 (15-49)	33 (10-97)

^aICD-10: International Classification of Diseases, Tenth Revision.

Smartwatch Data

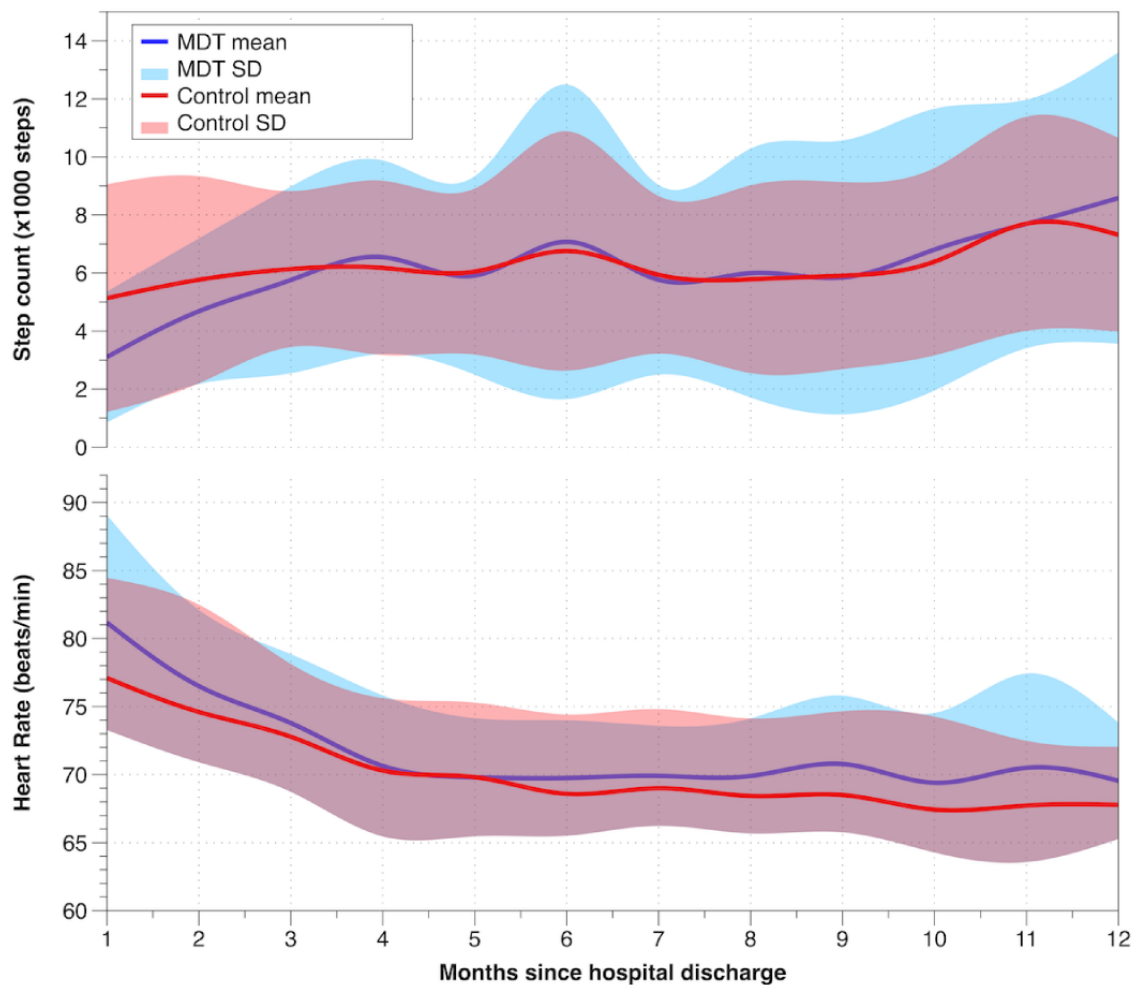
Step Count

The full cohort had an average of 4359 (SD 3488) steps per day in the first month following discharge. At 1 year, this had increased to an average of 7914 (SD 4146) steps per day ($P=.003$). Participants had increased their mean step count by 37% (+1630 steps; $P=.04$) from 0 to 3 months following

discharge. At 12 months, the mean step count increased by 82% (+3555 steps; $P=.003$) when compared with that for month 0.

MDT site participants' mean step count increased more than that of the control site participants (176% increase vs 42% increase, respectively; +5474 steps vs +2181 steps, respectively; $P=.04$) over 1 year. However, the MDT group was less active than the control site group in the first month (3107 steps vs 5133 steps), and increases were similar between the two groups until month 12 (8581 steps vs 7314 steps; [Figure 3](#)).

Figure 3. Monthly step counts and heart rates after hospital discharge for MDT-supported participants (blue line: mean; light-blue area: SD) and non-MDT, control site–supported participants (red line: mean; light-red area: SD). MDT: multidisciplinary team.



Daily Resting Heart Rate

Heart rates averaged 79 (SD 7) beats per minute in the first month following discharge and 69 (SD 4) beats per minute at 1 year following discharge for the full cohort. Participants had a reduction in mean heart rate of 7% (–6 beats/minute; $P < .001$) at 3 months after data collection and a total reduction in mean heart rate of 13% (–10 beats/minute) by 12 months ($P < .001$; Figure 3). There was no significant difference in heart rate reductions between MDT site (–11 beats/minute; 14% reduction) and control site (–8 beats/minute; 10% reduction) participants over the 1-year period ($P = .22$).

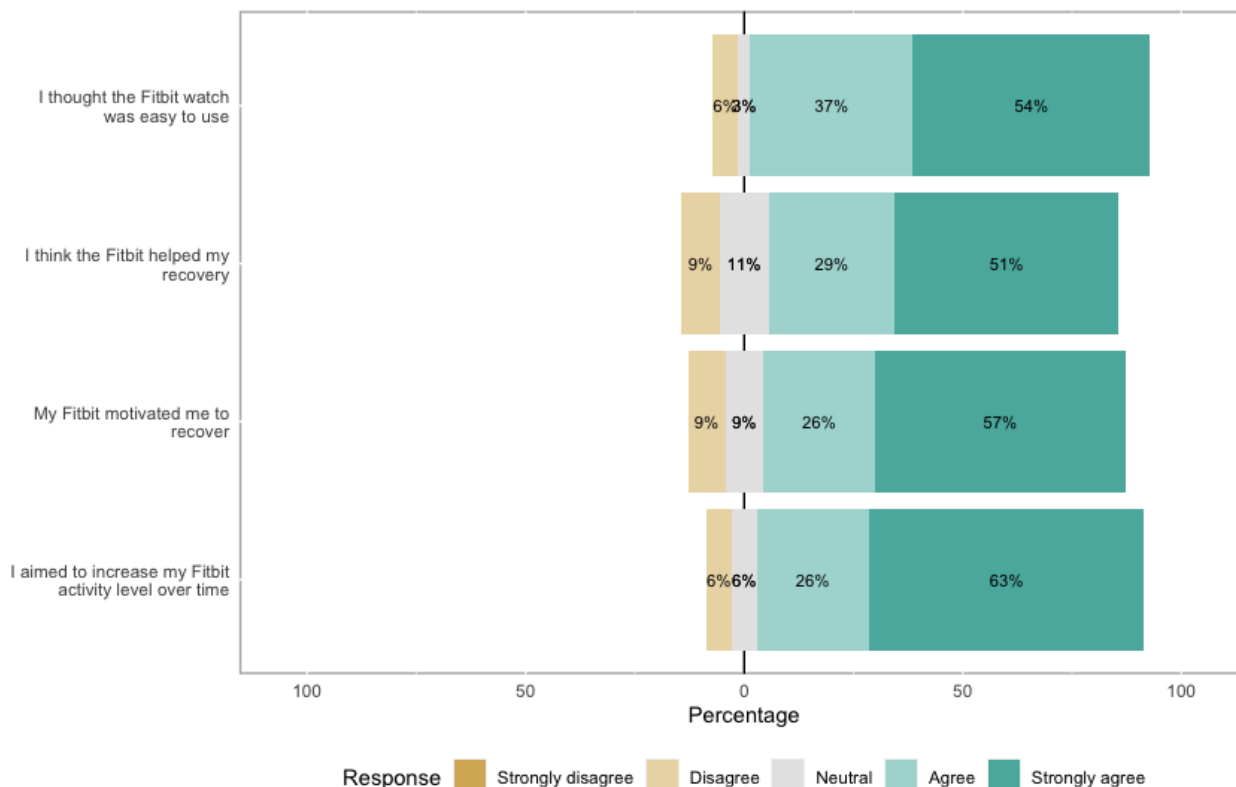
Smartwatch Usability and Use Within the MDT

The 1-year review questionnaire revealed that 91% (32/35) of smartwatch users agreed or strongly agreed that their smartwatch was easy to use, 80% (28/35) felt that smartwatches helped them and motivated them to recover, and 83% (29/35) aimed to increase their activity level over time (Figure 4). Participants

at the MDT site reported more frequently that they used their smartwatches to help them increase their activity over time (10/14, 71%) and felt that their smartwatch provided more motivation to recover (12/14, 86%) when compared with the control site participants (10/21, 48% and 10/21, 48%, respectively; Multimedia Appendix 4).

In the cohort whose smartwatch data were used to inform the rehabilitation MDT, a sudden reduction in step count among 3 separate participants raised a concern that could be addressed by the MDT. These participants initially received a telephone call to enquire about this reduction in step count. They were then referred to specialist services as required. This prompted the rapid recognition of specific patient problems prior to the patients self-reporting the problem to a clinician. Examples of such problems include acute joint inflammation and myocardial ischemia. Further feedback from the MDT members suggested that participants in the MDT subgroup felt supported and reassured by the observations of the clinical team, and this positively improved participants' recovery.

Figure 4. Smartwatch review questionnaire (n=35).



Adherence

The adherence rates for smartwatch use were 70% (35/50) in the overall cohort, 74% (14/19) in the MDT group, and 68% (21/31) at the control site (Table 2). Of the 35 participants included for analysis, 12 (34%) had a complete data set with activity data and heart rate recorded for every month of the

1-year period. Further, 25 patients had data for the first and last months of this study. For the 23 participants with incomplete data sets, the average number of months with data was 7 for both step count and heart rate. Additionally, 2 watches failed and were returned to the manufacturer, and 1 watch strap broke, which rendered a user unable to wear their watch until another was provided.

Table 2. Comparison of smartwatch users and nonusers by site.

Characteristic	Overall cohort (N=50)	Multidisciplinary team site participants (n=19)	Control site participants (n=31)
No smartwatch use (excluded from analysis), n (%)	15 (30)	5 (26)	10 (32)
Adherent to smartwatch use, n (%)	35 (70)	14 (74)	21 (68)
Complete data set at 1 year, n (%)	12 (24)	4 (21)	8 (26)

Discussion

Principal Findings

This multicenter study demonstrated that smartwatches can be used to observe a significant increase in participants’ daily step counts over a 12-month recovery period from COVID-19–induced critical illness. This study also provides information on the use of a remote critical care rehabilitation MDT that used smartwatch data to support patient recovery. Smartwatches were perceived to be user-friendly, were well tolerated, and added value by providing rapid feedback to the MDT. On 3 occasions, the smartwatch data provided actionable data to the MDT that triggered referrals to other specialties.

Participants were discharged from hospitals after critical care admissions and significant deconditioning, and step counts were

well below those of active adults (8000 to 10,000 steps per day) [32,33] and those found to be associated with a decreased risk of all-cause mortality [34]. Capturing this trajectory of improvement via the smartwatches provided data that suggest physiological recovery and are reassuring for patients with severe illness.

This study demonstrated that smartwatches can allow monitoring of physical activity remotely, though a considerable number of participants, despite perceiving their devices to be easy to use, did not use them regularly. This presents a limitation to this study but also adds important information to critical care rehabilitation literature, and future studies might need to include a similar dropout rate when using smartwatches in a similar cohort or assessing a smartwatch intervention. Our smartwatch usage rates are broadly similar to those of previous studies

[35,36], though there were no identified studies with a similar cohort that allowed for direct comparisons of use.

Device use was similar between the MDT site and control sites and suggested that some participants were not motivated to use their smartwatch despite regular reminders from a member of the MDT. The reasons for inadequate data included the infrequent use of the smartwatch; hardware failure; the failure to sync data despite participants using the watch; and lastly, participants not wearing the device at night.

Although the quantitative results suggested limited differences between the MDT subgroup and control groups, the feedback from participant feedback questionnaires suggested an increased perception that the smartwatches provided motivation for recovery and for increasing activity levels over time in the MDT site group. Further, while we acknowledge that recovery is a complex phenomenon and that, similarly, an MDT is a complex intervention, these responses might provide insight into an intervention group that could be encouraged to become fitter via the use of smartwatches.

Comparison With Prior Work

Although the use of smartwatches is increasing [20] and the adoption of digital technology during the COVID-19 pandemic has become widespread [37], many related studies adopt technology for diagnosis [38], surveillance [39], and the prevention of disease, with few targeting technology for rehabilitation, empowerment, or patients' engagement with rehabilitation. To our knowledge, this is the first study of its kind to use smartwatches in this way for COVID-19 survivors. One study [40], which is in the early recruitment phase, is looking to evaluate the feasibility of delivering a remotely monitored rehabilitation program for critical care survivors with COVID-19.

There are limited reports of 1-year outcome data for post-critical care survivors with COVID-19. However, data from 1-year outcome studies are in line with our data, and such studies have reported significant recovery from COVID-19 illness [41], albeit in survivors who vary widely in terms of disease severity.

Strengths and Limitations

First, the resource limitations involved in recruitment during the first wave of a global pandemic resulted in little data being

available regarding the number of patients who were initially approached but declined to participate in this study. Centers approached as many participants as their resources allowed, and despite our demographic data suggesting that our participant samples were representative of the critical care population at the time, the little data we have regarding the number of initially approached participants and those who declined to participate may limit the generalizability of our results.

Second, in a multicenter observational study using wearable technology during a pandemic, missing data are inevitable. The management of these missing data was challenging and was carefully considered. We believe that our data, which were collected for at least 10 days in a given month, were representative of the sample, especially given the high sampling frequency (amount of data collected per minute) of the smartwatches.

Future Directions

This study explored the use of a smartwatch-enabled MDT, and the next steps should be to robustly assess clinical effectiveness and cost-effectiveness in an adequately powered randomized controlled trial. The analysis of patients' perceived recovery and smartwatch-assessed activity levels in a larger study would also provide further insight into the use of smartwatch devices. Overall, this smartwatch-assisted approach could lend itself to other clinical contexts where physical optimization is crucial, such as perioperative settings for those undergoing major surgery.

Conclusion

Smartwatches can be used to observe an increase in activity among patients following hospital admission with COVID-19 critical illness. The observed trend in daily step counts was encouraging, given the severity of the illness and the level of deconditioning at hospital discharge. Though a considerable number of participants did not use their smartwatches as intended, the technology was used to support the care delivered to participants in a remote MDT setting and was able to detect significant changes in activity levels. Further work is required to assess the clinical effectiveness and cost-effectiveness of this intervention and whether it can result in improved patient outcomes and quality of life.

Acknowledgments

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Data Availability

Smartwatch data are available on request from the lead author.

Authors' Contributions

AH, TL, BH, DF, AR, and LH contributed to the concept and design of this study. AH, TL, OC, BH, MKS, AR, and LH were responsible for the acquisition, analysis, and interpretation of data. AH, TL, DF, ACG, CK, AR, and LH drafted the manuscript. DF, TL, CK, AR, and LH were responsible for funding acquisition.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Further smartwatch data acquisition information.

[[DOCX File , 14 KB - rehab_v9i2e25494_app1.docx](#)]

Multimedia Appendix 2

Smartwatch assessment questionnaire.

[[DOCX File , 13 KB - rehab_v9i2e25494_app2.docx](#)]

Multimedia Appendix 3

Demographic comparison of users versus nonusers of smartwatches.

[[DOCX File , 16 KB - rehab_v9i2e25494_app3.docx](#)]

Multimedia Appendix 4

Smartwatch response questionnaire by site.

[[DOCX File , 96 KB - rehab_v9i2e25494_app4.docx](#)]

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Abbreviations

BASEM: British Association of Sports and Exercise Medicine

COVID-OR: Coronavirus Disease-Observation of Recovery

MDT: multidisciplinary team

NHS: National Health Service

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Original Paper

Rehabilitation of Upper Extremity by Telerehabilitation Combined With Exergames in Survivors of Chronic Stroke: Preliminary Findings From a Feasibility Clinical Trial

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Abstract

Background: Exergames are increasingly being used among survivors of stroke with chronic upper extremity (UE) sequelae to continue exercising at home after discharge and maintain activity levels. The use of virtual reality exergames combined with a telerehabilitation app (VirTele) may be an interesting alternative to rehabilitate the UE sequelae in survivors of chronic stroke while allowing for ongoing monitoring with a clinician.

Objective: This study aimed to determine the feasibility of using VirTele in survivors of chronic stroke at home and explore the impact of VirTele on UE motor function, quantity and quality of use, quality of life, and motivation in survivors of chronic stroke compared with conventional therapy.

Methods: This study was a 2-arm feasibility clinical trial. Eligible participants were randomly allocated to an experimental group (receiving VirTele for 8 weeks) or a control group (receiving conventional therapy for 8 weeks). Feasibility was measured from the exergame and intervention logs completed by the clinician. Outcome measurements included the Fugl-Meyer Assessment-UE, Motor Activity Log-30, Stroke Impact Scale-16, and Treatment Self-Regulation Questionnaire-15, which were administered to both groups at four time points: time point 1 (T1; before starting the intervention), time point 2 (after the intervention), time point 3 (1 month after the intervention), and time point 4 (T4; 2 months after the intervention).

Results: A total of 11 survivors of stroke were randomized and allocated to an experimental or a control group. At the onset of the COVID-19 pandemic, participants pursued the allocated treatment for 3 months instead of 8 weeks. VirTele intervention dose was captured in terms of time spent on exergames, frequency of use of exergames, total number of successful repetitions, and frequency of videoconference sessions. Technical issues included the loss of passwords, internet issues, updates of the system, and problems with the avatar. Overall, most survivors of stroke found the technology easy to use and useful, except for 9% (1/11) of participants. For the Fugl-Meyer Assessment-UE and Motor Activity Log-30, both groups exhibited an improvement in >50%

of the participants, which was maintained over time (from time point 3 to T4). Regarding Stroke Impact Scale-16 scores, the control group reported improvement in activities of daily life (3/5, 60%), hand function (5/5, 100%), and mobility (2/5, 40%), whereas the experimental group reported varied and inconclusive results (from T1 to T4). For the Treatment Self-Regulation Questionnaire-15, 75% (3/4) of the experimental group demonstrated an increase in the autonomous motivation score (from T1 to time point 2), whereas, in the control group, this improvement was observed in only 9% (1/11) of participants.

Conclusions: The VirTele intervention constitutes another therapeutic alternative, in addition to conventional therapy, to deliver an intense personalized rehabilitation program for survivors of chronic stroke with UE sequelae.

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KEYWORDS

stroke; rehabilitation; virtual reality; video games; telerehabilitation; upper extremity; motivation; mHealth; mobile health; personalized care; stroke rehabilitation

Introduction

Background

Many survivors of stroke experience sequelae in the upper extremity (UE; eg, weakness, loss of coordination, and nonuse syndrome) [1], which may affect activities of daily living in the long term [2]. Exergames are increasingly being used among survivors of stroke for different functional skills (eg, physical activity, UE exercises, mobility, and balance) in various practice settings (eg, rehabilitation centers, hospitals, clinics, community health centers, and homes) [3]. Given the chronic nature of stroke, exergames present a relevant solution to continue exercising at home after discharge to maintain physical function and activity levels.

Exergames: Types and Efficacy

Two main types of exergames have been described in the literature: commercially available off-the-shelf systems and customized systems [4,5]. Commercially available off-the-shelf systems, such as Nintendo Wii [6], Sony Playstation EyeToy games [7], Xbox 360 Kinect [8], and new technologies (the Xbox Series X [9] and Xbox one X [10]) present simple solutions for real-time video capture at a low cost (Xbox 360 costs US \$250) [11], which encourages their adoption in clinical studies, especially when home interventions are considered [5].

Customized systems are generally designed through research and use cutting-edge technology to create a virtual environment, such as the Computer Assisted Rehabilitation Environment (Motek) [12] or the Interactive Rehabilitation Exercise (IREX; Gesture Tek) System 2D [13]. Compared with commercially available off-the-shelf systems, these technologies offer personalized game settings (speed, range of movement, and number of repetitions). Indeed, environments of customized exergames offer conditions of practice similar to those of the physical world, allowing task-specific activities (eg, in IREX, placing boxes on different shelves, catching a ball instead of a soccer goalkeeper, and juggling balls) and mass repetition of the movement, which may promote neuroplasticity [14].

Although customized exergames can be expensive (eg, the price of the IREX system can cost >US \$15,000) and accessible only through specialized rehabilitation centers (eg, the Computer Assisted Rehabilitation Environment requires a large space and

supervision) [15], some customized commercial systems can be more accessible to the population and only require a readily available Kinect camera to capture movement, in addition to computer and internet access [4], such as Doctor Kinetic (Doctor Kinetic), SaeboVR (Saebo), VirtualRehab (Evolv), and Jintronix (Jintronix).

A recent meta-analysis by Aminov et al [16] showed statistically significant efficacy of both types of exergames (customized vs commercially available off-the-shelf systems) in improving UE motor function (eg, Fugl-Meyer Score), activity (eg, Box and Blocks Test), and social participation (eg, Motor Activity Log-30 [MAL-30]) when compared with conventional therapy. Commercially available systems demonstrated a low mean effect size (Hedges g 0.33, 95% CI 0.14-0.51; $P=.01$), whereas customized exergames showed a moderate mean effect size (Hedges g 0.58, 95% CI 0.41-0.76; $P=.01$) [16]. During the follow-up periods (4-6 weeks and 8-26 weeks), the authors observed maintenance of these gains with weak to moderate effects on function and activity, and small to nonsignificant effects on social participation [16].

Overall, exergames offer several advantages compared with conventional therapy (eg, mass repetitions, feedback on activity, and motivation), which could explain the efficacy of these interventions in several meta-analyses [15-20]. Several neuroscience studies have highlighted the ability of virtual reality (VR) to stimulate motor learning in the context of stroke [14,21,22]. Moreover, Maier et al [19] explained the superior efficacy of customized exergames compared with commercially available systems based on the presence of more elements promoting neuroplasticity (in 11/22, 50% of studies using customized systems), such as varied practice, feedback (eg, score, encouragement, and real-time visualization of the hand), increasing difficulty, or specific task practice. Given the promising potential of customized exergames, it is worthwhile to consider implementing them at the homes of survivors of stroke to optimize the recovery of persistent UE sequelae and maintain gains over time.

Telerehabilitation Combined With Exergames

Telerehabilitation refers to the use of information and communication technology that provides remote rehabilitation [23]. Considering the context of the COVID-19 pandemic, telerehabilitation has been ideal to maintain the provision of

rehabilitation services to those who need it most (older adults, people with difficulty accessing rehabilitation services, and people with deficits). The use of customized exergames combined with telerehabilitation may be an interesting alternative for rehabilitating UE deficits in survivors of chronic stroke while allowing for ongoing monitoring. When considering home interventions, exergames were usually provided with no supervision [24,25] or only follow-up sessions by telephone [26-28], which may have left the window open to compensation, mismatch of difficulty progression and improvement, a decrease in motivation [29], and feelings of loneliness [30]. In addition, exergames using the Kinect camera aimed at UE rehabilitation mainly offer exercises for the shoulder and elbow, with no emphasis on hand exercises. For example, the Kinect camera in the Jintronix exergame does not detect the hand and fingers; therefore, specific hand exercises are not provided [31]. Thus, the use of VR and customized exergames combined with telerehabilitation (eg, VirTele) is particularly relevant for providing a survivor of stroke-centered and exergame-based rehabilitation program [32,33]. The VirTele technology was previously tested with a survivor of stroke and was shown to be feasible for use in remote UE rehabilitation, which helped inform this study's protocol [33]. The preliminary efficacy results showed improvement in UE motor function, quantity and quality of use, and impact on quality of life, along with a high level of autonomous motivation [33], hence the interest in continuing to study the VirTele intervention with more participants. In addition, given the novelty of VirTele, information on the optimal dose, time since stroke, and criteria for identifying participants who may benefit the most from VirTele is needed.

Therefore, it is necessary to conduct a feasibility clinical trial to (1) determine the feasibility of using VirTele with survivors of chronic stroke at home and (2) explore the impact of VirTele on UE motor function, quantity and quality of use, quality of life, and motivation in survivors of chronic stroke compared with conventional therapy.

Methods

Study Design

This study was a 2-arm feasibility clinical trial. Until the study could be pursued, considering the rapid progress of VR and telerehabilitation technologies, we considered it relevant to present the findings collected during the first 9 months (before the onset of the COVID-19 pandemic) to inform future technology development and implementation.

Eligible participants were randomly allocated to an experimental group (receiving VirTele for 8 weeks) or a control group (receiving conventional therapy for 8 weeks). Block randomization (block size of 6) was used, given the time and access to materials (3 computers were available at a time). There were 42 phone inquiries, during which 29 potential participants were excluded. A total of 13 potential participants were assessed for eligibility by in-person screening, and 11 were retained and randomly allocated to the control or experimental groups.

Outcome measurements were administered to both groups at four time points: before starting the intervention (time point 1 [T1]), after the end of the 2-month intervention (time point 2 [T2]), 1 month later (time point 3 [T3]), and 2 months later (time point 4 [T4]). Research team members who were blinded to group assignment and not involved in the interventions (VirTele or conventional therapy) were responsible for the randomization. During the period of the COVID-19 pandemic, evaluators could not be blinded to the group assignment as the participants in the experimental group were evaluated using the telerehabilitation system used in VirTele intervention.

Ethics Approval

Before enrollment, all participants provided informed consent. This feasibility clinical trial was registered at ClinicalTrials.gov (NCT03759106) and was approved by the Research Ethics Board of the Center for Interdisciplinary Research in Rehabilitation of Greater Montreal (review number CRIR-1319-0218) [32]. This study was conducted according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines [34].

Participant Selection and Recruitment Strategy

Participants were recruited from the archives of rehabilitation centers (offline via a database of potential participants) and the community situated in Montreal (via the ClinicalTrials.gov website; Quebec, Canada) [32]. Eligible participants included survivors of stroke (ischemic or hemorrhagic) with residual UE impairment (Chedoke-McMaster arm component, scores 2-6), who stopped receiving rehabilitation services and were able to use the exergame system (eg, move the exergame avatar with the affected UE) [32]. Participants were excluded if they had severe cognitive or communication impairment, uncontrolled medical conditions (eg, cardiac condition), balance deficits, visual impairment, and UE mobility deficits (restricted movements or inability to move the avatar).

Eligibility was assessed by a research assistant. The study therapists included physiotherapists working in the Montreal area with experience in stroke rehabilitation.

Intervention Protocol

Experimental Group

The experimental group received the VirTele program. VirTele is an 8-week home rehabilitation program that includes Jintronix exergames [31] for UE rehabilitation and the Reacts app (Technologies innovatrices d'imagerie and Reacts) [35] to conduct videoconference sessions with clinicians. The experimental group received the VirTele equipment at home which included a computer, a Kinect camera, the Reacts app, the Jintronix software, and a USB internet key (if needed). Before starting the intervention, participants, including clinicians and survivors of chronic stroke, received a 1-hour training session to familiarize themselves with the Jintronix exergames and the Reacts app [32].

The Jintronix exergames included 5 games for UE training (*Space Race*, *Fish Frenzy*, *Pop Clap*, *Catch and Carry an apple*, and *Kitchen clean-up*) [31]. The clinician adjusted the difficulty parameters of each game remotely (eg, speed, duration, number

of repetitions, and direction of the trajectory) according to the participant's preference and functional abilities. An automated log system of the participant's performance during exergames was available on the Jintronix portal (eg, active time spent on exergames, scores, number of tasks completed, and amount of trunk compensation), allowing the clinician to monitor the participant's progression. The training protocol included five 30-minute sessions of Jintronix exergames per week for 8 weeks, targeting 20 hours of training overall.

The Reacts app [35], a videoconferencing platform, was used by the clinician to schedule videoconference meetings synchronized with sessions when the survivor of stroke was playing exergames to, for example, supervise the participant's performance, correct their posture, grade the difficulty based on performance, and match games to the participant's preferences and needs. Furthermore, the Reacts app was also used by the clinician to administer motivational interviewing [36].

Motivational interviewing is a person-centered approach used in behavioral interventions, which comprises behavior change techniques (BCTs) [37] and relational techniques [36]. Motivational interviewing has also been associated with the self-determination theory (SDT) [38]. The SDT is an approach that highlights the importance of autonomy and engaging individuals in their decision-making processes [39]. According to the SDT, clinicians can create a social environment that fosters autonomy (volition in one's actions), competence (belief in one's actions), and relatedness (a sense of belonging), which are 3 dimensions that are essential for promoting autonomous motivation and well-being [39]. In line with the SDT, survivors of stroke were given greater autonomy in determining their program by being able to choose from a range of exercises, being involved in grading the difficulty level of the games, and identifying strategies to increase the use of their affected UE in the long term through self-directed exercises and daily activities (eg, using the affected UE for dressing). In addition to exergames, supplementary exercises targeting hand fine motor skills and UE were suggested by the clinician to meet the individual goals of the survivors of stroke.

The videoconferencing sessions were scheduled as follows: 3 times a week for the first 2 weeks, twice a week for the following 2 weeks, and then once a week for the remaining 4 weeks to maintain motivation, ensure that the exercises are adequately tailored, and identify strategies to maintain the activity level of the UE after the study ended.

The training of the VirTele group was conducted at the participant's home after the installation of the equipment and lasted approximately 30 minutes to 1 hour. The training included a practical workshop on the use of the exergames and videoconferencing system. At the end of the training, a VirTele user manual (developed by the research team) was provided to the participants. Clinicians were trained in motivational interviewing [36] before the start of the study. A motivational interviewing guide (discussion plan) based on BCTs [37] and motivational techniques [36] was conceived by the research team and provided to the clinicians as a support tool that can help them choose strategies adapted to the client's needs.

For further information regarding the Reacts app, Jintronix exergames, and motivational interviewing, refer to the published study protocol [32] or previous case studies exploring VirTele use among survivors of stroke [33,40].

Control Group

In Canada, survivors of chronic stroke receive the Graded Repetitive Arm Supplementary Program (GRASP) [41] as a home rehabilitation training program to exercise the affected UE and use it in activities of daily living [2]. Therefore, the control group received the GRASP, which included exercises for the arm and hand (strengthening and range of motion) and functional activities targeting the UE [41]. The GRASP equipment included various sizes of Lego and wooden blocks, poker chips, clothes pegs, popsicle sticks and toothpicks, paper clips of various sizes, various jars, a weight of 0.45 kg, tennis ball, foam ball, plastic cup, modeling clay, knife and fork, and a target board [41]. The control group was invited to perform the GRASP exercises for 8 weeks, 5 days per week (30-minute sessions), targeting 20 hours of exercise overall (same as the experimental group) [32]. The time spent on the GRASP program, the number of sessions, and events such as fatigue and pain were reported at T2 after the intervention was terminated. No follow-up was provided during the 8-week intervention period, similar to conventional therapy. However, at the end of the study, the participants were offered one session with the clinician to discuss strategies for improving the use of UE in activities of daily living [32]. All participants received a 30-minute training to familiarize themselves with the GRASP equipment and exercises [32].

Outcomes Measures

Overview

At the start of the study, participant evaluations were conducted at the Center for Interdisciplinary Research in Rehabilitation of Greater Montreal in the presence of an evaluator. At the start of the COVID-19 pandemic, all research activities at the research site were suspended, and all evaluations were conducted remotely. For the experimental group, the evaluations were conducted using the Reacts videoconferencing system. For the control group, the evaluations were conducted either by phone or by a videoconferencing system available at the participant's home.

Feasibility Indicators

Given the novelty of VirTele, the feasibility data collected for the experimental group included the number and active time spent on exergame sessions, frequency and time spent by the clinician during videoconferencing sessions, exercise adherence, and resource use (equipment and technical support). These were obtained directly from the Jintronix and Reacts systems, as well as from intervention logs completed by the clinician at the end of each session. Safety indicators, such as the occurrence of adverse events (eg, pain, fatigue, and dizziness), were documented by the clinician and technical team [32]. Information about technical difficulties was obtained from a log completed by the clinicians and technical team [32]. Satisfaction with the technology and the interaction between the clinician and the survivor of stroke were assessed using the

Modified Short Feedback Questionnaire (adapted from Davis [42]) and the Health Care Climate Questionnaire (Perceived Autonomy Support) [43]. The Modified Short Feedback Questionnaire includes 2 subscales with 6 items, including a 7-point Likert-type scale ranging from *extremely likely* (score 1) to *extremely unlikely* (score 7). The first subscale evaluates the perceived usefulness (total score range 6-42; a lower score indicates that the technology is extremely useful) and the second subscale evaluates the perceived ease of use (total score range 6-42; a lower score indicates that the technology is extremely easy to use). The Health Care Climate Questionnaire includes 6 items with a 7-point Likert-type scale ranging from *strongly agree* (score 1) to *strongly disagree* (score 7), evaluating the need for support from the clinician, as perceived by the survivor of stroke (total score range 6-42; a high score indicates a higher perceived need for support from the clinician).

The process indicators were also documented to inform the validity of the study protocol and included data on recruitment rate (rate of participants per month and duration of recruitment) and retention rate (percentage of participants who completed the VirTele program) [32].

Performance Outcome Measure

The Fugl-Meyer Assessment-UE (FMA-UE) [44,45] motor function score was used as the primary outcome to evaluate UE motor function impairment. The FMA-UE motor function score [44,45] captures synergy, coordination, and sensorimotor functions (UE, wrist, and hand). The FMA-UE score has been shown to be valid in participants with stroke [46] and reliable for administration at a distance (video observation of an evaluator administering the FMA-UE on site) [47]. Given the COVID-19 pandemic, we tested the feasibility of administering the FMA-UE motor function at a distance with no on-site evaluator (video observation of the participant's performance), which was pretested in a previous study with a first survivor of stroke [33]. With respect to the various collection methods (by videoconferencing, by telephone, or on site), the FMA-UE motor function score was adjusted to 60 in all participants (experimental and control groups) by eliminating the parts of the scale that could not be evaluated remotely (reflex activity component).

Self-reported Questionnaires

The secondary outcomes included the Motor Activity Log-30 (MAL-30) [48,49], the Stroke Impact Scale-16 (SIS-16) [50,51], and the Treatment Self-Regulation Questionnaire-15 (TSRQ-15) [52].

The MAL-30 captures both quality (MAL-30 quality of use) and quantity of use (MAL-30 amount of use) of the affected UE in 30 daily activities (eg, writing on paper, brushing teeth, and using a fork or spoon for eating) [48,49]. The MAL-30 is reliable and valid for the poststroke population [53].

The SIS-16 is a 16-item questionnaire that captures the impact of stroke on the quality of life regarding hand function, activities

of daily living, and mobility [50,51]. The SIS-16 has demonstrated good reliability and validity [54].

The TSRQ-15, a 15-item questionnaire, captures different processes of motivation consistent with the SDT, including autonomous motivation, "where a person accepts changes and behaves autonomously"; amotivation or the "lack of motivation"; external regulation, "where a person behaves to obtain a reward, or avoid punishment"; and introjected regulation, "where a person behaves for pride or to avoid feeling guilty" [52]. The TSRQ-15 has demonstrated good reliability and validity across health care and rehabilitation contexts [52,55].

Data Analysis

Descriptive statistics (means, frequencies, and SDs) were used to (1) describe the sociodemographic characteristics of survivors of chronic stroke in both groups (age, sex, dominance, time since stroke, type of stroke, side of stroke, Chedoke-McMaster UE score, living arrangement, and ability to use a computer), (2) report feasibility indicators (eg, time spent on exergames, frequency of use, total number of repetitions, number of videoconferencing sessions, satisfaction with the technology, and perceived autonomy support), and (3) report impact indicators (frequency of participants who improved and worsened for each outcome measure). All outcome measure changes were compared with their minimal clinically important differences (MCIDs) when applicable [32].

Results

Overview

As research activities were suspended because of the COVID-19 pandemic, data collection, as scheduled in the research protocol [32], was delayed and extended. A total of 11 survivors of stroke were randomized and allocated to a treatment group (VirTele intervention or conventional therapy). The attrition rate was 18% (2/11), as 2 participants from the VirTele group did not complete the study (Figure 1). One of the patients was lost at follow-up because of an inability to commit time, and one discontinued the VirTele intervention because of difficulties using technology (unable to use the mouse or the keyboard and to start the computer).

Approximately 50% (2/4) of participants in the experimental group and 20% (1/5) of participants in the control group received their allocated treatment at the onset of the COVID-19 pandemic in Canada (March 2021). At that time, every research activity was suspended, and outcome measurements at T2 could not be administered. Thus, participants were offered the opportunity to pursue the allocated treatment for 3 months instead of 8 weeks and were evaluated remotely at the end of the 3-month intervention (T2), a month later (T3), and 2 months later (T4). The sociodemographic data are provided in Table 1.

Figure 1. Group allocation, follow-up, and data analysis. *Recruitment was interrupted because of the COVID-19 pandemic.

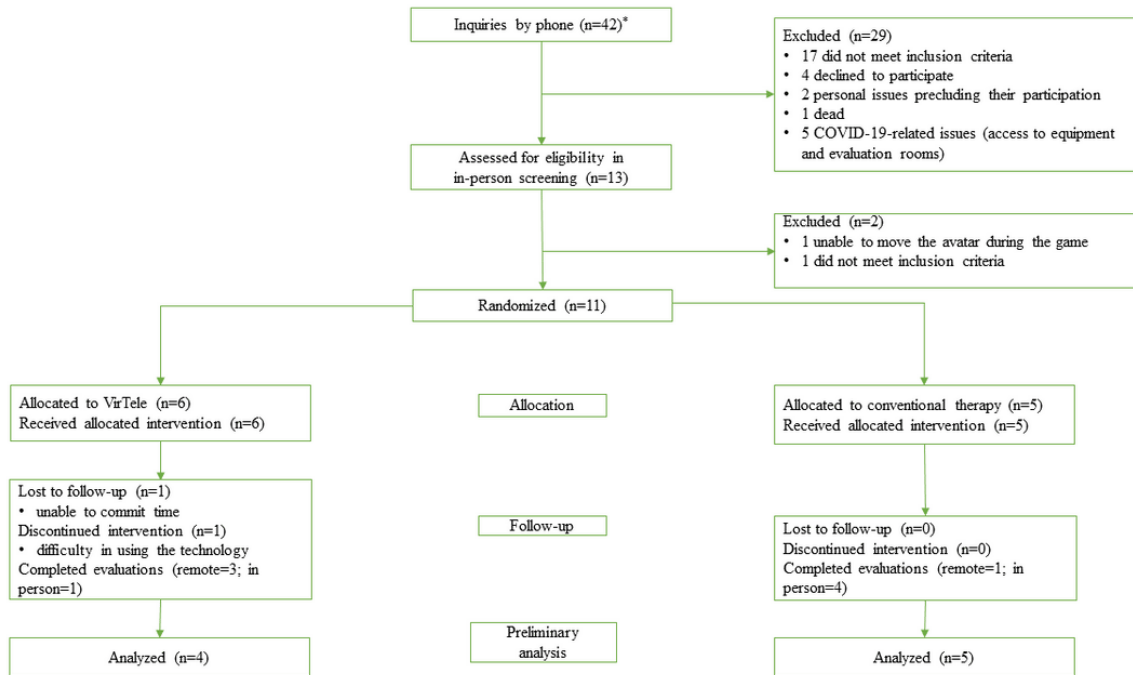


Table 1. Sociodemographic data (N=9).

Characteristics	VirTele group (n=4)	Control group (n=5)
Age (years), mean (SD)	57.8 (21.8)	56.4 (17.3)
Sex, n (%)		
Male	2 (50)	2 (40)
Female	2 (50)	3 (60)
Hand dominance, n (%)		
Right	3 (75)	3 (60)
Left	— ^a	2 (40)
Ambidextrous	1 (25)	—
Time since stroke (years), mean (SD)	8 (2)	9.8 (3.0)
Type of stroke, n (%)		
Hemorrhagic	1 (25) ^b	2 (40)
Ischemic	2 (50) ^b	3 (60)
Side of stroke, n (%)		
Right	4 (100)	3 (60)
Left	0 (0)	2 (40)
Chedoke-McMaster UE ^c score, mean (SD)	3.8 (1.0)	4.8 (1.3)
Living arrangement, n (%)		
Living with family	3 (75)	2 (40)
Living alone	1 (25)	3 (60)
Ability to use a computer, n (%)		
Excellent	1 (25)	2 (40)
Good	2 (50)	2 (40)
Poor	1 (25)	1 (20)

^aNot available.

^bInformation regarding the type of stroke was not available for participant ID11 at the time.

^cUE: upper extremity.

Feasibility Indicators

Process Indicators

Of the 42 inquiries by phone, 11 (26%) participants met the eligibility criteria and accepted to participate in the study. The rate of participant recruitment per month ranged from 0 to 6. In the VirTele group, 85% (5/6) of the participants completed the 8-week intervention (or the 3-month intervention during the COVID-19 pandemic). One of the participants discontinued the intervention because of persistent technical difficulties in accessing the VR system despite training (Figure 1).

Resources

The active time spent on exergames, the number of exergame sessions, the total number of repetitions, and activities performed in parallel to VirTele (which implies the use of UEs) of each

participant receiving VirTele intervention are reported in Table 2.

The frequency of videoconference sessions varied between 9 and 11 sessions during the first 4 weeks (mean 9.8, SD 1.0), followed by 3 to 7 sessions during the second month (mean 5. SD 1.826) and 4 to 6 sessions during the third month (mean 5.0, SD 1.4).

The frequency of use and time spent on GRASP, as well as activities performed in parallel with GRASP (which implied the use of UEs), are reported in Table 3. Participant ID4, who did not use the GRASP during the 8-week intervention, reported that he was discouraged by the program as it mainly focused on his hand and wrist, which he could not move anymore since the stroke. Although participant ID9 received GRASP for 3 months, he only used the program for 6 weeks.

Table 2. Exergame sessions and activities performed by each participant receiving VirTele intervention.

Participant ID and total	Time spent on exergames (hours)		Frequency of use of exergames	Total number of repetitions ^a		Activities (other than those provided in VirTele)
	2 months	Third month		2 months	Third month	
ID1	18	N/A ^b	84	17,101	N/A	Stretching, cooking, and housework (cleaning and laundry)
ID5	20	N/A	49	12,854	N/A	Exercises
ID10	15.03	14.28	59	13,130	18,759	Housework (cleaning and laundry)
ID11	13.18	4.23	58	11,649	5312	Housework (cleaning and laundry)
Total, mean (SD)	16.6 (3.0)	9.2 (7.1)	62.5 (15.0)	13,683 (2367)	12,035 (9508)	— ^c

^aReflects the number of successful tasks or movements completed during the exergame.

^bN/A: not applicable.

^cNot available.

Table 3. Frequency of use and time spent on GRASP^a in the control group.

Participant ID and total	Time spent on GRASP (hours)		Frequency of use of GRASP	Activities (other than GRASP)
	2 months	Third month		
ID3	4	N/A ^b	16	Bodybuilding, housework, and cooking
ID4	0	N/A	0	Tennis (nonaffected hand), cooking, and housework
ID6	8	N/A	16	Swimming, exercises, and housework
ID7	84	N/A	56	Housework, using a computer, and exercises
ID9	30	0	30	Gardening and shopping
Total, mean (SD)	25.2 (34.86)	0 (0)	23.6 (20.99)	— ^c

^aGRASP: Graded Repetitive Arm Supplementary Program.

^bN/A: not applicable.

^cNot available.

Management

Technical issues were reported from the clinicians' logs and included loss of password (to access the Reacts app) by the participant, internet issues, update of the system, sound or video cut off, and problems with the avatar (did not follow the movements of the UE). Technical issues were mainly managed by the clinician, the participant, or the participant's caregiver. The technical team intervened once on site to deliver a 3G key, as the participant had no more internet access, and once by telephone with a participant to help them recover their passwords.

The clinicians' logs showed that BCTs and motivational techniques were applied during the VirTele intervention with each participant in the experimental group. Among the 4 participants who completed the VirTele intervention, 3 (75%) participants (ID1, ID10, and ID11) reported more frequent use of the affected UE in activities of daily life and self-directed exercises (during the intervention), and 3 (75%) participants (ID1, ID5, and ID10) maintained the use of the affected UE after the intervention was terminated.

Scientific Feasibility

The 4 participants in the experimental group reported fatigue of the affected UE, which was managed by the clinician (by suggesting rest and stretching postures). Participant ID10 reported an increase in pain in the less-affected UE during the third month of VirTele; however, it did not seem to affect his adherence to the intervention, as recorded in the automatic logs accessible in the Jintronix portal (executed 59 sessions of exergames and spent 14 hours playing during the third month; Table 2).

The Health Care Climate Questionnaire showed a high score for perceived autonomy support in the experimental group (mean score 41.0, SD 1.7). Regarding the results of the perceived usefulness and perceived ease of use, most participants (3/4, 75%) found the technology extremely easy to use (mean score 11.0, SD 6.6) and extremely or quite useful (mean score 13.8, SD 15.5). Participant ID5 found the technology extremely or quite difficult to use (score 37/42) and slightly useful (score 20/42).

Performance Outcome Measure

For the primary outcome (FMA-UE motor function score), 50% (2/4 in each group) exhibited an improvement with important

change scores equal to or within the MCID ranges (between 4.25 and 7.25), maintained over time from 1 (T3) to 2 months (T4) after the intervention (Table 4). Participant ID9 in the

control group could not be evaluated as the FMA-UE could not be administered by phone (the only technology used by the participant) during the COVID-19 pandemic.

Table 4. Fugl-Meyer Assessment–Upper Extremity motor function score in the experimental and control groups.

Group and participant ID	Fugl-Meyer Assessment–Upper Extremity motor function score (0-60)			
	Time point 1	Time point 2	Time point 3	Time point 4
Experimental group				
ID1	24	31	28	41
ID5	50	43	48	51
ID10	18	14	18	18
ID 11	25	29	31	24
Control group				
ID3	43	48	42	41
ID4	4	9	8	6
ID6	46	47	57	59
ID7	52	42	46	46

Self-reported Questionnaires

MAL-30 Questionnaire

Regarding the MAL-30 quantity of use, 100 % (4/4) of all participants in the experimental group exhibited improvement from baseline (T1) to postintervention (T2), with the maintenance of benefits over time from 1 (T3) to 2 months (T4) after the intervention, whereas the control group showed improvement in 80% (4/5) of the participants from baseline (T1) to postintervention (T2), with maintained gains over time

from 1 (T3) to 2 months (T4) after the intervention (Table 5). The MCID of the MAL-30 quantity of use was not available at that time.

For the MAL-30 quality of use, all participants in the experimental (4/4, 100%) and the control (5/5, 100%) groups demonstrated improvement from baseline (T1) to postintervention (T2), maintained over time from 1 (T3) to 2 months (T4) after the intervention, 2 of which reached the MCID (between 1.0 and 1.1; Table 5) [49].

Table 5. Motor Activity Log-30 scores in the experimental and control groups.

Group and participant ID	Motor Activity Log-30: quantity and quality of use of the affected upper extremity							
	Score quantity of use (from 0 to 5)				Score quality of use (from 0 to 5)			
	Time point 1	Time point 2	Time point 3	Time point 4	Time point 1	Time point 2	Time point 3	Time point 4
Experimental group								
ID1	0.26	0.87	0.63	0.98	0.26	0.93	0.70	0.78
ID5	1.64	2.07	2.91	2.71	1.32	1.68	2.45	2.34
ID10	0.10	1.13	0.63	0.53	0.13	1.17	0.90	0.47
ID 11	0.00	0.34	0.36	0.32	0.00	0.38	0.41	0.38
Control group								
ID3	0.70	0.57	1.00	1.13	0.83	1.30	1.06	1.18
ID4	0.00	0.07	0.07	0.10	0.00	0.03	0.07	0.10
ID6	1.86	3.19	3.14	3.36	2.10	3.34	3.39	3.86
ID7	1.21	2.69	2.64	3.14	1.52	2.72	2.58	2.93
ID9	0.03	0.20	0.22	0.22	0.01	0.31	0.38	0.24

SIS-16 Questionnaire

For the SIS-16 hand function, only one of the participants in the experimental group exhibited improvement for the item “carry heavy objects (eg, bag of groceries),” with a score higher

than the MCID (between 9.4 and 14.1) [51]. All participants in the control group (5/5, 100%) demonstrated improvement from baseline (T1) to postintervention (T2), maintained over time from 1 (T3) to 2 months (T4) after the intervention, with all scores higher than the MCID (Table 6).

Table 6. SIS-16^a scores in the experimental and control groups.

Group and participant ID	SIS-16 hand function (from 0 to 100)				SIS-16 activities of daily life (from 0 to 100)				SIS-16 mobility (from 0 to 100)			
	T1 ^b	T2 ^c	T3 ^d	T4 ^e	T1	T2	T3	T4	T1	T2	T3	T4
Experimental group												
ID1	100	100	100	100	100	100	100	100	96	100	100	100
ID5	0	0	25	0	47	50	53	38	46	61	46	54
ID10	75	75	0	0	97	81	88	78	82	82	57	61
ID 11	75	50	50	50	69	72	78	75	75	68	79	79
Control group												
ID3	25	25	25	50	84	88	91	94	82	100	89	93
ID4	75	75	100	75	91	75	81	81	89	86	96	93
ID6	0	25	50	50	56	63	78	69	61	75	71	75
ID7	25	50	100	100	100	97	97	94	100	100	96	100
ID9	0	50	50	50	66	63	84	94	68	50	75	68

^aSIS-16: Stroke Impact Scale-16.

^bT1: time point 1.

^cT2: time point 2.

^dT3: time point 3.

^eT4: time point 4.

For the SIS-16 activities of daily life, 50% (2/4) of the participants in the experimental group demonstrated improvement from baseline (T1) to postintervention (T2), maintained over time from 1 (T3) to 2 months (T4) after the intervention in only 1 participant (MCID was not detected). In the control group, 60% (3/5) of the participants exhibited improvement higher or within the MCID from baseline (T1) to 2 months after the intervention (T4; [Table 6](#)).

Regarding the SIS-16 mobility, 50% (2/4) of participants in the experimental group exhibited improvement from baseline (T1) to postintervention (T2), maintained over time from 1 (T3) to 2 months (T4) after the intervention, with a score higher than the MCID in only 1 participant. In the control group, 40% (2/5) of the participants exhibited improvement from baseline (T1) to postintervention (T2), maintained over time from 1 (T3) to 2 months (T4) after the intervention, with scores within or higher than the MCID ([Table 6](#)).

TSRQ Measure

In the experimental group, 75% (3/4) of the participants demonstrated an increase in their autonomous motivation score from baseline (T1) to 2 months after the intervention (T4). Further examination of the regulations that define the controlled

motivation in the experimental group showed an increase in introjected regulation from baseline (T1) to postintervention (T2) in 75% (3/4) of the participants, maintained over time from 1 (T3) to 2 months (T4) after the intervention in only 1 participant. In parallel, the external regulation showed an increase of 75% (3/4) in the participants from baseline (T1) to postintervention (T2), with a tendency to decrease in the follow-up period from 1 (T3) to 2 months (T4) after the intervention. The motivation score was substantially low in all participants at all times ([Table 7](#)).

In the control group, only one of the participants demonstrated an increase in autonomous motivation from baseline (T1) to postintervention (T2), maintained over time from 1 (T3) to 2 months (T4) after the intervention. The examination of the introjected regulation showed substantially no change from baseline (T1) to postintervention (T2) in 80% (4/5) of the participants. The external regulation scores showed a tendency of increase in 40% (2/5) of the participants, maintained over time from 1 (T3) to 2 months (T4) after the intervention in only 1 participant. One of the participants showed a decrease from baseline (T1) to 2 months after the intervention (T4) in both introjected and external regulations. Amotivation scores tended to increase in 80% (4/5) of participants ([Table 7](#)).

Table 7. Treatment self-regulation scores in the experimental and control groups.

Group and participant ID	Autonomous motivation				Introjected regulation				External regulation				Amotivation			
	T1 ^a	T2 ^b	T3 ^c	T4 ^d	T1	T2	T3	T4	T1	T2	T3	T4	T1	T2	T3	T4
Experimental g roup																
ID1	42	42	42	43	14	14	14	8	4	10	4	4	3	3	3	3
ID5	34	41	41	36	10	14	11	8	15	19	20	4	9	9	8	9
ID10	42	42	42	42	2	8	14	12	16	11	16	22	9	6	9	9
ID 11	19	27	24	24	5	10	5	6	9	13	12	11	8	7	4	11
Control g roup																
ID3	38	40	42	40	2	2	3	2	4	7	7	7	3	7	9	3
ID4	40	39	42	39	10	11	11	11	8	6	17	12	6	6	8	8
ID6	40	27	40	39	10	2	2	2	11	4	5	7	6	9	3	9
ID7	40	32	33	33	13	13	13	2	24	10	16	4	9	3	8	3
ID9	30	24	21	24	9	8	2	2	6	10	4	4	6	3	9	9

^aT1: time point 1.

^bT2: time point 2.

^cT3: time point 3.

^dT4: time point 4.

Discussion

The objectives of this feasibility clinical trial were to (1) determine the feasibility of using VirTele with survivors of chronic stroke at home and (2) explore the impact of VirTele on UE motor function, quantity, quality of use, quality of life, and motivation in survivors of chronic stroke compared with conventional therapy.

Feasibility and Impact Indicators

Feasibility Indicators

Criteria of VirTele Use

The results of this study suggest that VirTele is feasible to use at home among survivors of chronic stroke, aged 41 to 89 (mean 56.8, SD 21.8) years with 8 (SD 2) years since the stroke. However, certain criteria should be respected to benefit as much as possible from this technology, such as minimum knowledge of using computers (how to use a mouse and keyboard) or having a caregiver who is comfortable with computers and no severe aphasia that limits communication between the clinician and the survivor of the stroke. Overall, most survivors of stroke found the technology easy to use and useful, except for one of the participants.

The training provided before starting the intervention seems adequate for survivors of chronic stroke who have used a computer before but should be adjusted to better prepare participants who are not familiar with computers (never used before), such as a longer period of familiarization and personalized training. Although the clinicians reported no difficulties regarding technology use, novice clinicians may require support to address interoperability issues and acquire new skills (eg, choose exergames based on client capacities and goals, create exergame-based rehabilitation programs, select

appropriate clients, and grade difficulty levels) to enhance their self-efficacy during practice [3].

Dose of the VirTele Intervention

In the context of this study, VirTele intervention dose was captured in terms of time spent on exergames (2 months: mean 16.6, SD 3.0 hours; third month: mean 9.3, SD 7.1 hours), frequency of use (mean 62.5, range 49-84 sessions), and the total number of successful repetitions (2 months: mean 13,683, SD 2367; third month: mean 12,035.5, SD 9508.46). Interestingly, dose in terms of time spent on exergames and frequency of use did not seem to have any moderating effect on FMA-UE and SIS-16 scores, which echo the findings of a previous study that found no advantages for higher dosing (duration and frequency of use) of VR approaches on rehabilitation outcomes (eg, FMA-UE, box, block) [16]. However, the performance of approximately 17,000 repetitions of successful tasks or movements during exergames appears to be the gold standard for achieving clinical improvements in UE motor function. Although participant ID10 attained 30,000 repetitions, no improvement was observed in the FMA-UE, which suggests that intense repetition is not always the gold key to recovery, as reported in a previous study (where UE improvement was attained following 30,341 repetitions) [33]. Furthermore, participant ID10 reported increased fatigue in the affected UE and pain in the less-affected UE, which reflects symptoms of overexercising and may prevent or reduce potential improvement. An evaluation of the FMA-UE score after the 8-week intervention in participant ID10 could have provided a better indicator of the UE motor condition (before the onset of symptoms at the third month).

Although all participants in the experimental group improved their MAL-30 scores, the MCIDs were only detected in participants ID5 and ID10, who spent the longest time on exergames (range 20-29 hours), which suggests a potential link

between doses in terms of time spent on exergames and clinical improvement at the MAL-30. Previous studies conducted by Levin et al [56] (delivered 6.8 hours of video capture exergames) and Housman et al [57] (delivered 24 hours of gravity-supported exergames) intending UE rehabilitation in survivors of chronic stroke found no change and significant improvement, respectively, sustained at 6 months on the MAL scores. These findings suggest that longer exposure to exergames may lead to better outcomes in participation in real-life activities and support the potential transfer of gains from the virtual environment to physical real-life activities.

The Optimal Duration of the VirTele Intervention

The optimal effective duration of VirTele intervention (8 or 12 weeks) is not yet clear, considering the varied results of the primary and secondary outcomes between participants in the experimental group. However, it is worth noting that the total number of repetitions and frequency of use of the technology are not always affected by VirTele duration. For example, participant ID1, who used VirTele for 8 weeks, achieved a higher dose of repetition and frequency of use of the exergames than participant ID11, who used VirTele for 3 months. Further examination of the level of amotivation at baseline showed that participants with the lowest level of amotivation (ie, high motivation) had the highest dose of repetition and frequency of use during the first 8 weeks. This may suggest that motivation should be evaluated before starting the VirTele intervention to determine the adequate duration (8 or 12 weeks) necessary to achieve a high dose of repetition and frequency of use and that an appropriate motivational strategy should be provided to individuals who are amotivated.

Factors That May Affect Adherence to VirTele Intervention

During the first 8-week intervention period, female participants (ID1 and ID5) achieved the highest level of adherence to exergames compared with male participants (ID10 and ID11), which suggests that sex may play a role in choosing to play or not the VirTele exergames. A previous study [58] conducted on healthy participants aged 18 to 51 (mean 21.65, SD 4.43) years, showed that women preferred physically internet-based games compared with men, which may explain the higher level of adherence to VirTele exergames in women, although it should be carefully interpreted, considering the small sample size and other factors related to motivation and stroke (eg, UE weakness and pain), which may affect adherence to the system.

Age did not seem to affect adherence to the VirTele program, although lack of knowledge in information technology was often associated with older participants. Participant ID5, who was not familiar with information technology, had a caregiver who helped her use the system and was compliant with the VirTele program. However, previous experience in information technology may facilitate the use of this technology.

VirTele Impact Indicators

Regarding the primary outcome (FMA-UE), the experimental group reached the MCID from baseline (T1) to 2 months after the intervention (T4). This result is particularly relevant as the MCID was detected even if the total score of the scale was adjusted to 60, which supports the feasibility of administering

the FMA-UE motor function remotely (without an evaluator on site). This result also supports the findings of a previous study [47] that examined the measurement properties of FMA-UE when administered remotely.

Regarding the secondary outcomes, both groups demonstrated improvement in the MAL-30 quantity and quality of use, which may suggest that the VirTele intervention is comparable with conventional therapy in terms of somatosensory information feedback, affecting the UE quality of movement. The supplementary exercises provided in VirTele (in addition to exergames) may have played a role in the integration of somatosensory information by manipulating real-life objects with force and tactile feedback, which are important for motor learning [14].

Regarding the quality of life (SIS-16 scores), the control group reported improvement in activities of daily life and hand function in 60% (3/5) and 100% (5/5) of the participants, respectively. In contrast, the experimental group reported varied and inconclusive results in terms of activities of daily life and hand function, despite the increased use of the UE (MAL-30 quantity) and improvement in the quality of use (MAL-30 quality). Participant ID1 reported a score of 100% (from T1 to T4) in SIS-16 hand function and activities of daily life, which indicates that no further gains can be achieved. Participant ID10 reported the appearance of pain in the less-affected UE (during the third month of VirTele intervention), which may have affected his performance during activities of daily life and the score of the SIS-16 hand function for the item “carry heavy objects (eg, bag of groceries)” as survivors of stroke often use compensatory strategies by the less-affected UE to help or assist the performance of the affected UE [59].

Further explanation of the difference between the two groups regarding the SIS-16 scores may be associated with the training paradigm; the GRASP mainly targeted the hand and wrist, with little focus on gross motor skills, whereas the VirTele intervention mainly targeted gross motor skills, with supplementary exercises for the hand. Thus, training with the GRASP might better meet individual needs when it comes to performance in activities that require fine motor skills, although both groups demonstrated improvements in the quality and quantity of use of the UE. This also suggests that combining VirTele with conventional therapy such as the GRASP may maximize the recovery potential, which echoes the findings of Laver et al [60] who determined that the use of VR combined with conventional therapy had a significant effect on UE outcomes compared with when it was used alone (not significant).

Role of Motivational Interviewing

In the experimental group, 75% (3/4) of the participants demonstrated an increase in autonomous motivation compared with 20% (1/5) in the control group. In parallel, the experimental group demonstrated no change in the amotivation score, whereas the control group tended to show an increase in 80% (4/5) of participants. These results may suggest that VirTele intervention is more motivating than conventional therapy and that motivational interviewing delivered in the experimental group could have played a role in the development of autonomous

motivation, which is important to maintain behavior changes of the UE.

Other factors that may stimulate autonomous motivation include enjoyment and improving skills [61]. In this context, VirTele exergames offer playful and varied exercises with different levels of difficulty that could give survivors of stroke a real feeling of competence and more confidence in their abilities when they manage to succeed. Furthermore, some components of exergames, such as visual and auditory feedback (encouragement, score of the game, and indication of successful vs unsuccessful movement) [62] and quality of graphics [30], may enhance the enjoyment of participants and increase autonomous motivation, which may affect adherence to exercise.

Furthermore, a multiple case study conducted with participants ID5, ID1, and ID11 showed that VirTele clinicians used many motivational interviewing strategies (BCTs and motivational techniques) that would support participants' psychological needs [33]. Such an environment may lead to effective behavior changes [63], such as that experienced by participants ID5 and ID10 (high adherence to exergames and maintained use of the affected UE at the end of the VirTele intervention) [33]. In addition, the experimental group performed an enormous amount of repetition and had a higher frequency of use of the allocated treatment than the control group.

In contrast, participant ID11 did not express any intention to continue using the affected UE when the intervention was terminated, which may be explained by the miscommunication encountered between the participant and the respective clinician because of aphasia [33]. An interview with ID11's clinician in the multiple case study showed that the latter had difficulty understanding the needs of the participant to provide adequate motivational support [33]. In addition, participant ID11 was ambidextrous, which may have increased the use of compensatory strategies by the less-affected UE.

Limitations and Recommendations

The findings of this feasibility clinical trial should be carefully interpreted as some limitations were identified. First, the VirTele

and GRASP interventions presented different training paradigms (gross and fine motor skills); however, only gross motor skills (coordination, volitional movement within synergies, or no synergy of shoulder and elbow) were captured through the primary outcomes (FMA-UE motor function) as the evaluation of the hand and wrist could not be performed remotely (requires the physical presence of the assessor). Second, it is important to note the inconsistency in the intervention duration among the participants in the 2 groups (experimental vs control). In the experimental group, 50% (2/4) of the participants received a 3-month intervention and 50% (2/4) received a 2-month intervention. In the control group, 20% (1/5) of the participants received a 3-month intervention, whereas 80% (4/5) received the initial 2-month intervention. That said, it is interesting to note that this variability in duration allowed us to determine the role that the dose (repetition or time spent) played in the recovery. Third, it is important to note that neither the evaluators nor the person in charge of data analysis was blinded to the group assignment. Finally, sex and age factors that may affect exergame use should be further examined using a larger sample size.

In conclusion, the findings of this study should be interpreted with caution, given the small sample size. All explanations provided for the primary and secondary outcomes in both groups remain speculative and need further examination in a larger clinical trial.

Conclusions

The VirTele intervention constitutes another therapeutic alternative, in addition to the GRASP, to deliver an intense personalized rehabilitation program to survivors of chronic stroke (at least 8 years since the stroke) with UE deficits. Descriptive statistics showed that the highest scores for autonomous motivation were achieved in the experimental group, who achieved a high frequency of use of the exergames and a very high number of repetitions. The study results indicate that the study protocol is valid and can be used to inform larger-scale studies, regardless of the adaptations made because of the context of the COVID-19 pandemic.

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Conflicts of Interest

None declared.

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Abbreviations

- BCT:** behavior change technique
- CONSORT:** Consolidated Standards of Reporting Trials
- FMA-UE:** Fugl-Meyer Assessment–Upper Extremity
- GRASP:** Graded Repetitive Arm Supplementary Program
- IREX:** Interactive Rehabilitation Exercise
- MAL-30:** Motor Activity Log-30
- MCID:** minimal clinically important difference
- SDT:** self-determination theory
- SIS-16:** Stroke Impact Scale-16
- T1:** time point 1
- T2:** time point 2
- T3:** time point 3
- T4:** time point 4
- TSRQ-15:** Treatment Self-Regulation Questionnaire-15
- UE:** upper extremity
- VR:** virtual reality

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Original Paper

Robotic Table and Serious Games for Integrative Rehabilitation in the Early Poststroke Phase: Two Case Reports

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Abstract

Background: BrightArm Compact is a new rehabilitation system for the upper extremities. It provides bimanual training with graduated gravity loading and mediates interactions with cognitively challenging serious games.

Objective: The aim of this study is to design and test a robotic rehabilitation table-based virtual rehabilitation system for functional impact of the integrative training in the early poststroke phase.

Methods: A new robotic rehabilitation table, controllers, and adaptive games were developed. The 2 participants underwent 12 experimental sessions in addition to the standard of care. Standardized measures of upper extremity function (primary outcome), depression, and cognition were administered before and after the intervention. Nonstandardized measures included game variables and subjective evaluations.

Results: The 2 case study participants attained high total arm repetitions per session (504 and 957) and achieved high grasp and finger-extension counts. Training intensity contributed to marked improvements in affected shoulder strength (225% and 100% increase), grasp strength (27% and 16% increase), and pinch strength (31% and 15% increase). The shoulder flexion range increased by 17% and 18% and elbow supination range by 75% and 58%. Improvements in motor function were at or above minimal clinically important difference for the Fugl-Meyer Assessment (11 and 10 points), Chedoke Arm and Hand Activity Inventory (11 and 14 points), and Upper Extremity Functional Index (19 and 23 points). Cognitive and emotive outcomes were mixed. Subjective rating by participants and training therapists were positive (average 4, SD 0.22, on a 5-point Likert scale).

Conclusions: The design of the robotic rehabilitation table was tested on 2 participants in the early poststroke phase, and results are encouraging for upper extremity functional gains and technology acceptance.

Trial Registration: ClinicalTrials.gov NCT04252170; <https://clinicaltrials.gov/ct2/show/NCT04252170>

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KEYWORDS

subacute stroke; virtual reality; gamification; therapeutic game controller; integrative rehabilitation; BrightArm Duo; BrightArm Compact; upper extremity; cognition; depression

Introduction

Background

Upper extremity (UE) functional deficits after stroke include reduced range of movement, muscle weakness, low tone, and tremors [1,2]. These motor limitations can be compounded by deficits affecting major cognitive domains of attention, processing speed, executive functioning, memory, and language. Cognitive impairments due to stroke in turn can affect the reacquisition of tasks and new learning. Thus, the combined motor and cognitive deficits adversely affect speed of recovery [3] and the regaining of independence in activities of daily living (ADLs) [4]. The rehabilitation after stroke needs to be integrative, targeting motor UE function *as well as* cognitive functioning. In many health care models, inpatient therapy is limited, expensive, and involves multiple professionals. The ideal training option is leveraging technology for rehabilitation at a single point of care for optimal results and reduced costs.

A high number of task-oriented UE repetitions are needed during therapy to induce the neural rewiring needed to regain function. Brain plasticity is at its peak in the first 6 months after a stroke [5,6]. High-intensity training, meaning many repetitions per minute, is not sufficient by itself. Equally important is the adaptability of the training to individual differences in deficits to improve outcomes and maintain the patient's motivation.

Technologies increasingly relied upon to meet poststroke-rehabilitation needs include robotic and virtual reality (VR)-based training systems [7]. Both types of systems are popular because they ensure the needed intensity, motivation, and customization. Rehabilitation robots can induce a high number of repetitions and serve as motion guides to improve motor control of the arm during reaching movements [8]. Robots can also assist in UE strengthening [9] in instances where voluntary movement is resisted. However, robotic rehabilitation exoskeletons that wrap around the arm pose safety concerns because of actuators located close to the trained upper limb [10]. The exoskeletons thus require constant supervision and skilled providers to assist in donning and doffing. Robotic systems can be optimized to harness the benefits, reduce skilled supervision, and avoid undesired strain to the UE during training [10]. A promising alternative is a robotic table that automatically adapts for UE training in individuals with stroke.

Bilateral UE training has many advantages over the standard of care (SOC). SOC typically involves unilateral training focused on the affected arm and hand. Advantages of bilateral training include more neural rewiring, strengthening the less-affected UE [11], and ability to train at higher cognitive levels during integrative rehabilitation [12]. However, bilateral robotic rehabilitation using currently available technology is cost prohibitive and requires space, especially in home and community settings [13]. The rehabilitation field needs passive and safe technology (without actuators acting on the trained limbs) to allow bilateral training on a single low-cost and compact system.

VR therapeutic games induce a high number of arm repetitions and are enjoyable. Game-based motor therapy for stroke offers significantly more training [14-17]. Because of the engaging nature of video games, it is easier to alleviate learned disuse and boredom and to induce the number of UE repetitions beneficial to neural recovery after stroke [18]. Moreover, game-based therapy has been widely used in stroke rehabilitation to boost patient motivation, increase exercise intensity, and provide the means to measure objective session-specific outcomes in a quantifiable way [19]. Therapeutic games can be paired with a safe robotic system to amplify the benefits of both forms of rehabilitation training when used together.

Related Work

A precursor to the robotic system reported here was the BrightArm Duo robotic table (Figure 1A). It used a low-friction motorized table to help forward arm reach, assisted supported reaching by tilting its distal side down, and resisted reaching by tilting the table surface up. Arms were placed in low-friction forearm supports with embedded infrared (IR) light-emitting diodes. The arm supports could slide on the rehabilitation table and were tracked by a pair of overhead IR cameras. The cameras communicated with a PC running the table actuators as well as its therapeutic games. These games were presented on a large display in front of the patient and could be played during unilateral or bilateral rehabilitation (Figure 1A).

For all its advances, BrightArm Duo had shortcomings too. It was a large system with complex controls, owing to its 2 table-lifting and 2 table-tilting actuators. Furthermore, the flat bottom of the forearm supports made it impractical to train pronation and supination while supported on the table. Moreover, it was not possible to train finger extension, which is key to grasping objects and critical to increasing ADL independence. Thus, the BrightArm Duo did not address a missing element in the field of rehabilitation technology [11,20,21], namely the lack of an integrative system of training finger extension, forearm pronation and supination, hand grasping, bilateral movements, and engaging cognitive rehabilitation.

Our novel *BrightArm Compact* (BAC) system addresses the aforementioned missing element. The redesign of the system and a rigorous evaluation process allowed us to embed new and improved features. The modulation of gravity bearing can support the weaker side and enable UE strengthening [20,21]. The table can facilitate integrative motor and cognitive training when coupled with challenging therapeutic games [22]. However, the testing of the BAC system with individuals with stroke (preferably in the early stages after stroke) is essential to measure the impact on function. Findings from the preliminary evaluation can then inform larger studies and advance the field of rehabilitation technology. This is the motivation behind this study.

This paper presents the first clinical study of the next-generation BAC rehabilitation robotic table. It consists of 2 case studies who trained on the BAC system during the early subacute phase after stroke.

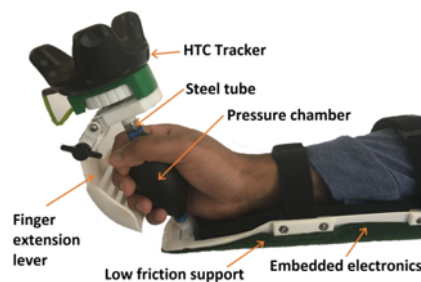
Figure 1. Robotic rehabilitation tables and controller: (A) the BrightArm Duo system, (B) the BrightArm Compact system training case 1, and (C) the BrightBrainer Grasp therapeutic game controller. Reprinted by permission of Bright Cloud International Corp.



(A)



(B)



(C)

The following research questions were addressed:

1. Primary: How does bilateral training with the integrative rehabilitation system impact UE function?
2. Secondary: Does the integrative rehabilitation system have an impact on the secondary outcomes of cognition, emotion, and game performance?

3. What is the perception (positive or negative) of the participants and the therapists who used the new system at an inpatient clinic?

Technology details of the robotic table and its integrative therapeutic games are presented first. The recruitment procedures, training protocol, and outcome measures are described subsequently, followed by the case-specific results and the *Discussion* and *Conclusions* sections.

Methods

The BAC Rehabilitation Table

The BAC rehabilitation table had a streamlined design using a single linear actuator for lifting movement and a second linear actuator for work-surface tilting. The first linear actuator adjusted the table to the patient's height such that the arms could be supported without shoulder discomfort (Figure 1B). The second actuator was used to adjust the work-surface tilt angle between 20° up tilt and -15° down tilt. In this design, 0° corresponded to a horizontal table. Both actuators were housed in a central column that also supported a large television displaying therapeutic games. Because of its more compact design, the BAC system's overall footprint was 45% smaller than that of the Duo precursor, while still allowing full bilateral supported arm reach.

Arm lifting off the table was possible because, unlike in the case of other rehabilitation robots, no actuators directly pushed on the UEs. The added advantages were increased freedom of movement and enhanced patient safety. Another component of the BAC safety mechanism was an array of IR illuminator strips located on the underside of the work surface. The IR sensing strips were arranged to detect a patient's presence while seated at the table in a chair or wheelchair. Proximity with the patient's knees was also detected, in which case the table motion for lifting or tilting was momentarily paused. Another safety measure was a mechanism designed to detect imminent collision between the table underside and the top of a wheelchair wheel. Such collisions could occur during the upward tilting of the table, depending on the height and type of wheelchair. Finally, a pair of emergency power shutoff switches were mounted on either side of the central tower assembly. It was easy to reach the location of the switches regardless of which side of the patient the therapist stood to assist with right- or left-arm training.

Rehabilitation with the BAC robotic table was facilitated by a pair of BrightBrainer Grasp (BBG) therapeutic game controllers which our group developed [23]. As shown in Figure 1C, the BBG used an HTC tracker (HTC Corp) to measure hand movement in 6 degrees of freedom. The HTC tracker should not be confused with the VIVE controller (HTC Corp), which was not used with the BAC system. The HTC tracker's position and orientation were measured in real time with the aid of a pair of VIVE IR illuminators (or *lighthouses*). The 2 VIVE lighthouses were located on either side of the central actuating column.

The BBG controller had a rubber pear and a pressure sensor to measure grasp strength and a rotating mechanical lever to measure finger extension. The underside of the controller was curved to allow supported pronation and supination and covered in a low-friction material to facilitate supported arm reach. The same curved shell housed electronics and batteries as well as a wireless transmitter for bidirectional communication with a PC running the therapeutic games.

Therapeutic game controllers must be simple to use to avoid taxing the limited resources of individuals with a disability and

avoid increasing the setup time for their therapists and families. Furthermore, the controller's shape must accommodate hands of various sizes and functional levels. In the BBG game controllers, these general principles were applied to detect finger extension and grasping. The curved shape of the mechanical lever maintained positive contact with the outer side of the patient's hand to detect extension regardless of which finger or fingers pushed it outward. Conversely, grasping was detected regardless of which finger or fingers flexed around the BBG rubber pear. Additional details of the BAC design and its usability evaluation study can be found in Burdea et al [24], whereas the clinical results in individuals in the chronic phase after stroke using the BBG can be found in Burdea et al [25].

A baselining process enabled adaptation to a particular patient's motor function level. The baseline mapped different motor functions of the weak and strong UEs to the normal functions of the left and right avatars in the therapeutic games. The baseline was captured for grasp, finger extension, arm pronation, arm supination, vertical reach, and horizontal reach. Vertical reach and horizontal reach baselines were recorded for 1 arm at a time, as previously described for the BrightArm Duo [20]. The other baselines were captured simultaneously for both UEs to reduce overall system setup time.

During the finger-extension baseline, the patient watched a scene showing 2 simplified controllers moving their respective mechanical levers in response. Simultaneously, 2 vertical tubes were filled with color to visualize the magnitude of the extension angle of the corresponding hand. The grasp baseline scene was similar, and the amount of color in the vertical tubes was proportional to each hand's grasping strength. The baseline process was repeated 3 times, and the net value was calculated after subtracting the residual force.

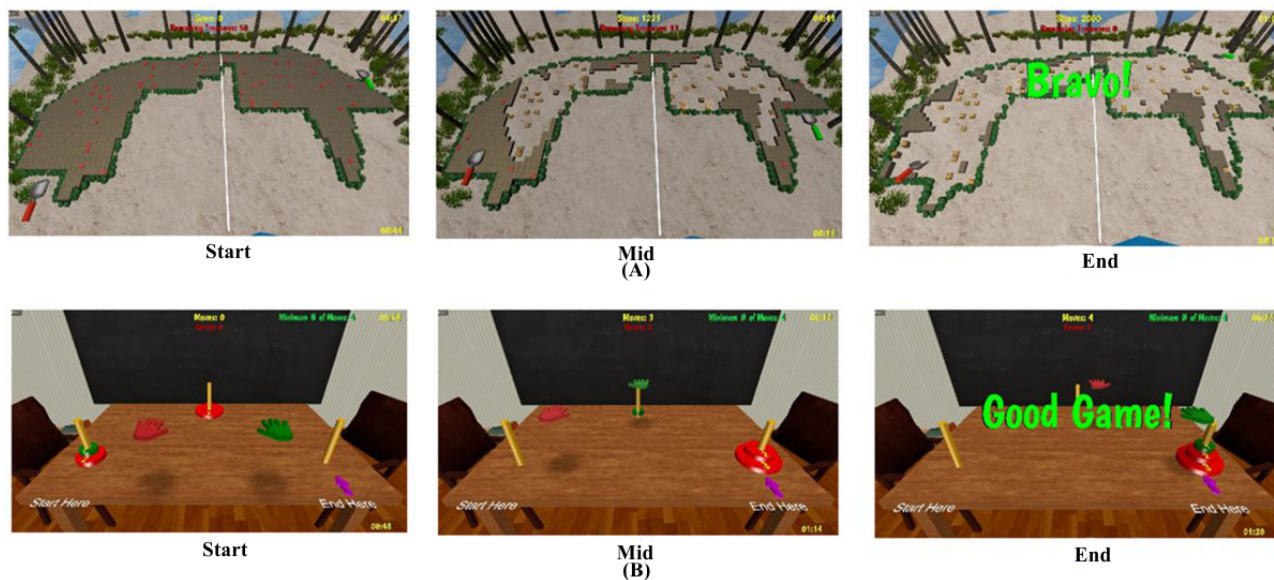
Baselines were subsequently used to determine gains between UE movements and those of the avatars controlled in a game. The impaired UE limited reach was mapped to the full extent of VR scenes. Presenting fully functional avatars was aimed at making the games winnable to reduce depression [26]. Only a fraction of the maximal finger-extension range and maximal grasping force were used to control the game. The use of fractional values reduced fatigue and discomfort during prolonged virtual rehabilitation sessions. The baseline was used to determine thresholds for hand-avatar flexion or extension. Once a threshold was exceeded in the extension direction, the game software commanded a hand avatar to open fully. Similarly, once a grasping force threshold had been exceeded, the hand avatar was commanded to close fully.

What follows is a description of 2 of the therapeutic games used in the BAC rehabilitation system. *Treasure Island* (Figure 2A) was a game training UE endurance, coordination, and short-term visual memory. An island was depicted where treasures were dug out from an area marked with boulders. Patients were required to use a grasp for lowering the shovel avatar into the sand or move the shovel to other locations using the extension. Treasures were given different gold counts, with those closest to the boulder wall (which visualized the horizontal reach baseline) containing more gold. The game ended once all treasures had been found or the allotted time had ended. Lower

levels of difficulty had markings on the sand to indicate where treasures were buried, and the weather was calm. There were more treasures at higher levels of difficulty (more repetitions) to be dug out in a shorter time (faster movements), and no

markings were present. For even higher levels, sandstorms would cover some of the treasures that had been discovered such that their locations needed to be remembered and more UE movements were elicited to dig them up again.

Figure 2. A sample of integrative therapeutic games played during the BrightArm Compact study. Sequence, from left to right, shows game scenes at start, midgame, and end for (A) *Treasure Island* and (B) *Towers of Hanoi 3D*. Reprinted by permission of Bright Cloud International Corp.



Towers of Hanoi 3D (Figure 2B) was used to train primarily executive function. The game trained decision-making by asking the patient to restack disks of varying diameters from 1 of 3 poles to another while using the third pole as a waypoint. The version of the game for the BBG and BAC required grasping to pick up a disk, reaching to bring that disk above a pole, then extending fingers to release the disk onto that pole. Decision-making was trained by rules requiring that a larger diameter disk could never be placed on top of a smaller one and that disks be handled only by like-colored hand avatars. The smaller disk had the color of one of the hand avatars (eg, red), and the other disks had the color of the other hand avatar (eg, green). The aim was to restack the disks with a minimal number of moves, which depended on the number of disks in the game (eg, restacking 3 disks required a minimum of 7 arm-reach moves, 7 grasps, and 7 finger extensions).

A total of 8 different games were used in this study. Each game had up to 16 levels of difficulty to ensure variety and challenge during BAC training. When a game was repeated in several sessions, its actual difficulty was set automatically, based on a particular patient's past performance in that game. If the patient failed to finish the game or obtained a low score 2 consecutive times, the difficulty level was reduced by 1 level in the next play. In contrast, if a patient won a game 3 consecutive times, then that game difficulty was increased by 1 level in the next play.

Recruitment

In early September 2018, 1 BAC system was placed at PowerBack Rehabilitation (Piscataway, New Jersey, United States), an inpatient rehabilitation facility specializing in early subacute recovery stages. The inpatient rehabilitation director (an occupational therapist [OT]) and another licensed OT were

trained in the use of the BAC system. Subsequently, 2 cases described here who received SOC at the facility were screened, and both provided informed consent to participate in this study.

Case 1 was a right-handed African American male, 83 years of age, with left arm affected by a hemorrhagic stroke to the right frontal lobe, right inferior thalamus, and right superior cerebellar peduncle. The stroke had occurred 7 weeks before enrollment. He presented with hypertension, atrial fibrillation, and a visual field cut on his left side. Case 1 was taking 10 prescription medications at the time of enrollment (Milk of magnesia, Lisinopril, Dulcolax, Dorzolamide, Allopurinol, Brimonidine tartrate, Pravastatin, Eliquis, Flomax, and Amlodipine). He was able to ambulate 70 feet with a single-point cane, with supervision. The initial Fugl-Meyer UE [27] score was 45 out of 66, indicating mild impairment. He had 12 years of formal education, was a native English speaker, and a retired truck driver.

Case 2 was a left-handed White male, 66 years of age, with affected left UE after a right hemorrhagic stroke (basal ganglia infarct) that occurred 3 weeks before enrollment. He was higher functioning in motor performance than case 1, with an initial Fugl-Meyer UE score of 52 out of 66, indicating mild impairment. Case 2 had anemia, hypertension, and was on 6 medications during this study (Atorvastatin, Calcium, Cyanocobalamin, Midodrine, Polyethylene glycol powder, and Folic Acid). He was able to ambulate 50 feet using a rolling walker independently. Case 2 had 12 years of formal education, was an English speaker, and his previous occupations were painter and landscaper.

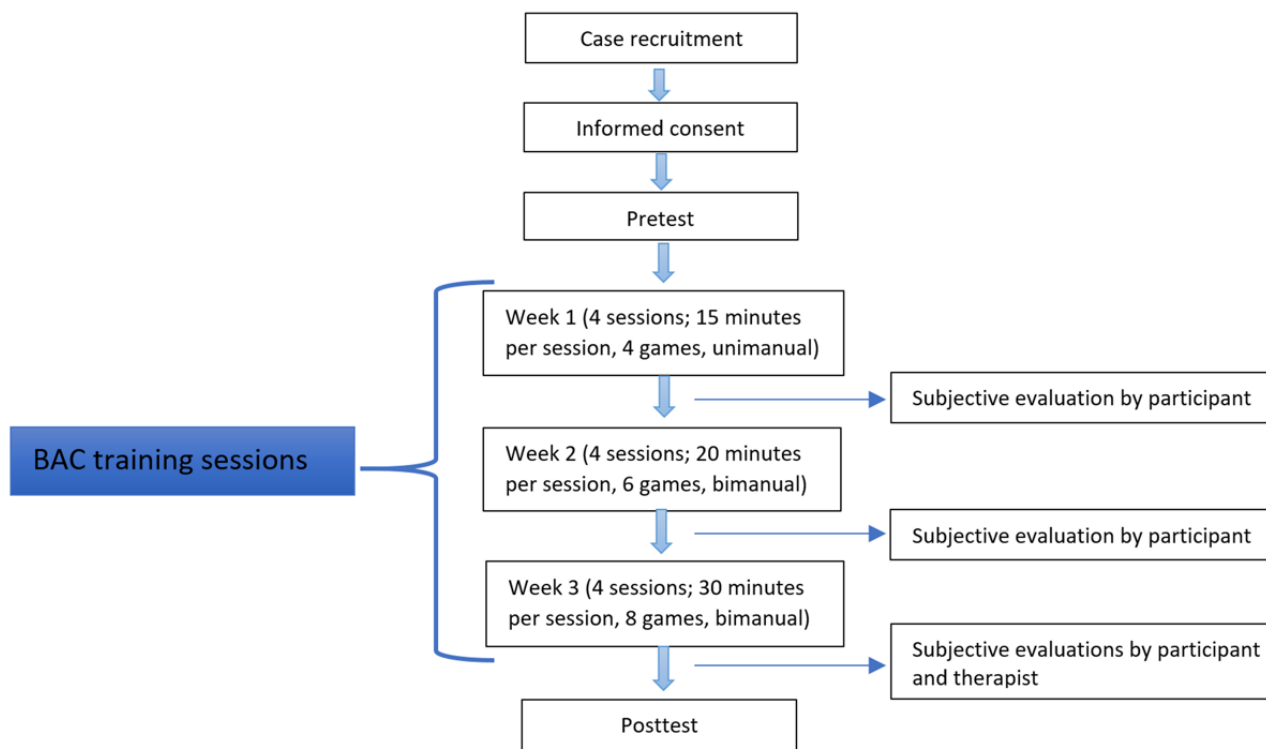
Data Collection Instruments

Overview

This study followed an ABA protocol, with data collected at baseline or pretest (A), at every training session (B), and at the end of rehabilitation on the experimental system (A; [Figure 3](#)).

The pre- and posttraining clinical evaluations measured motor impairment and function, cognitive function, and emotional state. These were assessed using standardized instruments and supplemented by data from nonstandard measures, as described in the next sections.

Figure 3. Flowchart diagram of the case study protocol. Reprinted by permission of Bright Cloud International Corp. BAC: BrightArm Compact.



Evaluation of Motor Impairments

Active range of motion was measured using a standard goniometer to determine the active arm's and fingers' range of movement on both the impaired and unimpaired sides. Calibrated wrist weights were used to determine shoulder strength when lifting the straight arm in front of the body to a horizontal position (anterior deltoid) and lateral to the body to a horizontal position (lateral deltoid). A mechanical Jamar dynamometer was used to measure grasp strength, and a Jamar pinch gauge was used to assess finger pinch strength. Both instruments have been shown to have adequate reliability and validity for this purpose [28].

Function of the UE

This was assessed with (1) the UE subscale of the Fugl-Meyer Assessment with a score ranging from 0 to 66, where 0 is most severely impaired and 66 is normal UE function; (2) the Jebsen Test of Hand Function [29], a timed test of 7 simulated ADLs, each timed from 0 to 180 seconds; (3) the Chedoke Arm and Hand Activity Inventory [30], which measures independence in 9 bimanual ADLs, each scored from 0 to 7. Here, a 0 means the participant needs total assistance in performing a task, whereas a 7 means complete independence in performing it; and (4) the Upper Extremity Functional Index (UEFI) [31], a self-report of independence in 20 ADLs, each scored on a 0-4 scale, where 0 corresponds to inability to perform a task and 4

corresponds to no difficulty at all in performing it. All these measures have been reported to have good psychometric properties for assessing function in stroke.

Emotive State

This was measured with the Beck Depression Inventory, Second Edition (BDI-II), as an indication of depression severity, compatible with its reliability and validity for this use [32].

Cognitive Function

This was assessed with the Brief Visuospatial Memory Test, Revised [33], for delayed visual memory recall (forms 1 and 2); Hopkins Verbal Learning Test, Revised [34], for delayed verbal memory recall (forms 1 and 2); the Neuropsychological Assessment Battery (NAB) word generation subtest of the executive functioning module [35] for executive function and verbal fluency (forms 1 and 2); the NAB digit span forward and backward test for auditory attention and working, as well as the Dots subtest for visual working memory; Trail Making Test Part A for visual attention and information-processing speed; and Trail Making Test Part B as a measure of executive function and mental flexibility. The psychometric properties of these measures for stroke indicate high reliability and validity [36].

Game Performance Data

These consisted of objective measures of therapeutic gameplay performance. Motor domain variables were arm repetitions,

grasp and finger-extension repetitions, the intensity of training (as repetitions per minute), and area and shape of arm reach (measured by the BAC system). In the cognitive domain, data stored were game average difficulty level (per session), game average duration, and total cognitive exercise time. This training time was reported for the specific cognitive domains of executive function, attention, and memory. These game data were deidentified, automatically sampled at each experimental session, and uploaded on a Microsoft Azure [37] secure cloud server.

A remote graphing capability was developed to allow researchers to log in to the project portal and remotely review an individual's game performance data.

Subjective Evaluation Custom Forms

These were developed for the participants, and separate, somewhat different forms, were developed for the OTs assisting in their training. The evaluation form to be completed by the participants after stroke, shown in Table 1, had 15 items. Each item used a 5-point Likert rating scale, with 1=least desirable outcome and 5=most desirable outcome. Participants were requested to complete the form at the end of every experimental training week to longitudinally determine changes in rating as games became harder with longer sessions. The participants' ratings of the system are included in the table as well but will be discussed later.

Table 1. Subjective evaluation scores (1=least desirable outcome and 5=most desirable outcome) from 2 case studies. Each participant submitted 1 feedback form per week for 3 weeks^a.

Item	Participants' scores								Question average score (SD) ^b
	Case 1 ^c				Case 2 ^d				
	Week 1	Week 2	Week 3	Average (SD)	Week 1	Week 2	Week 3	Average (SD)	
1. Instructions given to me were useful	4	4	4	4.0 (0.00)	4	4	3	3.7 (0.58)	3.8 (0.41)
2. The system was easy to use	4	4	2	3.3 (1.15)	4	4	4	4.0 (0.00)	3.7 (0.82)
3. The game controllers worked the way I wanted them to	4	3	2	3.0 (1.00)	4	3	4	3.7 (0.58)	3.3 (0.82)
4. It was easy to put the controllers on and take them off	5	4	4	4.3 (0.58)	4	3	4	3.7(0.58)	4.0 (0.63)
5. The controllers made little noise	5	4	5	4.7 (0.58)	4	4	4	4.0 (0.00)	4.3 (0.52)
6. The television was a suitable distance away	4	4	4	4.0 (0.00)	4	4	4	4.0 (0.00)	4.0 (0.00)
7. The games were interesting	4	4	4	4.0 (0.00)	4	4	4	4.0 (0.00)	4.0 (0.00)
8. I had no muscle pain or discomfort	5	5	4	4.7 (0.58)	4	4	4	4.0 (0.00)	4.3 (0.52)
9. I was not fatigued by the end of the game therapy session	3	4	3	3.3 (0.58)	4	4	3	3.7 (0.58)	3.5 (0.55)
10. I was not bored while exercising	4	4	5	4.3 (0.58)	4	4	4	4.0 (0.00)	4.1 (0.41)
11. The length of game exercising in a day was appropriate	4	3	4	3.7 (0.58)	4	4	4	4.0 (0.00)	3.8 (0.41)
12. There were few technical problems	3	4	4	3.7 (0.58)	4	3	4	3.7 (0.58)	3.7 (0.52)
13. I would encourage other patients to use it	4	4	4	4.0 (0.00)	4	5	4	4.3 (0.58)	4.1 (0.41)
14. I liked the system overall	4	4	4	4.0 (0.00)	4	4	4	4.0 (0.00)	4.0 (0.00)
15. The controllers were easy to slide along the table	4	4	5	4.3 (0.58)	4	5	5	4.7 (0.58)	4.5 (0.55)

^aReprinted by permission of Bright Cloud International.

^bParticipants' average score for all questions is 3.97 (SD 0.03).

^cParticipant 1 average score for all questions is 3.95 (SD 0.67).

^dParticipant 2 average score for all questions is 3.95 (SD 0.42).

Table 2 shows the subjective evaluation items for the attending therapists. This involved rating on a similar 5-point Likert scale,

but the items used were different from those presented in Table 1. The therapists' questions were designed to gauge their ability

to learn how to use the system, their perceived level of case discomfort, the appropriateness of training intensity on the BAC robotic table, and overall level of satisfaction with the system.

The therapists' ratings of the system are included as well in Table 2.

Table 2. Therapist evaluation scores (1=least desirable outcome and 5=most desirable outcome) for the BrightArm Compact system at the completion of the experimental training (session 12)^a.

Items	Scores		Question average score (SD) ^b
	Therapist 1 ^c	Therapist 2 ^d	
1. It was easy to learn how to use this system	4	4	4.0 (0.00)
2. It was easy to show the patient how to use the system	4	2	3.0 (1.41)
3. It was easy to set up and run the session	4	2	3.0 (1.41)
4. It was easy to manually enter notes during the session	3	4	3.5 (0.71)
5. It was easy to put the controller on and take it off	4	4	4.0 (0.00)
6. The controller provided good grasp training	5	5	5.0 (0.00)
7. The controller provided good finger-extension training	4	5	4.5 (0.71)
8. Patients did not appear to experience discomfort during exercises	4	5	4.5 (0.71)
9. The system reduced amount of OT ^e assistance needed	4	3	3.5 (0.71)
10. There were few technical problems using the system	4	2	3.0 (1.41)
11. The length of exercise was appropriate for the patient	4	4	4.0 (0.00)
12. The session reports provided useful information	4	4	4.0 (0.00)
13. The intensity of training was appropriate	5	3	4.0 (1.41)
14. Overall, I am satisfied with this system	5	4	4.5 (0.71)

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^bTherapist's average score for all questions is 3.89 (SD 0.62).

^cTherapist 1 average score for all questions is 4.1 (SD 0.53).

^dTherapist 2 average score for all questions is 3.6 (SD 1.08).

^eOT: occupational therapist.

Protocol

Each participant was seated at the BAC system such that the abdominal area touched the inside of the table cutout. Next, the table height was set to ensure comfortable supported movement of the arms, with minimal shoulder discomfort. Subsequent to the vital signs being checked and the game controllers being donned, the therapist instructed the participant to perform arm reach horizontally and vertically, grasp, extend fingers, and finally move the supporting arm in pronation and supination directions. The protocol set week 1 training to be unimanual (unilateral); thus, baselining captured only the affected UE. In weeks 2 and 3, both UEs were baselined and trained. Each session was paused automatically midway to allow the therapist to recheck vital signs. Checking of vital signs was repeated at the end of every session. Sessions could be paused to introduce a rest period in case the participants felt fatigued or experienced pain.

Each case study participant trained every other day, including weekends, and completed 12 sessions over 3 weeks of experimental training. The session duration lengthened progressively, from 15 minutes of exercising in week 1 to 20 minutes in week 2 and 30 minutes of gameplay in week 3.

During this period, the participants played 4 different games in week 1, 6 games in week 2, and 8 games in week 3. These game sequences were repeated as needed to complete the prescribed session exercise duration for that week. Game difficulty was preset to easiest level in week 1 and was progressed automatically such that the hardest levels were in week 3. Playing bimanually (using both hands) in weeks 2 and 3 increased physical and cognitive effort requiring hand-eye coordination and split attention.

During each session, the engineer used TeamViewer [38] to remotely access the system. The remote access allowed the engineer to monitor and assist experimental sessions in real time remotely, if needed. Technical issues were addressed in consultation with the therapist, and any required software updates were completed overnight.

Researchers also accessed a password-protected project portal separately. Information stored on this portal was graphed longitudinally to better gauge participants' progress based on system-generated variables and system-generated rehabilitation session reports. These functionalities were available at any time, regardless of whether a rehabilitation session was in progress.

In addition to the BAC experimental therapy, the 2 cases received physical therapy, occupational therapy, and speech therapy as inpatients at the PowerBack Rehabilitation facility. Each week they received 6-7 sessions of physical therapy lasting for 45 to 60 minutes each, 6-7 sessions of occupational therapy lasting for 45 to 60 minutes each, and 5 sessions of speech therapy lasting for 30 minutes each.

Ethical Considerations

Initial human participant approval was received from the Western Institutional Review Board (Protocol#20101313; now renamed WCG IRB), and participants provided informed consent.

Table 3. Game performance outcomes for the 2 cases over 3 weeks of training with the BrightArm Compact therapeutic game system. Each case's session 1 game performance and highest one are presented for comparison^a.

Outcomes	Case 1		Case 2	
	Session 1	Highest	Session 1	Highest
Games targeting motor training				
Session arm repetitions	75	504	122	957
Repetitions per minute	5	18	8	29
Session grasps	50	220	108	224
Grasps per minute	3	7	7	7
Finger extensions	10	198	62	179
Extensions per minute	<1	6	4	6
Games targeting cognitive training				
Game average difficulty (per session)	1.5	3.5	1.5	2.9
Cognitive training time (minutes per session)	16	34	16	33

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Results

Outcomes

The participants' game performance progression during the 3 weeks of experimental BAC training is shown in [Table 3](#).

The changes in motor impairment, function, and ADL independence are shown in [Table 4](#), whereas [Table 5](#) shows changes in the participants' emotive and cognitive functions.

The main game performance variables over the 12 experimental sessions are displayed in [Figure 4](#). The systolic and diastolic blood pressure progression over the 3 weeks of experimental training for the 2 cases are represented by graphs in [Figure 5](#).

Table 4. Changes in the cases' affected upper extremity impairments, function, and independence in activities of daily living over 3 weeks of training with the BrightArm Compact system^a.

Outcomes	Case 1			Case 2		
	Before the training	After the training	Difference	Before the training	After the training	Difference
Upper extremity motor impairments						
Shoulder strength (anterior deltoid; N ^b)	4.4	11.1	6.7	8.9	20.0	11.1
Shoulder strength (lateral deltoid; N)	0	6.7	6.7	6.7	13.3	6.6
Grasp strength (N)	194	247	53 (61) ^{c,d}	96	111	15 (49) ^{c,d}
Three-finger pinch strength (N)	36	47	11	12	14	2
Shoulder flexion (°)	100	117	17	118	139	21
Shoulder extension (°)	N/A ^e	N/A	N/A	22	24	2
Shoulder abduction (°)	92	118	26	110	121	11
Shoulder adduction (°)	20	33	13	41	50	9
Elbow flexion (°)	120	131	11	127	141	14
Elbow extension (°)	-20	-10	10	0	0	0
Elbow pronation (°)	45	70	25	63	90	27
Elbow supination (°)	40	70	30	57	90	33
Thumb MCP ^f flexion (°)	80	84	4	90	90	0
Index finger MCP flexion (°)	78	82	4	90	90	0
Middle finger MCP flexion (°)	85	85	0	90	90	0
Ring finger MCP flexion (°)	80	87	7	90	90	0
Little finger MCP (°)	78	78	0	90	90	0
Upper extremity motor function						
Fugl-Meyer upper extremity score (maximum 66; higher is better)	45	55	11 (9 to 10) ^d	52	62	10 (9 to 10) ^d
Jebsen Test of Hand Function total completion time (seconds; less is better)	147	126	-21 (-20.8) ^d	82	57	-25 (-20.8) ^d
Chedoke Arm and Hand Activity Inventory score (maximum 63; higher is better), bimanual	40	51	11 (6.3) ^d	44	58	14 (6.3) ^d
Upper Extremity Functional Index 20	32	51	19 (8) ^d	57	80	23 (8) ^d

^aReprinted by permission of Bright Cloud International.

^bN: newton.

^cDifferent minimal clinically important difference values for grasp strength reflect arm dominance versus arm affected. A 0° angle value indicates full extension to a straight arm (for elbow) and a straight hand for finger metacarpophalangeal joints.

^dMinimal clinically important difference for that measure.

^eN/A: not applicable.

^fMCP: metacarpophalangeal joint

Table 5. Emotive and cognitive outcomes of the cases who were in the early subacute phase after stroke^a.

Categories and assessment	Case 1		Case 2	
	Before the training	After the training	Before the training	After the training
Emotive				
Mood and personality				
Beck Depression Inventory, Second Edition	4(↓ ^b is better)	0	5	8 (60% ↑ ^c)
Cognitive				
Attention and processing speed				
Neuropsychological Assessment Battery				
Digits forward	10	6 (40% ↓)	5	10 (100% ↑)
Longest digit span forward	7	5 (40% ↓)	5	7 (40% ↑)
Digits backward	3	4 (33% ↑)	3	4 (33% ↑)
Longest digit span backward	2	4 (100% ↑)	4	4 (0%)
Dots	3	1 (66% ↓)	2	5 (150% ↑)
Trail Making Test A				
Trails A	189	>300 I (59% ↑)	72	82 (14% ↑)
Verbal memory				
Hopkins Verbal Learning Test–Revised				
Trials 1 to 3	18	19 (5% ↑)	12	11 (40% ↓)
Delayed recall	5	4 (20% ↓)	0	0
Recognition discrimination score	7	12 (71% ↑)	4	6 (50% ↑)
Visual memory				
Brief Visuospatial Memory Test, form 2				
Trials 1 to 3	5	6 (20% ↑)	5	4 (40% ↓)
Delayed recall	2	3 (50% ↑)	3	2 (40% ↓)
Recognition discrimination score	2	2 (0%)	1	3 (200% ↑)
Orientation				
Neuropsychological Assessment Battery, form 2				
Person	14	14 (0%)	14	14 (0%)
Time	8	7 (12% ↓)	6	5 (40% ↓)
Place	3	3 (0%)	3	4 (33% ↑)
Executive functioning				
Trail Making Test B	>300 (D/C) ^d	>300 (D/C)	>300 (D/C)	194 (35% ↓)
Neuropsychological Assessment Battery				
Word generation, total number of words	5	4 (20% ↓)	4	5 (25% ↑)
Word generation, total number of perseverations	0	0 (0%)	1	0 (100% ↓)

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^bArrows pointing down symbolize a decrease in the respective variables post intervention.

^cArrows pointing up symbolize an increase in the respective variables post intervention.

^dD/C: test discontinued after exceeding 300 seconds maximum allowed time.

Figure 4. Game performance for the 2 participants early subacute phase after stroke training on the BrightArm Compact robotic rehabilitation table. Reprinted by permission of Bright Cloud International Corp.

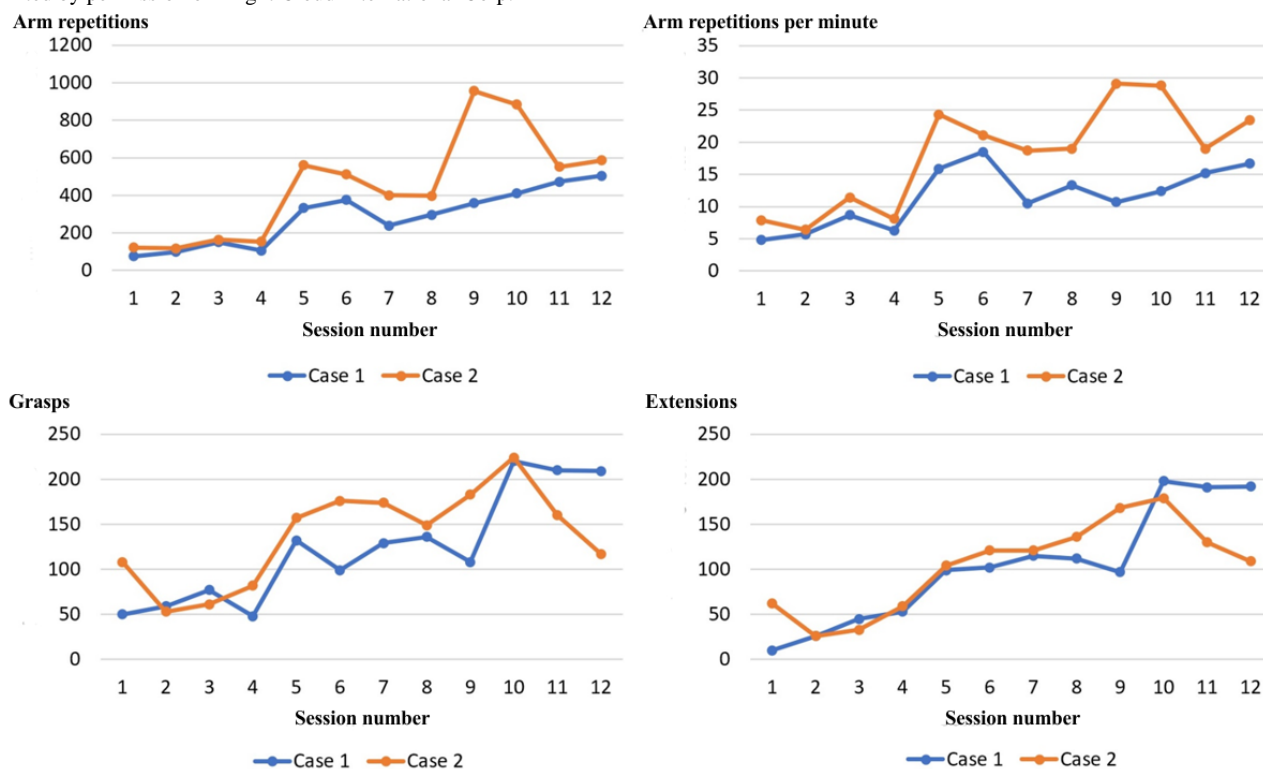
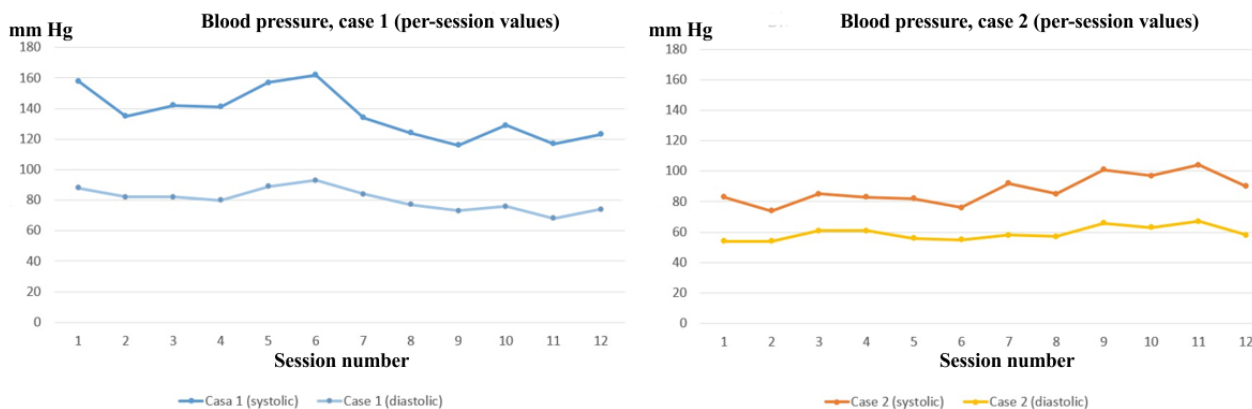


Figure 5. Participants’ blood pressure progression over 12 BrightArm Compact rehabilitation sessions. Reprinted by permission of Bright Cloud International Corp.



Case 1

Game Performance Outcomes

As seen in Figure 4, case 1’s first session on the BAC system had only 75 movement repetitions of the affected left arm. However, he attained 504 total (right+left) arm repetitions by his last experimental training session, which was played bimanually. The number of grasps grew from 50 in the first session to a maximum of 220 grasps for left and right hands combined. Similarly, the number of finger extensions grew from 10 for the hand in the first session to a high of 198 combined left- and right-hand extensions per session in session 10.

The aforementioned increases in repetitions were due in part to longer sessions, more challenging game levels, and progressing from unilateral training in week 1 to bilateral training in weeks

2 and 3. A measure that normalizes for session duration is the training intensity because it reports repetitions per minute. For case 1, training intensity grew by 360% for arm movements per minute, 233% for grasps per minute, and 600% for finger extensions per minute.

As the game-based rehabilitation was integrative, it incorporated cognitive training. As a measure of cognitive task complexity (cognitive load), the game difficulty increased for case 1 from an average level of difficulty of 1.5 in the first session to a high of 3.5 average game difficulty per session during the 3-week training. The number of cognitive training minutes per session, indicating cognitive endurance, more than doubled, from 16 minutes in session 1 to 34 minutes of cognitive training per session during the 3-week training.

Motor Impairment

The motor impairment before and after the training for case 1 is shown in [Table 4](#) for the affected nondominant left arm. Shoulder strength increased by 6.7 N for the anterior and lateral deltoid muscles, indicating the efficacy of the gravity-modulating rehabilitation table. Hand grasp strength increased from 194 N before the training to 247 N after the training. This gain of 53 N was below the 61 N minimal clinically important difference (MCID) in grasp strength increase in the nondominant arm for populations in the subacute phase after stroke. The 3-finger pinch strength went from 36 N before the training to 47 N after the training (31% improvement). There were increases in the affected arm's active range of movement, most notable for shoulder abduction (26° range increase), elbow pronation (25° increase), and supination (30° increase). Range of movement when flexing fingers improved slightly from before the training to after the training for the metacarpal joint. His finger-extension range did not improve because he had normal extension before the training.

Motor UE Function

Case 1's UE function improved, with his Fugl-Meyer score increasing 11 points, above the MCID of 9-10 points for individuals in the subacute phase after stroke [39]. He became faster in simulated ADLs, with a 21-second reduction in the time it took to complete the Jebsen Test of Hand Function (MCID -20.8 seconds for chronic stage [40]; however, no value exists for patients in the subacute phase after stroke). Case 1's independence in bimanual ADLs, measured by his score on the Chedoke Arm and Hand Activity Inventory, increased by 11 points, well above the MCID of 6.3 points for this measure [30]. On the standardized UEFI 20-question self-report, case 1's score increased by 19 points, more than double the corresponding MCID of 8 points [31].

Emotive and Cognitive Outcomes

Before the training, case 1's BDI-II score of 4 indicated minimal depression. After the training, his score was 0, indicating normal mood. As seen in [Table 5](#), case 1's neurocognitive evaluation showed a negative gain in his executive function (NAB word generation raw score decreased from 5 before the training to 4 after the training). This was matched by worse performance in Trail Making Test Part A from 189 seconds before the training to >300 seconds after the training (unable to perform), indicating diminishing attention and processing speed. However, there was improvement in 2 of the 3 scores of visual memory, measured with the Brief Visuospatial Memory Test-Revised, and similarly in 2 of the 3 scores of verbal memory, measured with the Hopkins Verbal Learning Test-Revised.

Subjective Evaluations

[Table 1](#) shows case 1's rating of the technology at the end of every week of training (3 forms were filled). With the increase in game difficulty and session duration, his score for the question "The game controllers worked the way I wanted them to" progressively dropped from 4 to 3 to 2 (an average of 3, SD 1.00, out of 5). Scores for the question "The system was easy to use" saw a similar downward trend in the last and most difficult week of training (from 4 to 4 to 2). Case 1 indicated

that he felt fatigued and scored low on the question "I was not fatigued at the end of the game therapy sessions," with an average rating of 3.3, SD 0.58, out of 5. The highest scores were for the questions "The controllers made little noise" and "I had no muscle pain or discomfort," both receiving an average score of 4.7, SD 0.58, out of 5. Despite some perceived difficulties with the controllers and his fatigue, case 1 gave an average score of 4, SD 0.00, out of 5 to the statements "I would encourage other participants to use it," and "I liked the system overall."

The attending OT for case 1 was equally positive, giving perfect scores to the statements "The controller provided good grasp training," "The intensity of training was appropriate," and "Overall, I am satisfied with the system." The therapist was neutral (3 out of 5) when rating the ease of manually entering notes during the session, but 10 other statements were rated 4 out of 5.

Vital Signs

Over the 3-week training, case 1's systolic and diastolic blood pressure values showed a decreasing trend at the end of each session. Readings dropped from 157/91 mm Hg after session 1 was completed to 126/74 mm Hg at the end of the last therapy session ([Figure 5](#)). Pulse increased slightly from 63 to 73 beats per minute for the same timeline.

Case 2

Game Performance Outcomes

As seen in [Figure 4](#), affected arm movement repetitions for case 2 started at 122 in session 1 and grew to a high of 957 total (left+right) arm repetitions per session in session 9. His grasp counts grew from 108 in session 1 to a maximum of 224 grasps (left and right hands combined) in session 10. Similarly, finger-extension counts increased from 62 in the first session to a high of 179 combined left- and right-hand extensions per session during the 3-week training. Case 2's training intensity (repetitions per minute) grew by 362% for the arms and 150% for extensions per minute, but there was no increase in intensity for grasp training. Furthermore, there was a drop in grasp and finger-extension repetitions for the last 2 sessions. During that time, case 2 was tired; his last session had to be postponed by 1 day and ended up being shorter by one-third than initially planned.

Cognitive load increased for case 2 in proportion to the average game difficulty, which grew from 1.5 on average in the first session to a high of 2.9. Cognitive endurance, reflective of the length of play minutes per session, grew from 16 minutes in session 1 to 33 minutes of cognitive training per session toward the end of the 3-week training.

Motor Impairment

Motor impairment changes for case 2 on his affected left arm (also his dominant UE) are shown in [Table 4](#). From before the training to after the training, his shoulder strength increased by 11.1 N for the anterior deltoid and by 6.6 N for the lateral deltoid, a vital outcome of the gravity-modulating feature of the BAC robotic rehabilitation table. Grasp strength improved from 96 N before the training to 111 N after the training. The 15-N gain was less than the MCID in the dominant arm of 49

N. With regard to 3-finger pinch strength, it grew from 12 N before the training to 14 N after the training (a 16% improvement). Affected arm active range of movement saw increases mainly in shoulder flexion (21° increase), elbow pronation (27° increase), and supination (33° increase). Case 2 had no change in his fingers' range of movement, either in flexion or in extension, because they had normal range before the training.

Motor UE Function

Case 2's UE function improved, with his Fugl-Meyer score increasing 10 points, equal to the MCID of 9-10 points for this measure. His speed of completing simulated ADLs, measured by the Jebsen Test of Hand Function, increased, resulting in a reduction in the task completion time of 25 seconds. This is better than the MCID of 20.8 seconds reduction for this measure. Bimanual ADL independence, measured by the Chedoke Arm and Hand Activity Inventory, improved by 14 points, well above the corresponding MCID of 6.3 points. On the standardized subjective UEFI 20-question self-report, the score improved 23 points for case 2, almost 3 times the UEFI MCID of 8 points.

Emotive and Cognitive Outcomes

Before the training, case 2's BDI-II score of 5 indicated minimal depression. After the training, his depression severity had increased in the minimal range (score of 8). Case 2's neurocognitive evaluations showed across-the-board gains in all his 6 tests of attention and processing speed. Executive function (NAB word generation raw score) increased from 4 before the training to 5 after the training. There were mixed outcomes in the tests for visual memory and similarly in those for verbal memory.

Subjective Evaluations

Case 2 gave an overall positive rating of the technology, averaging 3.95, SD 0.42, out of 5. His lowest average score of 3.7, SD 0.58, out of 5 was for the questions "Instructions given to me were useful," "The game controllers worked the way I wanted them to," "It was easy to put the controllers on and take them off," "I was not fatigued by the end of the game therapy sessions," and "There were few technical problems." In addition to these above-average scores, case 2 responded very positively to the question "I would encourage other patients to use it," which he scored at an average of 4.3, SD 0.58, out of 5. His highest average rating of 4.7, SD 0.58, out of 5 was for the statement "The controllers were easy to slide along the table."

A different OT attending case 2's training was equally positive, giving perfect scores to the statements "The controller provided good grasp training," "The controller provided good finger extension training," and "Patient did not appear to experience discomfort during exercises." The lowest ratings of 2 out of 5 were for "It was easy to show the patient how to use the system," "It was easy to set up and run the session," and "There were few technical problems using the system." The therapist agreed that they were satisfied with the system overall, with a rating of 4 out of 5.

Vital Signs

Case 2 started with very low blood pressure (80/52 mm Hg after session 1) and an elevated pulse of 81 beats per minute. Nonetheless, the attending physician and therapist had approved the participant for all activities, including the research study. Over the 3 weeks of experimental training, his systolic and diastolic blood pressure values increased steadily and his pulse rate improved. By the end of the last session, case 2's blood pressure reading was 98/61 mm Hg and his pulse was 69 beats per minute.

Discussion

Principal Findings

The BAC rehabilitation system described here is an improvement over its BrightArm Duo predecessor in compactness (smaller footprint), the functionality of game controllers (added ability to detect finger extension as well as arm pronation and supination), and better tracking of UE 3D movement (tracking on and off the table vs only on the table for the BrightArm Duo). According to the subjective evaluation results, the OTs who were assisting the participants were satisfied with the technology (average score of 3.89, SD 0.62, out of 5) and successfully used it throughout the protocol. This indicates ease of learning of the new system because 2 different OTs were able to use it successfully.

Participants did not drop out or miss sessions. Their overall rating was positive (average 3.97, SD 0.03, out of 5), despite technical problems encountered, because this was the first clinical feasibility trial of the BAC system. Another possible explanation for the score stems from the exhaustion the participants may have experienced. The system received a positive rating in spite of game-based training intensity (up to 18-29 arm repetitions and 7-8 grasps every minute) and the fact that the participants were in the early subacute phase after stroke.

In this study, both participants improved from before the training to after the training in terms of their grasp strength (27% and 16%) and 3-finger pinch strength (31% and 17%). The improvements in grasp strength were below the MCID for subacute phase after stroke, which may be due to splitting of training time among finger flexion, extension, and forearm rotation movements instead of focusing on grasp alone.

By comparison, both participants had an improvement in UE function that was at or above the MCID for all four functional outcomes (Fugl-Meyer Assessment, Jebsen Test of Hand Function, Chedoke Arm and Hand Activity Inventory, and UEFI). The improvements in coordinated movements may explain the functional improvements seen in these individuals.

In the mood domain, the results were mixed, with depression severity reducing for case 1 (from minimal to normal) but increasing minimally (within normal variability) for case 2 (Table 5). In the cognitive domain of attention, both participants improved their auditory working memory as measured by the NAB digits backward subtest. In verbal memory, both improved in the recognition discrimination score (part of the Hopkins Verbal Learning Test-Revised). However, in the executive function domain, case 2 improved substantially in Trail Making

Test B and in the NAB word generation subtest, whereas case 1 recorded negative gains on these tests. The combination of lower hand function, cognitive deficits, and depression may explain the overall lesser gains made by case 1.

Exit interviews were not conducted with the 2 cases, and their subjective evaluation form did not provide for comments on their experience. However, the therapists assisting the 2 participants took notes during their BAC sessions and on their feedback forms. The therapist assisting case 1 wrote that all movements needed assistance during week 1: "Patient needs verbal cues most of the time to squeeze/release and at times cues for which direction to move arm." In week 2, this therapist noted as follows: "Different card categories is a nice element," and in week 3, presumably with case 1 showing improvement, the therapist suggested, "Obstacles needed for Pick-and-Place to raise items over structure." In the subjective BAC evaluation, this therapist wrote as follows: "Consider 'symbols' to encourage bimanual hand use. Larger Dum Circles for [week 3] difficulty."

The therapist assisting case 2 wrote that during the first sessions, the movements needing assistance were forward reaching and lifting arm up: "[Case 2 needed] verbal/tactile cues to lift UE up when choosing game...voice cues to extend/grasp hand during Towers game." During the last week's sessions, this therapist noted, "Subject enjoyed to use both hands simultaneously for Pick-and-Place rather than unilaterally...[had] difficulty with Drums." This observation provides a clue to the degree of functional improvement in case 2. Specifically, being able to simultaneously move the arms to reach targets while following 2 ideal trajectories implies ability to split attention and improved motor control.

Limitations

This study included a limited number of participants (N=2), and the results cannot be generalized. This was due to a temporary drop in new admissions to the facility after the system had been installed, combined with the logistics of starting a follow-up randomized controlled trial (RCT) at another facility. This combination of factors limited the pool of potential candidates for the feasibility study described in this paper.

The BAC virtual rehabilitation component was added to the SOC rehabilitation that the participants were receiving as patients at an inpatient rehabilitation facility for patients in the subacute phase after stroke. During the 3 weeks of participation, the participants had 12 virtual rehabilitation sessions and 4 times as many SOC sessions (physical therapy, occupational therapy, and speech therapy). Thus, it is not possible to tell whether the VR intervention, SOC, or natural recovery was responsible for the improvements in their motor and cognitive domains. However, the improvements in gameplay were specific to BAC, as was the much higher training intensity (repetitions per minute), as opposed to SOC.

Comparison With Prior Work

Other robotic rehabilitation tables exist in clinical use, such as the Bi-Manu-Track (HASOMED). Its shape resembles that of the BAC rehabilitation table in its center cutout, although the table is only horizontal, and bimanual training is for pronation

and supination and finger flexion and extension. Although the Bi-Manu-Track does not have a VR component, its electrical actuators allow active and passive training of the impaired arms, whereas the BAC rehabilitation table only allows active UE training.

An open question within the rehabilitation robotics research community is whether robotic rehabilitation is superior to SOC of equal dosage and intensity when outcomes and costs are compared. One such study involved the Bi-Manu-Track as part of an RCT on 50 patients who were in the subacute phase after their first stroke [40]. The experimental group underwent training on several electrical devices, including Bi-Manu-Track, for 30 minutes, plus 30 minutes of individualized arm therapy, 5 days per week for 4 weeks. The control group had a matched duration and frequency of individualized arm therapy. The researchers reported no between-group differences in pre-post gains in the Fugl-Meyer Assessment, with the robot-assisted group therapy bearing half the cost of individualized arm therapy.

Another open question is whether game-based training *added to* SOC UE rehabilitation for patients in the subacute phase after stroke will produce higher outcomes than SOC alone. An RCT conducted by Wang et al [41] involved individuals who averaged 7.5 weeks after stroke and were assigned equally to an experimental group (n=13) and a control group (n=13). Each group received daily sessions of occupational therapy for 45 minutes, 5 days per week for 4 weeks. The experimental group received *additional* daily gaming sessions for 45 minutes each over the same duration, whereas the control group received a second occupational therapy session of equal length each day. Once the 4 weeks of experimental intervention were completed, all participants continued with one 45-minute session of standard occupational therapy, 5 days per week for 4 weeks. The pre-post outcome comparison using the Wolf Motor Function Test [42] showed a higher quality score for the experimental group, and the Wolf Motor Function Test time for the experimental group was significantly shorter than that for controls.

In a more recent study on patients in the acute and early subacute phase after stroke [43], researchers reported on an RCT where 7 participants had SOC (occupational therapy, physical therapy, and speech therapy) plus 8 sessions (1 hour each) of UE VR and robotics training. The control group consisted of 6 participants who received only their SOC rehabilitation. The pre-post comparison showed significantly larger gains on the Fugl-Meyer Assessment and the wrist active range of motion for the experimental group than for the control group. This study supports the belief that adding robotic and VR rehabilitation to SOC benefits patients early after a stroke. Although the BAC case study presented here did not compare with SOC alone, experimental training was nonetheless beneficial to the 2 participants.

Conclusions

The feasibility case study presented here is the first clinical trial of the novel BAC system. Experimental training could be administered easily by OTs at an inpatient rehabilitation facility for patients in the subacute phase after stroke and benefited the 2 participants. To better determine the effect of added BAC

training on SOC, an RCT involving participants in the acute and early subacute phase after stroke has been conducted. Data from this RCT are currently being analyzed, and results will be presented elsewhere.

In sum, the study contributes to the state of the science by illustrating that individuals with stroke are able to train on an integrative rehabilitation system with gains in UE motor function for different levels of severity of motor deficits. Another key contribution to the field is the limited gain noted in mood and cognition with training on the integrative system, which indicates that the training protocol with and without SOC needs

to be re-examined. The responders and nonresponders to technology-based rehabilitation training systems need to be identified based on severity of deficit.

Another important finding is that participants liked the BAC system and would recommend it to others, with overall rating of their experience at 79% (3.95 out of 5). This is remarkable in view of the relative novelty of the system to, and high technology use by, older adults. This study supports an increasing body of evidence that shows older adults as being accepting of advanced technology in rehabilitation as long as the technology is intuitive to use [44-46].

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Conflicts of Interest

GB is the majority owner of Bright Cloud International, which developed the medical device described in this paper. GB and NK are coinventors on several US patents covering the BrightArm Compact device and its therapeutic games.

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Abbreviations

- ADL:** activity of daily living
- BAC:** BrightArm Compact
- BBG:** BrightBrainer Grasp
- BDI-II:** Beck Depression Inventory, Second Edition
- IR:** infrared
- MCID:** minimal clinically important difference
- NAB:** neuropsychological assessment battery
- OT:** occupational therapist
- RCT:** randomized controlled trial
- SOC:** standard of care
- UE:** upper extremity
- UEFI:** Upper Extremity Functional Index
- VR:** virtual reality

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Review

Programs Using Stimulation-Regulating Technologies to Promote Physical Activity in People With Intellectual and Multiple Disabilities: Scoping Review

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Abstract

Background: People with intellectual and multiple disabilities tend to engage in very low levels of physical activity.

Objective: This review paper aims to provide a comprehensive picture of intervention programs using stimulation-regulating technologies to promote forms of physical activity in people with intellectual and multiple disabilities.

Methods: Following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist, a scoping review was conducted to identify and provide a synthesis of eligible studies published in English between 2010 and 2021. Studies were identified by searching PubMed, Web of Science, PsycINFO, ERIC, and CINAHL as well as by using Google Scholar and manual searches. Studies were included if they involved individuals with intellectual or multiple disabilities, used stimulation-regulating technology systems to help participants engage in physical activity, and reported data on the impact of the intervention.

Results: A total of 42 studies met the inclusion criteria. These studies were divided into 2 groups based on whether they pursued the increase in physical activity through technology-aided delivery of brief periods of preferred stimulation contingent on specific responses or the use of video games (exergames) and related auditory and visual stimulation. Subsequently, a narrative synthesis of the studies was provided.

Conclusions: The evidence reported by the 2 groups of studies is encouraging. However, further research is needed to compare the overall applicability and impact of the intervention strategies proposed by these groups of studies.

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KEYWORDS

technology; intellectual disabilities; sensory impairments; multiple disabilities; physical activity; video games; exergames; response-contingent stimulation; mobile phone

Introduction

Background

People with intellectual disabilities or multiple disabilities, such as combinations of intellectual disability and motor or sensory impairments, tend to have low (minimal) levels of physical activity compared with their typical counterparts [1-6]. Some of the more frequently reported consequences of people's reduced levels of physical activity include (1) curtailment of their interaction with the surrounding environment and of their opportunities to learn new associations and (2) weakening of their health condition in areas such as breathing, muscle tone, and blood circulation [7-11]. Lack or reduced levels of physical activity may also create a sense of dependence and helplessness, which seriously interferes with people's acquisition of initiative and self-determination and thus with their development and social achievement [12-15].

In light of this, there is a consensus on the need to develop intervention strategies to help people with intellectual and multiple disabilities increase their level of physical activity and hence reduce or even prevent the aforementioned consequences of low physical activity levels [16,17]. Different types of intervention programs have been suggested for this purpose. A number of those programs, for example, were based on the use of staff, parents, or caregivers' supervision and prompts for guiding the participants through various forms of activity, which could also involve the use of exercise devices (eg, treadmills and stationary bicycles) [18-23].

Other programs have relied on the use of stimulation-regulating technologies. Such technologies generally involve sensors linked to computers or virtual reality systems that monitor the participants' activity engagement and respond to the engagement by delivering specific forms of stimulation aimed at motivating and enhancing it. In essence, these technologies are designed to facilitate participants' engagement in a pleasant and motivating manner and, to a large extent, independent of staff direct and consistent guidance [24-28]. Programs based on these technologies, which have received increasing recognition over the years [29-32], seem to represent a relevant intervention option for several reasons [10,33-37].

First, ensuring stimulation delivery may be critical to promote activity motivation in people who, owing to their intellectual disabilities, (1) may fail to understand the importance of engaging in physical activity (the positive impact that engaging in physical activity may have on one's physical condition, appearance, and well-being) and thus (2) may lack such motivation [27,38,39]. Second, the possibility of resorting to stimulation-regulating technologies to manage the intervention approach, that is, response monitoring and appropriate stimulation delivery, would (1) avoid extra demands on staff time and (2) create practical and affordable conditions for facilitating and supporting physical activity in people who need improvement in this area [26,40]. Third, programs based on stimulation-regulating technologies do not force the individual to engage in activity, but rather promote the individual's self-determination and ultimate choice of engaging in activity [27,39,41]. This last point may be considered important because

it emphasizes the programs' respect for individual freedom while supporting the individual's rights to rehabilitation opportunities and well-being. Moreover, free (self-determined) activity engagement is likely to prevent any experience of stress and anxiety, which could materialize in the case of strict staff supervision and repeated prompting [42-45].

Perspective

An overview of studies that have assessed intervention programs based on stimulation-regulating technologies to promote physical activity in people with intellectual and multiple disabilities could provide practically relevant information with regard to (1) the characteristics of the participants involved in the programs, (2) the technology arrangements used to monitor the participants' activity responses and deliver stimulation, (3) the measures used to determine the impact of the programs, and (4) the overall impact findings. Although a recent effort was reported to synthesize the evidence in this area [46], such an effort (1) focused exclusively on studies assessing the impact of programs relying on video games and (2) included only 7 studies directed at people with intellectual disability over the 2010-2021 period.

This paper provides a comprehensive picture of intervention programs that use stimulation-regulating technologies to promote forms of physical activity in people with intellectual and multiple disabilities by reviewing studies carried out between 2010 and 2021 (ie, a period of relevant innovations in the field of stimulation-regulating technologies [47-49]). Such a picture would be expected to help professionals working in the area gain a clear appreciation of (1) the applicability (potential and limits) of intervention programs based on stimulation-regulating technologies and (2) the importance of exploring new intervention options and pursuing new research initiatives.

Methods

Search Strategy

A systematic search was conducted following the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) [50] to identify studies that reported intervention strategies based on stimulation-regulating technologies to promote physical activity in persons with intellectual and multiple disabilities. A scoping review approach was used, as our aim was to portray the technology options being used in the area and their overall applications and reported outcomes [51]. The systematic search for articles was conducted using the following databases: PubMed, Web of Science, PsycINFO, ERIC, and CINAHL. The last 3 databases were searched using the EBSCO platform. The same free-text terms were used for each database and combined by means of Boolean logical operators (*and*, *or*) to reduce the number of nonpertinent results. The resulting search syntax for all databases was as follows: "mobility" OR "physical activity" OR "exercise" OR "passive" OR "sedentary" OR "obesity" AND "technology" OR "computer" OR "mobile" OR "digital" OR "smart" OR "wearable" OR "game" OR "exergame" AND "learning disability" OR "intellectual disability" OR "developmental disability" OR "multiple

disability.” Databases and search terms were chosen based on consensus among the authors.

In an attempt to possibly find additional suitable material, the systematic search of the databases was supplemented with hand searches and a Google Scholar–based *cited by* search of the references of the articles identified through the systematic search and other literature sources dealing with stimulation-regulating technologies and physical activity in people with disabilities.

Inclusion and Exclusion Criteria

Three basic inclusion criteria were used to select the studies for the review. First, the studies involved individuals with intellectual disability or multiple disabilities, that is, a combination of intellectual disability with additional disorders, such as sensory and motor impairments. Second, the studies used stimulation-regulating technology systems aimed at helping the participants engage in forms of physical activity such as arm or leg stretching, walking, jogging, dancing, and bicycle pedaling. All these forms of engagement required a certain level of physical exertion and thus could be viewed as physical activity or exercise. Third, the impact of the intervention with the technology systems on (1) the level of activity (frequency of responses) performed or (2) some parameters of physical functioning, such as resting heart rate and balance or leg strength, was documented through specific data. There were no restrictions in the inclusion criteria with regard to the age and level of intellectual disability of the participants or the settings in which the studies were conducted. Studies were excluded if they (1) did not meet one of the aforementioned criteria (eg, focused on participants with autism spectrum disorder [52-54]), (2) were aimed at correcting the participants’ inappropriate or problem behaviors during their activity engagement [55-57], or (3) indicated the performance of occupational and functional tasks as the primary goal of the intervention, relegating the issue of physical activity to a subordinate position with no specific attention to it [58].

Data Extraction and Coding

A data charting form was developed by the first author (GEL) and iteratively reviewed by all authors until a consensus was achieved. In line with this form, the data extracted for each study included (1) the year in which the study was published and the country in which it was carried out, (2) the participants involved, (3) the technology and stimulation conditions available, (4) the design and sessions used (the protocol followed to assess the impact of intervention), (5) the responses (measures) recorded, and (6) the outcome. Finally, following a consensus-based approach among authors, codes were created to group the studies included in the review into 2 categories. The difference between categories was based on whether the studies pursued the increase in physical activity through (1) the delivery of brief periods (eg, 10 seconds) of preferred stimulation contingent on (occurring immediately after the performance of) specific responses, or (2) the use of active video games (exergames) with related auditory and visual stimulation (see the *Results* section).

Interrater Agreement

Interrater agreement was checked between the first (GEL) and the last (LD) authors (1) on scoring the eligibility of the 92 full-text articles, which were downloaded after the initial screening of titles and abstracts and (2) on reporting the data extracted from the articles reviewed (see the *Results* section). The percentage of interrater agreement on the 92 full-text articles was 92%; that is, the authors agreed (provided the same score *included* or *excluded*) on 85 of the 92 articles. Consensus between the authors on the 7 articles with initial disagreement was then achieved after a brief discussion. The percentage of interrater agreement on reporting the data extracted from the articles reviewed (which was checked over the data extracted from 10 articles) was 100%.

Results

Overview

The database search resulted in 2756 papers. The number of papers was reduced to 2215 after duplicates and papers that were not in English were removed. [Figure 1](#) illustrates the search process and outcomes. Initially, the titles and abstracts of the 2215 papers were screened. When the titles and abstracts were judged to be in line with the inclusion criteria, the corresponding full-text articles were downloaded. Following this process, 92 full-text articles were downloaded. The full-text articles were then read by the first (GEL) and last (LD) authors, and 30 of them were found suitable for inclusion in the review. The supplementary searches led to the finding of 12 additional articles, which were considered suitable for the review; consequently, 42 articles were finally included in the review ([Figure 1](#)).

The 42 studies ([Tables 1 and 2](#), [Multimedia Appendix 1](#) [10,12,27,28,32,35,37,59-78], and [Multimedia Appendix 2](#) [26,33,34,36,47,79-88]) were conducted in Italy (n=15, 36%), Taiwan (n=14, 33%), the United States (n=5, 12%), Chile (n=1, 2%), Egypt (n=1, 2%), France (n=1, 2%), Hong Kong (n=1, 2%), Israel (n=1, 2%), New Zealand (n=1, 2%), Portugal (n=1, 2%), and the Netherlands (n=1, 2%). A total of 465 participants were included in the studies. This number concerns persons who were exposed to the intervention conditions (and excluded persons exposed to control conditions). The studies were divided into 2 groups (see the *Data Extraction and Coding* section). The first group includes studies that focused on promoting specific physical activity responses through technology-regulated delivery of preferred stimulation contingent on those responses (eg, promoting arm stretching, ambulation, or pedaling responses by delivering brief periods of preferred stimulation immediately after the performance of those responses [27,35,37]). The second group includes studies that focused on promoting physical activity through the use of video games (exergames) and related auditory and visual stimulation (eg, Wii- or other system-supported video games involving activities such as dancing or playing sports [33,79,80]).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

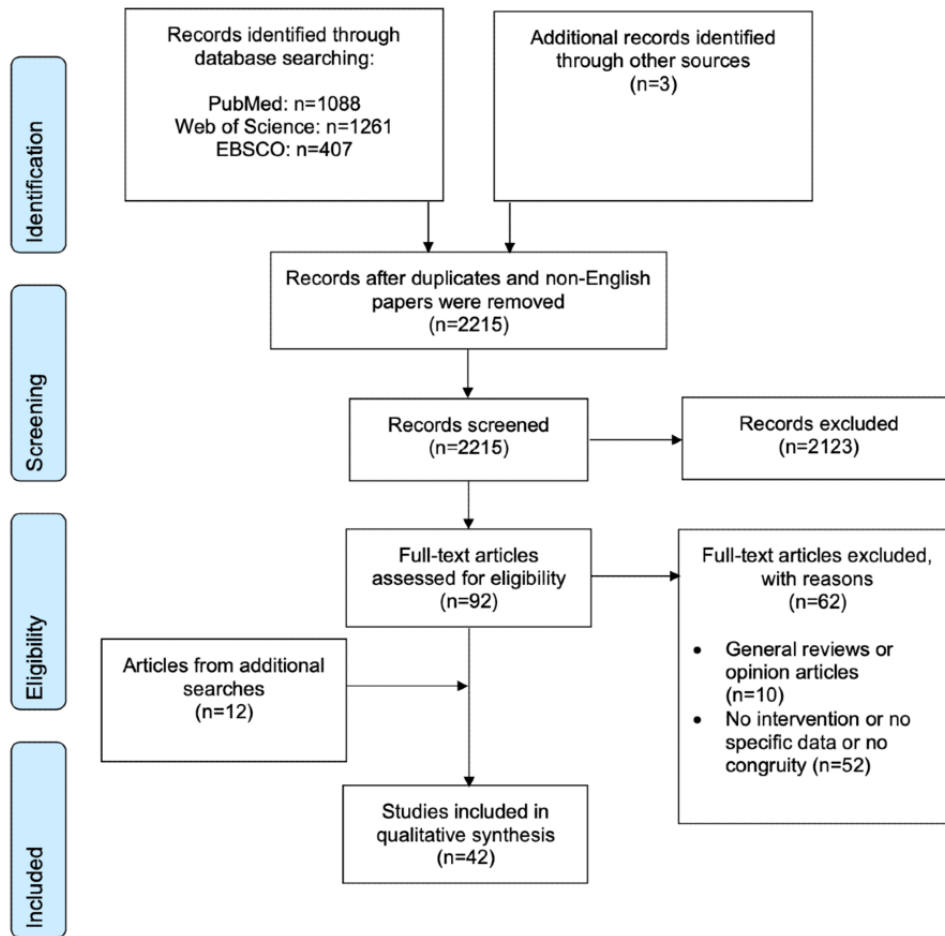


Table 1. Studies based on the use of response-contingent stimulation.

Studies and countries of origin	Participants, n (age in years)	Technology	Design	Responses (measures)	Outcome
Lancioni et al [59], Italy	5 (5.6-11.4)	Optic or pressure sensors linked to a control system	Single-subject (ABAB; baseline-intervention-baseline-intervention) design	Walker-aided step responses	Positive
Shih et al [60], Taiwan	2 (17 and 19)	Wii remote control devices linked to a mini computer and television	Single-subject (ABAB) design	Arm and leg movements	Positive
Shih et al [61], Taiwan	2 (9 and 11)	A Wii balance board linked to a mini computer and television	Single-subject (ABAB) design	Change of standing posture	Positive
Shih [62], Taiwan	2 (17 and 18)	2 Wii balance boards linked to a mini computer and television	Single-subject (ABAB) design	Walking from one Wii balance board to the other	Positive
Shih et al [35], Taiwan	2 (17 and 18)	3 Wii balance boards linked to a mini computer and television	Single-subject (ABAB) design	Walking across all Wii balance boards	Positive
Tam et al [63], New Zealand	6 (38-48)	Pressure sensors linked to electronic devices	Single-subject (multiple probe) design	Arm-hand and head movements	Mainly positive
Shih et al [64], Taiwan	4 (14-17)	Technology was as in Shih et al [35]	Single-subject (ABAB) design	Walking across the Wii balance boards	Positive
Lancioni et al [12], Italy	3 (22-42)	Optic sensors linked to a computer system	Single-subject (multiple probe) design	Right and left leg-foot lifting	Positive
Lancioni et al [65], Italy	3 (10.5-34)	Technology was as in Lancioni et al [59]	Single-subject (ABAB) design	Walker-aided ambulation	Positive
Shih et al [10], Taiwan	2 (16 and 17)	A gyration air mouse linked to a mini computer and television	Single-subject (ABAB) design	Body movements	Positive
Stasolla and Caffò [66], Italy	2 (12 and 17)	Wobble and optic sensors linked to a control device	Single-subject (multiple probe) design	Object manipulation, walker-aided ambulation, indices of happiness, and stereotypies	Positive
Chang et al [67], Taiwan	2 (16 and 17)	Technology was as in Shih et al [10]	Single-subject (ABAB) design	Pedaling	Positive
Shih and Chiu [68], Taiwan	2 (16 and 17)	A dance pad linked to a mini computer and television	Single-subject (multiple probe) design	In-place walking	Positive
Lin and Chang [69], Taiwan	2 (3.9 and 4.1)	A sensor area, a webcam, and a computer	Single-subject (ABAB) design	Feet lifting	Positive
Chang et al [70], Taiwan	4 (10-18)	Technology was as in Shih et al [10]	Single-subject (ABAB) design	Walking	Positive
Lancioni et al [71], Italy	2 (19 and 38)	Optic, wobble and pressure sensors linked to a computer	Single-subject (extended ABAB) design	Arm-hand stretching and standing	Positive
Lancioni et al [72], Italy	9 (10-29)	Technology was as in Lancioni et al [71]	Single-subject (ABAB or multiple probe) design	Arm-hand and body stretching	Positive
Stasolla et al [37], Italy	2 (5 and 6)	An optic sensor linked to a control system	Single-subject (extended ABAB) design	Walker-aided ambulation and indices of happiness	Positive
Lancioni et al [27], Italy	11 (18-50)	Optic sensors linked to a computer	Single-subject (ABAB) design	Leg or hand pedaling, stepping movements, and heart rates	Positive
Lancioni et al [28], Italy	6 (16-40)	Technology was as in Lancioni et al [71]	Single-subject (ABAB or multiple probe) design	Head, arm-hand and leg-foot responses	Positive
Stasolla et al [73], Italy	5 (13-17)	Technology was as in Stasolla et al [37]	Single-subject (extended ABAB) design	Walker-aided step responses and indices of happiness	Positive
Lancioni et al [74], Italy	7 (27-52)	A smartphone and cards with code identification tags	Single-subject (multiple baseline) design	Arm and body stretching and indices of satisfaction	Positive

Studies and countries of origin	Participants, n (age in years)	Technology	Design	Responses (measures)	Outcome
Lancioni et al [75], Italy	7 (9-42)	A smartphone and a small panel	Single-subject (multiple probe) design	Arm, leg, and head responses, heart rates, and indices of happiness	Positive
Stasolla et al [32], Italy	6 (5.8-9.6)	Technology was as in Stasolla et al [37]	Single-subject (extended ABAB) design	Ambulation responses, indices of positive participation, and self-injurious behavior	Positive
Lancioni et al [76], Italy	7 (30-74)	Technology was as in Lancioni et al [74]	Single-subject (multiple baseline) design	Arm and body stretching, heart rates, and indices of satisfaction	Positive
Shih et al [77], Taiwan	3 (17 or 18)	A dance pad linked to a mini computer and toy cargo train	Single-subject (multiple probe) design	Walking or running responses	Positive
Lancioni et al [78], Italy	4 (24-39)	A smartphone	Single-subject (multiple baseline) design	Independent or walker-aided ambulation	Positive

Table 2. Studies based on the use of video games (exergames).

Studies and countries of origin	Participants, n (age in years)	Technology	Design	Responses (measures)	Outcome
Abdel Rahman [81], Egypt	15 (10-13)	Wii Fit with balance games	Pre- and posttest plus comparison with a control group	Standing balance	Positive
Lotan et al [80], Israel	20 (37-58)	GestureTek GX single camera-based video capture VR ^a system	Pre- and posttest plus comparison with a control group	Heart rates at rest	Positive
Wuang et al [82], Taiwan	52 (7-12)	VR using Wii gaming technology	Pre- and posttest plus comparisons with 2 control groups	Motor proficiency, visual integration, and sensory integration	Positive
Berg et al [83], United States	1 (12)	VR using Wii gaming technology	Pre- and posttest assessment	Coordination, dexterity, balance, and motor proficiency	Positive
Lin and Wuang [84], Taiwan	46 (mean 15.6)	VR using Wii gaming technology	Pre- and posttest plus comparison with a control group	Muscle strength and agility performance	Positive
Salem et al [85], United States	20 (3.3-4.8)	Wii Fit and Wii sports	Pre- and posttest plus comparison with a control group	Gait speed, balance, walking, and grip strength	Partially positive
Coyle et al [26], United States	23 (19-54)	Sony Play Station's Dance Dance Revolution and Nintendo's Wii sports	Cross-over design	Heart rates and self-reported preferences	DDR more effective and Wii preferred
Hsu [79], Taiwan	8 (mean 17.5)	Wii Fit balance games	Pre- and posttest plus comparisons with 2 control groups	Static balance, dynamic balance, and speed strength index	Positive
Silva et al [36], Portugal	12 (18-60)	Wii Fit balance board with strength and other games	Pre- and posttest plus comparison with a control group	Balancing, running, dancing, and others	Positive
Gómez Álvarez et al [86], Chile	9 (6-12)	Wii Fit balance board with a variety of sport related games	Pre- and posttest plus comparison with a control group	Gross motor development, balance, locomotion, and manipulation	Positive
Ryuh et al [34], United States	7 (mean 20.3)	Just Dance 3 in connection with the Xbox 360 and Kinect	Alternation of control and video games	Heart rates, perceived exertion, and enjoyment	Mainly positive
McMahon et al [87], United States	4 (14-21)	VR exercise gaming headset, stationary bicycle, and computer	Single-subject (multiple probe) design	Bicycle pedaling, heart rates, and calories burned	Positive
Lau et al [33], Hong Kong	121 (8-18)	Active video games (Sport series) and the Xbox 360 Kinect	Pre- and posttest plus comparison with a control group	Body composition, physical activity level, and motor proficiency	Inconclusive
Enkelaar et al [47], The Netherlands	9 (38-68)	2×3-m Light Curtain device with light-emitting diodes and Kinect	Single-subject (multiple baseline) design	Physical activity, happiness, and well-being	Positive
Perrot et al [88], France	6 (mean 49.3)	Wii exercise games including Wii Sports and Wii Fit Plus	Pre- and posttest plus comparison with a control group	Muscular endurance, physical fitness, and cognitive functioning	Mainly positive

^aVR: virtual reality.

Tables 1 and 2 provide preliminary information about the studies conducted within the 2 groups. Multimedia Appendices 1 and 2 include brief summaries for all these studies. Finally, the text presents a more detailed description of some studies. More detailed descriptions are aimed at helping the reader (1) acquire a more accurate view of the intervention strategies implemented and outcomes obtained and (2) develop ideas for new research and intervention strategies that would advance the level of knowledge available in the area.

Studies Based on the Use of Response-Contingent Stimulation

Of the 42 studies, 27 (64%; including 112 participants; Table 1 and Multimedia Appendix 1) were conducted to promote

physical activity via technology-regulated delivery of preferred stimulation contingent on specific participants' responses [10,12,27,28,32,35,37,59-78]. The reasoning at the basis of these studies was that (1) the possibility of helping people with intellectual and multiple disabilities engage in physical activity may largely depend on the context's ability to motivate them to do so and (2) an effective way of motivating them could involve the use of preferred stimulation contingent on responses considered functional for their physical activity [10,27,35].

As shown in Table 1 and, more specifically in Multimedia Appendix 1, the studies adopted technology solutions, which included, among others, sensors (microswitches) linked to an electronic control system and stimulation devices, and dance

pads or Wii balance boards linked to a mini computer and a television set. The preferred stimulation available for the single responses targeted during the studies could include auditory, visual, and vibrotactile events. The single events could last between approximately 2 and 12 seconds [10,27,71,72,74], with the possibility of producing a continuous stimulation input if responding occurred with consistency [12,37,65,68].

For example, Lancioni et al [59] worked with 5 children aged 5.6 to 10.1 years who presented with severe to profound intellectual disability and motor and sensory impairments and tended to be passive and sedentary. The study aimed to promote walker-aided ambulation (step) responses and was conducted according to an ABAB design (a single-subject design alternating A-baseline and B-intervention phases) for 4 participants, whereas it only included an AB sequence for the fifth participant. The stimulation-regulating technology consisted of pressure sensors fixed to the children's shoes or optic sensors fixed to the walker and an electronic control system. This system, which was linked to the sensors and stimulation devices, monitored the participants' performance of step responses throughout the A and B phases of the study and regulated the delivery of preferred (auditory and vibrotactile) stimulation contingent on those responses during the B phases. The stimulation events set for these responses typically lasted from 3 to 5 seconds. The participants' mean frequency of step responses during the first baseline varied between approximately 7 and 26 per 5-minute session. During the first intervention phase of the study, the frequency showed more than a 3-fold increase over the baseline levels. The frequency declined during the second baseline phase and increased again during the second intervention phase.

Shih [62] investigated the possibility of increasing the physical activity of 2 participants aged 17 and 18 years with moderate or profound intellectual disability and sedentariness. One of these participants was also obese. The technology involved 2 Wii balance boards and a control system consisting of a mini computer linked to the balance boards and a television set. The participants were to walk from one balance board to another and stand on it. This study was conducted according to an ABAB design. During the A phases, the system only recorded the number of responses (walking to and standing on a balance board) the participants performed during the 3-minute sessions. During the B phases, the system also provided the participants with 6 seconds of preferred videos and music contingent on each response. During the first baseline phase, participants had a mean of approximately 3 responses per session. During the first intervention phase, their response means increased 4 to 5 times, reaching nearly 13 and 15 per session. The frequency decreased during the second baseline and increased again during the second intervention.

Chang et al [67] worked with 2 participants aged 16 and 17 years with mild to moderate or severe intellectual disability and excessive body weight. The aim of this study was to promote the participants' effective use of a stationary bicycle. The technology system included a sensor (air gyration mouse) fixed to a pedal of the bicycle and a mini computer linked to the air mouse and a television set. The television set served to present participants' preferred videos and music. The study was carried

out according to an ABAB design and included sessions of 3 minutes. During the baseline, the technology simply recorded the participants' pedaling time. During the B phases, the technology also activated the participants' preferred stimulation, contingent on their pedaling behavior. An interruption of ≥ 1 second in pedaling led to the interruption of the stimulation. During the first A phase, the participants' pedaling accounted for approximately 48% and 10% of the session time. During the first intervention phase, pedaling showed a nearly 2-fold or 9-fold increase, reaching approximately 90% of the session time. The percentages decreased during the second baseline and increased again above the 90% level during the second B phase.

Stasolla et al [32] carried out a study with 6 children aged 5.8 to 9.6 years who were characterized by severe to profound intellectual disability linked to the Cornelia de Lange syndrome. The aim was to promote walker-aided ambulation in the participants. The technology system included (1) an optic sensor, which served to detect the participants' step responses throughout the study, and (2) a control system that counted the step responses and their execution time and regulated the delivery of preferred stimulation events (eg, music, lights, and voices) during the intervention phases of the study. During these phases, the control system was set to activate one or more stimulus devices for a period of 4 seconds every time the participant completed 6 step responses within a 4-second interval. In addition to a basic ABAB design, the study also included control phases in which the stimulation was available during the sessions noncontingently; that is, independent of the participants' step responses. The sessions lasted 5 minutes. During the first baseline phase, blocks of 6 step responses occurring within 4-second intervals averaged between approximately 3 and 6 per session. During the first intervention phase, the mean frequency of the blocks increased to approximately 24 to 30 per session. The frequency declined during the second baseline phase and increased again during the second intervention phase. During the intervention phases, the participants also experienced a reduction in problem behaviors and an increase in positive (eg, alertness and happiness) behaviors. Moreover, the data improvements observed during the intervention phases were largely lost during the control phases, in which the stimulation was freely available rather than contingent on blocks of steps performed within 4-second intervals.

Lancioni et al [75] worked with 7 participants aged 9 to 42 years who presented with moderate or severe to profound intellectual disability, motor impairments confining them to a wheelchair, and blindness or minimal residual vision. The aim was to help the participants perform responses that were functional from a physiotherapeutic standpoint and relevant in terms of physical activity. Two responses, which included arm stretching to reach and push a ball and leg-foot forward moving to push a box, were selected for each participant. A multiple probe across responses was the single-subject design used to conduct the study for each participant. Accordingly, the intervention for these responses occurred at successive times. The technology involved a smartphone whose functioning was automated via MacroDroid so that it could detect (via its proximity sensor) the participants' responses and present a variety of auditory

stimuli (eg, music and familiar voices) contingent on those responses during the intervention phases of the study. Each stimulation event lasted 10 seconds, and the sessions lasted 5 minutes. The results indicated that baseline levels of zero or near zero increased for both target responses during the intervention, reaching mean frequencies that ranged between approximately 15 and 22. During the intervention sessions, the participants also showed an increase in heart rate and in indices of happiness.

Studies Based on the Use of Video Games (Exergames)

Of the 42 studies, 15 (36%; including 353 participants; [Table 2](#) and [Multimedia Appendix 2](#)) were conducted to promote physical activity through the use of video games (eg, games varying from dancing to sporting events and based on systems such as Nintendo Wii and virtual reality) and the auditory and visual stimulation involved in those games [[26,33,34,36,47,79-88](#)]. Video games are considered a relevant tool that can provide adaptable, inclusive, and modifiable physical activity options to people who may be unable to access sophisticated exercise equipment and may also have low exercise motivation [[46,89](#)].

As shown in [Table 2](#) and, more specifically, in [Multimedia Appendix 2](#), the studies carried out in this area varied in terms of the games used, the length of time those games were played, and the type of responses (measures) they relied on to determine the impact of the games. For example, Hsu [[79](#)] investigated the capacity of Wii Fit balance games to improve the balance abilities of students with mild intellectual disabilities. Three groups of 8 participants were included in the study; that is, a Wii Fit balance game training group, a physical education group, and a sedentary activity group. The Wii Fit game training group (experimental group) received two 40-minute Wii Fit balance game sessions per week over a period of 8 weeks. The same number of sessions and weekly schedules were available for the other 2 (control) groups. The mean age of the different groups ranged from 17.4 to 17.8 years. The dynamic and static balance parameters of the experimental and control participants and their speed strength index were dependent measures. Data for the Wii Fit balance game training group showed significant pre- to postintervention differences in the duration of standing on 1 leg with the eyes closed, anteroposterior movement speed, swing area per unit time, and speed strength index. The physical education group showed significant pre- to postintervention differences in the speed strength index. The sedentary activity group did not show any significant pre- to postintervention difference.

McMahon et al [[87](#)] investigated the use of an immersive virtual reality game as a means to increase the duration and intensity of pedaling on a stationary bicycle for 4 participants with moderate intellectual disability, which in one case was combined with autism spectrum disorder. The virtual reality exercise gaming platform consisted of a Virzoom exercise bicycle and an HTC VIVE virtual reality headset. In essence, the participants could use the bicycle as a means to master various games. For example, the faster the participants pedaled on their bicycle, the faster race cars, helicopters, or other objects would move for them. They could see all these objects moving through the

headset they wore during the activity sessions. The study was conducted according to a multiple probe design across participants, which meant that the baseline was extended over different periods for different participants. Sessions were set to last up to 30 minutes, but the participants could stop them at any time. The participants increased their pedaling time from approximately 3 to 6 minutes per session during baseline to between approximately 17 and 29 minutes per session during the intervention. During the intervention, the participants also (1) showed large increases in heart rate and calories burning and (2) were reported to enjoy the games available.

Lau et al [[33](#)] conducted a study involving an experimental group of 121 participants and a control group of 73 participants. The participants presented with mild intellectual disability and were aged between 8 and 18 years. The technology consisted of an Xbox 360 Kinect, and the participants in the experimental group were exposed to the intervention sessions in pairs. The sessions lasted 30 minutes and were implemented twice per week for 12 weeks. A variety of games were involved in each session, and participants could choose among those available (eg, boxing, volleyball, football, baseball, and skiing). Body composition, physical activity level, and motor proficiency were used as the outcome measures. The data showed significant changes in BMI and body fat percentage within both groups of participants during the posttest. The same trend was observed for motor proficiency. However, the effect of the intervention (after adjustment for the intervention group relative to the control group) was not statistically significant for any of the outcome measures.

Discussion

Principal Findings

This paper provides an overall picture of studies involving the use of stimulation-regulating technologies to promote physical activity in people with intellectual disabilities and multiple disabilities. The results of the 2 groups of studies included in the review suggest that the technologies used for the intervention programs were suitable for the participants involved and generally effective in helping them increase their physical activity or improve their physical condition. In light of the reported results and technologies, several points may be discussed. These points concern (1) the strength and characteristics of the evidence available, (2) the foundation and applicability of the intervention strategies, and (3) the practicality of the intervention strategies and related technologies. Future research directions to advance the present knowledge in this area and some limitations of the paper may also be examined.

Strengths and Characteristics of the Evidence

Three considerations can be made with regard to this point. First, the studies using preferred stimulation contingent on participants' responses relied on single-subject designs to determine the impact of the intervention on the level of responding (physical activity). The ABAB design (a design in which A-baseline conditions are alternated with B-intervention conditions; [Table 1](#) and [Multimedia Appendix 1](#)) was the most frequently used. Multiple probe and multiple baseline across

participants designs (designs in which the participants' baseline phase includes different numbers of sessions or spreads over different time periods) were also used. The studies using video games mostly relied on group (randomized controlled) designs. Comparisons were carried out between the pre- and postintervention data of the experimental group, as well as between the experimental group's data and the data of 1 or 2 control groups. On the basis of the designs used, one could argue that the evidence on the impact of the intervention reported by the studies may be considered reliable.

Second, notwithstanding the overall methodological adequacy of the studies, it may be difficult to compare and contrast the results obtained by the 2 groups; that is, the group based on response-contingent stimulation and the group based on video games. In fact, the studies in the first group typically focused on assessing whether the intervention was effective in increasing the responses targeted with contingent stimulation, assuming that this increase would in turn have beneficial effects on the participants' physical and health conditions. The studies in the second group (except for those by Enkelaar et al [47] and McMahon et al [87]) did not assess the extent to which the intervention increased the participants' responses. Rather, they concentrated on determining whether the intervention period would bring about benefits to participants' physical condition (eg, balance, BMI, and muscle strength).

Third, comparisons of the results of the 2 groups of studies are difficult also because of the differences in the length of the intervention sessions and the characteristics of the participants. The length of the sessions varied between 2 and 10 minutes in the first group of studies and between 10 and 60 minutes in the second group of studies (Multimedia Appendices 1 and 2). The participants in the first group of studies often presented with severe to profound intellectual disability, which could be combined with severe and extensive motor impairments. The participants in the second group of studies were generally reported or presumed to be in the mild or moderate intellectual disability range and did not present with specific motor impairments.

Foundation and Applicability of the Intervention Strategies

The intervention strategies used by the first group of studies were designed to deliver preferred stimulation contingent on participants' specific activity responses, and this stimulation was assumed to (1) motivate the participants to reproduce those specific responses and thus (2) increase their activity level. Within this type of framework, the efficacy of the stimulation in promoting the acquisition and maintenance of responding is linked to its contingency value and attractive (reinforcing) power [90,91]. The more attractive the stimulation, the higher the probability that the participant would be motivated to produce the response for which the stimulation is available.

Intervention strategies based on the use of video games are also assumed to work through motivation and enjoyment. In essence, the game-specific prompting and stimulating images and auditory events are expected to facilitate the participants' initial engagement. The additional game-related stimulation events or stimulation variations connected to the participants' engagement

are considered relevant or critical to strengthen and maintain such engagement and thus bring about an increase in the participants' physical activity. In light of this reasoning, the game-related stimulation seems to play a role similar to that attributed to the contingent stimulation used in the first group of studies. However, notwithstanding this reasoning no assessment was reported by the second group of studies of the participants' stimulation preferences or of whether the participants perceived the stimulation variations occurring in relation to their game engagement as truly enjoyable.

With regard to the issue of applicability, the strategies based on contingent stimulation for specific responses may be viewed as largely suitable for people with severe or profound intellectual disabilities and extensive motor or sensory impairments as well as for people with mild to moderate intellectual disabilities. For example, these strategies could be applied to help participants with different levels or combinations of disabilities to perform responses such as arm stretching and walker-supported ambulation responses or use exercise devices (1) without the need for external prompting (pressure) and (2) with apparent enjoyment of their activity engagement [27,37,68,72,74,75].

The use of video games may not be suitable for participants with severe to profound intellectual disabilities and extensive motor impairment. These participants, in fact, may possess only a narrow range of responses, which is insufficient for playing most games. Moreover, the same participants may be attracted to (motivated by) only a few types of stimuli, and these stimuli may not be included in a variety of games and should be identified through careful stimulus preference screening before the beginning of the intervention. Finally, participants with severe to profound intellectual and multiple disabilities may have serious difficulties in finding strong motivation to respond in a game situation in which much of the stimulation is available noncontingently (independent of participants' responding) [37,73].

Practicality of the Intervention Strategies and Related Technologies

Two considerations may be in order with regard to the practicality issue. First, the use of intervention strategies aimed at providing preferred stimulation contingent on specific participants' responses is typically based on a multistep plan that involves (1) the identification of the responses that are feasible for the participants to perform and suitable for promoting relevant forms of physical activity, (2) the identification of stimulation events that the participants prefer (apparently enjoy), (3) the selection of sensors adequate to detect the responses and trigger a control system, and (4) the programming of the control system to deliver a brief segment of preferred stimulation any time it is triggered (any time the target responses occur). Working out this plan may be relatively demanding in terms of staff time and skills as well as technical devices. Despite its possible costs, such an approach may be critically relevant, particularly when working with people with severe to profound intellectual and multiple disabilities (see the *Studies Based on the Use of Response-Contingent Stimulation* section and Multimedia Appendix 1).

Second, the use of video games to promote physical activity might be perceived as a relatively simple approach given the availability of a wide range of games. However, in reality, it may not necessarily prove easier to arrange or more practical to manage than the use of strategies based on contingent stimulation [36,47,92]. Moreover, the fact that a variety of games are commercially available does not automatically imply that they can be considered equally suitable for all participants and that they can be implemented in any context in which the participants live [33,47].

Future Research Directions

Future research should address several relevant issues. First, studies could be conducted to clarify different aspects of interventions using video games, such as (1) the implementation conditions (ie, the level and characteristics of staff support required to get participants involved in the games), (2) the measurement of the participants' activity level (eg, range and frequency of responses they display during the games), and (3) variability or consistency in the activity level during the intervention period. Clarifying these aspects would help determine the procedural conditions and time costs required for the application of those games, as well as the immediate and long-term functions of the games. This information could also serve to estimate the practicality and applicability of game-based interventions in daily contexts.

Second, studies comparing interventions based on the delivery of preferred stimulation contingent on specific participants' responses with interventions based on video games might be very important to enhance our knowledge in the area. These studies may be instrumental to determine (1) the relative value of the 2 intervention approaches with different groups of people (particularly people in the moderate range of intellectual disability) and (2) the relative cost of the approaches in terms of technology and staff involvement.

Third, in addition to measuring the increases in the participants' levels of physical activity and related health benefits, new studies may also be focused on assessing the participants' levels of satisfaction (indices of happiness) during the intervention sessions with the 2 types of approaches. Although some data on this issue are available [37,47,73,75], additional evidence is important to determine whether and how much these approaches can help participants experience a positive emotional condition during their activity engagement.

Fourth, social validation studies would be important to determine the opinion of staff, families, and service providers about the usability and potential of the different approaches (thus adding to early data in the area [32,73]). Social validation could be carried out by (1) showing staff, families, and service providers a few segments of the intervention sessions carried out with the 2 approaches and (2) asking them for their ratings of those segments and the technology solutions used in terms of perceived efficacy, friendliness, and overall applicability across participants and contexts [32,93].

Fifth, encouraging different research groups from different countries to be involved in new research initiatives in the area could constitute a meaningful objective to increase the generality

and representativeness of the findings. This objective might be particularly relevant for studies focusing on the use of stimulation contingent on specific participants' responses, given that the research thus far available was almost exclusively concentrated in 2 countries (Italy and Taiwan).

Limitations

This review paper has 3 limitations. First, one might argue that a literature search restricted to articles written in English may have prevented the detection and inclusion of relevant studies published in other languages. Indeed, we have no knowledge of whether or how many potentially relevant studies were published in other languages and were not included in this review. Second, the use of free-text terms (rather than specific indexed terms) for the search of different databases might have made the search process slightly less precise (less effective in identifying all relevant articles in the area). Third, one might consider the exclusion of studies involving people with autism spectrum disorder as another limitation of this review paper. In fact, the inclusion of studies involving the participation of people with autism would have provided (1) a more comprehensive picture of the use of stimulation-regulating technologies for promoting physical activity and (2) a wider amount of evidence to determine the overall applicability and impact of those technologies within services for people with special needs. Notwithstanding the aforementioned limitations, this review paper presents a picture of the technologies and their applications and effects based on a relatively large number of studies (ie, 42 studies). This may provide credibility for the picture presented here. At the same time, it may also be a prompt for (1) extending the search to non-English articles and (2) reviewing the studies that focused on people with autism spectrum disorder and comparing their results with those obtained from people with intellectual and multiple disabilities.

Conclusions

People with intellectual and multiple disabilities need to increase their level of physical activity, and intervention programs have been developed to help them reach this goal. This paper provides a picture of 2 groups of studies that relied on the use of stimulation-regulating technologies to work toward that goal. One group of studies sought to promote physical activity via technology-regulated delivery of preferred stimulation, contingent on specific participants' responses. Another group of studies sought to promote physical activity through the use of video games and the auditory and visual stimulation involved in those games.

Both groups of studies reported encouraging results; however, these results cannot be easily compared and contrasted. In fact, the studies of the first group were typically focused on assessing whether the intervention was effective in increasing the responses targeted with contingent stimulation, whereas the studies of the second group mainly focused on whether the intervention would bring about benefits on the participants' physical condition.

Future research will need to address a number of issues, including (1) the identification of the procedural conditions required for the implementation of video games; (2) comparisons

between the 2 strategies in terms of impact, accessibility, practicality, and participants' satisfaction; and (3) social validations of the 2 strategies.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of the studies based on the use of response-contingent stimulation.

[[DOCX File , 29 KB - rehab_v9i2e35217_app1.docx](#)]

Multimedia Appendix 2

Summary of the studies based on the use of video games (Exergames).

[[DOCX File , 19 KB - rehab_v9i2e35217_app2.docx](#)]

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Abbreviations

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

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Review

Inertial Measurement Units and Application for Remote Health Care in Hip and Knee Osteoarthritis: Narrative Review

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Abstract

Background: Measuring and modifying movement-related joint loading is integral to the management of lower extremity osteoarthritis (OA). Although traditional approaches rely on measurements made within the laboratory or clinical environments, inertial sensors provide an opportunity to quantify these outcomes in patients' natural environments, providing greater ecological validity and opportunities to develop large data sets of movement data for the development of OA interventions.

Objective: This narrative review aimed to discuss and summarize recent developments in the use of inertial sensors for assessing movement during daily activities in individuals with hip and knee OA and to identify how this may translate to improved remote health care for this population.

Methods: A literature search was performed in November 2018 and repeated in July 2019 and March 2021 using the PubMed and Embase databases for publications on inertial sensors in hip and knee OA published in English within the previous 5 years. The search terms encompassed both OA and wearable sensors. Duplicate studies, systematic reviews, conference abstracts, and study protocols were also excluded. One reviewer screened the search result titles by removing irrelevant studies, and 2 reviewers screened study abstracts to identify studies using inertial sensors as the main sensing technology and a primary outcome related to movement quality. In addition, after the March 2021 search, 2 reviewers rescreened all previously included studies to confirm their relevance to this review.

Results: From the search process, 43 studies were determined to be relevant and subsequently included in this review. Inertial sensors have been successfully implemented for assessing the presence and severity of OA (n=11), assessing disease progression risk and providing feedback for gait retraining (n=7), and remotely monitoring intervention outcomes and identifying potential responders and nonresponders to interventions (n=14). In addition, studies have validated the use of inertial sensors for these applications (n=8) and analyzed the optimal sensor placement combinations and data input analysis for measuring different metrics of interest (n=3). These studies show promise for remote health care monitoring and intervention delivery in hip and knee OA, but many studies have focused on walking rather than a range of activities of daily living and have been performed in small samples (<100 participants) and in a laboratory rather than in a real-world environment.

Conclusions: Inertial sensors show promise for remote monitoring, risk assessment, and intervention delivery in individuals with hip and knee OA. Future opportunities remain to validate these sensors in real-world settings across a range of activities of daily living and to optimize sensor placement and data analysis approaches.

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KEYWORDS

wearable technology; accelerometer; gyroscope; magnetometer; remote monitoring; biofeedback

Introduction

Background

Delivery of care and assessment of outcomes in patients' natural environments have made large strides in recent years. The COVID-19 pandemic has further created a need for and accelerated the adoption of remote approaches to health care. Wearable sensors, which are used to describe small, lightweight measurement devices that can be worn on the body [1], have become integral to models of remote care and assessment. These devices can be worn directly on the body or within an accessory (eg, a watch) without altering the user's natural behavior.

Osteoarthritis (OA) is a mechanically driven disorder and a leading cause of disability in middle-aged and older age adults [2]. The burden of OA is primarily due to the greater prevalence of knee and hip OA [3], including those who undergo joint replacement surgery for hip or knee OA [4]. In people with hip or knee OA, abnormal joint loading during daily activities has been associated with pathogenesis [5], driving interest in assessing the relationships between repetitive loading during everyday movements and disease outcomes and interventions to alter these loads [6]. Although there is a large body of literature on understanding movement patterns during daily activities in people with knee or hip OA, a majority of the prior work has used laboratory or clinical assessments, which have limited ecological validity [7]. Furthermore, the gold standard for measuring human movement, optical motion capture, requires expensive equipment, skilled technicians, and a large calibrated measurement space, limiting its deployment on a large scale. In contrast, wearable technology can provide large volumes of data from real-world settings with relative ease. These data could improve health care quality by allowing remote monitoring to inform treatment planning [8], for remote care delivery to address provider and patient time constraints [9], and for promoting active patient engagement through actionable insights [9]. Thus, wearable sensors offer tremendous opportunities to advance research and care for people with hip or knee OA, including those who undergo joint replacement surgery, most frequently total hip arthroplasty (THA) or total knee arthroplasty (TKA) of the arthritic joint.

The most common wearable movement sensors that have been used for OA applications are accelerometers, gyroscopes, and magnetometers. Accelerometers measure the applied acceleration (ie, rate of change of linear velocity) along a sensitive axis [10]. Gyroscopes measure angular velocity (ie, the rate of change of angular motion) within a rotating reference frame [11]. Magnetometers capture data that can provide heading information, including body orientation, by sensing Earth's gravitational field [12]. All 3 of these sensors have limitations: accelerometers suffer from signal drift [13], poor reliability in measuring nondynamic events [14], and the impact of gravity on acceleration signals [12]; gyroscopes experience problems with drift, particularly during turning movements [11]; and magnetometers can be affected by other magnetic

fields (eg, nearby ferromagnetic objects) [15]. Consequently, these technologies are often used in combination, especially as inertial measurement units (IMUs; also known as *inertial sensors*), consisting of an accelerometer, gyroscope, and sometimes a magnetometer. Inertial sensors are relatively inexpensive, small, lightweight, and unobtrusive, allowing for implementation in large cohorts; these sensors can be used alongside other technologies or types of sensors to provide feedback to users (eg, mobile apps).

Objectives

The aim of this review was to analyze the current uses and limitations of using inertial sensors for assessing movements during daily activities in individuals with hip or knee OA, including those who undergo joint replacement surgery, and to identify how this may translate to improved remote health care in this population. We conclude with a discussion highlighting the potential future applications and remaining areas where further development is required. This review may be used to inform current practices and further research on these promising technologies.

Methods

Search Strategy

For this narrative review, we performed an initial literature search in the PubMed and Embase databases in November 2018 and repeated the search in July 2019 and March 2021. The keywords used for the search were ("IMU" OR "inertial sensor" OR accelerometer OR gyroscope OR magnetometer OR wearable* OR sensor) AND (osteoarthritis OR arthritis OR "TKR" OR "TKA" OR "knee replacement" OR "knee arthroplasty").

Data Extraction

We included studies that met the following criteria: (1) original studies published in the English language, (2) published within the previous 5 years, (3) used inertial sensors for the study of human movement, and (4) included data from people with OA or those with knee replacement. We excluded studies that used inertial sensors to study other related constructs (eg, sleep quality and physical activity) but did not directly study movement patterns. We excluded studies that focused on individuals with knee injuries without a diagnosis of knee OA (eg, anterior cruciate ligament tear and meniscus injury). Duplicate studies, systematic reviews, conference abstracts, and study protocols were also excluded. One researcher (either SE or MJR) screened the search result titles, removing studies that were not relevant to this review. For the remaining studies, 2 researchers (either SE and DK or MJR and KEC) read each study abstract to determine whether the study should be included. The final decision on inclusion was made in consensus by MJR, KEC, and DK. A total of 2 authors (SE and MJR) reviewed the included studies and annotated key information, including study objective, study population, details of the inertial sensor, specifics of the application for which the sensors were

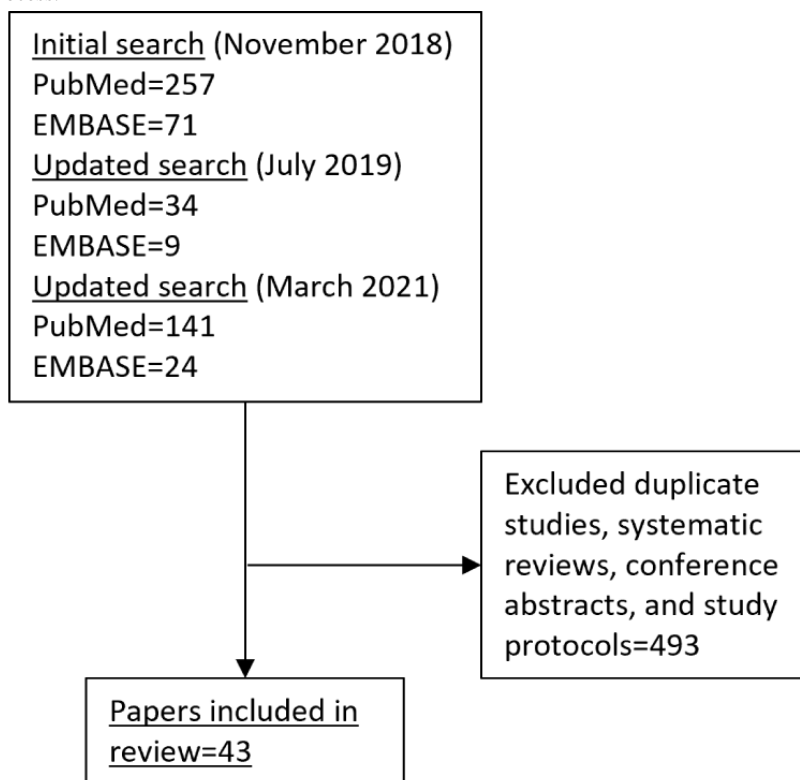
used, and the findings. After reviewing this information, we categorized the included studies based on the study objective to organize this review for the reader. Specifically, we categorized the studies into those related to the validity and repeatability of inertial sensor measurements ($n=8$), assessment of OA presence and severity ($n=11$), assessment of movement patterns associated with OA progression and gait retraining ($n=7$), assessment of OA intervention outcomes ($n=14$), and sensor placement and data analysis ($n=3$). For each of these sections, we synthesized the findings from the included studies

with a focus on applications, limitations, challenges, and possible future directions. Tables are presented for each section, summarizing the key information from the included studies. Detailed descriptions of the study and sensor applications can be found in tables in [Multimedia Appendix 1](#) [16-56].

Results

Our literature search identified a total of 536 papers, of which 43 were determined relevant and included in this review ([Figure 1](#)).

Figure 1. Literature search process.



Validity and Repeatability of Inertial Sensor Measurement of Movement

As the use of wearable technology for movement quality assessment has increased, there is a need to assess the repeatability and validity of these technologies ([Table 1](#); [Table S1](#) in [Multimedia Appendix 1](#)). In people with hip OA, waveforms recorded from a single pelvic IMU were reported to have a shape and magnitude similar to those recorded by optical motion capture [57]. Using a robotic arm and anthropomorphic leg phantom to simulate knee flexion at 3 different speeds, Fennema et al [16] identified acceptable test-retest repeatability of IMU-based joint angle measurements ($<+5^\circ$ or -5°) across different knee flexion speeds or with repositioning of the IMUs. In healthy young adults, the foot progression angle (FPA), that is, the angle of the foot relative to the direction of travel, has also been measured with good to excellent validity (intraclass correlation coefficient=0.89-0.91) and reliability (intraclass correlation coefficient=0.95) [17] and with errors $<2^\circ$ compared with optical motion capture [58] using a shoe-embedded IMU. Many IMU systems have been successfully validated against optical motion capture, including

a 17-IMU system used to estimate knee adduction moment (KAM) and tibiofemoral joint contact forces [18]; a 4-IMU system used to measure spatiotemporal gait variables and knee range of motion (ROM) [19]; and a 7-IMU system used to measure ankle, knee, and hip joint angles in populations with hip [20] and knee OA [21]. In addition, Bravi et al [22] found a single, lower trunk IMU valid for measuring spatiotemporal gait parameters in both healthy participants and patients with recent TKA or THA walking with crutches; however, the device struggled with gait cycle phase recognition in the patient group. Youn et al [59] found that variables related to initial loading behavior (ie, knee flexion moment, KAM, anterior ground reaction force, and vertical ground reaction force) could be predicted ($R^2 \geq 0.60$) from 10 temporal and kinetic parameters extracted from 2 ankle-worn accelerometers in patients post TKA. These studies suggest that wearable sensors can be used to estimate joint kinetics. IMU-based systems have also been found to provide valid metrics compared with optical motion capture during more demanding tasks (ie, stair ascent, stair descent, and sit-to-stand) in healthy older adults [18] and during level walking in individuals post THA [60]. Furthermore, low

coefficient of variance values (<10%) was reported when IMUs were placed by different operators or when sensors were displaced along the anteroposterior and mediolateral axes by +20 to -20 mm [23]. As hardware enhancements continue and

with the availability of larger data sets, it is anticipated that the performance of these devices will continue to improve, particularly with the use of advanced machine learning approaches for data analysis.

Table 1. Inertial sensors validity and reliability measuring movement.

Study	Population	Sensor	Findings
Bravi et al, 2020 [22]	Healthy (n=10), THA ^a (n=10), and TKA ^b (n=10)	Single IMU ^c (G-WALK, BTS Bioengineering) on trunk	Single IMU reliable for measuring spatiotemporal gait in individuals using crutches
Charlton et al, 2019 [17]	Healthy (n=20)	Single IMU ^c (MPU-9150, InvenSense) embedded in shoe sole under heel	Good to excellent reliability measuring foot progression angle in overground walking
Fennema et al, 2019 [16]	Anthropomorphic phantom leg	2 IMU ^c (MetaMotionR, mbientlab) on thigh and shank	Acceptable repeatability in range of motion measurements from 2 different IMU placements
Hafer et al, 2020 [19]	Healthy (n=20) and knee OA ^d (n=9)	4 IMU ^c (OPAL, APDM) on foot, shank, thigh, and lower back	Minimal IMU setup and reproducible methods can accurately capture gait metrics
Ismailidis et al, 2020 [20]	Healthy (n=45) and hip OA (n=22)	7 IMU ^c (RehaGait, Hasomed) on pelvis, feet, shanks, and thighs	Validated commercial IMU system against literature on marker-based data differences between hip OA and healthy individuals
Ismailidis et al, 2021 [21]	Healthy (n=46) and knee OA (n=22)	7 IMU ^c (RehaGait) on pelvis, feet, shanks, and thighs	Sensors able to discriminate between knee OA and healthy individuals and between affected and unaffected sides in unilateral knee OA
Konrath et al, 2019 [18]	Healthy (n=8)	17 IMU ^c (Xsens Awinda, Xsens Technologies BV) on entire body	Moderate to strong Pearson correlation coefficients found between knee adduction moment and tibiofemoral joint contact force calculations
Zügner et al, 2019 [60]	THA (n=49)	6 IMU ^e (GaitSmart, Dynamic Metrics Ltd) on iliac crests, thighs, and shanks	Validated IMUs for measuring mean pelvic tilt and knee flexion angles

^aTHA: total hip arthroplasty.

^bTKA: total knee arthroplasty.

^cIMU: inertial measurement unit (with accelerometer, gyroscope, and magnetometer).

^dOA: osteoarthritis.

^eIMU with accelerometer and gyroscope.

Assessment of OA Presence and Severity

One of the most common applications of inertial sensors identified in this review was to determine the presence or severity of hip or knee OA using IMU-derived movement parameters (Table 2; Table S2 in Multimedia Appendix 1). Across these studies, there was a wide variation in the methods used to extract various movement parameters. Simpler approaches rely on using raw sensor data and focus on walking gait. For instance, Tanimoto et al [24] compared the peak shank angular velocity during swing directly measured from a gyroscope between people with knee OA and controls. The authors determined gait cycles using an acceleration signal. Although they did not find any significant differences in the average and variability measures of peak shank angular velocity between groups, they observed that greater angular velocity and lower variability of peak angular velocity were related to lower pain and better participant-reported function. Another relatively simple approach included using the mean and root mean square

of the acceleration and angular velocity signals from foot-worn IMUs without undertaking any gait cycle detection [23]. Using this approach, Barrois et al [23] identified 4 of 61 parameters to be discriminative between people with knee or hip OA with moderate impairments, those with severe impairments, and healthy controls. However, given the large number of comparisons with a relatively small sample and no adjustment of the *P* value, their findings may be susceptible to type 1 errors. Finally, Na et al [25] reported a greater magnitude of tibial acceleration and tibial jerk (ie, the time derivative of acceleration) during the midstance phase of walking in people with knee OA compared with controls and greater acceleration being related to greater self-reported knee instability. The findings from these studies suggest that information extracted from the raw acceleration or angular velocity signals, even from a single sensor, may be useful to discriminate between people with knee OA and controls and could be related to clinically meaningful participant-reported outcomes.

Table 2. Inertial sensors and assessment of osteoarthritis presence and severity.

Study	Population	Sensor	Findings
Barrois et al, 2016 [23]	Healthy (n=12) and knee or hip OA ^a (n=48)	4 IMU ^b (MTw, Xsens Technologies BV) on feet, lower back, and head	Found discrimination capacity between OA severity groups in parameters of mean and root mean square of horizontal acceleration in both feet
De Brabandere et al, 2020 [31]	Hip OA (n=20)	Single IMU ^c (Samsung Galaxy J5 2017, Samsung) inside cell phone, attached to hip	Trained machine learning pipeline to estimate hip and knee joint loading; error too large for clinical use
Dindorf et al, 2020 [32]	Healthy (n=27) and THA ^d (n=20)	7 IMU ^c (Awinda, Xsens Technologies BV) on feet, shanks, thighs, and back	Automatically extracted features gave best machine learning accuracy in discriminating THA from healthy individuals
Ismailidis et al, 2020 [61]	Healthy (n=48) and hip OA (n=24)	7 IMU ^b (RehaGait, Hasomed) on pelvis, feet, shanks, and thighs	Significant changes in hip and knee kinematics exist between hip OA and healthy individuals in speed matched conditions
Ismailidis et al, 2020 [26]	Healthy (n=28) and knee OA (n=23)	7 IMU ^b (RehaGait) on pelvis, feet, shanks, and thighs	Significant differences in all spatiotemporal parameters between groups when walking at self-selected speed
Na and Buchanan, 2021 [25]	Healthy (n=13) and knee OA (n=26)	5 IMU ^c (3D myoMOTION, Noraxon) on pelvis, thighs, and shanks	Linear acceleration (significant) and jerk (insignificant) negatively associated with self-reported instability
Odonkor et al, 2020 [27]	Healthy (n=10) and knee OA (n=10)	2 IMU ^b (Shimmer3, Shimmer Sensing) on feet	Stance and double support ratio 2 most consistent discriminating features between OA and controls
Tadano et al, 2016 [28]	Healthy (n=8) and knee OA (n=10)	7 IMU ^c (H-Gait system, Laboratory of Biomechanical Design, Hokkaido University) on pelvis, thighs, shanks, and feet	Angle between knee trajectories nearly twice as large in OA individuals compared with healthy controls
Tanimoto et al, 2017 [24]	Healthy (n=11) and knee OA (n=12)	Single IMU ^c (MVP-RF8-GC-500, Microstone) on anterior shank	No differences between 2 groups for any parameters for peak shank angular velocity
Van der Straaten et al, 2020 [29]	Healthy (n=12) and knee OA (n=19)	15 IMU ^b (MVN BIOMECH Awinda) on entire body	Individuals with knee OA walked with significantly less trunk rotation, less internal pelvic rotation during stance to swing, and reduced knee flexion among other discriminating differences
Van der Straaten et al, 2020 [30]	Healthy (n=12) and knee OA (n=19)	15 IMU ^b (MVN BIOMECH Awinda) on entire body	Knee OA individuals had more lateral trunk lean toward contralateral leg and more hip flexion throughout performance of unipodal stance task

^aOA: osteoarthritis.

^bIMU: inertial measurement unit (with accelerometer, gyroscope, and magnetometer).

^cIMU with accelerometer and gyroscope.

^dTHA: total hip arthroplasty.

Other studies have used more computationally complex approaches to extract spatiotemporal parameters and joint kinematics during walking using IMU data. Ismailidis et al [26,61] published 2 studies, one each in people with end-stage hip OA and those with end-stage knee OA, in which they compared spatiotemporal and sagittal plane kinematics from IMUs between OA and control populations. Using statistical parametric mapping, they observed differences in multiple parameters (eg, cadence, knee, and hip kinematics) between each OA population and controls. Differences in spatiotemporal parameters between people with knee OA and controls [27] and in joint kinematics among knees with varying OA severity [28] have also been reported by other studies. These approaches are closer to the information traditionally obtained using 3D motion capture systems and allow for comparisons with existing literature. However, most of these studies relied on commercial systems, which raises concerns about the accuracy and validity of the data because the algorithms tend to be proprietary.

In addition to walking, IMUs were used to compare movement patterns during other daily activities between individuals with OA and controls. In 2 studies from the same cohort of people with end-stage knee OA and controls, van der Straaten et al [29,30] compared movement patterns during various activities, including walking, lunge, stair climbing, squatting, sit-to-stand, and single-leg balance. They reported differences in multiple measures, including those representing motions of the trunk and pelvis, which had not been previously reported. These authors also used a commercial system but undertook a validation study against optical motion capture. They concluded that the given IMU system was not ready for the assessment of movement patterns in patients with knee OA, particularly for motions in the frontal plane.

The final 2 studies in this section used machine learning approaches during the postprocessing of IMU data [31,32]. Going beyond spatiotemporal parameters and joint kinematics,

De Brabandere et al [31] estimated hip and knee contact forces during various daily activities from a single IMU within a smartphone using machine learning. They observed differences in the model performance across joints (hip vs knee) and activities. They concluded that their approach, which was easy to use and promising in terms of model performance, did not result in an estimate of contact force that was sufficiently accurate for clinical use. However, this study represents an important advancement in the estimation of joint contact forces from IMUs, and future work with multiple sensors and more advanced machine learning approaches may yield better results. Finally, Dindorf et al [32] used explainable artificial intelligence to classify people into those post total hip replacement and controls using data from 7 IMUs during walking. They used both raw data and joint kinematic data as inputs in different models and observed excellent model performance. They reported that sagittal movement of the hip, knee, and pelvis, along with transversal movement of the ankle, was especially important for classification [32]. The use of machine learning and deep learning approaches is only expected to increase,

particularly as IMUs facilitate the collection of data in cohorts much larger than is possible with traditional motion capture. These approaches could eventually lead to digital biomarkers of OA from data collected using simple and inexpensive IMU sensors.

Assessment of Movement Parameters Related to OA Progression and Gait Retraining

Although discriminating between people with and without OA is important, being able to identify individuals at risk of worsening disease early in the disease process would be even more valuable. To this end, another key application of inertial sensors was in using these relatively low-cost sensors to quantify important gait parameters that have previously been associated with knee OA progression (Table 3; Table S3 in Multimedia Appendix 1), such as varus thrust, KAM [62,63], and FPA [64]. Capturing these parameters would traditionally require expensive 3D motion capture technologies, but inertial sensors may allow these risk factors to be captured with relative ease and at low cost in large samples.

Table 3. Inertial sensors and assessment of movement patterns associated with osteoarthritis progression and gait retraining.

Study	Population	Sensor	Findings
Costello et al, 2020 [33]	Knee OA ^a (n=26)	3 IMU ^b (Trigno IM Sensors, Delsys Inc) on thigh, midshank, and distal shank	Single-leg sensor metrics were associated with surrogate measures of varus thrust, and midhigh adduction velocity was significantly associated with peak external knee adduction moment
Ishii et al, 2020 [34]	Knee OA (n=44)	2 IMU ^c (WAA-010, ATR-Promotions) placed on tibia and foot	Positive correlation between lateral thrust and change in medial meniscus extrusion
Iwama et al, 2021 [35]	Knee OA (n=22)	6 IMU ^c (TSND151, ATR-Promotions) on pelvis, sternum, shanks, and thighs	Moderate correlation found between acceleration peak in IMU frame and KAM, values from shank IMU had strongest correlation
Karatsidis et al, 2018 [38]	Healthy (n=11)	7 IMU ^b (MTw, Xsens Technologies BV) on pelvis, thighs, shanks, and feet	High accuracy and repeatability of foot progression angle measures, and feedback effectiveness was similar between wearable and laboratory feedback setups
Wang et al, 2020 [36]	Healthy (n=12), knee OA (n=78)	2 IMU ^c (DA14583, Dialog Semiconductor) on malleoli	Two machine learning algorithms were highly accurate (R^2 approximately 0.95) in predicting KAM using IMU input
Wouda et al, 2021 [37]	Healthy (n=5)	2 IMU ^b (MTw Awinda, Xsens Technologies BV) on feet	Good correlation coefficients to discriminate between different foot progression angle walking conditions
Xia et al, 2020 [39]	Healthy (n=10)	Single IMU ^b (custom-made) embedded in shoe sole	Participants were able to respond to feedback during walking and adopt target foot progression angle conditions

^aOA: osteoarthritis.

^bIMU: inertial measurement unit (with accelerometer, gyroscope, and magnetometer).

^cIMU with accelerometer and gyroscope.

Different sensor configurations during walking have been used to quantify varus thrust in gait; and one study using sensors on the thigh, midshank, and distal shank showed that midhigh sensor metrics were associated with optical motion capture thrust measurements while having less variability than midshank sensors [33]. Another study using sensors on the tibial tubercles and dorsal surface of the foot found greater peak varus thrust in the severe OA group when compared with their early-stage OA group [34]. Iwama et al [35] assessed the correlation between peak KAM and peak-to-peak difference of acceleration in the medial-lateral axis using sensors on the sternum, pelvis, thighs, and shanks and found that the shank sensor had the

highest correlation ($R=0.57$). Wang et al [36] trained 2 machine learning algorithms using raw IMU data from sensors on the bilateral lateral malleoli to provide an accurate, real-time estimation of KAM during walking. The models—XGBoost and an artificial neural network—were trained to estimate KAM from a data set of both healthy individuals and those with knee OA, with both models having an R^2 value of approximately 0.95 [36]. Finally, single sensors on top of the shoes were used to estimate the FPA with a maximum mean error of approximately 2.6° [37]. These approaches show promise for the use of wearables for accurate estimations of these important gait parameters in people with knee OA with the potential for

gait retraining interventions that can directly target these parameters. However, further validation of these approaches in free-living conditions is required before they can be implemented in future interventions.

Gait retraining to alter parameters related to OA progression is a natural follow-up to the aforementioned work. In knee OA, gait retraining typically aims to decrease the KAM [36,65,66], a parameter linked to the severity and progression of knee OA [67,68]. Karatsidis et al [38] used Microsoft HoloLens, an augmented reality headset, to provide feedback on FPA from 7 IMUs (on the pelvis, thighs, shanks, and feet) and found similar effectiveness between this approach and a laboratory approach (ie, projection screen in front of the participant) based on steps falling within a $+2^\circ$ to -2° targeted range. Furthermore, IMU-based FPA estimates closely matched those obtained from optical motion capture (overall root mean square difference of 2.38°) [38]. Xia et al [39] developed a shoe with an IMU-embedded insole and vibration motor to provide haptic feedback directly during walking to correct FPA, with participants successfully adopting 5 different FPA walking patterns after training. Although all these prior studies attempted to indirectly reduce KAM by altering other parameters (eg, FPA), some of the approaches discussed earlier that attempted to directly estimate KAM could potentially be used for gait retraining interventions in the future by adding feedback about this parameter [35,36].

Assessment of OA Intervention Outcomes

There has also been considerable interest in using wearable technology to remotely monitor data following interventions

for OA (Table 4; Table S4 in Multimedia Appendix 1). Lebleu et al [40] used inertial sensors to track improvements in lower limb joint angles before and after administering a genicular nerve blockade in patients with knee OA and found a 9.3° increase in sagittal plane ROM during gait and a 3.3° decrease in pelvic transverse ROM when walking upstairs. In a novel application, Gošlińska et al [41] used IMUs to measure proprioception during physical therapy in patients with knee OA to assist in patient evaluation. Wearable sensors are used more often to monitor outcomes in patients undergoing joint replacement surgery. Hsieh et al [42] used a 6-sensor system during the timed up and go test to identify subphases with this task using machine learning for patients with TKA; using preoperative and postoperative data, they achieved a classification accuracy of 92% for segmentation of subphases during the timed up and go test. Inertial sensors have also been used to identify remaining gait asymmetry following a 4-week rehabilitation program in individuals post THA [69]. These studies demonstrate the potential of wearable technologies to monitor functional recovery after joint replacement surgeries in patients with knee or hip OA, potentially identifying individuals who may require additional rehabilitation or other medical care. When combined with patient factors (BMI, anesthesia status, and hemostatic use), data from wearables were used to identify associations between these factors and knee ROM post TKA [43]. Thus, inertial sensors could be used not only to understand how interventions affect biomechanics or movement quality but also how patient factors are related to these outcomes.

Table 4. Inertial sensors and assessment of osteoarthritis intervention outcomes.

Study	Population	Sensor	Findings
Bloomfield et al, 2021 [51]	TKA ^a (n=82)	4 IMU ^b (MetaMotionR, MBientLab) on thighs and shanks	Using only sensor data and no method of feature selection, random forest model was able to separate responders from maintainers with 93% accuracy
Bloomfield et al, 2019 [50]	TKA (n=68)	4 IMU ^b on thighs and shanks	Successfully grouped patients using preoperative functional data into high function and low function short-term recovery groups
Bolink et al, 2016 [44]	Healthy (n=30) and THA ^c (n=36)	Single IMU ^d (Inertia-Link, MicroS-train) on posterior superior iliac spine	Preoperative differences in gait parameters between low and high function groups disappeared by 3-month postoperative time point
Chiang et al, 2017 [43]	TKA (n=18)	2 IMU ^b (OPAL, APDM) on thigh and shank	Different range of motion patterns present in patients that received different hemostatic agents shortly after surgery
Di Benedetto et al, 2019 [46]	TKA (n=26)	4 IMU ^b (Bioval, Movea)	One TKA implant performed better in rotational flexion and freedom than other
Goślińska et al, 2020 [41]	Healthy (n=27) and TKA (n=54)	2 IMU ^b (Orthyo, Aisens) distal to both greater trochanter and tibial tuberosity	No significantly impact of different rehabilitation programs on affected knee position sense in OA ^e groups
Grip et al, 2019 [47]	Healthy (n=8), THA (n=15)	5 IMU ^d (MoLab, AnyMo AB) on pelvis, thighs, and shanks	Large femoral head THA surgery group had greater hip flexion range of motion than traditional THA surgery group
Hsieh et al, 2020 [42]	THA (n=26)	6 IMU ^d (OPAL) on chest, back, thighs, and shanks	Accuracy >90% in timed up and go subtask segmentation with AdaBoost machine learning technique
Kluge et al, 2018 [49]	Healthy (n=24), TKA (n=24)	2 IMU ^d (Shimmer3, Shimmer Sensing) on each foot	Wearable-derived metrics consistent with previous literature on gait function in post-TKA populations
Kobsar et al, 2017 [52]	Knee OA (n=39)	4 IMU ^d (iNEMO inertial module, STMicroelectronics) on foot, shank, thigh, and back	Sensor data were more accurate than patient-reported outcome measures in predicting response to hip strengthening program
Kobsar, and Ferber, 2018 [53]	Knee OA (n=8)	4 IMU ^d (iNEMO inertial module) on foot, shank, thigh, and back	Average of 84 principal components needed to describe 95% of variance in gait patterns related to improvements in clinical outcomes
Lebleu et al, 2020 [40]	Healthy (n=12), knee OA (n=14)	7 IMU ^b (x-IMU, x-io Technologies) on waist, thighs shanks, and feet	Cadence and stride time changed significantly after nerve blockade injections, tending toward values of healthy individuals
Menz et al, 2016 [48]	First metatarsophalangeal OA (n=97)	4 IMU ^d (LEGSys, Biosensics) on thighs and shanks	Orthoses did not produce significant changes on spatiotemporal and kinematic parameters, rocker-sole reduced cadence to small effect and increased % stance time and reduced sagittal plane hip ROM to medium effect
Shah et al, 2019 [45]	THA (n=10) and TKA (n=7)	Single IMU ^b (Lumo Lift, Lumo Bodytech) on pelvis	Raw data give better understanding than 24-hour summarized data for correlating with patient-reported outcome measures

^aTKA: total knee arthroplasty.

^bIMU: inertial measurement unit (with accelerometer, gyroscope, and magnetometer).

^cTHA: total hip arthroplasty.

^dIMU unit with accelerometer and gyroscope.

^eOA: osteoarthritis.

Wearable sensor data may provide information about recovery beyond that captured by the subjective measures of change. Bolink et al [44] identified that objective gait parameters capture a dimension of physical function that is distinct from Western Ontario and McMaster Universities Arthritis Index scores in

individuals post THA. Although Western Ontario and McMaster Universities Arthritis Index scores improved in patients with both low and high preoperative function at 3-month post THA, gait parameters only improved in those with low preoperative function [44]. This finding that individuals with lower function

have more functional improvement to gain from THA highlights the potential of inertial sensors to capture additional insights that are not clear from subjective data alone [44]. Furthermore, Shah et al [45] determined that increasing the sampling frequency of the sensor improves the accuracy of machine learning algorithms in predicting patient-reported outcomes.

Wearable sensors have also been used to compare the outcomes of various OA treatments. Di Benedetto et al [46] used a 4-IMU system (Bioval) to compare kinematic outcomes in patients who underwent TKA using different implants, finding a significant increase in knee flexion in one group. In addition, using sensors on the pelvis, thighs, and shanks, Grip et al [47] found larger ROM during squats, gait, and stair ascent and descent in individuals receiving a THA implant with a larger femoral head than in those who received a conventional implant. IMUs have similarly been used to compare the effects of prefabricated foot orthoses and rocker-sole footwear on spatiotemporal parameters, hip and knee kinematics, and plantar pressure in individuals with OA of the first metatarsophalangeal joint [48]. Using IMUs on the shanks, thighs, and lower back, along with plantar pressure insoles, Menz et al [48] demonstrated that both interventions reduced the peak pressure beneath the first metatarsophalangeal joint and heel, but the rocker-sole footwear additionally reduced the pressure across the second through fifth metatarsophalangeal joints, whereas the orthoses increased the peak pressure under the lesser toes and midfoot. Although this study had a small sample relative to the number of comparisons, it highlights a novel application of wearable technology to study how interventions affect muscle force [70]. In general, the studies discussed above highlight the potential of inertial sensors to provide objective outcomes in clinical trials with relative ease.

With a heterogeneous OA population that may respond differently to interventions, an exciting area of development is in predicting the response to treatment. For example, high preoperative gait function assessed using 2 feet-worn IMUs was predictive of functional decreases post TKA, suggesting that those with lower preoperative function have more to gain [49]. In addition, positive and negative responders can be predicted

with an accuracy of up to 89% [49]. Bloomfield et al [50] used IMU data from sensors above and below the knee on participants during the timed up and go test preoperatively to group patients by functional improvement likelihood and to predict expected functional recovery after TKA [51]. Similarly, Kobsar et al [52] classified nonresponders, low responders, and high responders to a 6-week hip and core strengthening program for knee OA with 81.7% accuracy using preintervention data from IMUs on the lower back, thigh, shank, and foot, and similar results were obtained using a simplified 2-sensor system (thigh and back IMU data only). Furthermore, using a subsample of participants, Kobsar et al [53] identified gait pattern changes that were associated with self-reported pain and function outcomes using a novel, subject-specific, machine learning approach, suggesting that machine learning analyses can be used with wearable sensor data in clinically meaningful ways.

Most studies discussed in this section had small sample sizes with some being preliminary in nature. However, these studies demonstrated a wide range of possibilities with the use of wearable sensors to monitor intervention outcomes and predict responses to interventions.

Sensor Placement and Data Analysis

Given the variety of different parameters and sensor configurations used in studies using inertial sensors in populations with hip and knee OA or joint replacement, there has also been interest in investigating the effect of sensor configuration and data analysis on outcomes (Table 5; Table S5 in Multimedia Appendix 1). For example, Sharifi et al [54] used machine learning to analyze 15 combinations of data from a maximum 7-IMU system (feet, pelvis, shank, and thigh sensors) on individuals with OA and TKA to determine the optimal sensor combination to capture spatiotemporal gait parameters, with the feet-thigh combination having the best overall rank based on normalized absolute percentage error compared with the other sensor combinations. A few of the studies mentioned in this review also incorporated a comparison of different sensor locations into their work [16,33,35,52], with the goal of optimizing the balance between convenience and patient burden (ie, low number of sensors) and valid data.

Table 5. Inertial sensors sensor placement and data analysis.

Study	Population	Sensor	Findings
Boekesteijn et al, 2021 [56]	Healthy (n=27), knee OA ^a (n=25), and hip OA (n=26)	4 IMU ^b (OPAL, APDM) on feet, lumbar spine, and sternum	Stride length and cadence had strongest effect sizes for both OA groups during turning and dual-task performance during walking
Sharifi et al, 2020 [54]	Knee OA (n=14) and TKA ^c (n=15)	7 IMU ^d (Xsens Technologies BV) on pelvis, thighs, shanks, and feet	Feet-thigh sensor combination identified as best for measuring spatiotemporal gait parameters
Teufl et al, 2019 [55]	Healthy (n=24) and THA ^e (n=20)	7 IMU ^b (Xsens Technologies BV) on pelvis, thighs, shanks, and feet	Joint angles yielded 97% accuracy in differentiating gate between groups, spatiotemporal metrics gave 87.2% accuracy

^aOA: osteoarthritis.

^bIMU: inertial measurement unit (with accelerometer, gyroscope, and magnetometer).

^cTKA: total knee arthroplasty.

^dIMU with accelerometer and gyroscope.

^eTHA: total hip arthroplasty.

In addition to various sensor placement combinations, various methods for analyzing inertial sensor data have been explored. Teuffl et al [55] trained 2 different support vector machines—one using spatiotemporal gait parameters and one using joint angles, both from a 7-IMU system—to differentiate between impaired and nonimpaired gait using healthy controls and individuals post TKA. Both machines were successful (87.2% and 97.0% accuracy), and hip ROM symmetry was the most important single predictive feature, being roughly 3 times more important than the next feature, pelvic sagittal ROM [55]. In a study of individuals with knee OA, hip OA, and healthy controls, Boekesteijn et al [56] created 4 independent gait domains as a way to reduce the dimensionality of their data set and found the domains containing stride length, cadence, and lumbar sagittal ROM to be the most sensitive to detecting the presence of knee or hip OA. Other studies previously mentioned in this review (Tables 1-4) examined a variety of extracted metrics, with a few using machine learning for feature extraction or outcome prediction [31,32,36,51,53]. These studies provide initial information about how sensor placement and data analysis affect outcomes; however, given the variety of factors used in the current literature, more work is needed in this area to identify the ideal sensor placements and extracted datatypes for specific applications of inertial sensors in lower limb OA.

Discussion

Principal Findings

This review sought to examine the use of inertial sensors to assess the movement in the context of hip and knee OA clinical care in patients' natural environments. We identified various applications of inertial sensors in hip and knee OA that have been published over the past 5 years, including assessment of OA presence and severity, assessment of and intervention on risk factors for OA progression, tracking intervention outcomes, and identifying individuals most likely to respond to interventions. Although further work is needed to validate the findings in real-world environments and determine optimal sensor placement and data analysis methods, the use of inertial sensors for these applications in hip and knee OA could improve opportunities for remote research and clinical care, particularly given the shifting health care landscape resulting from the COVID-19 pandemic [71].

Comparison With Prior Work

There have been 2 previous reviews of wearable sensors in OA or postarthroplasty populations; however, these focused on very specific applications (gait analysis or postsurgical outcomes), whereas this review sought to assess all current and potential uses of inertial sensors in these populations. A scoping review by Kobsar et al [72] on inertial sensors for gait analysis in individuals with OA identified multiple studies using inertial sensors for this application, with a range of sensor placements and outcomes used among the included studies. Although we similarly identified a range of sensor placements and outcome measures used in the studies included in this review, our results are based on the assessment by Kobsar et al [72] regarding sensor protocols and outcome measures by examining the range of challenges and problems to which wearable sensors can and

have been applied, including those beyond gait analysis. Importantly, both reviews identified the need to validate inertial sensor assessment of gait in free-living environments. Another review focused solely on wearable sensors in assessing functional outcome measures after lower extremity arthroplasty and found wearable sensors to be more sensitive than traditional functional outcome measures [73]. Both this review and the current one suggest that more work is needed to understand the clinical relevance of sensor measures.

Finally, we would like to recognize the timeliness of this review within the wider scope of the current research and global events. At the time of writing, the global COVID-19 pandemic is still ongoing [74]. This event accelerated both the adoption of remote health care [75] and the use of digital health technologies for the remote assessment of participants in clinical trials [76]. By rerunning our literature search in March 2021, we were able to capture and include many studies using inertial sensors that were published during the first year of the pandemic. Of the 43 studies included in this review, 24 were published in either 2020 or the first 3 months of 2021. As the landscape of both data collection in general and the management of clinical trials moves outside of the laboratory with inertial sensors and wearable technology, we believe this review adds an important summary of new and current sensor applications to the existing body of literature.

Limitations

A number of limitations should be considered when interpreting the results of this review. First, although, in this study, we aimed to provide a narrative overview of the various applications of wearable inertial sensors for assessing movement quality in OA populations, the narrative format and change in search scope could have led to a selection bias in the studies included. To mitigate the risk of selection bias, 2 researchers (MJR and KEC) reviewed all identified abstracts from the final search strategy for potential inclusion and additionally reviewed studies selected for inclusion in the earlier searches to determine if they met the updated scope. Second, given the narrative format of this review, the quality of included studies was not assessed. Third, limiting the search to studies published within the past 5 years may have resulted in the exclusion of relevant studies published outside this range. This pragmatic choice was made owing to a significant increase in the number of publications on wearable sensors in recent years to present current results from this rapidly moving field. Fourth, the significant variability in sensor placement across the included studies limited our ability to draw conclusions regarding best practices for specific applications. Finally, this review does not address patients' and clinicians' perspectives on wearable technology. The reader is advised to consider stakeholder perspectives when implementing inertial sensors to assess movements in OA populations.

Future Directions

The results of this review highlight the potential of wearable sensors for remote monitoring of patients with OA and identification of those at risk for whom interventions may be needed. However, this work has primarily been done in relation to walking gait, with relatively few studies examining other types of movement (lunges, stair ascent and descent, squatting,

sit-to-stand, and single-leg stance) [29,31,47] commonly experienced during everyday life. In addition, as described by Kobsar et al [72] in a scoping review of inertial sensors for gait analysis in individuals with OA, more work is required in free-living environments. Given the low number of nongait studies and the high prevalence of laboratory-based data collection in the studies included in this review, further work is needed to validate whether inertial sensor data captured from various real-world activities are sensitive to disease initiation and risk of progression and thus could be used for remote monitoring and risk screening.

In addition, we found only a handful of studies focused on training of movement patterns for individuals with OA, and of those we did identify, all focused on the feasibility and validation of gait retraining interventions. Questions remain around the large-scale deployment of inertial sensor—driven gait retraining or similar programs. The conclusions on the efficacy and acceptability of the interventions are of interest. Finally, although a few of the studies included in this review reported good reliability and validity of metrics extracted from

inertial sensor data, a wide range of inertial sensor systems and extracted parameters were used in the various applications reviewed here. Continued research into optimal sensor placement to best capture relevant outcomes with minimum burden on the individual patient or participant may encourage the widespread use of these systems to capture biomechanical data in real-world settings.

Conclusions

Multiple opportunities exist to use inertial sensors to enhance remote health care for hip and knee OA. Within the last 5 years, research using inertial sensors in these populations has focused on the validity and repeatability of measurements, assessment of OA presence and severity, assessment of movement patterns associated with OA progression and gait retraining, assessment of OA intervention outcomes, and sensor placement and data analysis. Although these applications show great promise, further work is needed to investigate the use of inertial sensors in real-world settings, in a variety of activities of daily living, and in larger samples of individuals with hip and knee OA.

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Authors' Contributions

DK conceived of the study. MJR, KEC, SE, and DK selected journal articles to be included. All authors contributed to the synthesis and approval of the manuscript. DK takes responsibility for the integrity of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed tables on studies included in Results section of paper. Additional information given on study population (demographics data), sensor use and specifications, and application specifics.

[[DOCX File , 62 KB - rehab_v9i2e33521_app1.docx](#)]

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Abbreviations

FPA: foot progression angle

IMU: inertial measurement unit

KAM: knee adduction moment

OA: osteoarthritis

ROM: range of motion

THA: total hip arthroplasty

TKA: total knee arthroplasty

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Review

Applications of Digital Health Technologies in Knee Osteoarthritis: Narrative Review

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Abstract

Background: With the increasing adoption of high-speed internet and mobile technologies by older adults, digital health is a promising modality to enhance clinical care for people with knee osteoarthritis (KOA), including those with knee replacement (KR).

Objective: This study aimed to summarize the current use, cost-effectiveness, and patient and clinician perspectives of digital health for intervention delivery in KOA and KR.

Methods: In this narrative review, search terms such as *mobile health*, *smartphone*, *mobile application*, *mobile technology*, *ehealth*, *text message*, *internet*, *knee osteoarthritis*, *total knee arthroplasty*, and *knee replacement* were used in the PubMed and Embase databases between October 2018 and February 2021. The search was limited to original articles published in the English language within the past 10 years. In total, 91 studies were included.

Results: Digital health technologies such as websites, mobile apps, telephone calls, SMS text messaging, social media, videoconferencing, and custom multi-technology systems have been used to deliver interventions in KOA and KR populations. Overall, there was significant heterogeneity in the types and applications of digital health used in these populations. Digital patient education improved disease-related knowledge, especially when used as an adjunct to traditional methods of patient education for both KOA and KR. Digital health that incorporated person-specific motivational messages, biofeedback, or patient monitoring was more successful at improving physical activity than self-directed digital interventions for both KOA and KR. Many digital exercise interventions were found to be as effective as in-person physical therapy for people with KOA. Many digital exercise interventions for KR incorporated both in-person and web-based treatments (blended format), communication with clinicians, and multi-technology systems and were successful in improving knee range of motion and self-reported symptoms and reducing the length of hospital stays. All digital interventions that incorporated cognitive behavioral therapy or similar psychological interventions showed significant improvements in knee pain, function, and psychological health when compared with no treatment or traditional treatments for both KOA and KR. Although limited in number, studies have indicated that digital health may be cost-effective for these populations, especially when travel costs are considered. Finally, although patients with KOA and KR and clinicians had positive views on digital health, concerns related to privacy and security and concerns related to logistics and training were raised by patients and clinicians, respectively.

Conclusions: For people with KOA and KR, many studies found digital health to be as effective as traditional treatments for patient education, physical activity, and exercise interventions. All digital interventions that incorporated cognitive behavioral therapy or similar psychological treatments were reported to result in significant improvements in patients with KOA and KR when compared with no treatment or traditional treatments. Overall, technologies that were blended and incorporated communication with clinicians, as well as biofeedback or patient monitoring, showed favorable outcomes.

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KEYWORDS

digital health; knee osteoarthritis; knee replacement; mobile health; telemedicine; mobile phone

Introduction

Digital health can be broadly defined as the use of technologies such as websites, mobile phones, wearable devices, and telemedicine for the diagnosis, treatment, prevention, and maintenance of health [1]. Digital health has been increasingly used for remote and personalized care across a range of health conditions, and the COVID-19 pandemic has further highlighted the need for and accelerated the adoption of these technologies [2]. With the increasing use of the internet and mobile computing devices in older adults [3-5], digital health holds promise for clinical and research applications in people with knee osteoarthritis (KOA) [6].

The core recommendations for KOA management include patient education, self-management, and exercise [7-11]. However, current treatment approaches are largely inconsistent with the guidelines [12,13]. Barriers to the implementation of clinical practice guidelines in osteoarthritis include limited access to health care settings, lack of knowledge of treatment approaches and guidelines, psychological barriers (eg, poor self-efficacy), and system-related factors (eg, limited health care provider time) [14,15]. Digital health may help address many of these barriers and increase the uptake of clinical practice guidelines, for example, by improving access to care and information, delivery of behavioral interventions, and remote patient monitoring.

Prior reviews on digital health for the management of KOA were mostly systematic reviews [16-21]. These systematic reviews focused on one type of digital health (eg, telerehabilitation [16,17] or mobile health technology [18,20]) or on one rehabilitation goal (self-management [21]) or only included populations with knee replacement (KR) surgeries [16,17,19]. Although systematic reviews are rigorous, they tend to have a narrow scope because of the focus on evidence related to the effectiveness of interventions [22]. Currently, a comprehensive overview with a wider focus on the various digital health technologies used for the management of KOA is lacking in the literature. Such a review is needed to identify what has been accomplished in the field of digital health, thus allowing researchers and clinicians to build on previously published research. Thus, the objective of this narrative review was to summarize the current state of digital health in KOA and provide an overview of the cost-effectiveness and patient and clinician perspectives related to digital health in these populations.

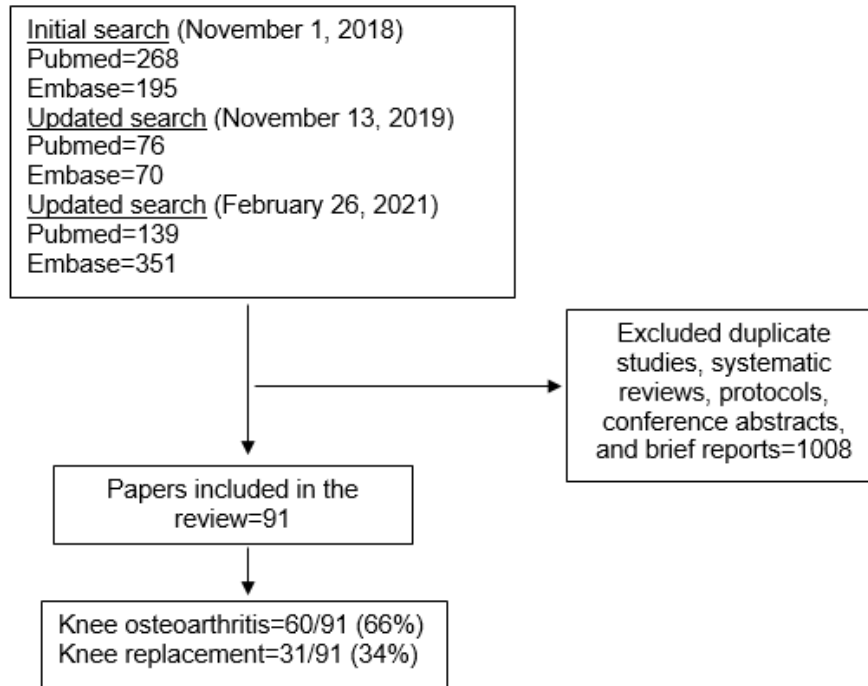
Methods

A literature search was conducted in 2 databases, PubMed and Embase, in October 2018, November 2019, and February 2021. The keywords used for the search at all 3 time points were as follows: (*mobile health OR mobile phone OR smartphone OR mobile application OR mobiletechnology OR ehealth OR text message* OR mhealth OR internet OR web based OR social media OR Facebook OR YouTube OR Twitter*) AND (*osteoarthritis OR TKA OR total knee arthroplasty OR total knee replacement*).

The inclusion criteria were (1) original studies published in the English language, (2) studies published in the past 10 years, and (3) technologies used for rehabilitation of KOA or KR. Studies that investigated the use of technology for diagnosis, decision aid, informed consent, or movement assessments were excluded from this review. Furthermore, duplicates, conference abstracts, protocol papers, and previously published reviews, including systematic reviews, were excluded. One of the researchers (NS) initially screened the titles of the studies in the search results against the aforementioned inclusion and exclusion criteria, removing studies that were not relevant to the review. The remaining studies were reviewed by 3 researchers (NS, KEC, and DK) who read the abstracts of each study to determine whether they should be included in the review. For the included studies, one of the authors (NS) extracted pertinent information as applicable, including objective, design, intervention characteristics, outcomes and findings, and limitations. After reviewing this information, we grouped the studies based on the applications of digital health to organize this review for the readers. We grouped the studies into digital health for delivering patient education, physical activity, exercise (asynchronous and synchronous exercise delivery), and psychological treatments such as cognitive behavioral therapy (CBT) or pain coping skills training (PCST) in the KOA and KR populations. We also discuss the findings related to cost-effectiveness and patient and clinician perspectives on digital health.

Results

After a careful review process, 91 studies were included in this review (Figure 1). Of the 91 studies included in this review, 60 (66%) were from KOA populations and 31 (34%) were from KR populations.

Figure 1. Flow diagram of the search process.

Digital Health for Patient Education

Overview

This section includes interventions that delivered patient education to individuals with KOA or KR to improve disease-related knowledge and symptoms related to osteoarthritis. We defined patient education as information on

a health condition, its treatment, and related self-management techniques [7]. This section also includes studies that have investigated the educational quality of content on osteoarthritis-related websites or videos on YouTube. Although a brief overview of the studies included in this section is shown in Table 1, a detailed description of the studies and features of technology used in the studies included in this section is presented in Table S1 in Multimedia Appendix 1 [23-35].

Table 1. Digital health for patient education in people with KOA^a and KR^b.

Study	Population	Design	Intervention		Comparator		Primary outcome findings
			Description	Sample size	Description	Sample size	
Brosseau et al [28]	Self-reported osteoarthritis or RA ^c	Pre or post	Social media (Facebook)	41	N/A ^d	N/A	Improvements in disease-related knowledge from baseline
Umapathy et al [24]	Knee or hip osteoarthritis	Pre or post	Access to website-based education and use of the website	104	Access to website-based education but no use of the website	91	Significant improvements in the Osteoarthritis Quality Indicator measures for users of the website vs no significant improvement for nonusers
Timmers et al [23]	Knee pain	RCT ^e	Phone app providing daily patient education	91	Information offered during medical consultation	122	Disease-related knowledge was 52% higher in the intervention group
Wang et al [25]	Knee or hip osteoarthritis	Quasi-experimental study	Users of the updated version of My Joint Pain for education	35	Nonusers	87	No significant difference in the Health Evaluation Impact Questionnaire scores between users and nonusers of the website
Fralval et al [26]	Presurgery (KR or HR ^f)	RCT	Website+discussion with surgeon	103	Discussion with surgeon	108	Improvements in disease-related knowledge but not anxiety scores in the intervention vs comparator
Campbell et al [27]	Postsurgery (KR or HR)	RCT	SMS text messaging bot+traditional education	76	Traditional education	83	Improvements in exercise adherence in the intervention vs comparator
Timmers et al [35]	Postsurgery (KR)	RCT	Phone app providing specific education at specific times from date of discharge	114	Phone app providing standard education biweekly	99	The intervention group had improvements in pain on NRS ^g at rest, at night, and during activity vs the comparator at 4 weeks after discharge
Meldrum et al [29]	Knee pain	Qualitative content analysis	Comments on videos related to knee pain on YouTube	3537 (comments) and 58 (videos)	N/A	N/A	Comments included soliciting advice for knee pain (19%), appreciation for others' inputs (17%), and asking questions regarding videos (15%)

Study	Population	Design	Intervention		Comparator		Primary outcome findings
			Description	Sample size	Description	Sample size	
Barrow et al [30]	Osteoarthritis	Cross-sectional survey	Websites providing educational content for patients with osteoarthritis	50	N/A	N/A	68% of the websites scored more than half of the maximum available quality score
Murray et al [32]	Osteoarthritis	Readability and quality assessment	Websites on osteoarthritis	37	N/A	N/A	Readability ranged from 8th- to 12th-grade reading level, and the quality of web-based osteoarthritis information was rated as "poor" to "fair"
Chapman et al [31]	Osteoarthritis	Nonexperimental, descriptive, internet-based study	Websites on self-management in knee, hip, hand osteoarthritis	49	N/A	N/A	Reading grade levels ranged from 6 to 15
Wong et al [34]	Osteoarthritis	Quality assessment	Videos on KOA and KR on YouTube	56	N/A	N/A	Approximately 65% of videos had poor educational quality, 30% had acceptable educational quality, and <10% had good educational quality
Bahadori et al [33]	KR	Readability assessment	Information on KR apps	15	N/A	N/A	Only one app was found to be "easy to read"

^aKOA: knee osteoarthritis.

^bKR: knee replacement.

^cRA: rheumatoid arthritis.

^dN/A: not applicable.

^eRCT: randomized controlled trial.

^fHR: hip replacement.

^gNRS: Numeric Pain Rating Scale.

Patient Education for People With KOA: Facebook, Mobile App, and Website

Approximately 2% (2/91) of studies, one single-arm study and a randomized controlled trial (RCT), found significant improvements in disease-related knowledge in people with KOA with the use of a Facebook group page (*People getting a grip on arthritis II*) [28] and with a mobile app (*Patient Journey App*) compared with education via medical consultation [23]. In contrast, health education via an open-access website (*My Joint Pain*) [24,25] did not result in significant improvements in health education outcomes such as the Health Evaluation Impact Questionnaire and the Osteoarthritis Quality Indicator, even with the updated version of the website [25]. Although these findings might suggest that osteoarthritis education via an open-access website [24,25] does not improve disease-related

knowledge compared with a mobile app [23] or Facebook group page [28], it is important to consider that assessment of disease-related knowledge with the open-access website was done much later (12 and 24 months) than assessments of disease-related knowledge with the mobile app (7 days) and Facebook group page (3 months) [23-25,28]. Second, the studies with open-access websites reported higher attrition rates than the studies with mobile apps and Facebook group pages (29% and 30% vs 22% and 16%) [23-25,28]. Furthermore, although the open-access website *My Joint Pain* [24,25] allowed users to access the website at their convenience, both the mobile app [23] and Facebook group page [28] interventions improved engagement with push notifications and reminders. Notably, the mobile app also included features such as web-based quizzes [24], and the Facebook group page [28] incorporated peer support by allowing users to comment on and share their

experiences with the health education videos. Collectively, this evidence suggests that digital patient education (mobile apps and Facebook group pages) improves disease-related knowledge at shorter follow-up periods and that it might be helpful to include features such as feedback, push notifications, and reminders in a digital intervention for people with KOA.

Patient Education for People With KR: Website, Text Messaging, and Mobile Apps

Fraival et al [26] reported greater improvements in knowledge (regarding orthopedic surgery) in people who received website-based disease-related education along with a surgical consultation than in people who received the surgical consultation alone. Similarly, those who received (automated) encouraging SMS text messages and personalized video messages from their surgeons regarding recovery along with traditional perioperative education spent more time participating in home exercises than participants who only received perioperative education (mean difference 8.6 minutes; $P < .001$) [27]. In terms of postoperative pain, Timmers et al [35] found statistically significant but clinically nonsignificant improvements in pain outcomes in people who used a mobile app delivering specific information related to the individual's recovery compared with people who received basic unstructured information biweekly through the app [35]. Timmers et al [35] also found that using push notifications to alert users of new information resulted in the increased use of the app by the user (26 times per user). Overall, these studies suggest that education via different digital modes (ie, websites, SMS text messages, or mobile apps) improves surgery-related knowledge, time spent performing exercises, and pain outcomes in people undergoing KR. Moreover, similar to populations with KOA, it might be beneficial to include features such as push notifications to

improve engagement in digital interventions for individuals with KR.

Educational Quality of Web-Based Information on KOA or KR: Websites, Mobile Apps, and YouTube Videos

For KOA, information on websites was investigated. Although the educational quality of information related to KOA has improved recently, there is still poor readability, substantial variability, and inconsistencies in the information available on websites [29-32]. For KR, the information on mobile apps was investigated; however, no app that provided information related to KR met the recommended readability levels (the one app that was found *easy to read* provided information on hip replacement surgeries) [33]. Similar to websites and mobile apps, the educational quality of information related to KOA and KR on YouTube has also been found to be of poor quality [34]. Despite issues with educational quality, analysis of the comments section on YouTube videos on knee pain management revealed that people with knee pain were comfortable sharing experiences and seeking advice on knee pain from other people on YouTube [29]. Therefore, although peer support via digital health can serve as a useful and informative tool for patients, the current educational and readability quality of osteoarthritis-related information needs improvement.

Digital Health for Physical Activity Interventions

Overview

This section includes interventions that were delivered with the purpose of improving physical activity (ie, step count, mobility, and time spent inactive in people with KOA; Table 2). A detailed description of the studies and technology used in the papers in this section is shown in Table S2 in [Multimedia Appendix 1](#) [36-41].

Table 2. Digital health for PA^a interventions in people with knee osteoarthritis.

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Bossen et al [38]	Knee or hip osteoarthritis	Pre or post	Join2Move (fully automated web-based PA program)	20	N/A ^b	N/A	No improvements in PA or self-perceived effect
Li et al [41]	Knee osteoarthritis	RCT ^c	Group in-person education+ activity monitor+ telephone counseling	17	Same intervention delayed by 1 month	17	Greater improvement in moderate to vigorous PA in the intervention vs comparator
Skrepnik et al [36]	Knee osteoarthritis treated with Hyalan G-F 20	RCT	Hyaluronic acid injection+unblinded activity monitor phone app	107	Hyaluronic acid injection+blinded activity monitor	104	Improvements in mobility in the intervention vs comparator
Bartholdy et al [37]	Knee osteoarthritis	RCT	Motivational SMS text messaging related to PA	19	No treatment	19	No difference between groups for time spent physically inactive
Zaslavsky et al [39]	Osteoarthritis	Pre or post	Activity monitor, motivational SMS text messaging, telephone coaching, and phone app for feedback	24	N/A ^b	N/A	Improvements in sleep but not PA from baseline
Allen et al [40]	Knee or hip osteoarthritis	Pre or post	PA screening, coaching phone calls, emails, and phone follow-up	67	N/A ^b	N/A	No difference in improvement in minutes of moderate to vigorous PA

^aPA: physical activity.

^bN/A: not applicable.

^cRCT: randomized controlled trial.

Digital Health for Physical Activity in People With KOA: Mobile App, Text Messaging, Multi-Technology, and Website

Digital physical activity interventions for people with KOA were delivered via website programs (1/91, 1%), telephone calls or SMS text messaging (1/91, 1%), mobile apps with or without activity monitors (1/91, 1%), or a combination of these technologies (3/91, 3%). Although 4% (4/91) of these interventions were self-directed or self-paced [36-39], 2% (2/91) of physical activity interventions included calls with a personal coach [40] and physical therapist [41] for individualized goal setting.

In an RCT, Skrepnik et al [36] reported greater improvements in daily step counts in adults with KOA after 90 days of using an activity monitor with visible feedback and access to a mobile app (*OA GO*) than in those who used a blinded activity monitor, despite regular follow-ups with care providers for both groups. The mobile app *OA GO* in this study provided motivational SMS text messages (on pain and mood monitoring) along with feedback, progress reports, and monthly trends related to physical activity from the activity monitor [36]. However, when SMS text messages related to generic physical activity advice

were given to people with KOA, the improvements in physical activity and the time spent inactive were nonsignificant compared with those who received no treatment [38]. The findings of these studies indicated that visible biofeedback and user-relevant content with motivational interviewing principles might be more effective in improving physical activity than general physical activity advice. These findings were confirmed by Li et al [41] in a delayed-control design, preliminary RCT, where an initial in-person education session, activity monitor, and weekly telephone coaching provided by physical therapy (PT) were successful in improving physical activity and reducing sedentary behavior in people with KOA, suggesting that a blended format (a combination of in-person and digital) might also be beneficial for favorable results. However, when a single-arm pilot study used a mobile app for biofeedback from an activity monitor, personalized weekly SMS text messages, and motivational interviewing via 3 phone calls, they found no significant improvement in the overall step counts at 14 or 19 weeks [39]. As the participants in the study discussed valuing the person-specific messages during the exit interviews, the authors speculated that the nonsignificant findings might be related to the insufficient frequency of SMS text messages (weekly) during the study [39].

Similar nonsignificant improvements in physical activity were reported in 2% (2/91) of single-arm pilot studies that used a website (*Join2Move*) and a multi-technology web-based intervention (osteoarthritis physical care pathway). The website (*Join2Move*) was self-paced, fully automated, and provided weekly physical activity assignments based on the goals and a self-test of recreational activities selected by the user [38]. The use of a self-directed intervention (*Join2Move*) with minimum personal contact resulted in a high attrition rate, with only 55% of participants completing at least 75% of the program, potentially resulting in nonsignificant improvements in physical activity [38]. In contrast, the osteoarthritis physical care pathway intervention used the website and telephone calls for 4 phases (ie, physical activity screening, brief coaching calls for goal setting based on motivational interviewing principles, access to community and local resources to support physical activity, and follow-up coaching calls) [40]. Although this intervention included person-specific information using motivational interviewing, it did not include visible biofeedback or physical activity self-monitoring, which might have resulted in nonsignificant results. Interestingly, although 5% (5/91) of

studies in this section found no significant changes in physical activity [36-40], 2% (2/91) of studies observed statistically significant but clinically nonsignificant improvements in secondary outcome measures of sleep [39] and pain and function subscales on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [40].

Digital Health for Physical Activity in People With Knee KR

No studies investigating physical activity interventions in people with KR were identified.

Digital Health for Exercise Interventions

Overview

Exercise remains the most effective nonpharmacologic intervention for KOA [7,9]. This section includes interventions that delivered exercises (ie, a structured program for the purpose of improving osteoarthritis-related symptoms) to people with KOA and KR (Table 3). A detailed description of the studies and technology used in the studies in this section is shown in Table S3 in [Multimedia Appendix 1](#) [6,42-53].

Table 3. Self-directed or asynchronous digital exercise interventions.

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Dahlberg et al [44]	Knee or hip osteoarthritis	Pre or post	Joint Academy (website with videos on education and exercise and asynchronous chat support from PT ^a)	53	N/A ^b	N/A	68% (16/53) of responders defined by individual improvement of >1.5 on the NRS ^c pain score
Nero et al [45]	Knee or hip osteoarthritis	Observational and quasi-experimental	Joint Academy (website with videos on education and exercise and asynchronous chat support from PT)	350	Published data from in-person PT	— ^d	Significant improvements in NRS pain score or function on 30-second chair stand test
Allen et al [52]	Knee osteoarthritis	RCT ^e	IBET ^f (website with tailored exercise, exercise videos, automated reminders, and progress tracking)	140	In-person PT and waitlist control	140 (in-person) and 70 (waitlist)	No difference between groups for improvements in WOMAC ^g score
Pignato et al [43]	Knee osteoarthritis	Secondary analysis from an RCT [52]	Website	124	In-person PT	135	More PT visits resulted in greater improvement in WOMAC scores
Nelligan et al [42]	Knee osteoarthritis	Participants and assessors blinded RCT	My Knee Exercise website with education+prescription for a 24-week knee strengthening regimen+ automated personalized SMS text messages	103	Access to My Knee Exercise website with education+automated SMS text messages without specific information on exercises	103	Greater improvements in overall knee pain and WOMAC function in the intervention vs comparator
Dahlberg et al [6]	Knee or hip osteoarthritis	Longitudinal cohort study	Joint Academy website with videos on education and exercise and asynchronous chat support from PT	499	N/A	N/A	Improvement in monthly NRS pain score and physical function on 30-second chair stand test at week 12
Gohir et al [53]	Knee osteoarthritis	RCT	Joint Academy website	48	Usual care delivered by a general practitioner or physical therapist	57	Greater improvements in NRS pain score in the intervention vs comparator at 6 weeks
Piqueras et al [51]	Post-KR ^h	RCT	Asynchronous platform with inertial sensors to measure movement, avatar-based exercise, and web portal for PT	90	In-person PT	91	No difference in knee flexion and extension after the intervention between groups

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Bini et al [50]	Post-KR	RCT	Phone app with videos prescribed by PT	14	In-person outpatient PT	15	No difference between groups for VAS ⁱ , Veterans RAND 12-item health survey mental component and physical component scores, and KOOS ^j
Chughtai et al [46]	Pre-KR	Pre or post study	Mobile app “Pre-Hab” with prehabilitation program before TKA ^k	114	Nonusers	362	Shorter length of stay in the hospital and more favorable discharge disposition status in those who used the app
Fleischman et al [49]	Post-KR	Randomized non-inferiority trial	Inpatient PT until hospital discharge+web-based unsupervised PT with patient monitoring and communication portal	96	Inpatient PT until hospital discharge+printed PT manual and in-person PT	96 (inpatient) and 97 (in-person)	No difference in change in knee flexion in intervention and comparator at 4-6 weeks or 6-months postop
Klement et al [48]	Post-KR	Retrospective intervention	Web-based self-directed PT—automated emails with exercises	296	In-Person PT+web-based self-directed PT	101	Greater difference in knee flexion, SF-12 ^l physical scores, and KOOS pain but not knee extension or SF-12 mental scores in the intervention vs comparator
Ramkumar et al [47]	Pre-KR	Pre or post	Knee sleeve with inertial sensors+phone app	25	N/A	N/A	Improvements in mobility but not knee flexion or KOOS scores at 3 months after operation

^aPT: physical therapy.

^bN/A: not applicable.

^cNRS: Numeric Pain Rating Scale.

^dNot available.

^eRCT: randomized controlled trial.

^fIBET: Internet-Based Exercise Therapy.

^gWOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

^hKR: knee replacement.

ⁱVAS: Visual Analog Scale.

^jKOOS: Knee Osteoarthritis Outcome Score.

^kTKA: total knee arthroplasty.

^lSF-12: Short Form-12.

Self-directed and Asynchronous Digital Exercise Interventions for People With KOA: Websites and Mobile App

This section includes exercise interventions that were not delivered by a physical therapist in real time. Specifically, the interventions that were self-directed or monitored through asynchronous communication with a physical therapist (communication portal or chat feature on a website: 4/91, 4%; videos uploaded on a mobile app: 1/91, 1%) are included in this section.

In a parallel superiority RCT, Nelligan et al [41] found that people with KOA who received additional strength training, personalized SMS text messages, and guidance to improve physical activity along with disease-related education (*My Knee Exercise* website) showed greater improvements in pain on the Numeric Pain Rating Scale and function on the WOMAC than people who only received access to the disease-related education on the website (*My Knee Education*). Moreover, the within-group improvements in pain on the Numeric Pain Rating Scale and function on the WOMAC in the *My Knee Exercise* group had large effect sizes and exceeded the minimal clinically important difference (MCID) in the study [54,42]. In another RCT, Allen et al [40,52] (Physical Therapy versus Internet-Based Exercise Training [PATH-IN] trial) compared an unsupervised website exercise program called Internet-Based Exercise Therapy (IBET) with in-person PT and waitlist controls. Interestingly, the study found that IBET was noninferior to in-person PT in improvements on the WOMAC and that both IBET and in-person PT were not superior to the waitlist at the 4 or 12 months follow-up [52]. However, the within-group improvements in all 3 groups were above the minimal clinically important changes (>1.33 points) [55] at 4 and 12 months but had small effect sizes [52]. Notably, IBET [52] had more features and flexibility (tailored exercise videos, exercise progressions, automated reminders, and progress tracking) than *My Knee Exercise* (education, a prescription for 24-week strengthening exercises, and personalized SMS text messages) [42]. The authors of the PATH-IN trial speculated that greater doses in both intervention groups and greater engagement in the IBET group may be needed to determine efficacy. However, secondary analyses from the PATH-IN trial did not show an association between adherence to IBET and changes in outcomes, and interestingly, no participant characteristics were related to adherence to IBET [43].

Approximately 2% (2/91) of single-arm studies investigated a 6-week website program called the *Joint Academy*, a program comprising short educational lectures, daily exercise videos, and asynchronous chats with physical therapists [44,45]. These studies reported statistically significant but clinically not significant [54,56,57] improvements in pain [44,45], function [45], and walking difficulty [45]. Similarly, when a mobile app version of the *Joint Academy* was used, there were statistically significant and clinically nonsignificant improvements in pain and function at 6 weeks when compared with usual care [53]. However, a longitudinal cohort study used data from a self-management program registry and found that 72% and 67%

of participants who used *Joint Academy* achieved the MCID for pain [54,57] at longer follow-up periods of 24 and 48 weeks, respectively, therefore suggesting that longer digital health interventions may be required for clinical benefits [6]. Moreover, given that these digital health interventions were not directly compared with in-person PT, it is unclear whether they are superior or similarly effective compared with in-person PT.

Self-directed and Asynchronous Digital Exercise Interventions for People With KR: Multi-Technology and Websites

For people undergoing KR, self-directed exercise interventions were provided using multi-technology (2/91, 2%) systems [46,47]. Ramkumar et al [47] used a knee sleeve with inertial motion sensors and a mobile app, and Chughtai et al [46] used a web or phone-based platform with a daily activity checklist, exercise instructions, nutritional advice, education, mindfulness, and other components. Both studies reported significant within-group improvements in mobility, symptoms, length of hospital stay, and other outcomes with their multi-technology systems [46,47]. For individuals after KR, 2% (2/91) of RCTs investigated the use of self-directed website exercise interventions [48,49]. Fleischman et al [49] found similar improvements in knee range of motion and self-reported symptoms on the Knee Osteoarthritis Outcome Score in those who received the website intervention and in those who received in-person PT at short (4-6 weeks) and long (6 months) follow-up periods. Similarly, Klement et al [48] found that 65.9% of participants who received their self-directed website intervention did not require in-person PT 2 weeks after the operation. The improvements with these website interventions may be because of their various features such as weekly exercise programs with video demonstrations [48,49], patient monitoring [49], and a communication portal for asynchronous conversation with the physical therapist [49]. Similarly, telerehabilitation exercise programs that allowed communication with a physical therapist (telephone) and patient monitoring via asynchronous video uploads [50] and sensor-based feedback [51] elicited similar improvements in knee range of motion and self-reported symptoms as in-person PT at early (10 days) and later (3 months) follow-up periods [50,51]. Taken together, multi-technology self-directed exercise interventions and websites that allow biofeedback, patient monitoring or communication with clinicians have been successful in eliciting positive outcomes such as range of motion and self-reported symptoms in people with KR.

Directly Supervised Exercise Interventions for Populations With KOA: Blended and Telephone-Based

This section includes exercise interventions that were directly delivered by a clinician, generally physical therapists, in real time (Table 4). A detailed description of the studies and the technology used in the studies in this section is presented in Table S4 in Multimedia Appendix 1 [58-74]. The exercise interventions in this section were provided in blended formats (ie, a combination of in-person PT and digital strategies [58,59,73] or over the phone) [60,61] or via real-time videoconferencing software.

Table 4. Digital health for directly supervised exercise interventions.

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Cuperus et al [73]	Generalized osteoarthritis	RCT ^a	2 in-person group sessions+telephone monitoring by a nurse	77	Multidisciplinary in-person group intervention led by PT ^b	81	No difference in daily function on Health Assessment Questionnaire Disability Index between groups
Bennell et al [70]	Inactive adults with knee osteoarthritis	RCT	In-person PT+telephone coaching	84	In-person PT	84	Greater improvements in the NRS ^c pain score and the WOM-AC ^d function in the intervention vs comparator
Kloek et al [59]	Knee or hip osteoarthritis	Cluster RCT	Website+in-person PT	109	Usual in-person PT	99	No difference between groups for KOOS ^e , timed up and go, and subjective and objective physical activity
De Vries et al [62]	Knee or hip osteoarthritis	Mixed methods study embedded within an RCT [59]	Web-based component of e-exercise used by Kloek et al [59]	Quantitative analysis=90; qualitative analysis=10	N/A ^f	N/A	Adherence was highest for participants with middle education, 1- to 5-year osteoarthritis duration, and participants who were recruited by physical therapists
Chen et al [58]	Knee osteoarthritis	Quasi-experimental study	Blended intervention: in-person group PT+home exercises, exercise diary, and telephone check-in calls	84	In-person group health education sessions and telephone check-in calls	87	Greater improvements for WOM-AC pain and joint stiffness on a Likert scale in the intervention vs comparator
Baker et al [60]	Knee osteoarthritis	Single-blind parallel-arm RCT	BOOST-TLC ^g (motivational behavior change telephone calls+monthly automated phone reminder messages to exercise)	52	Monthly automated phone reminder messages to exercise	52	No difference between groups in adherence
Doiron-Cadrin et al [63]	Pre-KR ^h and HR ⁱ	RCT	Real-time videoconferencing	12	In-person outpatient PT and usual care	12 (in-person) and 11 (usual care)	High compliance and satisfaction with the tele-rehabilitation program

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Hinman et al [61]	Knee osteoarthritis	Participant and assessor-blinded RCT	5-10 calls from a physical therapist for exercise advice and prescription+information folder+exercise bands+access to website for exercise videos+≥1 call from a nurse for self-management advice	87	≥1 telephone call from a nurse for self-management advice	88	Improvements in function but not pain in the intervention vs comparator
Lawford et al [71]	Knee osteoarthritis	Exploratory trial using data from the intervention arm of RCT [61]	5-10 calls from a physical therapist for exercise advice and prescription+information folder+exercise bands+access to website for exercise videos+≥1 call from a nurse for self-management advice	87	N/A	N/A	Weak association between therapeutic alliance and improvements in knee pain, self-efficacy, function, quality of life, adherence, and physical activity
Russell et al [72]	Post-KR	RCT	Computer-based system with real-time videoconferencing, measurement tools, and video capture	31	In-person outpatient PT	34	No difference between groups for improvement in WOMAC scores
Tousignant et al [65]	Post-KR	RCT	Custom hardware with videoconferencing and remote-controlled cameras	24	In-person PT	24	No significant difference between groups for knee extension and WOMAC total score
Moffet et al [64]	Post-KR	RCT	Custom hardware with videoconferencing and remote-controlled cameras	104	In-person home-based PT	101	No difference in WOMAC score between groups
Correia et al [69]	Post-KR	RCT	Platform with inertial sensors, phone app, and web portal for PT+2 home visits and telephone support by PT	30	In-person home-based PT	29	Greater improvement in the intervention vs comparator for timed up and go scores at 8 weeks
Correia et al [68]	Post-KR	RCT	Platform with inertial sensors, phone app, and web portal for PT+2 home visits and telephone support by PT	30	In-person home-based PT	29	Greater improvement in the intervention vs comparator for timed up and go scores at 6 months
Bell et al [66]	Post-KR	Pilot RCT	In-person PT+interACTION (monitoring remote rehabilitation platform with portable IMUs ¹ +mobile app with back end clinician portal)	13	In-person PT+unsupervised home exercise program	12	No difference in value (change in activities of daily living scale and total cost) between groups

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Chughtai et al [67]	Post-KR	Pre or post	3D motion-tracking cameras, exercise avatar, clinician monitoring, outcome reporting, and communication with a clinician—TKA ^k and UKA ^l	18 (TKA) and 139 (UKA)	N/A	N/A	Improvements in Knee Society Scores, WOMAC scores, and Boston University Activity Measure for Post-Acute Care scores
El Ashmawy et al [74]	Post-KR or HR	Retrospective study	Remote joint replacement clinic follow-up at 1-year, 7-years, and every 3-years after in-person consultations at 2 weeks and 6-weeks	1749	N/A	N/A	92% response rate, 87% completed the outcome forms and radiographs, 7% required further in-person appointments, and 89% satisfaction; 1 web-based appointment cost £79 (US \$99), with estimated savings of £42,644 (US \$53,439.93) per year ^m

^aRCT: randomized controlled trial.

^bPT: physical therapy.

^cNRS: Numeric Pain Rating Scale.

^dWOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

^eKOOS: The Knee Osteoarthritis Outcome Score.

^fN/A: not applicable.

^gBOOST-TLC: Boston Overcoming Osteoarthritis through Strength Training Telephone-linked Communication.

^hKR: knee replacement.

ⁱHR: hip replacement.

^jIMU: inertial motion sensor.

^kTKA: total knee arthroplasty.

^lUKA: unilateral knee arthroplasty.

^mCurrency conversions calculated on May 24, 2022.

Chen et al [58] developed a blended intervention comprising 4 in-person group sessions of health education and exercise and telephone follow-up, with the remaining sessions at home. Although the blended intervention of Cuperus et al [73] comprised 2 in-person group exercise sessions and 4 telephone calls from a specialized nurse, the blended intervention in Kloek et al [59] comprised 5 in-person PT and home exercises using a website that provided education along with a graded activity and exercise. All 3 studies found similar improvements in either self-reported symptoms or physical activity between those who received blended interventions and those who received health education [58] or in-person PT [59,73]. In another RCT, Kloek et al [59] reported statistically significant and clinically nonsignificant improvements at 3 and 12 months in physical function and physical activity with a 3-month blended intervention (in-person PT sessions+website with incremental physical activity program, exercise, and education) compared

with in-person usual PT. De Vries et al [62] then used data from the blended intervention arm of this RCT to investigate factors related to the adherence to the digital component of the blended intervention. The authors observed the highest adherence for participants with middle (vs low or high) education level, duration of symptoms of 1 to 5 years (vs <1 year or >5 years), and those recruited by physical therapists [62]. Other factors positively related to adherence included participants' internet skills, self-discipline, the execution of the exercise plan and usability, flexibility, design, added value, and time required for the digital intervention [62]. Thus, although blended interventions may elicit improvements similar to in-person PT, a number of individual and program-related factors are associated with adherence to the web-based component of blended interventions.

Baker et al [60] developed a 2-year telephone-based intervention comprising the assessment of exercise behavior, goal setting, counseling, and alerts when exercise adherence lapsed but found similar improvements in exercise adherence in those who received the telephone intervention and those who received automated reminder messages to exercise. Similarly, Hinman et al [61] found similar improvements in overall knee pain in those who received telephone counseling from both nurses and PT and in those who received counseling from nurses only. Despite the nonsignificant improvements in pain, Hinman et al [61] found statistically significant but clinically nonsignificant improvements in function, satisfaction, and adherence to the telephone intervention. Lawford et al [71] speculated that these clinical improvements in participants might be associated with their relationship with PT. However, secondary analysis of the data revealed only weak associations between therapeutic alliance and improvements in pain, function, and fear of movement [71].

Directly Supervised Exercise Interventions for Populations With KR: Real-time Videoconferencing, Multi-Technology, and Telephone-Based

In individuals before and after KR, digital health PT interventions were mostly investigated as replacements for traditional in-person PT (Table 4).

Doiron-Cadrin et al [63] found high satisfaction and clinically meaningful within-group improvements in pain and function with a 12-week prehabilitation program using real-time videoconferencing, which were similar to those in people who received the 12-week prehabilitation program in person. Similar outcomes between digital and in-person PT interventions have also been reported in individuals after KR for video-based and inertial motion sensor-based digital health interventions [63-66].

However, some outcomes (physical activity, muscle strength, exercise behavior, climbing stairs, walking, and body pain) favored in-person PT at longer follow-up periods (2, 4, 12, or 18 months after the intervention) [65,52]. Moreover, better outcomes with digital health than with in-person PT have been seen when using multi-technology platforms, with improvements in pain and function [67-69] above the MCID [55,75] and persisting even at longer follow-up periods of 3 and 6 months [68,69]. This suggests that these intensive multi-technology digital interventions may be more effective than simpler digital health interventions. These multi-technology platforms included motion-tracking sensors paired with a mobile app for biofeedback; a website portal to report activity to a therapist who could modify the exercise program as needed; or motion-tracking cameras with an avatar for exercise delivery, outcome reporting, and clinician monitoring [67-69]. Finally, a retrospective study found a high response rate (92%), satisfaction (89%), and acceptability (87%) for an internet-based rehabilitation follow-up [74]. However, the lack of comparison with in-person follow-up limits the conclusions on the efficacy of internet-based follow-ups in this population.

Digital Health for Psychological Interventions for Chronic Pain Management

Overview

In addition to patient education and exercise, there is growing evidence showing the efficacy of behavioral interventions such as CBT and PCST for the management of chronic pain because of KOA [7,9]. This section includes digital interventions that incorporated such psychological treatments (Table 5). A detailed description of the studies and the technology used in the studies is shown in Table S5 in Multimedia Appendix 1 [76-87].

Table 5. Digital health for psychological interventions.

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Nevedal et al [80]	Chronic pain, including osteoarthritis	Pre or post design	Commercially available web-based program	645	None	N/A ^a	Improvements in pain intensity and pain unpleasantness on a 0- to 10-point Likert scale
Rini et al [79]	Hip or knee osteoarthritis	RCT ^b	PainCoach (internet-based PCST ^c)	58	No intervention	55	Significant improvements in pain on the Arthritis Impact Measurement Scale 2
Bennell et al [76]	Chronic knee pain	RCT	Website for education and PCST program and videoconferencing for exercises delivered by PT ^d	74	Website for education	74	No difference in improvements between groups for the NRS ^e pain score and the WOMAC ^f function at 6 months
Lawford et al [85]	Chronic knee pain	Exploratory analyses from an RCT	Website for education and PCST program and videoconferencing for exercises delivered by PT	74	Website for education	74	Greater improvements for the NRS pain score in employed people in the intervention vs employed people in the comparator; greater NRS pain improvements in people who had higher self-efficacy
Mecklenburg et al [77]	Chronic knee pain	RCT	Inertial movement sensors and tablet computer with an app that includes an exercise plan, CBT ^g , weight loss, personal coach, and peer support	101	Digitally delivered patient education	61	Greater improvements for the KOOS ^h pain and function in the intervention vs comparator
O'Moore et al [78]	Knee osteoarthritis with major depressive disorder	RCT	Internet-based CBT program)+usual treatment	44	Usual treatment	25	Improvements in intervention for depression and psychological distress
Stome et al [81]	Osteoarthritis	Pre or post	12-week goal achievement program using behavior change app Vett (personalized goals+2-3 corresponding weekly tasks decided during an in-person consultation with physician+self-monitoring+cues and reminders+individual feedback and communication with an assigned mentor)	12	N/A	N/A	High levels of acceptability, utility, and usability

Study	Population	Design	Intervention		Comparator or comparators		Primary outcome findings
			Description	Sample size	Description	Sample size	
Bennell et al [82]	Knee osteoarthritis and obesity	2-group superiority RCT (TARGET trial)	24-week behavior change, theory-informed, automated, SMS text messaging interventions that address barriers to and facilitators of adherence	56	No SMS text messaging	54	Greater improvements in exercise adherence on the Exercise Adherence Rating Scale in the intervention vs comparator
Dharmasri et al [83]	African Americans with osteoarthritis	Mixed methods RCT: data from the intervention arm of the trial	STAART ⁱ trial: 11-session, telephone-based PCST program delivered by counselors+ handouts+audio recording for progressive muscle relaxation	93	N/A	N/A	Participants found the program helpful and described the following themes: improved pain coping, mood and emotional benefits, improved physical functioning, and experiences related to intervention delivery
Pronk et al [87]	Post-KR ^j	Unblinded RCT	PainCoach app that gave advice on pain medication use, exercise or rest, and when to call the clinic in response to a patient's input of pain experienced	38	Same advice as PainCoach given in usual care	33	No difference between groups in improvements in pain at rest, during activity, or at night
Buvanendran et al [86]	Pre-KR	RCT	8-week telehealth CBT and 4-week telehealth CBT	30 (8 weeks) and 20 (4 weeks)	4-week in-person CBT and no CBT	15 (4 week) and 15 (no CBT)	Improvements in PCST but not WOMAC pain scores in the intervention vs comparator
McCurry et al [84]	Moderate to severe osteoarthritis and insomnia	RCT	Telephone-based 8-week CBT for insomnia+daily sleep diaries+sleep hygiene education+cognitive strategies	136	Education related to living with chronic osteoarthritis	146	Improvement on Insomnia Severity Index in the intervention vs comparator

^aN/A: not applicable.

^bRCT: randomized controlled trial.

^cPCST: pain coping skills training.

^dPT: physical therapy.

^eNRS: Numeric Pain Rating Scale.

^fWOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

^gCBT: cognitive behavioral therapy.

^hKOOS: Knee Osteoarthritis Outcome Score.

ⁱSTAART: Skills Training for African Americans with Osteoarthritis study

^jKR: knee replacement.

Digital Health for Psychological Interventions for Populations With KOA: Websites, Mobile App, Text

Messaging, Multi-Technology, Telephone-Based, and Real-time Videoconferencing

These technologies (website: 3/91, 3%; telephone: 1/91, 1%; SMS text messages: 1/91, 1%; mobile apps 1/91, 1%; real-time videoconferencing: 1/91, 1%) typically included features such

as easy-to-use interfaces, tailored goal-setting and daily assignments, education, behavioral coaching by animated characters or by counselors, reminders, activity and sleep logs, wearable sensors for tracking movement, and communication with clinicians. Although the content of these interventions varied, overall, all studies that included CBT or PCST showed statistically and clinically meaningful small to medium improvements in knee pain, as reported by MCID and effect sizes, with a digital health intervention [76-84]. Furthermore, in people with KOA who also met the criteria for major depressive disorder, web-based CBT (6 web-based lessons, regular homework assignments, access to supplementary sources, and contact with clinical psychologists if scores on self-reported outcome measures deteriorated significantly) along with usual treatment was found to be more effective than usual treatment alone in improving depression symptoms and psychological health, in addition to improving pain, function, and self-efficacy [78]. Similarly, in people with KOA who also had insomnia, an 8-week telephone-based CBT intervention comprising six 20- to 30-minute telephone calls, sleep hygiene education, and techniques to reduce hyperarousal and nonsleep activities in bed at night improved insomnia, pain, and fatigue immediately after treatment, which were sustained at the 12-month follow-up [84]. However, these improvements in pain did not reach clinical significance [84]. Despite these promising results, none of these studies compared digital interventions alone with in-person interventions; hence, it is not clear whether digital interventions for chronic pain management are noninferior or superior to in-person interventions in people with KOA. In addition, in an exploratory study, employment and self-efficacy—but not age, education, expectation of outcome, BMI, or pain catastrophizing—appeared to moderate the effects of a 3-month digital health program on pain [85], suggesting that these factors may be considered when assessing the effectiveness of these interventions.

Digital Health for Psychological Interventions for Populations With KR: Mobile App, Telephone, and Real-time Videoconferencing

Psychological treatment such as a 4-week telehealth CBT for people with high pain catastrophizing scores undergoing KR showed moderate improvements in psychological health (pain catastrophizing scores), which did not translate to clinical

improvements in pain [86]. In contrast, an unblinded RCT investigated a digital health intervention *PainCoach*, which coached or provided advice to the patient on what to do in response to the patient's input of pain and showed a statistically significant reduction in opiate use but nonsignificant improvements in pain compared with usual care [87]. However, given the preliminary nature of these studies and the limited number of studies in KR populations, definitive conclusions regarding the efficacy of psychological interventions delivered by digital health in KR populations cannot be made.

Cost-effectiveness of Digital Health

Another important component in understanding the utility of digital health in KOA or KR is the relative costs of these programs. A detailed description of the studies included in this section is provided in Table S6 of [Multimedia Appendix 1](#) [74,88-93].

Cost-effectiveness of Digital Health Interventions for People With KOA

We identified 2% (2/91) of studies that explicitly focused on cost-effectiveness analyses of digital health interventions for KOA (Table 6). These studies used data from clinical trials described previously in this review. Kloek et al [92] reported that a 12-week blended intervention for patients with hip osteoarthritis or KOA comprising 5 in-person PT sessions and a website program with education, exercise, and a graded activity module had lower intervention and medication costs but similar societal and health care costs than in-person PT. It should be noted that similar improvements were seen in both groups, despite the participants in the digital arm receiving 7 fewer sessions on average than those in the in-person arm [92]. In contrast, Cuperus et al [88] reported that a multidisciplinary in-person intervention to improve self-management skills was slightly more cost-effective than a blended intervention of 2 PT group sessions and 4 telephone calls (€387 [US \$483.62] vs €252 [US \$314.92], respectively) in patients with generalized osteoarthritis. Given the differences in study design (eg, populations, components of digital interventions, and comparators) and the overall lack of research in this area, it is challenging to draw any conclusions regarding the cost-effectiveness of digital health interventions for people with KOA.

Table 6. Cost-effectiveness of digital health.

Study	Population	Design	Intervention		Comparator or comparators		Findings
			Description	Sample size	Description	Sample size	
Cuperus et al [88]	Generalized osteoarthritis	RCT ^a	2 in-person group sessions+telephone monitoring by nurse	72	Multidisciplinary in-person group intervention led by PT ^b	75	No difference in quality-adjusted life years and total societal costs
Kloek et al [92]	Knee or hip osteoarthritis	RCT	Website+in-person PT	108	Usual in-person PT	99	Lower intervention costs and medication costs for intervention vs comparator but no difference in total societal and health care costs
Marsh et al [89,90]	Post-KR ^c or HR ^d	RCT	Web-based platform to schedule patient visits	118	Usual protocol to schedule visits	111	Lower costs for intervention vs comparator
Tousignant et al [91]	Post-KR	RCT	Custom hardware with videoconferencing and remote-controlled cameras	97	In-person home-based PT	100	Lower costs for intervention vs comparator
Fusco et al [93]	Post-KR	Markov decision modeling	10 videoconferencing sessions and 10 in-person PT sessions	— ^e	20 in-person PT sessions	—	High probability of the intervention group being cost-effective, particularly when transportation was included
El Ashmawy et al [74]	Post-KR or HR	Retrospective study	Remote joint replacement clinic follow-up at 1-year, 7-years, and every 3-years after in-person consultations at 2 weeks and 6-weeks	1749	N/A ^f	N/A	Estimated saving of £42,644 (US \$53,439.93) per year with intervention

^aRCT: randomized controlled trial.

^bPT: physical therapy.

^cKR: knee replacement.

^dHR: hip replacement.

^eNot available.

^fN/A: not applicable.

Cost-effectiveness of Digital Health Interventions for People With KR

For people after KR, 5% (5/91) of studies suggested that digital health reduces patient and societal costs [74,89-91,93,94]. Marsh et al [89] evaluated the costs of a web-based follow-up, comprising web-based questionnaires following x-rays, email reminders, and alerts to schedule in-person appointments if necessary, and reported that after 1 year from surgery, digital health was more cost-effective than in-person follow-up after KR because of reduced travel and associated costs [90] and from a societal and health care perspective. Similarly, El Ashmawy et al [74] reported that remote follow-ups at longer postoperative periods (after a 1-year postoperative period) were more cost-effective than in-person follow-ups. Furthermore,

2% (2/91) of studies compared videoconferencing with or without in-person PT with in-person PT and reported that telerehabilitation was cost-effective when transportation costs were included in the analysis [91,93]. In individuals before KR, a mobile app-based prehabilitation intervention that provided individualized exercises, progressions, and daily pain monitoring was more cost-effective than no prehabilitation as the prehabilitation program reduced the length of hospital stay (7.6 vs 11.9 days) and consequently reduced hospital costs [94]. However, in this case, the reduced costs could be attributed to prehabilitation and not necessarily to digital health.

Patient and Clinician Perspectives on Digital Health

Patients' Perspectives on Digital Health

To determine the potential of digital health for KOA, an understanding of the patient and clinician perspectives on these technologies is needed. Several studies have reported patient and clinician perspectives on a variety of digital health interventions (Table 7).

Overall, patients with KOA had positive experiences with digital health technologies. Some of the key benefits noted by patients included anonymity, accessibility, convenience, tailored interventions, reduced travel costs, feedback and self-monitoring, progress reports, and enhanced patient-provider relationships [95-105]. Phone-based interventions were found to be acceptable and were valued for the undivided focus and communication from physical therapists [96-98]. However,

some patients who lacked confidence in their exercise technique wanted some form of visual supervision (videoconferencing) to be incorporated into their exercise intervention [97]. Although people with KOA had positive views about digital health technologies, they also discussed some concerns related to navigating these technologies. These concerns typically included challenges with the user interface, dislike for repetitive reminders and texts, lack of variation in exercises, accommodation for comorbidities (eg, decreased motor coordination and visual and hearing impairments), privacy and security, preference for customized notification, need for technological support, willingness to pay, and lack of in-person contact with clinicians [81,96,98-104,106]. Despite this, people with KOA were willing to use a digital program whether it was endorsed by their health care professional or by a credible organization [99-102].

Table 7. Patient and clinician perspectives on digital health.

Technology	Patient perspectives	Clinician perspectives
Telephone interventions [96,97,107,108]	<ul style="list-style-type: none"> • Willing to use • Less acceptable than videoconferencing 	<ul style="list-style-type: none"> • More acceptable after first-hand experience • Liked the focus on communication and self-management rather than manual therapy • Less acceptable than videoconferencing • Lack of visual cues and difficulty with examination • Requires training
Telerehabilitation and real-time videoconferencing [65,98]	<ul style="list-style-type: none"> • Acceptable, feasible, and satisfactory • Improved access and relationship with the therapist • Preferred over telephone • Convenience, ease of use, and privacy • More patient-focused than in-person visits • No consensus about willingness to pay • Requires technological assistance 	<ul style="list-style-type: none"> • High satisfaction with goal achievement, patient-therapist relationships, and quality and performance • Liked that patients may be more active in managing their disease • Preferred over telephone • Discomfort with lack of physical contact • Lack of experience can lead to low confidence and reduced interest
Websites [90,95,99-101]	<ul style="list-style-type: none"> • Moderate to high satisfaction • Cost and time savings • Anonymity, accessibility, and flexibility • Similarly preferred as in-person for scheduling visits • Preferred over social media, group self-management programs, or telephone helplines • Increased acceptance if endorsed by a health care professional • Monitoring progress, access to information, feedback from health care professionals, and connecting with peers • May depend on technological capabilities • Real-life avatar preferred over animation • Nonnative accents not preferred; desire for more context and culture specific 	<ul style="list-style-type: none"> • Professional autonomy and added value to practice • Effective, acceptable, and feasible • Apprehensive of extra time needed to incorporate digital health, especially during high workload • Need for flexibility to tailor to an individual • Need for training • Financial concerns
Mobile app [102,103]	<ul style="list-style-type: none"> • Prefer big buttons, tapping vs sliding, and vertical vs horizontal layout • Progress feedback reports and educational tips • High levels of acceptability, user satisfaction, and technical usability • Useful for self-management and improved communication with physicians • Do not prefer extra clicking, complicated user interface, and unnecessary information 	<ul style="list-style-type: none"> • Liked the weekly or monthly pain and activity reports • Prioritized precision of presentation and interpretation of questions • Useful for patient resources and accountability • Skepticism because of the need for internet access at the clinic and technological aptitude
Smartwatch app [104]	<ul style="list-style-type: none"> • Interest in direct phone call capability, weather apps, and health-tracking sensors such as accelerometer and heart rate sensor • Concerns regarding usability, accessibility, notification customization, and intuitive user design 	— ^a
Social media [109]	<ul style="list-style-type: none"> • Limited prior experience among participants • Less preferred compared with web-based and mailed information packs 	—
Wearable biofeedback system [110]	—	<ul style="list-style-type: none"> • Useful for movement feedback, monitoring, and adherence • Challenges with monitoring, reliability, information accuracy, and individualization

^aNot available. No relevant studies were identified.

Clinician's Perspectives on Digital Health

Clinicians also noted the benefits of digital health technologies but appeared more likely than patients to identify challenges. Although accessibility and convenience were noted as positive aspects, there were concerns related to implementation, apprehension about the technology, lack of physical contact, data protection, lack of digital health and communication training, and revenue loss [98,102,107,108,110,111]. Hurley et al [112] showed that appropriate training can lead to improvements in physical therapists' knowledge, skills, confidence, and the delivery of digital health interventions. Similar to patients, clinicians preferred video-based over telephone-based interventions [107]. However, training and experience were found to improve clinicians' perspectives on telephone-based interventions [108]. Physical therapists also found value in monitoring patients' data, particularly in being able to track movements, but were concerned with adoption in patients who may not be technologically proficient [103,110]. Furthermore, health care professionals discussed wanting more information on patients' compliance to exercise, relevant outcomes, and validity of tracking with the digital health program [113]. Interestingly, one of the studies noted that physicians did not support the use of mobile apps as they considered KOA to be a minor problem, were concerned about their involvement, and needed the internet at the clinic [102]. These findings provide opportunities for further improvements in digital health interventions based on patients' and clinicians' perspectives.

Discussion

Principal Findings

Digital health has been used to provide patient education, physical activity, and exercise interventions (self-directed, remotely monitored, or directly supervised by a clinician), as well as psychological interventions such as CBT and PCST, in people with KOA and KR. The types of digital health used for these purposes included websites, telephone calls, SMS text messaging, mobile apps (with or without visible feedback from activity monitors), real-time videoconferencing, and multi-technology systems that combined a few different technologies in their intervention. These technologies were typically used in place of or to augment in-person clinical care. Multiple technologies were often combined (eg, activity monitoring with mobile apps and wearable sensors with websites) in digital interventions to leverage the strengths of multiple technologies. Overall, we found substantial heterogeneity in the types of digital health interventions that have been investigated for people with KOA and KR.

Only a few recent studies on the use of digital health for patient education were identified [23,24,26-28,35]. Although these studies found improvements in disease-related knowledge—with digital interventions providing patient education—in people with KOA and KR [23,24,28], the clinical meaningfulness of these improvements is unclear. Irrespective of the technology used for the dissemination of patient education, all studies in KR populations found improvements in disease- and surgery-related knowledge in users before their KR or soon

after their KR [26,27,35]. However, the studies in KR populations were limited (3/91, 3%), and it is also not clear whether these results hold true at longer follow-up periods (ie, a few months after KR surgeries). In both the KOA and KR populations, it was noted that providing regular and person-specific information (eg, via push notifications in a mobile app or SMS text messaging) in contrast to general advice and relying on patients to access the information at their convenience may lead to improved disease-related knowledge [23,27,35]. It was also identified that publicly available content on social media may have incomplete or misleading information that could further erode patient trust in the information provided via digital means [29-32,34].

In people with KOA, the benefits of digital health for exercise and physical activity interventions in people with KOA appear mixed. In contrast, in people with KR, many studies reported significant improvements in self-reported outcomes with digital exercise interventions that were similar to in-person treatments [63-66]. Although the different technologies used in these studies (eg, websites, telephone, mobile apps, videoconferencing, and multi-technology systems) were generally acceptable to people with KOA and KR, some participants who used telephone-based interventions stated the need for visual contact with their physical therapists [96-98]. However, currently, research comparing different modes of intervention delivery using different technologies is lacking. Overall, it appears that interventions that use >1 technology and strategies to engage the participants (eg, activity monitoring with a mobile app, activity monitoring with motivational messaging, and telephone coaching) may be more promising than those that rely on a single modality (eg, website or SMS text messaging) [39,46,47,67]. For interventions delivered by physical therapists to people with KOA, blended interventions that use digital health strategies to augment in-person care may provide benefits similar to those of in-person care [41,59,70,73]. However, more research that directly compares blended, digital, and in-person care is required to comprehensively understand the potential of blended interventions. Digital health interventions that include CBT or PCST components have shown statistically significant and clinically meaningful improvements in outcomes in patients with KOA and KR. However, there is a lack of research comparing these approaches with traditional in-person approaches; thus, conclusions cannot be drawn about how they compare with in-person psychological interventions for chronic pain management. Finally, although digital health appears to be cost-effective when compared with in-person treatments, research on the cost-effectiveness of digital health is too limited to draw definitive conclusions.

Comparison With Prior Work

Choi et al [18] conducted a systematic review of mobile apps for osteoarthritis self-management. The authors concluded that digital health tools for the self-management of osteoarthritis mostly provided patient education and lacked rigorous evidence. They recommended that future mobile apps should include self-management, decision support, and shared decision-making as key functionalities for people with osteoarthritis. Our review expands on this prior work as we included all available types of digital health (eg, social media and websites) versus only

mobile apps. Our findings show that these tools improve patient knowledge; however, whether they translate into improved outcomes is not clear. Safari et al [21] also published a systematic review and meta-analysis of digital self-management interventions for people with KOA. They included interventions delivered via telephone plus audio and video, the internet, or mobile apps. They concluded that moderate-quality evidence suggests small to medium improvements in pain and function immediately after the intervention, which was sustained at 12 months. They included studies of self-guided exercise interventions as part of their analyses and considered any comparator (eg, usual care, other digital health, alternative treatment, and no treatment). Although we did not undertake a meta-analysis, our review provides more nuances and context by teasing out the findings by type of intervention (eg, education and self-guided exercise) and comparator (eg, in-person exercise).

In people with KR, 2 prior systematic reviews reported greater improvements in pain, function, knee extension, and quadriceps strength in people who received digital interventions than in those who received in-person PT [17,19], whereas another reported similar improvement in knee range of motion, physical activity, and function in people who received post-KR rehabilitation in person or by telerehabilitation [16]. Our review extends these results by including studies that investigated a range of digital health technologies (websites, mobile apps, SMS text messages, phone based, and synchronous and asynchronous videoconferencing). Furthermore, the findings of our review build on existing literature by noting that digital interventions for people with KR, which incorporated multi-technology platforms, were associated with statistically and clinically significant improvements in pain and function [55,74,75], which persisted even at longer follow-up periods of 3 and 6 months [74,75]. Hence, our review extends the findings reported in some prior studies and captures important advances in digital health spurred by the onset of the COVID-19 pandemic, when remote health care greatly expanded [2].

Limitations

There are a few limitations to be considered when interpreting the findings of this review. First, a comparison of specific digital health technologies (eg, websites vs mobile apps) or their components was beyond the scope of this review. Second, the focus of our review was on studies that used digital health for interventions in KOA and KR and thus did not address other applications of digital health such as informed consent, movement assessment, diagnosis, and data collection. Third, this review focused only on the primary outcomes reported in the included studies. Additional insights may be gained by reviewing the secondary and exploratory outcomes. Fourth, as this was not a systematic review, these findings should be interpreted with caution. The intent of this literature review is to provide researchers and clinicians with an overview of the digital health interventions currently used for KOA and KR. Finally, as our last search was conducted in February 2021; studies published after this date were not included in this review.

Future Directions

This review shows that digital health has promising potential in the future of health care for people with KOA and KR. For readability and quality of digitally delivered education, it may be valuable for digital interventions to curate content from credible websites, treatment guidelines, or cocreate educational resources with people with KOA. Moreover, the information provided by digital interventions should be validated by licensed health care providers before it is disseminated to patients. For physical activity and exercise interventions, future studies should consider leveraging existing knowledge of patient and clinician preferences while developing and implementing digital health approaches. Furthermore, given that user engagement and adherence remain a challenge in this population, providing technological support (eg, phone calls and easy-to-use user interface) and clinical support (eg, communication with a clinician via asynchronous or synchronous chats, phone, or video calls) could improve the adoption of digital health technologies in people with KOA. In addition to providing technological and clinical support, other patient-related contextual factors such as employment, educational attainment, and eHealth literacy, should be considered while prescribing digital treatments to ensure greater adherence [62,85]. Specific technological preferences in terms of intervention flexibility and user experience in the reviewed studies may also be important when prescribing digital health interventions [81,101,104,106,109,114]. Flexibility in interventions that allow for some degree of personalization, such as activating or deactivating features based on personal preferences and the ability to alter intervention design based on comorbidities (eg, visual impairments and hand osteoarthritis), may also foster adherence [106]. From the clinician's perspective, reimbursement models that incentivize the use of digital health interventions are needed [115]. Although these findings provide some guidance, the best practice would be to include all stakeholders (clinicians and patients) while developing new digital health interventions [116]. For example, researchers or research organizations could liaise with patient organizations to understand preferred sources of information (eg, YouTube videos) and lead efforts to improve the quality and readability of information available through those sources. Finally, concerns regarding privacy and data security continue to be raised by both patients and clinicians. Therefore, transparent disclosure of how data generated from digital health platforms will be used and kept secure may be vital for their uptake in real-world settings.

Conclusions

In conclusion, digital health offers exciting opportunities for improving care delivery for people with KOA or KR. For people with KOA and KR, interventions that are blended (digital health and in person), incorporate multiple technologies, patient monitoring or visible biofeedback, and communication with clinicians may have more favorable outcomes. However, comparative studies investigating the different technologies are lacking. Future implementation of these promising technologies should consider incorporating patient and clinician preferences into the digital health intervention design process.

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Authors' Contributions

DK conceived the study. NS and DK selected the journal articles to be included. All the authors contributed to the synthesis and final approval of the manuscript. DK takes responsibility for the integrity of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed description of studies included in the review.

[DOCX File, 77 KB - [rehab_v9i2e33489_app1.docx](#)]

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Abbreviations

CBT: cognitive behavioral therapy

IBET: Internet-Based Exercise Therapy

KOA: knee osteoarthritis

KR: knee replacement

MCID: minimal clinically important difference

PATH-IN: Physical Therapy versus Internet-Based Exercise Training

PCST: pain coping skills training

PT: physical therapy

RCT: randomized controlled trial

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

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Original Paper

Exercise-Based Real-time Telerehabilitation for Older Adult Patients Recently Discharged After Transcatheter Aortic Valve Implantation: Mixed Methods Feasibility Study

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Abstract

Background: The use of telehealth technology to improve functional recovery following transcatheter aortic valve implantation (TAVI) has not been investigated.

Objective: In this study, we aimed to examine the feasibility of exercise-based cardiac telerehabilitation after TAVI.

Methods: This was a single-center, prospective, nonrandomized study using a mixed methods approach. Data collection included testing, researchers' observations, logbooks, and individual patient interviews, which were analyzed using a content analysis approach. The intervention lasted 3 weeks and consisted of home-based web-based exercise training, an activity tracker, a TAVI information website, and 1 web-based session with a nurse.

Results: Of the initially included 13 patients, 5 (40%) completed the study and were interviewed; the median age was 82 (range 74-84) years, and the sample comprised 3 men and 2 women. Easy access to supervised exercise training at home with real-time feedback and use of the activity tracker to count daily steps were emphasized by the patients who completed the intervention. Reasons for patients not completing the program included poor data coverage, participants' limited information technology skills, and a lack of functionality in the systems used. No adverse events were reported.

Conclusions: Exercise-based telerehabilitation for older people after TAVI, in the population as included in this study, and delivered as a web-based intervention, does not seem feasible, as 60% (8/13) of patients did not complete the study. Those completing the intervention highly appreciated the real-time feedback during the web-based training sessions. Future studies should address aspects that support retention rates and enhance patients' information technology skills.

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KEYWORDS

telerehabilitation; transcatheter aortic valve implantation; cardiac surgery; cardiac rehabilitation; exercise training; older adults; tablet

Introduction

Background

Aortic valve stenosis affects approximately 3% of patients aged ≥ 75 years. Untreated aortic stenosis (AS) leads to dizziness, fainting, dyspnea, chest pain, heart failure, and sudden cardiac death [1]. Transcatheter aortic valve implantation (TAVI) is increasingly being used as a procedure of choice for older adult patients with severe AS and high perioperative mortality risk [1,2]. The number of TAVI procedures is expected to increase in the coming years because of an aging population [3] and the positive short- and long-term results of the procedure [4]. Thus, TAVI has recently been recommended in patients who are aged >65 years and are at low and intermediate risk from surgical aortic valve replacement [4].

To date, no major guidelines recommend cardiac rehabilitation (CR) after TAVI [5], although emerging evidence suggests that CR is safe and has the potential to reduce mortality and improve exercise capacity and quality of life [6-9]. Participation in CR soon after TAVI may be of particular importance as sedentary behavior in this often frail population with multiple comorbidities is related to a higher risk of mortality and functional decline 1 year after the procedure [10]. In Denmark, less than 20% of patients are referred to and participate in CR following TAVI [11]. Several factors hinder patients' participation in CR, including old age [12], lack of availability of municipality-based CR, lack of continuity between hospitals and local health centers where CR programs are performed, and lack of individualized rehabilitation [13].

Cardiac Telerehabilitation in General

Telerehabilitation is defined as the use of information and communication technologies to support rehabilitation [14,15]. Cardiac telerehabilitation (CTR) has proven to be as effective in decreasing morbidity and mortality as center- and hospital-based CR programs [16,17]. In a recently published systematic review, CTR was found to be as cost-effective as traditional center-based approaches [18]. CTR may enhance attendance rates and long-term adherence to rehabilitation recommendations because it is performed in the participants' own environment and can thereby be incorporated into their daily routines [19,20]. CTR often consists of digitally available cardiac-related patient information and the use of different devices (eg, activity trackers or weight scales) that collect and transfer data to a personal health record or digital platform [21,22], whereas others provide supervised exercise training [16,23]. Considering that the participation of older adult patients in center-based CR programs is poor [12,24], CTR may resolve barriers that hinder CR use and improve adherence to CR programs and sustainability of effects following the program [25].

CTR Following TAVI

The effectiveness of CTR following TAVI has not yet been investigated, probably because the use of modern technology in the older adult population is still limited [26-28]. Hence, we developed a digital CTR program (TeleTAVI) based on four elements: (1) supervised home-based web-based exercise

training, (2) an activity tracker, (3) a website containing disease-specific patient education and training videos, and (4) 1 web-based session with a nurse specializing in the care of patients undergoing TAVI. The development process was based on a participatory design [29], including individual patient interviews and workshops with patients, health professionals, researchers, and system developers [30]. The aim of this study was to investigate the feasibility and usability of a CTR program, named TeleTAVI, delivered via a tablet to an older adult population who had recently undergone TAVI surgery, with consideration given to the potential barriers in the use of technology for this particular population. We hypothesized that patients who undergo TAVI would be able to manage and use a tablet containing a TeleTAVI program at home and would be positive regarding the TeleTAVI content and approach.

Methods

Overview

A prospective nonrandomized, single-center study using a mixed methods approach was designed to investigate the feasibility of the TeleTAVI program and evaluate patient experiences with the program. In addition, we collected data on the running expenses of the program. Furthermore, this study was conducted to gather information about whether and how a future large-scale randomized controlled trial could be performed. The first author (BCB) was in charge of all procedures for recruitment and running the study, while the last author (CBT) performed patient interviews. The study was reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) extension for feasibility and pilot studies [31].

Setting

Participants were recruited from the Department of Cardiology, Aalborg University Hospital, Denmark, between August 18 and September 22, 2020. The hospital performs 120 TAVI procedures each year. The Danish National Health Service provides tax-supported health care, including general CR, for all inhabitants, guaranteeing free access to family physicians and public hospitals.

Ethics Approval

This study was approved by the Danish Data Protection Agency (registration 2020-054). The regional ethics committee stated that no approval was required for this study. Informed written consent was obtained from all participants before inclusion.

Inclusion and Exclusion Criteria

Eligible participants were adults who planned for elective TAVI and were capable of reading and understanding Danish. Indications for TAVI in the present patient cohort were primarily high-risk, symptomatic AS, and or aged >80 years. The exclusion criteria were physical deficits that adversely influenced physical performance, decreased cognitive functioning, or TAVI performed as acute or subacute surgery.

Surgery and Perioperative Management

TAVI was performed with local anesthesia and conscious sedation, with the insertion of a self-expandable aortic valve

using a balloon catheter through a transfemoral incision. The choice of heart valve used (Edwards Sapien Ultra, Edwards Lifesciences) or Merill MyValve (Life Sciences Pvt Ltd) was made by the surgeon. After surgery, patients were transferred to the intensive care unit for observation and returned to the ward on the evening of the day of surgery or, at the latest, the next morning. When stable, patients were mobilized to walk on the day of surgery and were discharged within 2 or 3 postoperative days.

Intervention

The technologies used for the pilot study are presented in [Multimedia Appendix 1](#). The intervention was multimodal, lasted 3 weeks, and consisted of supervised web-based exercise training, patient support, the use of an activity tracker, and access to a project website.

Technology and Management

The technologies were introduced during a home visit, 1 week after hospital discharge. A booklet containing written user instructions for each element of the intervention and a schedule of rehabilitation activities were provided to each patient before hospital discharge. The booklet was continuously adjusted during the study period according to patient feedback.

To deliver the video-training sessions at the hospital, we used a 49-in television monitor, a high-definition sound bar, and a Bluetooth headset to enable 2-way communication during each session.

Tablet

All the participants received a tablet (iPad, Apple) along with a SIM card for data coverage. For the web-based training sessions, we used an encrypted videoconferencing system (Videosamtale) hosted by Aalborg University Hospital, that complies with the General Data Protection Regulation (GDPR) for European countries. During the home visit, patients were thoroughly introduced to how to connect to the web-based program and how to access the project website [32] for information and videos related to themes identified as important by patients who had previously undergone TAVI. For simplicity, the tablet setup only allowed the patients to use the TeleTAVI project's website and an email program for assessing the link to the videoconferencing system.

Activity Tracker

We used 2 different activity tracker models measuring step counts: Fitbit Charge 3 (Fitbit LLC) and Beurer AS 87 (Beurer Germany) to identify the most feasible activity tracker for use in a later extension of the program. The patients filed the daily number of steps in their training diaries, and we uploaded the data stored in each activity tracker after collecting the equipment at the patients' homes.

Exercise Training

Individualized web-based home exercise training followed the national recommendations for CR with a combination of aerobic and strength training twice weekly, with each session lasting 30 to 45 minutes [33]. The target intensity for the aerobic exercises was either a heart rate of 80 to 100 beats/min (patients

wearing Fitbit) or a Borg CR10 dyspnea score from 3 to 5 [34] (patients wearing Beurer). The number of web-based sessions was set at 5. Patients were offered further sessions if they were able to attend. In addition, the patients were instructed to take a 30-minute walk daily with moderate intensity. Before hospital discharge, the patients were instructed to perform 3 exercises on alternate days until the home visit took place (home exercise program is provided in [Multimedia Appendix 2](#)).

Follow-up Session With a Nurse

The 1 web-based session with a project nurse was established as a follow-up after hospital discharge. The topics during the sessions were based on patients' perspectives on the development process of the TeleTAVI program [30]. Spouses participated in the sessions at their own discretion.

Data Collection and Analysis

Eligible patients were approached for inclusion the day before their surgery.

Assessments

Demographic and perioperative data were collected from patients' medical records. The following assessments were performed the day before surgery to evaluate patients' preoperative functional status and to target the exercise training program: 6-minute walk test [35]; 30 seconds-sit-to-stand test to assess functional lower extremity muscle strength [36]; 4-m walk test to assess gait speed. A gait speed <0.7 m/s is defined as frailty in TAVI [37]. Dominant hand grip strength was also assessed using the a digital hand dynamometer [36] and Mini Mental Scale Evaluation [38]. For health-related quality of life, we used HeartQol [39], which is a disease-specific questionnaire validated for patients who have undergone cardiac valve replacement surgery [39,40]. For frailty, we used the Tilburg Frailty Indicator, a validated self-administered instrument for assessing multidimensional frailty in older populations [41]. The number of steps was recorded and compared with those registered in the patients' step diaries. Furthermore, we collected data on the number of home visits for technical support and telephone calls regarding difficulties in using the tablet and log-in procedure. Data were stored using the REDCap (Research Electronic Data Capture) electronic data capture tool (REDCap Consortium, Vanderbilt University Medical Center) hosted by the North Denmark Region.

Field Notes and Logbooks

Field notes consisted of field observations and logbook registrations of each patient regarding their participation in the CTR program.

Patient Interviews

Individual interviews with patients completing the CTR program were performed to gain insight into their experiences of being part of the TeleTAVI program and the usability of technologies and devices. The interviews were based on a semistructured interview guide [42] ([Multimedia Appendix 3](#)) and lasted 30 to 90 minutes. All interviews were conducted in the patients' homes at the end of the intervention, and partners were invited to participate. The interviews were digitally recorded and transcribed verbatim by a research assistant.

Estimated Costs

The running expenses for the program were estimated per patient completing the program and expressed as costs related to the equipment delivered to each patient at home (tablet, activity tracker, and home training equipment) and staff costs (transportation for home visits, running the web-based intervention, and information technology [IT] support).

Data Analysis

Descriptive statistics were used to describe the study population, and nonparametric statistics were used to analyze the differences between patients who completed the study and those who did not. A 2-sided P value $<.05$ was considered statistically significant. Owing to the small number of cases and subsequent skewed data, we have presented the results as median, minimum, and maximum, as well as numbers, frequencies, and percentages when appropriate. Analyses were performed using SPSS software (IBM Analytics). No formal sample size calculation was performed because of the explorative character of the study and because no efficacy testing was performed [43].

The first author (BCB) read all the observations and comments registered in the research diaries. Themes were identified according to the elements that comprised the intervention, and the findings were reviewed and discussed with the last author (CBT). The analysis of each individual interview was conducted as a deductive manifest content analysis with the aim of creating a condensation of meaning [44]. After familiarization with the text, the interviews were coded and abstracted into categories and subcategories, using the NVivo (QSR International) coding system [45]. Both authors reviewed the categories and analyzed them according to the different elements of the intervention. The results are presented as a joint display [46], that is, both

quantitative and qualitative results are presented together, according to the source of data: patient citations from the interviews, logbooks, or field notes.

Results

Overview

In total, 20 consecutive patients admitted to Aalborg University Hospital for elective TAVI were assessed for eligibility; 13 patients with a median age of 83 years (range 74-87 years) agreed to participate and underwent baseline assessments. The median length of hospital stay was 3 days (range 3-30 days). Five patients (3 men and 2 women) completed the study. All had some experience with either the use of a computer or tablet, or they could get help from their relatives to manage the technology. Frailty was detected in a single patient completing the study, whereas 3 patients in the dropout group were categorized as frail (Table 1). The reasons for dropouts included tiredness after the surgery ($n=2$), hospital readmission ($n=1$), and poor mobile coverage ($n=1$; Figure 1, study flowchart). The first 3 patients included were introduced to the technology on the first postoperative day and reported that they were tired and could not concentrate on the technology at that time. Thus, the introduction of the technology was scheduled 1 week after hospital discharge.

The results and findings are presented as a joint display (Table 2) and summarized into the following categories: home-based rehabilitation, web-based exercise training, activity tracker, web-based session with the nurse, and website and technical issues. Each category was elaborated separately, and quotations from the interviews were provided to illustrate the findings.

Table 1. Demographics and surgical characteristics of participants.

Variables	Included (N=13)	Completed the study (n=5)	Did not complete the study (n=8)	P value ^a
Age (years), median (range)	83 (74-87)	82 (74-84)	83 (75-87)	.35
Gender (man), n (%)	8 (63)	3 (60)	5 (63)	.98
BMI (kg/m ²), median (range)	26 (23-30)	26 (23-27)	28 (24-30)	.22
Comorbidities, n (%)				
Arterial hypertension	8 (62)	3 (60)	5 (63)	.92
Ischemic heart disease	4 (27)	2 (40)	2 (25)	.57
Previous stroke	2 (15)	1 (20)	1 (13)	.83
Atrial fibrillation	3 (23)	2 (40)	1 (13)	.12
Diabetes mellitus	4 (27)	1 (20)	3 (37)	.67
Left ventricular ejection fraction, median (range)	60 (40-60)	60 (40-60)	60 (45-60)	.82
NYHA,^b n (%)				.28
NYHA class II	8 (62)	4 (80)	4 (50)	
NYHA class III	5 (38)	1 (20)	4 (50)	
American Society of Anesthesiology Score, n (%)				
3	3 (23)	1 (20)	2 (25)	.83
4	10 (77)	4 (80)	6 (75)	
Forced expiratory value first second, median (range)	77 (52-132)	61 (52-132)	80 (52-125)	.72
Aortic peak gradient, median (range)	83 (50-140)	77 (50-140)	87 (55-105)	.43
Hemoglobin, median (range)	8.2 (6.6-9.5)	8.5 (7.2-8.9)	8.2 (6.6-9.5)	.43
Length of hospital stay, ^c median (range)	3 (3-30)	3 (3-6)	3.5 (3-30)	.35
Physical functioning				
Walked distance (6-minute walk test; m), median (range)	400 (136-543)	460 (299-543)	391 (136-499)	.17
Walked distance % expected, median (range)	97 (36-143)	104 (63-143)	97 (36-113)	.52
Gait speed 4 m, median (range)	03.90 (02.98-10.20)	03.71 (03.15-04.26)	04.15 (02.98-10.20)	.28
Sit-to-Stand Test (30 seconds), median (range)	10 (6-16)	11 (8-15)	10 (6-16) ^d	.52
Hand strength % expected, median (range)	123 (82-162)	108 (84-162)	127 (82-160)	.99
Mini Mental State Examination, median (range)	30 (28-30)	30 (29-30)	30 (28-30)	.77
HeartQoL Quality of Life questionnaire, median (range)	0.79 (0.21- 2.14)	0.57 (0.29-2.14)	1.29 (0.21- 2.14)	.22
Sociodemographic, n (%)				
Living alone	3 (23)	1 (20)	2 (25)	— ^e
Educational level				
Public school or short education	8 (61)	2 (40)	6 (75)	.12
Medium education	3 (23)	0 (0)	3 (37)	
Long education	2 (15)	1 (20)	1 (12)	
Information technology skills				
Novice	3 (23)	0 (0)	3 (37)	.06
Acquainted with tablet or PC ^f	10 (77)	5 (100)	5 (62)	
Tilburg Frailty Indicator (total score), median (range)				
Not frail, n (%)	9 (69)	4 (80)	5 (63)	.51

Variables	Included (N=13)	Completed the study (n=5)	Did not complete the study (n=8)	P value ^a
Frail (≥5 points), n (%)	4 (31)	1 (20)	3 (38)	

^aA P value <.05 is considered statistically significant.

^bNYHA: New York Hear Academy Functional Classification.

^cIncludes operative day.

^dn=7.

^eNot available.

^fPatient or next of kin.

Figure 1. Study flowchart. TAVI: transcatheter aortic valve implantation.

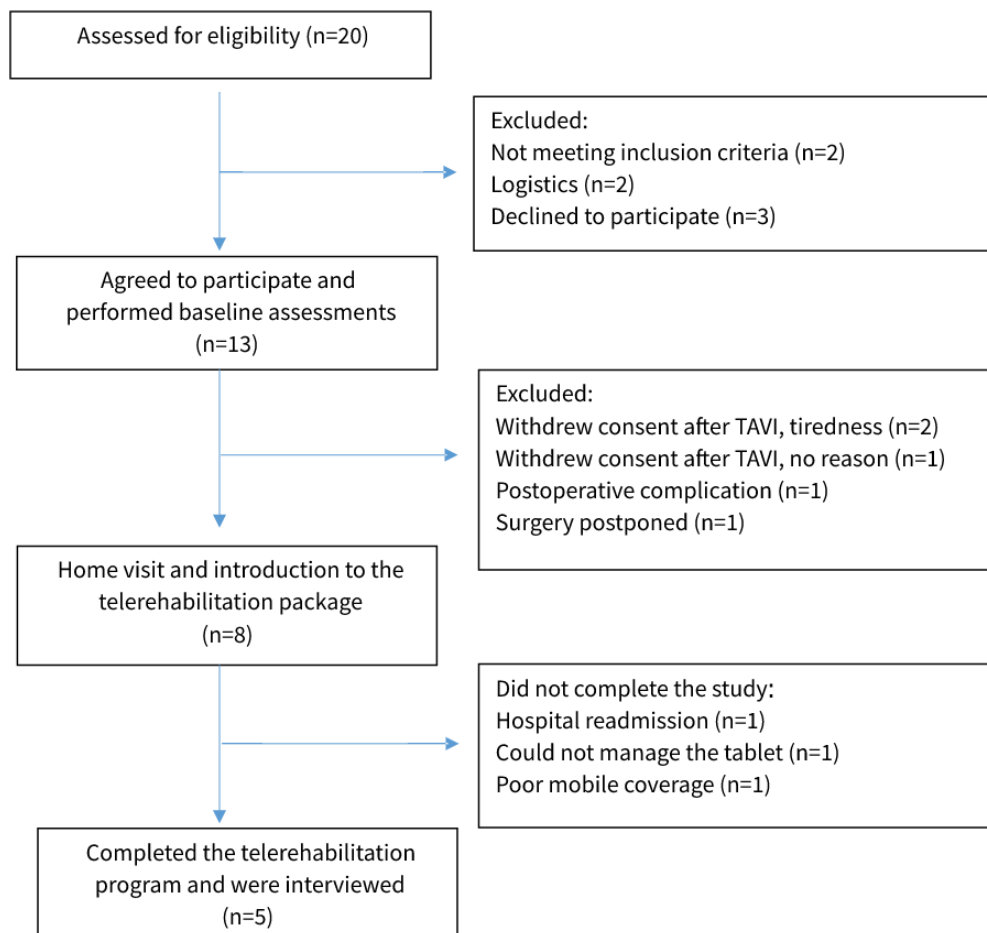


Table 2. Joint display of results and findings summarized into categories according to the source of data.

Categories	Source of data	
	Logbooks	Field notes
Home-based rehabilitation	<ul style="list-style-type: none"> Home visits for technology introduction: n=8; lasted 1.5-2 hours each. Additional home visits for technical support: n=6. Transportation between the hospital and patient's homes varied from 20 to 80 km. 	<ul style="list-style-type: none"> Easier to establish a relationship during the home visit when patients had met the health professional during hospital stay. Easier for patients to follow the instructions when these were practical.
Web-based exercise training	<ul style="list-style-type: none"> The number of training sessions per participant varied from 2 (n=1) to 7 (n=1). The number of participants per session varied from 1 to 3. The sessions lasted 30-40 minutes each. Heart rate during the aerobic exercises varied from 70 to 90 beats per minute. For the CR10 dyspnea, the reported rating was 3-4. 	<ul style="list-style-type: none"> Two spouses joined the training sessions. No adverse events occurred during the web-based training sessions. Giving individual guidance during web-based sessions was a challenge when ≥ 2 patients participated. An advantage to monitor the heart rate for targeting training intensity. Trying exercises and training equipment during the home visit supported individualization of exercises for the web-based sessions.
Activity tracker	<ul style="list-style-type: none"> Number of steps per day: 1.868 to 17.280; distance varied from 1.457 to 7.840 m Number of days the units were used: 7-28 days 	<ul style="list-style-type: none"> Three patients returned their training diaries. There was concordance between patient registered data and the unit's stored data. Only 1 user registered data for all days.
Web-based session with the nurse	<ul style="list-style-type: none"> Five sessions took place, lasting from 20 to 45 minutes each. One session was as a telephone call. 	<ul style="list-style-type: none"> Internet-based face-to-face meeting was a positive experience and the issues discussed were mostly of practical nature.
Website	<ul style="list-style-type: none"> Log-in entry data were not collected. 	<ul style="list-style-type: none"> The introduction to the use of the website took place as the last part of the home visit.
Technical issues	<ul style="list-style-type: none"> Telephone guidance to the log-in procedure given to 4 of 5 users, often for the first session. One participant needed telephone guidance for all the sessions. 	<ul style="list-style-type: none"> External challenge: unstable or insufficient 4G net coverage; program or net outage. User-related challenge: Information technology novice in the use of a touch screen or email program; guidance for session log-in was often necessary; impaired vision or hearing. Functionality <ul style="list-style-type: none"> Tablet: customized for each user; relatively small screen size, when ≥ 2 users are connected at the same time; user forgets to charge the battery. Equipment: a 124.5-cm monitor facilitates viewing users logged in; a large screen enhances provision of individual guidance for the web-based training.

Home-Based Rehabilitation

The home setting was practical, and patients felt privileged to participate. Meeting the same health professionals throughout the whole process facilitated continuity and was appreciated by the patients and health professionals involved. Meanwhile, the introduction to the technologies and provision of technical support were time-consuming for the health care professionals.

Field notes showed that the practical tasks learned during the home visit supported most patients in using the technology and joining the web-based sessions.

The interviews revealed that patients completing the program were positive about the TeleTAVI program and felt cared for instead of feeling lonely after hospital discharge. The home-based setting was perceived by the patients as practical

and as an advantage as no transportation to a community center was necessary. The home-based setting was also especially valued owing to restrictions on social interaction during the COVID-19 pandemic:

Well, my goodness, you have not only received a new heart valve, you have received such an embrace of what you [red. health professionals] have given, to be able to feel good afterwards and beyond. I just feel it's been so good. One is shown the way forward. [Patient, woman]

It's a good thing too because if people are debilitated and are in doubt about whether you can hold to such a training trip. You can just be at home, and then jump on. So, I, that's for sure. This is fine, Corona [red COVID-19] or not. [Patient, man]

Web-Based Exercise Training

The number of training sessions per participant ranged from 2 (n=1) to 7 (n=1), and no adverse events occurred. The instruction on the exercises and training equipment during the home visit was helpful for the later individualization of exercises and was also valued by the patients. Targeting the training intensity was feasible regardless of the method used (heart rate or level of dyspnea). However, it was a challenge for the instructor to provide individual guidance when more than 2 patients were connected in the same session.

Patients described web-based exercise training as motivating and “real,” and there were several contributory factors. First, it was owing to the use of known exercises. Second, the patients could see the physiotherapist on the screen when receiving guidance on correct exercise performance, and they were able to exercise the whole body. Third, they felt committed to the web-based sessions, although such commitment could also be a barrier to performing the usual daily activities. Although one-on-one web-based training seemed to be the most efficient, voiced as “to see the instructor was the most important,” exercising in a group could also be motivating as it enhanced the feeling of not being alone:

I think it has been nice to have things shown. And I think it has been great to have the tablet to look at when we did the exercises. So, it was nice, also like today where you could correct me if it was wrong or it was right, right? So, I think it's been fine. [Patient, woman]

“We often said to each other” There are some muscles we do not use, we think “you do not need to do”, but when we have finished [red. training], there were some muscles we have used, which we do not usually use, so just like the arms all the way up and like that, that's not how we are used to. [Spouse, woman]

It [red. training] was on certain days, so I had to get it over, then I could give myself to do something else. I could not go out in the fields or anything else before it was over. [Patient, man]

Well, I can tell you. When we stand and do it [red. training], I feel, well you're in here in the living room, you are standing and directing and your friends there, they are standing here. This is how I feel, we're a small bunch of people. [Patient, woman]

Activity Tracker

There was a large variation in the number of steps taken per day among the patients, varying from 1868 to 17,280. The patients perceived wearing an activity tracker as a way to verify the usual number of daily steps taken. Expressions such as “all steps count” often occurred throughout the interviews when patients described positive experiences while wearing the device, which could be a motivation to increase the daily number of steps. Others did not wear the device throughout the intervention period, either because they were reassured that their usual daily steps exceeded the recommendations or because they did not understand how to manage the device:

Well, it was motivating because that, then I reach the 1700 [steps] here, you know, well, then I'll take a walk up in the woods and reach 2.000 [Patient, man]

It has not worked, just lying on the table there, with power on. I thought it was missing power, but then you said I should wear it in my wrist, and then the shit worked. Then I went on the big walk, to get many steps. [Patient, man]

Web-Based Session With the Nurse

In total, 5 web-based sessions were conducted. The issues discussed were mostly of a practical nature, such as medication, pain, and sleeping. The project nurse experienced the internet-based face-to-face conversation with the patients as positive as their body language was visible, which indicated the patients' actual well-being. Although most of them could not recall the specific issues discussed, the patients and their spouses appreciated the provision of follow-up after hospital discharge:

Can well remember that we should get ready for the conversation. I think it gives a bit of reassurance, there is someone who is interested in you, right? [Spouse, woman]

Website

Overall, the project website was only occasionally used by the patients, mostly because they forgot that they could access it. When it was used, patients, and eventually their spouses, appreciated watching videos in which other patients talked about their own course of disease, treatment, and recovery. The patients were not interested in viewing videos with self-training information:

I watched patient and relatives' videos, that is, the different ones telling about how they have experienced it. The videos were very, very good, mostly listened to the videos, not read that much. [Patient, woman]

Technical Issues

Challenges regarding the use of this technology were experienced by both patients and health care professionals. These were categorized as external or user or functionality related.

The main external challenge was unstable or insufficient 4G data coverage, mostly in less-populated areas, which could often be solved by connecting the tablet to the users' Wi-Fi when available. One dropout was owing to unstable data coverage.

User-related challenges were associated with a lack of prior experience with web-based communication platforms, such as handling emails or dealing with a touch screen, and this lack often required IT support, which was provided by telephone. Customization of the tablet was provided when necessary, for instance, by adjusting the period for screen touch. Patients expressed different ways of managing challenges with the use of a tablet, ranging from confidence to a lack of faith in their own ability. One patient expressed that he had no interest in the use of digital technology and left such issues to his spouse. Regardless of the individual approach taken, patients managed to use the tablet to participate in web-based training sessions:

I am not used to using a tablet. I have a computer that I always use. So that way, I'm used to using technology, but I've never used a tablet before.
[Patient, man]

I totally get [goose] bumps when I think about, no, you have to, can you, you cannot figure it out.
[Patient, woman]

Challenges related to tablet functionality were also identified. The main challenge for the patients was related to the tablet's relatively small screen size and visual deficits as it was important to be able to see the instructor's complete body so that they could better follow the exercises:

If there were many [participants], then the pictures got small, and then you have to get closer. It would be better if there was a big picture of you [instructor], and small of the others. [Patient, man]

For the health care professionals, instructing the patients in the TeleTAVI during the home visits took 90 to 120 minutes, which meant that it was a time-consuming task and one that continued as they had to instruct and guide the patients afterward for logging into the training sessions.

Estimated Costs

The estimated running cost for the program was US \$ 1.467 per patient who completed the study. This included US \$840 for equipment delivered to each patient and US \$627 for staff costs.

Discussion

Principal Findings

Exercise-based telerehabilitation for the elderly after TAVI in the population as included in this study, and delivered as a web-based intervention, does not seem feasible as 60% (8/13) included patients did not complete the study. Barriers negatively influencing adherence to the program included poor data coverage, participants' limited IT skills, and functionality of the systems used. Meanwhile, qualitative findings suggest that the TeleTAVI program supported personalized, tailored training interventions in patients completing the program. The home-based web-based delivery form of the exercise training sessions was appreciated by the patients because there was no need for transportation, and they felt that they exercised their whole body while receiving real-time feedback. However, the program was time-consuming for the health care professionals as a great deal of time was used for transportation, home instruction, and IT support. No adverse events were reported. Aspects that support retention rates and enhance patients' IT skills need to be further addressed before the program can be used on a larger scale, such as in a randomized controlled setting, as intended.

Comparison With Prior Work

The findings from this first study on TAVI CTR are in line with existing knowledge of the use of CTR in patients with other cardiac conditions. In particular, easy access to exercise training without the need for transportation to a rehabilitation center is a well-described advantage that promotes patient engagement and adherence [24,47]. Exercise supervision is a key element

in center-based CR to individualize exercises and provide sufficient training load to achieve gain in cardiorespiratory fitness [33]. In this study, we found that virtual feedback allowed for individualization during the training sessions, whereas the provision of exercise equipment facilitated patients to reach a proper training load. This was facilitated by face-to-face introduction to the exercises during the introductory home visit. These elements were also voiced as being important by the participating patients and their spouses, possibly supporting their adherence to the program. Furthermore, the use of adequate equipment for video-training delivery at the hospital facility was vital for enabling two-way communication during each session.

We were particularly challenged as many patients did not complete our study because they could not manage the technology or because of technical issues. First, in the short study period, we experienced outages in both the broadband connection and the video conferencing app. Stable internet connectivity was the premise for the use of the videoconferencing system. Even though the tablet had a 4G SIM card, we still experienced unstable data coverage in both rural and urban areas, a reason for the 2 patient withdrawals. If required and available, we connected the tablets to the patients' own Wi-Fi to ensure proper running of the videoconferencing system and enhance program compliance. To date, many homes do not have internet. In 2019, up to 10% of Danish citizens reported not having broadband at home, particularly older adults aged 75 to 89 years, of whom 29% had never previously accessed the internet [48]. This may pose a challenge for future CTR telerehabilitation delivery, particularly in the elderly population. Second, according to the initial study protocol, we introduced patients to the technology during their hospital stay, which was probably not the best introduction time for new technology in this older population. Consequently, we adapted the protocol and introduced the technology during the home visit 1 week after hospital discharge and had no further patient withdrawals for this reason. Finally, the setup for the intervention was time-consuming for the health care professionals as a great deal of time was spent on introduction to the telerehabilitation packet, IT support, and transportation. This may also be a barrier to future implementation of CTR after TAVI.

Future Directions

Findings from our feasibility study indicate that the use of telerehabilitation technology in older persons who have undergone TAVI, although challenging, is also promising as many patients are acquainted with the use of smartphones and tablets, and patients completing the program appreciated the home-based web-based setting. Therefore, we recommend changes in future TAVI-CTR interventions. First, extension of the program to 12 weeks post-TAVI will follow current guidelines for the duration of CR [33,49]. Furthermore, a longer intervention period may also facilitate patients to get more acquainted with the technology with additional less cost to the program in the long term. Second, the provision of remote IT support may help patients in using the tablet properly. Third, the use of a wireless platform for automatic uploading and collection of data on daily steps should be considered,

conditional of complying with the GDPR regulations [22]. Devices with commercial applications that automatically upload to a tablet and store patients' data on daily number of steps may not comply with GDPR regulations for data safety and privacy in research [50], although it poses no concern when used privately by patients. Fourth, the ownership of a smartphone [28] and digital access to the internet may be used as proxies for screening older patients for CTR. Finally, a reduction in the number of functions in a CTR program might enhance the willingness to participate in CTR and thus enhance retention rates.

With as few as 10% to 20% of patients attending CR after TAVI [11,23], delivery models that are alternatives to the established center-based CR still need to be developed and tested to enhance patient uptake to rehabilitation after surgery, as well as to establish evidence on the effect of CR following TAVI. In this context, CTR may be a cost-effective alternative to add-on interventions [18]. However, it is also important to bear in mind that patients who undergo TAVI are often octogenarians and frail [6,51], which may have influenced patient withdrawal in our study.

Strengths and Limitations

As this was a single-center trial with no control group, our study has limited generalizability. In addition, we included only a

small number of participants owing to the study's proof-of-concept nature [43] with a limited inclusion period. However, it is a strength that we screened all the patients scheduled for TAVI in our hospital, which was similar to the feasibility randomized study performed by Rogers et al [8]. Apart from the walked distance, the age of the participants in our study and several clinical features, such as the presence of comorbidities, ejection fraction, and NYHA classification were similar to those in studies investigating the effect of CR following TAVI [8,51-54].

Conclusions

In conclusion, we found that exercise-based telerehabilitation in older adult patients after TAVI, in the population as included to this study, delivered as a web-based intervention, does not seem feasible, as 60% (8/13) of the included patients did not complete the intervention. Conversely, we found several promising aspects favoring the web-based setting as real-time feedback during home training was highly appreciated by those who completed the intervention. Aspects that support retainment rates and enhance patients' IT skills need to be further addressed before the program can be used on a larger scale, as intended, in the form of a randomized controlled trial.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Technologies.

[PDF File (Adobe PDF File), 82 KB - [rehab_v9i2e34819_app1.pdf](#)]

Multimedia Appendix 2
Home exercise program.

[PDF File (Adobe PDF File), 469 KB - [rehab_v9i2e34819_app2.pdf](#)]

Multimedia Appendix 3
Interview guide.

[PDF File (Adobe PDF File), 99 KB - [rehab_v9i2e34819_app3.pdf](#)]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials

CR: cardiac rehabilitation

CTR: cardiac telerehabilitation

GDPR: General Data Protection Regulation

IT: information technology

REDCap: Research Electronic Data Capture

TAVI: transcatheter aortic valve implantation

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Original Paper

Digitally Delivered Exercise and Education Treatment Program for Low Back Pain: Longitudinal Observational Cohort Study

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Abstract

Background: Exercise and education is recommended as first-line treatment by evidence-based, international guidelines for low back pain (LBP). Despite consensus regarding the treatment, there is a gap between guidelines and what is offered to patients. Digital LBP treatments are an emerging way of delivering first-line treatment.

Objective: The aim of this study is to evaluate outcomes after participation in a 3-month digitally delivered treatment program for individuals with subacute or chronic LBP.

Methods: We analyzed data from 2593 consecutively recruited participants in a digitally delivered treatment program, available via the national health care system in Sweden. The program consists of video-instructed and progressive adaptable exercises, education through text lessons, and a chat and video function connecting participants with a personal physiotherapist. The primary outcome was mean change and proportion reaching a minimal clinically important change (MCIC) for LBP (2 points or 30% decrease) assessed with the numerical rating scale (average pain during the past week, discrete boxes, 0-10, best to worst). Secondary outcomes were mean change and proportion reaching MCIC (10 points or 30%) in disability, assessed with the Oswestry Disability Index (ODI; 0-100, best to worst) and a question on patient acceptable symptom state (PASS).

Results: The mean participant age was 63 years, 73.85% (1915/2593) were female, 54.72% (1419/2593) had higher education, 50.56% (1311/2593) were retired, and the mean BMI was 26.5 kg/m². Participants completed on average 84% of the prescribed exercises and lessons, with an adherence of $\geq 80\%$ in 69.26% (1796/2593) and $\geq 90\%$ in 50.13% (1300/2593) of the participants. Mean reduction in pain from baseline to 3 months was 1.7 (95% CI -1.8 to -1.6), corresponding to a 35% relative change. MCIC was reached by 58.50% (1517/2593) of participants. ODI decreased 4 points (95% CI -4.5 to -3.7), and 36.48% (946/2593) reached an MCIC. A change from no to yes in PASS was seen in 30.35% (787/2593) of participants. Multivariable analysis showed positive associations between reaching an MCIC in pain and high baseline pain (odds ratio [OR] 1.9, 95% CI 1.6-2.1), adherence (OR 1.5, 95% CI 1.3-1.8), and motivation (OR 1.2, 95% CI 1.0-1.5), while we found negative associations for wish for surgery (OR 0.6, 95% CI 0.5-0.9) and pain in other joints (OR 0.9, 95% CI 0.7-0.9). We found no associations between sociodemographic characteristics and pain reduction.

Conclusions: Participants in this digitally delivered treatment for LBP had reduced pain at 3-month follow-up, and 58.50% (1517/2593) reported an MCIC in pain. Our findings suggest that digital treatment programs can reduce pain at clinically important levels for people with high adherence to treatment but that those with such severe LBP problems that they wish to undergo surgery may benefit from additional support.

Trial Registration: ClinicalTrials.gov NCT05226156; <https://clinicaltrials.gov/ct2/show/NCT05226156>

KEYWORDS

low back pain; telehealth; physiotherapy; digital care; exercise; rehabilitation; back pain; pain management; telemedicine; digital therapy; chronic pain; health outcome

Introduction

Low back pain (LBP) is the leading cause of years lived with disability worldwide [1]. Exercise and education is recommended as first-line treatment in clinical guidelines, but ineffective health care resources are too often used, providing low-value or at worst, harmful care [2].

The BetterBack model of care was developed and tested in primary care clinics in Sweden to facilitate guideline implementation [3]. Its biopsychosocial approach includes a face-to-face structured assessment by a physiotherapist (PT), education, and individualized exercises focusing on the core and back muscles. In a stepped-clustered randomized study, participants in the program did not differ in pain and disability compared to a group receiving routine physiotherapy care but reported higher satisfaction along with clinically meaningful improvement in LBP illness perception and quality of life [4].

Telehealth, defined as the “delivery of healthcare at a distance using information and communication technology” (ICT) has been rapidly adopted during the COVID-19 pandemic [5,6]. It may help overcome barriers in traditional face-to-face interventions, such as limited access, low adherence, lack of flexibility, and travel costs [7-9]. Systematic reviews suggest that ICT increases exercise adherence and may provide pain and function improvements similar to or better than those provided by face-to-face treatment for a variety of musculoskeletal (MSK) conditions [10-13].

In digital LBP treatment, published results showed considerable heterogeneity between studies with possible positive effects on pain and disability in the short-term [13-18]. However, sample sizes were small with participants being predominantly of working age.

To our knowledge, this study is the first to report real-world data collected from an LBP treatment app that is part of a public health care system. The aim is to evaluate change and proportion of responders in pain as a primary outcome, and disability and patient acceptable symptom state (PASS) as secondary outcomes; and to examine if sociodemographic, baseline health, and treatment-related factors are associated with pain reduction.

Methods

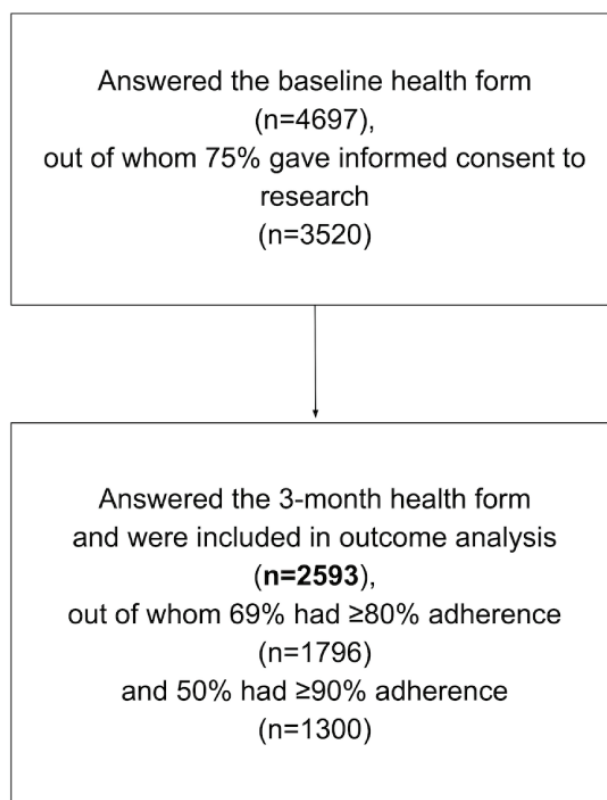
Ethics Approval

This was a longitudinal observational cohort study with consecutively recruited participants, approved by the Swedish Ethical Review Authority (diary #2021-04183, 2021-12-20) and registered at ClinicalTrials.gov (NCT05226156). Digital informed consent was obtained from participants at registration. The study adheres to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies [19].

Sample

Data were extracted from the database on March 16, 2022, and included all people that had given their informed consent and initiated their LBP treatment between April 27, 2021, and December 16, 2021 (Figure 1).

Participants joined the Joint Academy (JA) program on their own initiative via online advertisements and campaigns placed on search engines and social networks through recommendation by their local PT or general practitioner, or through their insurance company. Inclusion criteria for treatment were the following: an age >18 years and presence of subacute or chronic LBP (including nonspecific LBP, disc degeneration, spondylosis, spinal stenosis [20], olisthesis). Participants without a prior clinical diagnosis of nonspecific LBP (diagnosis code ICD-10 M54.5) required a clinical diagnosis confirmed by a PT via telephone or video call. In the app, participants first need to negate recent trauma within 0 to 6 months and symptoms of cauda equina syndrome in order to be registered in the program. At the start-up consultation with the PT, further exclusion criteria were considered before eligibility: malignant disease with or without suspected metastasis, fracture or vertebral compression within 6 months, and infection. If there were uncertainties regarding diagnosis or comorbidities, candidate participants were recommended to seek face-to-face care before inclusion in the program. Additional relative exclusion criteria were assessed by the PT: previous or current cancer or involuntary weight loss, radiculopathy below the knee, opioid-demanding pain or pain while resting, inflammatory back pain, pregnancy or postpregnancy, and older participants (>75 years) with multiple diseases and/or structural deformities (eg, scoliosis).

Figure 1. Flowchart of participants in the digital treatment for low back pain.

The Digital Treatment Program

The treatment program is available via the national health care system for all residents in Sweden. The procedure is similar to that of other JA (see [Multimedia Appendix 1](#)) programs managing osteoarthritis and MSK ailments [21,22]. The digital LBP program was inspired by the face-to-face BetterBack model of care [3,4].

Briefly, the program consists of a mobile app with 2 daily distributed individualized and progressively adaptable video exercises, focusing on strengthening the lower back, glutes, and core musculature. Short sessions of patient education are also delivered 2-3 times per week, followed by a quiz question to ensure the information has been understood properly. Correctly answering the quiz is mandatory to be able to continue the program. The program offers a peer-support chat room, and a registered PT supervises the participant and is available through a continuous asynchronous chat function during the full participation period. The program also contains 3 compulsory telephone or video consultations with the PT, 1 at the start, 1 after 6 weeks, and 1 after 3 months.

Variables

All participants answered relevant sociodemographic questions at baseline including those regarding sex, education, and work situation, using the question "Which alternative describes your current situation best?" (working, studying, sick leave full-time, sick leave part-time, retired, unemployed); weight and height, pain in other joints, and general health, using the question "Mark on the scale how good or bad your current health is?" as assessed

with the numerical rating scale (NRS; 0-10, worst imaginable to best imaginable); anxiety or depression according to the EQ-5D-5L (level 1-5, no problems to severe problems) [23]; medications, using the question "In the past months, have you taken any medication for the pain in your lower back?" (yes or no); wish to undergo surgery, using the question "Are your symptoms so severe that you wish to undergo surgery?" (yes or no); physical activity, using the question "How much time do you spend in a typical week on daily physical activity that is not exercise, such as walking, cycling or gardening?" (7-grade scale: 0, <30, 30-60, 60-90, 90-150, 150-300, >300 minutes/week) [24]; and motivation or readiness for exercising, using the question "How ready are you to start doing back exercises on a daily basis?" (NRS 0-10, not at all ready to extremely ready).

All questions were answered by self-report and collected digitally through the app. Pain was assessed weekly, and a larger health questionnaire was used at baseline and at 3-month follow-up.

Primary Outcome

LBP was assessed using the NRS (discrete boxes), with the instruction "Mark on the scale your average pain from your lower back in the past week," followed by a 0 to 10-digital scale where 0 indicates "No pain" and 10 indicates "Unbearable" [25]. An absolute improvement in back pain of ≥ 2 points or a relative improvement of 30% from baseline to 3 months was used to describe a minimal clinically important change (MCIC), in line with practical guidelines toward consensus in reporting MCIC in LBP [26].

Secondary Outcomes

The Oswestry Disability Index (ODI) version 2.1a was used to assess LBP-related disability. The ODI is divided into 10 sections to assess the level of pain and interference with several activities including sleep, self-care, sex life, social life, and traveling. Each question has 6 possible responses and is scored from 0 to 5 (good to bad). The score for each section is added and divided by the total possible score (50 if all sections are completed), and the resulting score is multiplied by 100 to yield a percentage score with 0% equivalent to no disability and 100% equivalent to a great deal of disability [27]. An absolute improvement of ≥ 10 points or a relative improvement of 30% from baseline to 3 months was used to describe MCIC, in line with guidelines toward consensus in reporting MCIC in LBP [26].

Radiating pain was assessed using the NRS (discrete boxes), with the instruction “Mark on the scale how much pain you have radiating down your leg,” followed by a 0 to 10–digital scale, where 0 indicates “No pain” and 10 indicates “Unbearable” [25].

PASS was assessed at baseline and follow-up with the question: “Considering your lower back function, do you feel that your current state is satisfactory? With lower back function you should take into account all activities you have during your daily life, sport and recreational activities, your level of pain and other symptoms, and also your quality of life related to your lower back” (yes or no). The PASS is a treatment-response criterion developed to determine the clinical relevance of a treatment effect [28]. Answering no is referred to as PASS(–), yes is referred to as PASS(+), and changing from no at baseline to yes at 3 months as PASS(–to+).

Treatment Failure and Adverse Events

If the answer to the PASS question was no, a question of treatment failure was asked at follow-up: “Would you consider your current state as being so unsatisfactory that you think the treatment has failed?” (yes or no).

Adverse events were assessed with the question: “Have you experienced any unwanted side effects of your Joint Academy treatment?” (yes or no). If the answer was yes, a follow-up question was asked: “What type of unwanted side effect?” (choices: severe pain not relieved after 24 hours, a fall or injury during exercising, other).

Adherence

We defined adherence as the percentage of completed activities out of those delivered to the participants over the course of the treatment period (2 exercises per day and 3-4 educational texts per week). As participants had to check an obligatory box after every exercise and educational text to be able to continue in the program, an estimate of the weekly adherence was available in the dashboard of the treating PT. The commonly used adherence cutoff of $\geq 80\%$ (in this program referring to performing activities ≥ 5 days a week) was considered as a lower limit for satisfactory adherence [29].

Information on the number of chat interactions with the PT, initiated either by the PT or the participant, and on if participants

chose to take part in an optional peer support group (yes or no) during the treatment was also available through the app.

Dropout was defined as having baseline data and starting the treatment, but not continuing until the 3-month follow-up. The week for the latest registered exercise or educational text was used to define the dropout week.

Statistical Analysis

To describe the sample, we use mean and SD, frequency, and percentage.

For outcomes at 3 months, we calculated median (percentile), mean (95% CI), and proportions for the total sample and for per protocol samples with $\geq 80\%$ and $\geq 90\%$ adherence. The paired *t* test was used to calculate mean change from baseline to 3 months, and McNemar test was used to calculate change in proportions. One-way analysis of variance (ANOVA) was performed in order to detect potential differences in pain reduction at 3 months between groups with different adherence levels (<40%, 40%-49%, 50%-59%, 60%-69%, 70%-79%, 80%-89%, and 90%-100%). We also present weekly mean (95% CI) pain during the 3 months, stratified by baseline pain and adherence.

We used univariable logistic regressions to explore variables associated with reaching an MCIC in pain and proportion, reporting a change from no to yes in PASS(–to+). The following variables were selected based on previous research [30,31]: sociodemographic (sex, age, occupational status, educational level), baseline health-related (BMI, NRS LBP, NRS radiating pain, pain medications, wish for surgery, pain in other joints, depression or anxiety, general health, physical activity), and treatment-related (motivation, adherence, interactions with PT, participation in a peer group). For PASS(–to+), we included only those answering no to PASS at baseline ($n=2080$) and we included reaching MCIC in pain as an independent variable.

We also used multivariable logistic regression, including all variables irrespective of bivariate *P* value. A test for multicollinearity showed variance inflation factor values below 2.5 for all variables, except for age and occupational status. As multicollinearity could be excluded for all other independent variables, they were all included in the multivariate analyses. Odds ratios (ORs) and 95% CIs were calculated and considered statistically significant if the 95% CI did not include 1.

Data analysis was performed using the Python Library Statsmodel version 0.13.2 [32].

Results

Participant Characteristics

A total of 4697 individuals answered the baseline questionnaire, of whom 74.94% (3520/4697) had given their informed consent. Out of these, 73.66% (2593/3520) answered the 3-month questionnaire and were included in the outcome analyses (Figure 1). Mean participant age was 63 years, 73.85% (1915/2593) were female, 54.72% (1419/2593) had a university level education, and 50.56% (1311/2593) were retired (Table 1).

Table 1. Characteristics of participants in digitally delivered exercise and education treatment for low back pain (N=2593).

Variables	Values
Sociodemographic characteristics	
Female, n (%)	1915 (73.85)
Age (years), mean (SD)	63.0 (11.0)
Educational level, n (%)	
Have not graduated high school	221 (8.52)
Graduated high school	953 (36.75)
College/university degree	1419 (54.72)
Occupational status, n (%)	
Working	1093 (42.15)
Studying	20 (0.77)
Sick leave full-time	67 (2.58)
Sick leave part-time	47 (1.81)
Retired	1311 (50.56)
Unemployed	55 (2.1)
Baseline health-related characteristics	
BMI (kg/m ²), mean (SD)	26.5 (4.4)
Baseline pain, NRS ^a (0-10), mean (SD)	4.9 (1.9)
Reported radiating pain (>0 NRS), n (%)	1630 (62.86)
Pain medications for back pain during last month, yes, n (%)	1252 (59.36) ^b
Problem severity such that surgery is desired, n (%)	138 (5.32)
Presence of pain in other joints, n (%)	1956 (75.43)
Depression or anxiety (any problem = level 2-5 EQ-5D-5L), n (%)	1351 (52.10)
General health, NRS (0-10), mean (SD)	6.2 (1.6)
Physical activity level, ≥150 min/week, n (%)	1065 (40.73)
Motivation/readiness ruler to start exercising (NRS 0-10, not at all to extremely), mean (SD)	9.3 (1.3)
Treatment-related characteristics	
Adherence to treatment during 3 months:	
Proportion of daily exercises/educational texts completed, mean (SD)	83.9 (17.0)
≥80% adherence, n (%)	1796 (69.26)
≥90% adherence, n (%)	1300 (50.13)
Number of chat interactions with the PT^c during the treatment	
Messages received from the PT, mean (SD)	21 (12)
Messages sent to the PT, mean (SD)	9 (7)
Participated in peer support group, n (%)	866 (33.40)

^aNRS: numerical rating scale.

^bDue to technical issues in the app, the total is 2109.

^cPT: physiotherapist.

Dropouts (ie, those who did not continue up to the 3-month follow-up) accounted for 26.34% (927/3520) of the total baseline sample (see [Multimedia Appendix 2](#) for graph of dropouts per week). Compared to the total sample, dropouts differed in most

baseline- and treatment-related characteristics. For example, they were more often of working age, more often reported problems with depression or anxiety, and had a lower physical activity level at baseline; furthermore, a lower proportion

participated in a peer group during the treatment (91/927, 9.82% vs 866/2593, 33.40%; $P < .001$; see [Multimedia Appendix 2](#) for comparison of baseline characteristics).

Adherence

During the 3-month treatment, participants completed on average 84% of the daily exercises and educational texts. An adherence of $\geq 80\%$ (corresponding to at least 5 days/week) was seen in 69.26% (1796/2593) and an adherence of $\geq 90\%$ (corresponding to 6-7 days/week) in 50.13% (1300/2593; [Table 1](#)). Those with $\geq 90\%$ adherence compared to those with $< 90\%$, were older, more often retired, had lower BMI, and less often reported problems with anxiety or depression at baseline; meanwhile, we observed no difference relative to sex or educational level (see [Multimedia Appendix 2](#) for comparison of baseline characteristics).

Outcomes at 3 Months

The median reduction in LBP from baseline to 3 months was an NRS of 2 points, and the mean reduction was NRS 1.7 (95% CI -1.8 to -1.6) points, corresponding to a 35% relative change. The mean reduction for ODI was 4.1 (95% CI -4.5 to -3.7) points, corresponding to a 16% relative change, and the mean reduction in radiating pain was NRS 0.6 (95% CI -0.7 to -0.5). An MCIC in LBP (defined as either NRS ≥ -2 points or 30% relative reduction) was seen in 58.50% (1517/2593) of participants, while for ODI (defined as either ≥ -10 points or 30% relative reduction), an MCIC occurred in 36.48% (946/2593). A total of 46.24% (1199/2593) reported yes to PASS(+) at 3 months, and 30.35% (787/2593) reported a change from no to yes in PASS(-to+; [Table 2](#)).

Table 2. Change in outcomes from baseline to 3-month follow-up among participants in digitally delivered exercise and education treatment for LBP.^a Results are for total sample (N=2593) and for subgroups with ≥80% (n=1796) and ≥90% adherence (n=1300).

	Baseline	3-month follow-up	Change
LBP, NRS^b			
Mean (95% CI)			
Total sample	4.9 (4.8 to 5.0)	3.2 (3.1 to 3.3)	-1.7 (-1.8 to -1.6)
≥80% adherence	4.9 (4.8 to 5.0)	3.0 (2.9 to 3.1)	-1.8 (-1.9 to -1.8)
≥90% adherence	4.9 (4.8 to 5.0)	3.0 (2.9 to 3.1)	-1.9 (-2.0 to -1.8)
Median (Q^c 1-Q3)			
Total sample	5.0 (3.0 to 6.0)	3.0 (2.0 to 4.0)	-2.00
≥80% adherence	5.0 (3.0 to 6.0)	3.0 (2.0 to 4.0)	-2.00
≥90% adherence	5.0 (3.0 to 6.0)	3.0 (2.0 to 4.0)	-2.00
ODI^d			
Mean (95% CI)			
Total sample	25.5 (25.0 to 26.0)	21.4 (20.9 to 21.9)	-4.1 (-4.5 to -3.7)
≥80% adherence	25.3 (24.7 to 25.9)	21.0 (20.4 to 21.6)	-4.3 (-4.8 to -3.9)
≥90% adherence	25.3 (24.6 to 26.0)	20.9 (20.2 to 21.6)	-4.4 (-4.9 to -3.8)
Median (95% CI)			
Total sample	24.0 (16.0 to 34.0)	20.0 (12.0 to 30.0)	-4.00
≥80% adherence	24.0 (16.0 to 34.0)	20.0 (12.0 to 30.0)	-4.00
≥90% adherence	24.0 (16.0 to 34.0)	20.0 (12.0 to 30.0)	-4.00
Radiating pain, NRS			
Mean (95% CI)			
Total sample	2.3 (2.2 to 2.4)	1.7 (1.6 to 1.8)	-0.6 (-0.7 to -0.5)
≥80% adherence	2.3 (2.2 to 2.4)	1.6 (1.5 to 1.7)	-0.7 (-0.6 to -0.8)
≥90% adherence	2.3 (2.2 to 2.4)	1.6 (1.5 to 1.7)	-0.7 (-0.6 to -0.8)
Median (95% CI)			
Total sample	2.0 (0.0 to 4.0)	1.0 (0.0 to 3.0)	-1.00
≥80% adherence	2.0 (0.0 to 4.0)	1.0 (0.0 to 3.0)	-1.00
≥90% adherence	2.0 (0.0 to 4.0)	1.0 (0.0 to 3.0)	-1.00
Reaching an MCIC^e in LBP, n (%)			
Total sample	N/A ^f	1517 (58.50)	N/A
≥80% adherence	N/A	1124 (62.58)	N/A
≥90% adherence	N/A	833 (64.08)	N/A
Reaching an MCIC in ODI, n (%)			
Total sample	N/A	946 (36.48)	N/A
≥80% adherence	N/A	671 (37.36)	N/A
≥90% adherence	N/A	484 (37.23)	N/A
Patient acceptable symptom state, n (%)			
Total sample	513 (19.78)	1199 (46.24)	787 (30.35) ^g
≥80% adherence	363 (20.21)	852 (47.44)	556 (30.96) ^g
≥90% adherence	279 (21.26)	647 (49.77)	419 (32.23) ^g
Considered treatment failed, n (%)			

	Baseline	3-month follow-up	Change
Total sample	N/A	117 (4.51)	N/A
≥80% adherence	N/A	75 (4.18)	N/A
≥90% adherence	N/A	44 (3.38)	N/A
Adverse events yes, n (%)		63 (2.43)	
Event type, n (%)			
Pain more than 24 h	N/A	16 (25.81)	N/A
Fall/injury	N/A	1 (1.61)	N/A
Other	N/A	45 (72.58)	N/A

^aLBP: low back pain.

^bNRS: numerical rating scale; score range 0 to 10 (best to worst).

^cQ: quartile.

^dODI: Oswestry Disability Index; 0% to 100% (no disability to a great deal of disability).

^eMCIC: minimal clinically important change; taken from Ostelo et al (26); pain NRS = absolute improvement of ≥2 points or relative improvement of 30%; ODI = absolute improvement ≥10 points or relative improvement of 30%.

^fN/A: not applicable.

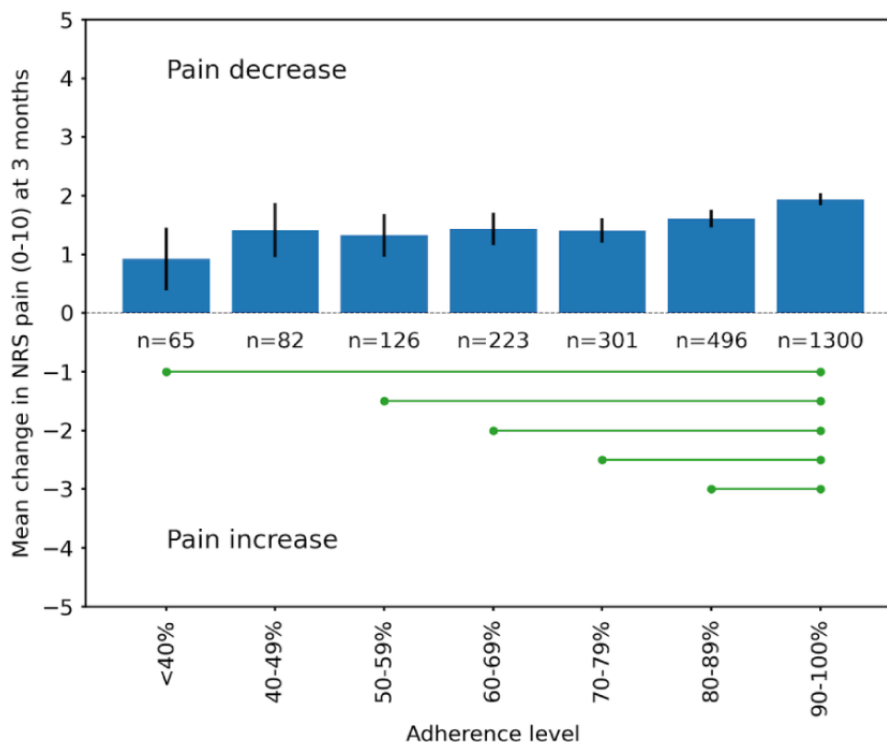
^gChange in patient acceptable symptom state refers to the proportion that changed from no at baseline to yes at 3-month follow-up.

Pain Reduction Relative to Adherence and Pain at Treatment Start

Those with ≥90% adherence had a greater mean pain reduction at 3 months compared to those with <90% adherence. The difference compared to those with 80%-90% adherence was small but statistically significant with a mean pain reduction of

1.9 (95% CI -2.0 to -1.7) versus 1.6 (95% CI -1.7 to -1.5; Figure 2). We observed no differences in mean pain reduction between those with 80%-90% and those with <80% adherence. The lowest pain reduction was seen among those with <40% adherence (0.9; 95% CI -1.5 to -0.4), with a similar pain reduction of 0.9 among dropouts at their last weekly measure before dropping out (95% CI -1.1 to -0.7; Figure 2).

Figure 2. Mean pain reduction from baseline to 3 months stratified by adherence to treatment. Green lines with dots show statistically significant pairs (analysis of variance $P<.05$) with all other pairs being nonsignificant. NRS: numerical rating scale.



Weekly pain during the treatment stratified by baseline pain is illustrated in Figure 3. Those in a higher compared to lower

tertile of baseline pain had a greater absolute and relative mean pain reduction at 3 months: NRS 2.8 (corresponding to a 38%

relative change), 2.0 (37% relative change), and 0.9 (28% relative change) in the 3 tertiles, respectively (ANOVA $P < .001$ for the differences between all groups; Figure 3). Figure 4

illustrates weekly pain stratified by $\geq 90\%$ versus $< 90\%$ adherence to treatment.

Figure 3. Weekly mean (95% CI bars) pain (NRS 0-10) during 3 months' participation in digitally delivered exercise and education treatment stratified by baseline pain. BL: baseline; NRS: numerical rating scale.

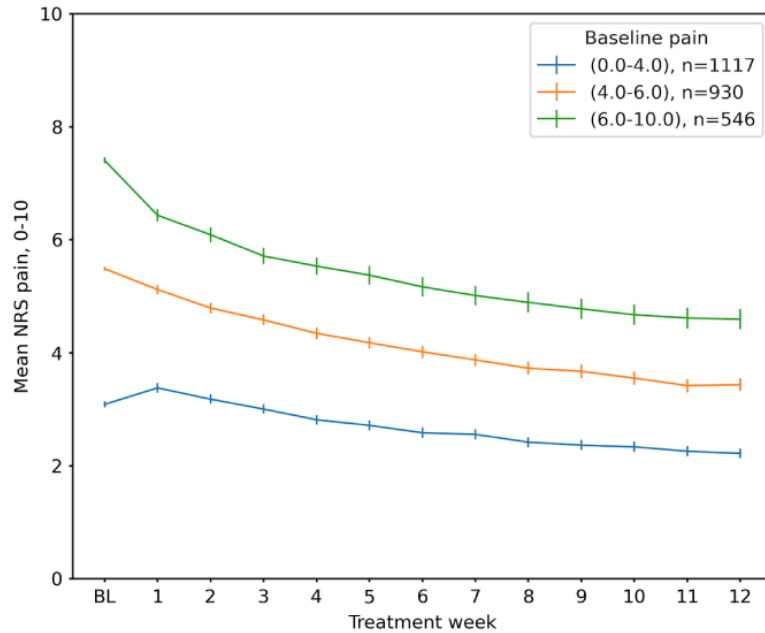
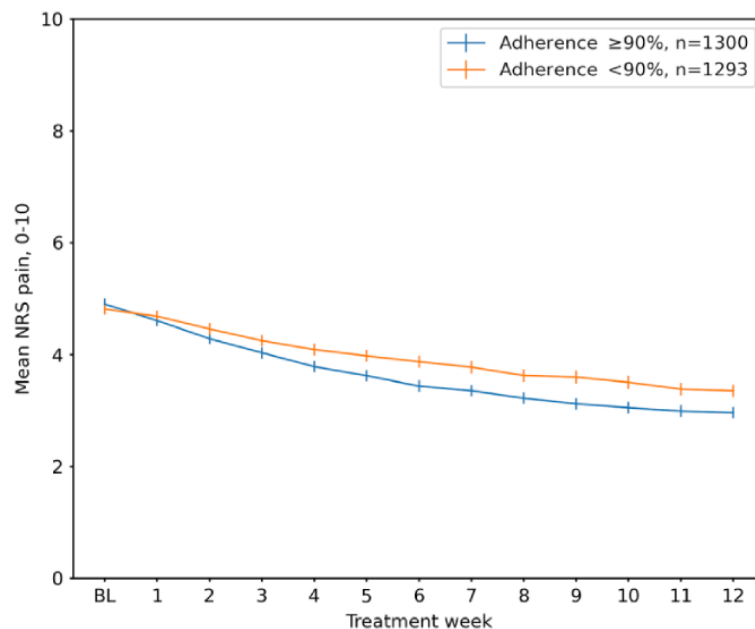


Figure 4. Weekly mean (95% CI bars) pain (NRS 0-10) during 3 months' participation in digitally delivered exercise and education treatment stratified by adherence. BL: baseline; NRS: numerical rating scale.



Associations With Reaching an MCIC in Pain at 3 Months

Bivariate analysis showed statistically significant associations between reaching an MCIC in pain and all sociodemographic characteristics with higher odds for the following: female compared to male (OR 1.4, 95% CI 1.3-1.5), age ≥ 65 compared to < 65 years (OR 1.5, 95% CI 1.3-1.7), university educated

compared to not (OR 1.5, 95% CI 1.3-1.6), and retired compared to working (OR 1.5, 95% CI 1.4-1.7). Variables indicating a worse baseline health were also statistically significantly associated with a higher odds of reaching an MCIC in pain as were the treatment-related variables of high motivation and high adherence (Table 3).

Multivariate analysis showed positive associations between reaching an MCIC in pain and high baseline pain (OR 1.9, 95% CI 1.6-2.1), high adherence (OR 1.5, 95% CI 1.3-1.8), and high motivation (OR 1.2, 95% CI 1.0-1.4). Further, we found negative associations for wish for surgery (OR 0.6, 95% CI 0.5-0.9) and pain in other joints (OR 0.9, 95% CI 0.7-0.9; [Table 3](#)).

Table 3. Variables associated with reaching a minimal clinically important change in LBP^a at 3-month follow-up (N=2593).

	Bivariate associations		Adjusted/multivariable associations	
	OR ^b (95% CI)	P value	OR (95% CI)	P value
Sociodemographic characteristics				
Sex (female)	1.4 (1.3-1.5)	<.001	0.9 (0.8-1.1)	.42
Age (≥65 years)	1.5 (1.3-1.7)	<.001	0.9 (0.7-1.2)	.34
Educational level (university)	1.5 (1.3-1.6)	<.001	1.1 (1.1-1.3)	.14
Occupational status (retired)	1.5 (1.4-1.7)	<.001	1.2 (0.9-1.5)	.27
Health-related characteristics				
BMI (>25)	1.5 (1.3-1.6)	<.001	1.1 (1.1-1.3)	.18
Baseline LBP (>5 NRS)	2.0 (1.7-2.3)	<.001	1.9 (1.6-2.1)	<.001
Having radiating pain (yes)	1.4 (1.3-1.6)	<.001	0.9 (0.8-1.1)	.37
Pain medications (yes)	1.4 (1.3-1.6)	<.001	1.1 (0.8-1.2)	.99
Wish for surgery	1.1 (0.8-1.6)	.5	0.6 (0.5-0.9)	.02
Pain in other joints	1.3 (1.2-1.5)	<.001	0.9 (0.7-0.9)	.01
Depression/anxiety	1.4 (1.2-1.5)	<.001	0.9 (0.8-1.1)	.24
General health, NRS ^c (0-10), (above mean)	1.5 (1.3-1.7)	<.001	1.1 (0.9-1.3)	.36
Physical activity ≥150 min/week	1.3 (1.2-1.5)	<.001	0.9 (0.8-1.0)	.16
Treatment-related characteristics				
High motivation to start treatment (NRS=10)	1.6 (1.4-1.7)	<.001	1.2 (1.0-1.5)	.02
≥90% adherence to treatment	1.8 (1.6-2.0)	<.001	1.5 (1.3-1.8)	<.001
Number of interactions with PT, ^d (above mean)	1.5 (1.3-1.7)	<.001	1.1 (0.9-1.3)	.29
Participated in peer group (yes)	1.4 (1.2-1.6)	<.001	0.9 (0.8-1.1)	.33

^aLBP: low back pain.

^bOR: odds ratio.

^cNRS: numerical rating scale.

^dPT: physiotherapist.

Associations With a Change From No to Yes for PASS (–To+)

Bivariate analysis showed statistically significant associations between all sociodemographic characteristics and reporting PASS(–to+) but in opposite directions to associations seen in relation to reaching an MCIC in pain: female compared to male (OR 0.6, 95% CI 0.6-0.7), age ≥65 compared to <65 years (OR 0.6, 95% CI 0.6-0.7), university educated compared to not (OR 0.6, 95% CI 0.5-0.7), and retired compared to working (OR 0.6, 95% CI 0.6-0.7). Variables indicating a worse baseline health were associated with lower odds for reporting PASS(–to+). We

found no association between reaching MCIC in pain and reporting PASS(–to+) in the bivariate analysis ([Table 4](#)).

Multivariable analysis showed a positive association between reporting PASS (–to+) and reaching an MCIC in pain (OR 4.1, 95% CI 3.4-5.1). Further, we found negative associations for wish for surgery (OR 0.3, 95% CI 0.2-0.5), high baseline pain (OR 0.5, 95% CI 0.4-0.6), depression or anxiety (OR 0.7, 95% CI 0.6-0.9), and high BMI (OR 0.8, 95% CI 0.7-1.0). We could not find that adherence was associated with PASS(–to+), but high motivation and high education were associated with a lower odds of PASS(–to+; [Table 4](#)).

Table 4. Variables associated with a change from no to yes for patient acceptable symptom state (PASS-to+) at 3-month follow-up (N=2080).

	Bivariate associations		Adjusted/multivariable associations	
	OR ^a (95% CI)	P value	OR (95% CI)	P value
Sociodemographic characteristics				
Sex (female)	0.6 (0.6-0.7)	<.001	1.0 (0.8-1.2)	.71
Age (≥65 years)	0.6 (0.6-0.7)	<.001	0.9 (0.6-1.2)	.49
Educational level (university)	0.6 (0.5-0.7)	<.001	0.7 (0.6-0.9)	.001
Occupational status (retired)	0.6 (0.6-0.7)	<.001	1.0 (0.7-1.4)	.88
Health-related characteristics				
BMI (>25)	0.6 (0.5-0.6)	<.001	0.8 (0.7-1.0)	.05
Baseline LBP ^b (>5 NRS ^c)	0.4 (0.4-0.5)	<.001	0.5 (0.4-0.6)	<.001
Having radiating pain (yes)	0.6 (0.5-0.6)	<.001	0.9 (0.7-1.1)	.29
Pain medications (yes)	0.5 (0.5-0.6)	<.001	0.9 (0.7-1.1)	.33
Wish for surgery	0.2 (0.1-0.3)	<.001	0.3 (0.2-0.5)	<.001
Pain in other joints	0.6 (0.5-0.6)	<.001	0.8 (0.7-1.0)	.06
Depression/anxiety	0.5 (0.5-0.6)	<.001	0.7 (0.6-0.9)	.002
General health, NRS (0-10; above mean)	0.8 (0.7-0.9)	<.004	1.2 (1.0-1.5)	.09
Physical activity ≥150 min/week	0.6 (0.6-0.8)	<.001	1.0 (0.8-1.2)	.84
Treatment-related characteristics				
High motivation to start treatment (NRS=10)	0.6 (0.6-0.7)	<.001	0.8 (0.6-1.0)	.02
≥90% adherence to treatment	0.6 (0.5-0.6)	<.001	1.0 (0.8-1.3)	.74
Number of interactions with PT, ^d (above mean)	0.6 (0.5-0.6)	<.001	0.8 (0.7-1.1)	.05
Participated in peer group (yes)	0.6 (0.6-0.7)	<.001	1.0 (0.8-1.2)	.90
Reaching an MCIC ^e in LBP at 3 months	1.0 (0.9-1.1)	<.84	4.1 (3.4-5.1)	<.001

^aOR: odds ratio.

^bLBP: low back pain.

^cNRS: numerical rating scale.

^dPT: physiotherapist.

^eMCIC: minimal clinically important change.

Discussion

Principal Findings

Participants in this digitally delivered treatment for subacute or chronic LBP reduced their pain at 3-month follow-up, and 58.50% (1517/2593) reported an MCIC in pain. We found no difference in pain reduction in relation to sociodemographic characteristics, but those with high baseline pain, high motivation, and high adherence to treatment were more likely to reach an MCIC in pain, while those who at treatment start reported wish for surgery or had pain in other joints were less likely.

Pain Reduction in Comparison to Prior Work

The pain reduction seen in this study is larger than that reported in initial digital self-management programs for LBP [13-15] but in line with recent apps with more complex ICT features and exercise support [17]. Baseline pain and disability among

participants in our study (NRS pain around 5, ODI 26) was similar to those in previous digital and face-to-face interventions [17,33], but the mean age in this cohort was around 20 years higher compared to other digital interventions [17]. Our results suggest that digitally delivered treatment programs may show similar results in older adults with more complex health problems as in younger populations.

Consistent with those of higher age, a majority reported problems from other joints indicating that symptoms and age-related changes are worse in our sample compared to those reported in previous studies [17]. An encouraging finding is, however, that we did not find pain medications, high BMI, or depression or anxiety to be associated with a lower odds of reaching an MCIC in pain. This is in contrast with previous research suggesting lower BMI and low depression or anxiety scores at baseline to be associated with a more rapid decrease in pain [34] but is in line with a recent paper on middle-aged participants with multimorbidity and co-occurring MSK pain

[35]. Few participants in our study reported that they wished to undergo surgery due to their LBP, but those who did were less likely to reach an MCIC in pain. Findings such as the ones reported here further reinforce the possibility that digital treatment programs can reduce pain at clinically important levels for older persons with more complex health problems, but people that report wish for surgery might need further attention.

Adherence to Treatment

The high adherence in our study compared to that seen in other studies, and specifically in those being retired and of higher age, matched another report where older adults were less likely to drop out [34]. A previous study from our research group reported a mean adherence of 75% to recommended exercises for participants with hip or knee osteoarthritis staying in the treatment for 6 months [22], suggesting that high adherence rates can be maintained with support from a digitally delivered treatment program during longer periods. Frequency and duration of exercises, how adherence is measured, and what is considered a high adherence varies between studies [34], making comparisons between reports challenging. There is no conceptualization of adherence, but our chosen limit of 80% of activities performed during the treatment is in line with a systematic review of therapeutic exercise for MSK that reported 80%-99% of the recommended exercise dose as the most common limit for satisfactory adherence [29]. Given that we had valid data logged through the app, we were able to complete subanalyses on different adherence rates, finding a benefit of those with $\geq 90\%$ adherence.

The dropout rate of 26% at 3 months was similar to that of other digitally delivered LBP treatment programs where dropouts have varied between 20% and 28% [17]. One digital program [36] reported substantial and increasing dropout rates during the treatment, with more than 80% dropping out before 12 weeks. Through app developments with systematically collected user feedback, dropouts could be reduced [37].

The association between adherence and pain reduction was not linear in this study in contrast to what has been shown in other studies [34,37]. One possible explanation might be that our program included a short duration and high frequency intervention (5-10 minutes/day) and not a longer duration and lower frequency (eg, 30 minutes 3 times/week) seen in most other programs. However, causality cannot be defined in an observational study such as the present one. It is well known that those with positive outcomes may adhere to treatment to a higher degree, while those not improving are more prone to missing out on exercises. However, a qualitative analysis in people participating in a digital program for hip and knee osteoarthritis revealed that reduced pain could also be a reason for lower adherence or not continuing with the program [8].

MCIC and PASS

What constitutes an MCIC in pain probably varies from person to person, between conditions and treatments, and across different life and disease courses. Baseline pain severity has an impact, as a lower baseline pain score gives less room for change. The comparatively low proportion reaching MCIC in pain in our study, compared to those in recent studies that used

a similar cutoff [34,38], may be related to participants in those studies being younger and at working age. Another way to estimate participant-relevant improvements is PASS. The proportion reporting PASS (+) at 3 months in our study is similar to that in a face-to-face randomized controlled trial when using an anchoring question of self-rated health and not the gold standard question used in our study [39].

MCIC reflects the concept of improvement (feeling better), while PASS deals with the concept of partial symptom remission or well-being (feeling good). We could not find that reaching an MCIC in pain was associated with reporting PASS(-to+) in bivariate analysis, but there was an association in the multivariable analysis. Those with high baseline pain and worse health were, in both bi- and multivariable analyses, less likely to report PASS, indicating that an MCIC of 2 points or 30% in pain is not enough to report "feeling good" for these people. Interestingly, we could not find an association between adherence and PASS(-to+). To our knowledge, there are no previous studies on the associations with PASS(-to+) after exercise treatment. Future studies on how factors such as duration of symptoms, expectations to treatment, and psychosocial aspects influence PASS would be of interest.

Strengths and Limitations

The strengths of this study are that the treatment program is part of the health care system in Sweden and therefore includes people seeking care on their own. Another strength is the use of structured assessments of outcomes and adherence rates in a relatively large cohort.

There are limitations to consider. First, this was an observational study without a control group, and we cannot discern between specific and placebo treatment effects or natural fluctuations in symptoms. However, stratifying participants into different pain levels at treatment start showed that weekly improvement occurs similarly for all participants with no increasing pain in those with lower starting pain during the 3-month period. Second, for ethical reasons, we cannot say if those not giving consent to research differ in characteristics and outcomes in a way that could have influenced the results. Third, people seeking digitally delivered treatment may differ in several unknown ways, such as being more highly educated, compared to people participating in face-to-face treatments and compared to the total population, which may challenge external validity. Fourth, we only have follow-up data for a 3-month treatment period and can therefore not determine whether improvements can be sustained after the treatment.

Conclusions

We found a clinically important reduction in pain for 58.50% (1517/2593) of participants after a 3-month digital treatment program for individuals with subacute or chronic LBP. We found no association with sociodemographic characteristics, but those with high baseline pain and high adherence were more likely to reach an MCIC in pain, while those wishing to undergo surgery or with pain in other joints at baseline were less likely to do so. Our findings suggest that digital treatment programs can reduce pain at clinically important levels for people with high adherence to treatment, but that those with such severe

LBP problems that they wish to undergo surgery may benefit from additional support.

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Authors' Contributions

HH, AK, HN, and LED contributed to the study design and analysis plan. HH was mainly responsible for drafting the manuscript. HH, LSL, AK, HN, LED, and AA contributed to the interpretation and editing of the manuscript. AK contributed to feedback on analysis strategy, and MM conducted statistical analysis.

Conflicts of Interest

HH, AK, and LSL are part-time employed by Joint Academy (JA); LED is the founder and chief medical officer at JA; HN is the vice president of clinical strategy at JA; MMI is full-time employed by JA as a data analyst. AA was a reviewer in the development of the content for the digital treatment program but received no compensation.

Multimedia Appendix 1

An example of what the app looks like when a patient enters the treatment.

[PDF File (Adobe PDF File), 729 KB - [rehab_v9i2e38084_app1.pdf](#)]

Multimedia Appendix 2

Supplementary tables and figures.

[DOC File , 97 KB - [rehab_v9i2e38084_app2.doc](#)]

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Abbreviations

ANOVA: analysis of variance

ICT: information and communication technology

JA: Joint Academy

LBP: low back pain

MCIC: minimal clinically important change

MSK: musculoskeletal

NRS: numeric rating scale

ODI: Oswestry Disability Index

OR: odds ratio

PASS: patient acceptable symptom state

PT: physiotherapist

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

Clinical Outcomes After a Digital Musculoskeletal Program for Acute and Subacute Pain: Observational, Longitudinal Study With Comparison Group

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Abstract

Background: Telerehabilitation for musculoskeletal (MSK) conditions may produce similar or better outcomes than usual care, but most telerehabilitation studies address only chronic or postsurgical pain.

Objective: We aimed to examine pain and function at 3, 6, and 12 weeks for individuals with acute and subacute MSK pain who took part in a digital MSK program versus a nonparticipant comparison group.

Methods: We conducted an observational, longitudinal study with a nonparticipant comparison group. The intervention group had video visits with physical therapists who recommended exercise therapies and educational articles delivered via an app. Nonparticipants were those who were registered but unable to participate because their benefit coverage had not yet begun. We collected pain and function outcomes through surveys delivered at 3-, 6-, and 12-week follow-ups. We conducted descriptive analyses, unadjusted regression, and mixed effects regression adjusting for baseline characteristics, time as fixed effects, and a time*group interaction term.

Results: The analysis included data from 675 nonparticipants and 262 intervention group participants. Compared to baseline, the intervention group showed significantly more pain improvement at 3, 6, and 12 weeks versus nonparticipants after adjusting for baseline factors. Specifically, the intervention group's pain scores decreased by 55.8% at 3 weeks versus baseline, 69.1% at 6 weeks, and 73% at 12 weeks. The intervention group's adjusted pain scores decreased from 43.7 (95% CI 41.1-46.2) at baseline to 19.3 (95% CI 16.8-21.8) at 3 weeks to 13.5 (95% CI 10.8-16.2) at 6 weeks to 11.8 (95% CI 9-14.6) at 12 weeks. In contrast, nonparticipants' pain scores decreased by 30.8% at 3 weeks versus baseline, 45.8% at 6 weeks, and 46.7% at 12 weeks. Nonparticipants' adjusted pain scores decreased from 43.8 (95% CI 42-45.5) at baseline to 30.3 (95% CI 27.1-33.5) at 3 weeks to 23.7 (95% CI 20-27.5) at 6 weeks to 23.3 (95% CI 19.6-27) at 12 weeks. After adjustments, the percentage of participants reporting that pain was better or much better at follow-up was significantly higher by 40.6% at 3 weeks, 31.4% at 6 weeks, and 31.2% at 12 weeks for intervention group participants versus nonparticipants. After adjustments, the percentage of participants with meaningful functional improvement at follow-up was significantly higher by 15.2% at 3 weeks and 24.6% at 12 weeks for intervention group participants versus nonparticipants.

Conclusions: A digital MSK program may help to improve pain and function in the short term among those with acute and subacute MSK pain.

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KEYWORDS

telemedicine; acute; subacute; musculoskeletal; pain; function; clinical; quality of life; intervention; longitudinal study; physical therapy; physiotherapy; physical therapist; physiotherapist; exercise; physical activity; telehealth; eHealth; digital health; patient

education; education material; education resource; health resource; mHealth; mobile health; health app; observational study; video consult; eConsult; virtual care

Introduction

Acute, subacute, and chronic musculoskeletal (MSK) conditions are a leading cause of disability and cost in the United States [1]. The rates of back pain, neck pain, and other MSK disorders in the United States are among the highest in the world [1]. In 2019, 39% of American adults reported back pain, 37% reported lower limb pain (eg, hips, knees, and feet), and 31% reported upper limb pain (eg, hands, arms, and shoulders) in the 3 months prior [2].

MSK conditions include injuries or pain in joints, ligaments, muscles, nerves, tendons, and structures that support limbs, neck, and back. They may be a result of exertion, repetitive motions, strain, or exposure to force, vibration, or awkward posture [3]. Acute pain is often defined as lasting 4 weeks or less. Subacute pain duration is from 4 to 12 weeks, and chronic pain duration is more than 12 weeks [4,5].

MSK conditions are a common cause of health care use in the United States. For example, 72.4 million office visits and 9.9 million emergency department visits were for MSK conditions in 2018 [6,7]. Of these, more than 4 million emergency department visits were for sprains and strains alone. Although providers and patients may pursue different pain management approaches for acute and subacute needs, numerous studies and clinical guidelines recommend education and exercise [8,9].

Telerehabilitation, a branch of telehealth that uses telecommunications technologies to control or monitor remote rehabilitation, is increasingly used to deliver MSK care [10]. Telerehabilitation for MSK conditions may produce similar or even better pain-, functional-, and health-related quality of life outcomes than usual care, but most telerehabilitation studies address only chronic or postsurgical pain [10-12]. Therefore, we aimed to determine whether telerehabilitation was associated with improved clinical outcomes in acute and subacute MSK conditions. Our primary objective was to examine pain and function at 3, 6, and 12 weeks for participants of a digital acute MSK program versus a nonparticipant comparison group. A secondary objective was to examine engagement among the intervention group. The findings contribute to a growing evidence base about the role of digital health for managing a range of MSK needs.

Methods

Study Design

We conducted an observational, prospective cohort study comparing digital MSK acute program participants (herein, intervention group) to nonparticipants at 3, 6, and 12 weeks.

Acute Program

Employers offered the acute program to employees and adult dependents as a health benefit. Recruitment was conducted through post and email. Registration involved creating a member profile and completing an application over the internet.

Developed by physical therapists (PTs), the acute program's goal was to help participants address acute or subacute MSK pain through digital physical therapy consultation, exercise therapy, and education. Participants had access to an acute program app for use on personal tablets or smartphones.

The acute program began with a video visit with a licensed PT. The PT conducted a subjective interview to learn more about the participant's history and goals and guided them through a series of movement tests to assess their current level of function. After the video visit, the PT provided a plan with recommended exercises and education that were available to participants through the app. The app provided this information through "sessions."

Each session presented a set of exercises that were specific to acute back, knee, shoulder, hip, neck/upper back, elbow/wrist/hand, or ankle/foot pain. Each session included stretching, strengthening, balancing, and mobility activities, based on the participant's functional limitations and goals determined during the consultation. The session presented 1 to 2 sets of 3 to 10 repetitions of each exercise (depending on the difficulty and type of exercise), with each session's duration ranging from 5 to 20 minutes. Graphics along with written and audio cues demonstrated how to perform the exercises, the number of repetitions for each exercise, and how long to hold the positions. As participants progressed through the program, their exercises were adjusted by the PT to gradually advance them toward their goals. This included adjusting the exercise variation, number of repetitions, hold time, and use of resistance with resistance bands (if applicable).

After participants completed the exercises for that session, the app presented educational resources about acute and subacute MSK pain-related topics, such as pain neuroscience, movement, treatment options, coping techniques, healthy lifestyle practices, relaxation tools, social support, and habit formation. Lastly, the participant was able to leave a note for their PT, rate their pain, or record any additional activity they had completed recently. As a wholly digital program, participants could choose when and where to meet with PTs via video and complete sessions.

Study Participants

First, for each week between July and October 2021, we identified individuals meeting the inclusion and exclusion criteria based on information provided in the application. Inclusion criteria were aged ≥ 18 years; back, knee, shoulder, hip, or neck pain; visual analog scale (VAS) pain score >0 ; pain for less than 12 weeks; and covered by employer's health plan. Exclusion criteria were signs of fracture, joint instability, infection, cancer, and cauda equina syndrome.

Second, we categorized the individuals as part of the intervention or nonparticipant group. The intervention group had a first video visit with a PT in the past week and a published care plan. Nonparticipants were those who applied to the acute program but were declined because their employers did not yet offer the acute program as a benefit. Everyone in the intervention

group and a sample of the nonparticipants were invited to the study. To sample nonparticipants, we stratified them by pain region (ie, back, knee, shoulder, hip, and neck) and conducted a propensity score match based on baseline pain and function.

Between August and November 2021, we invited participants to complete an email survey 3 weeks after registration

(nonparticipants) or video visit (intervention). We excluded individuals who did not provide informed consent or those who had pain for more than 12 weeks. Between August 2021 and January 2022, we sent surveys at 6 and 12 weeks after registration (nonparticipants) or video visit (intervention) to those who completed the 3-week follow-up survey and agreed to be recontacted (Table 1).

Table 1. Timeline for an example cohort who registered or had video visits between July 7, 2021, and July 13, 2021.

Date	Event
July 7-13	<ul style="list-style-type: none"> Nonparticipant group registers Intervention group has a physical therapist video visit
July 14	Apply inclusion and exclusion criteria and sample
August 4-11	Complete 3-week follow-up by email survey
August 25 to September 1	Complete 6-week follow-up by email survey
October 6-13	Complete 12-week follow-up by email survey

Ethics Approval

Study subjects acknowledged via the internet that they provided informed consent. The WIRB-Copernicus Group Institutional Review Board (Office of Human Research Protections/Food and Drug Administration Institutional Review Board registration number IRB00000533) at the WIRB-Copernicus Group reviewed and approved this study.

Outcomes

The primary outcome was pain improvement based on the response to the following question: “Over the past 24 hours, how bad was your [back/knee/shoulder/hip/neck] pain?” with a score from 0 (none) to 100 (worst imaginable).

A secondary outcome was the patient’s global impression of change (PGIC) based on the response to the following question: “Compared to when you first registered for Hinge Health, how would you rate your [back/knee/shoulder/hip/neck] pain now?” Pain rated as better or much better was coded as 1; pain rated as much worse, worse, a little worse, unchanged, or a little better was coded as 0.

Another secondary outcome was minimal clinically important difference (MCID) in functional improvement (herein, functional improvement). To create this dichotomous variable (no/yes), we gathered responses to the 11-item Roland Morris Disability Questionnaire (RMDQ-11, back only), Knee injury and Osteoarthritis Outcome Score Physical Function Short form (KOOS-PS, knee only), Hip disability and Osteoarthritis Outcome Score Physical Function Short form (HOOS-PS, hip only), Shoulder Pain and Disability Index (SPADI, shoulder only), and Neck Pain and Disability Scale short form (sf-NPAD, neck only). Next, we calculated the change from baseline to follow-up. MCID in functional improvement is defined as either at least 30% improvement on the RMDQ-11 [13,14]; 8-point improvement on the KOOS-PS [15-17]; 9.3-point improvement on the HOOS-PS [18,19]; 13-point improvement on the SPADI [20-22]; 12-point improvement on the sf-NPAD [23,24]; or no limitations at follow-up.

For the intervention group’s engagement, we collected the number of video visits and app-based exercise therapy sessions completed by 12 weeks. Exercise completion was recorded when participants used the app. We did not record exercises completed outside the app.

Exposures

Nonparticipants were those who were registered but did not take part in the acute program. The intervention group had one or more PT video visits, a published care plan, and access to exercise guidance and education via the acute program app.

Confounders

Model covariates included registration month (July, August, September, or October), age at baseline, pain region (back, knee, shoulder, hip, or neck), and the use of health care services at 12 weeks (no/yes). The health care services were conservative care (eg, office visit with a doctor or physical therapist), over-the-counter medications, prescription pain medications, and invasive procedures (eg, emergency department or urgent care center visit, overnight stay in a hospital, injections, or surgery).

Data Sources

The web-based application completed at program registration provided baseline data. We emailed follow-up surveys and up to 2 reminders at 3, 6, and 12 weeks after registration (nonparticipants) or the first PT video visit (intervention). Respondents received gift cards for US \$20 at 3 weeks, US \$25 at 6 weeks, and US \$35 at 12 weeks.

Study Size

Sample size was based on detecting noninferiority of the intervention versus nonparticipants at 6 weeks after registering or video visit. For VAS pain scores, we chose a noninferiority margin of 10 points because this is less than the 20-point reduction for MCID in pain improvement [25]. Assuming SDs of 21.4 for pain [26], 80% power, and a 1-sided 2.5% significance level, we needed 57 participants per arm (N=114).

Statistical Methods

Summary statistics were estimated for baseline characteristics of age, pain region, registration month, and baseline pain. We conducted 2-tailed *t* tests (for continuous variables) and chi-square tests (for categorical variables) to show whether there were significant differences between the intervention group and nonparticipants at baseline. Descriptive statistics reported at 3, 6, and 12 weeks were mean (SD) VAS pain scores, the number and percentage of participants who perceived better or much better pain (PGIC) at follow-up compared to registration, and the number and percentage of participants who achieved an MCID in functional improvement.

Unadjusted and adjusted linear mixed effects regression models were used to model pain improvement, and generalized linear mixed effects models were used for PGIC and functional improvement. Covariates were baseline age, pain region, registration month, and health care service use at 12 weeks.

PGIC and functional improvement models also included baseline pain. Time was treated as a categorical predictor to allow the modeling of nonlinear change trends over time. A 2-way time*group interaction term captured the treatment effect at each time point. Estimated predicted probabilities and marginal effects are presented below.

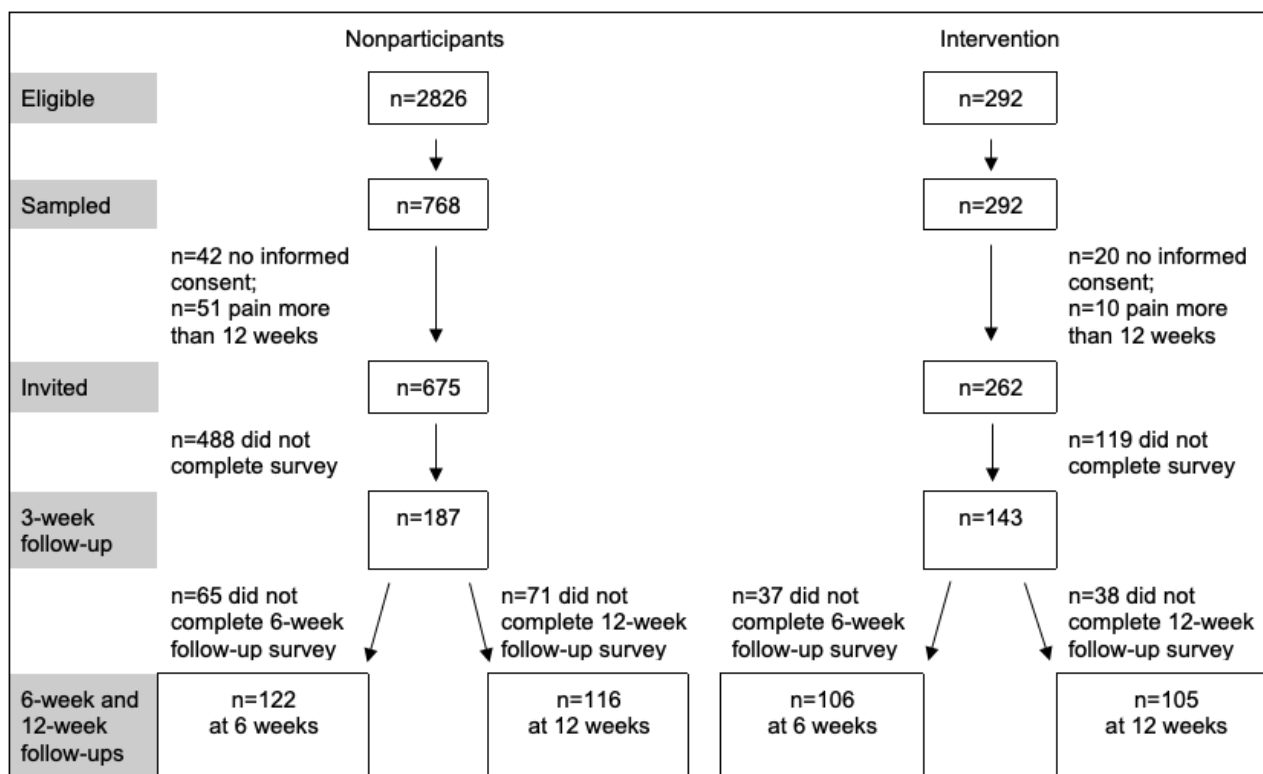
The primary analysis used all available data. The maximum likelihood estimation method was used, assuming data were missing at random. Analyses were performed in Stata (version 17.0; StataCorp) and R statistical software (version 4.0.5; R Foundation for Statistical Computing).

Results

Flowchart

Figure 1 reports the intervention and nonparticipant groups at each study stage.

Figure 1. Flowchart, by group.



Sample Characteristics

Table 2 shows the baseline characteristics for the nonparticipant and intervention groups. We detected no significant differences between the 2 groups at baseline. The mean age of the total

sample was 44.1 (SD 11.9) years. At registration, mean pain was 43.0 (SD 22.3) out of 100. The largest (31.9%, 299/937) percentage of the sample registered for back pain and the smallest (13.8%, 129/937) registered for hip pain.

Table 2. Baseline characteristics.

Characteristic	Nonparticipant group (n=675)	Intervention group (n=262)	All participants (N=937)
Age (year), mean (SD)	44.0 (12.1)	44.4 (11.3)	44.1 (11.9)
Baseline pain, mean (SD)	42.9 (22.5)	43.2 (21.7)	43.0 (22.3)
Pain region, n (%)			
Back	225 (33.3)	74 (28.2)	299 (31.9)
Hip	87 (12.9)	42 (16)	129 (13.8)
Knee	119 (17.6)	53 (20.2)	172 (18.4)
Neck	140 (20.7)	49 (18.7)	189 (20.2)
Shoulder	104 (15.4)	44 (16.8)	148 (15.8)
Registration month, n (%)			
July	124 (18.4)	54 (20.6)	178 (19)
August	170 (25.2)	60 (22.9)	230 (24.5)
September	236 (35)	77 (29.4)	313 (33.4)
October	145 (21.5)	71 (27.1)	216 (23.1)

Descriptive Results

Nonparticipants' absolute decrease in pain from baseline was 11.5 points at 3 weeks, 17.9 points at 6 weeks, and 18.2 points at 12 weeks. The intervention group's absolute decrease in pain from baseline was 24.0 points at 3 weeks, 29.0 points at 6 weeks, and 30.5 points at 12 weeks (Table 3).

The percentage of participants reporting that pain as better or much better (PGIC) was 69.3% (104/150) at 3 weeks, 73.9% (85/115) at 6 weeks, and 78.5% (95/121) at 12 weeks in the intervention group. For nonparticipants, the percentages were 26% (51/196) at 3 weeks, 38.5% (50/130) at 6 weeks, and 43.1% (53/123) at 12 weeks. PGIC was higher for the intervention

group than the nonparticipant group by 43.3 percentage points at 3 weeks, 35.4 percentage points at 6 weeks, and 35.5 percentage points at 12 weeks.

The percentage of participants reporting meaningful functional improvement was 56.5% (105/186) at 3 weeks, 67.9% (91/134) at 6 weeks, and 77.7% (94/121) at 12 weeks in the intervention group. For nonparticipants, the percentages were 39.3% (77/196) at 3 weeks, 51.6% (66/128) at 6 weeks, and 50.8% (62/122) at 12 weeks. The percentage reporting functional improvement was higher for the intervention group than the nonparticipant group by 17.2 percentage points at 3 weeks, 16.3 percentage points at 6 weeks, and 26.9 percentage points at 12 weeks (Table 3).

Table 3. Descriptive results: outcomes over time for nonparticipant and intervention groups.

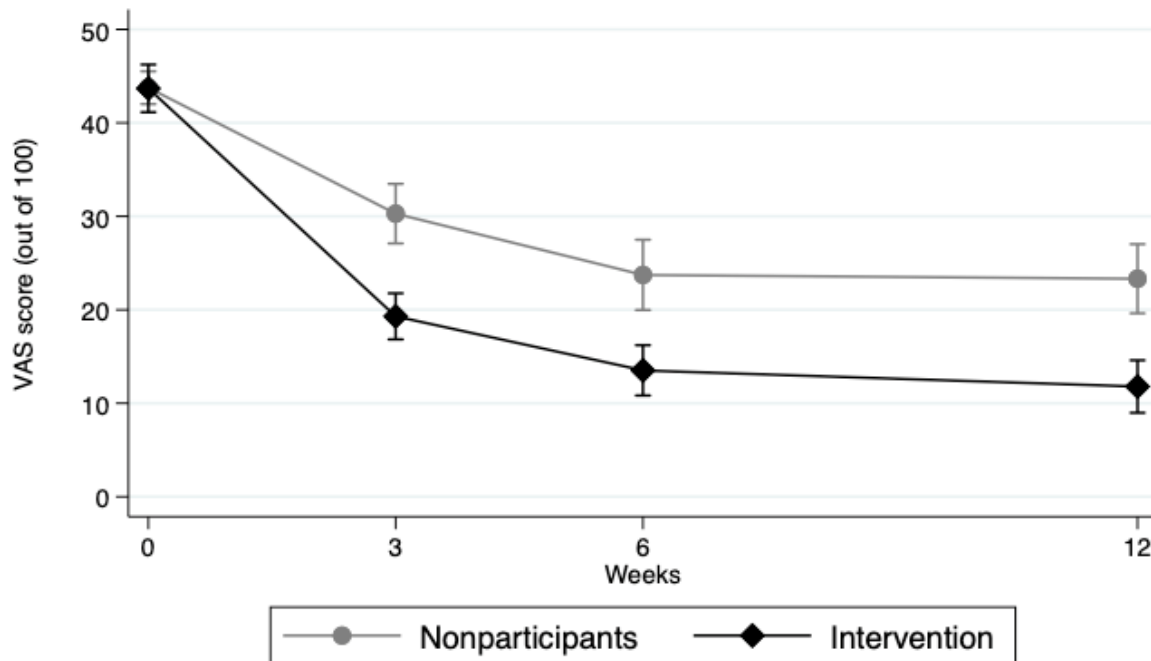
Outcome, timepoint	Nonparticipant group	Intervention group
Pain score, mean (SD)		
Baseline	42.9 (22.5)	43.2 (21.7)
3 weeks	31.4 (22.8)	19.2 (17.9)
6 weeks	25.0 (21.6)	14.2 (16.0)
12 weeks	24.7 (20.5)	12.7 (14.2)
Patient's global impression of change, n (%)		
3 weeks (nonparticipant group: n=196; intervention group: n=150)	51 (26)	104 (69.3)
6 weeks (nonparticipant group: n=130; intervention group: n=115)	50 (38.5)	85 (73.9)
12 weeks (nonparticipant group: n=123; intervention group: n=121)	53 (43.1)	95 (78.5)
Functional improvement, n (%)		
3 weeks (nonparticipant group: n=196; intervention group: n=150)	77 (39.3)	105 (56.5)
6 weeks (nonparticipant group: n=130; intervention group: n=115)	66 (51.6)	91 (67.9)
12 weeks (nonparticipant group: n=123; intervention group: n=121)	62 (50.8)	94 (77.7)

Main Results

The intervention group showed significantly lower adjusted pain scores at follow-up compared to nonparticipants (Figure 2). For nonparticipants, adjusted pain scores decreased from 43.8 (95% CI 42-45.5) at baseline to 30.3 (95% CI 27.1-33.5)

at 3 weeks to 23.7 (95% CI 20-27.5) at 6 weeks to 23.3 (95% CI 19.6-27) at 12 weeks. For the intervention group, adjusted pain scores decreased from 43.7 (95% CI 41.1-46.2) at baseline to 19.3 (95% CI 16.8-21.8) at 3 weeks to 13.5 (95% CI 10.8-16.2) at 6 weeks to 11.8 (95% CI 9-14.6) at 12 weeks.

Figure 2. Adjusted VAS score over time. Results adjusted for age, pain region, registration month, health care service use, and time as fixed effects. VAS: visual analog scale.



After adjustments, the intervention group showed a significantly higher percentage of people reporting pain was better or much better (PGIC) at follow-up versus nonparticipants. The adjusted percentage of nonparticipants who reported better or much better pain increased from 26.5% (95% CI 20.7%-32.4%) at 3 weeks to 40.9% (95% CI 32.7%-49.1%) at 6 weeks to 46.3% (95% CI 38%-54.6%) at 12 weeks. The adjusted percentage of intervention group who reported better or much better pain increased from 67.1% (95% CI 59.4%-74.9%) at 3 weeks to 72.3% (95% CI 64.1%-80.5%) at 6 weeks to 77.5% (95% CI 69.7%-85.3%) at 12 weeks (Figure 3).

The intervention group showed a significantly higher percentage of people reporting functional improvement at 3 weeks and 12

weeks compared to nonparticipants. The adjusted percentage of nonparticipants reporting functional improvement increased from 39.1% (95% CI 32.6%-45.5%) at 3 weeks to 53.2% (95% CI 44.9%-61.6%) at 6 weeks to 53.2% (95% CI 44.4%-61.9%) at 12 weeks. The adjusted percentage of intervention group reporting functional improvement increased from 54.3% (95% CI 48%-60.5%) at 3 weeks to 67.2% (95% CI 60%-74.3%) at 6 weeks to 77.8% (95% CI 70.7%-84.9%) at 12 weeks (Figure 4).

Multimedia Appendix 1 shows the unadjusted and adjusted regression model results.

Figure 3. Adjusted proportion of participants reporting pain is better or much better over time. Results adjusted for age, baseline pain, pain region, registration month, health care service use, and time as fixed effects.

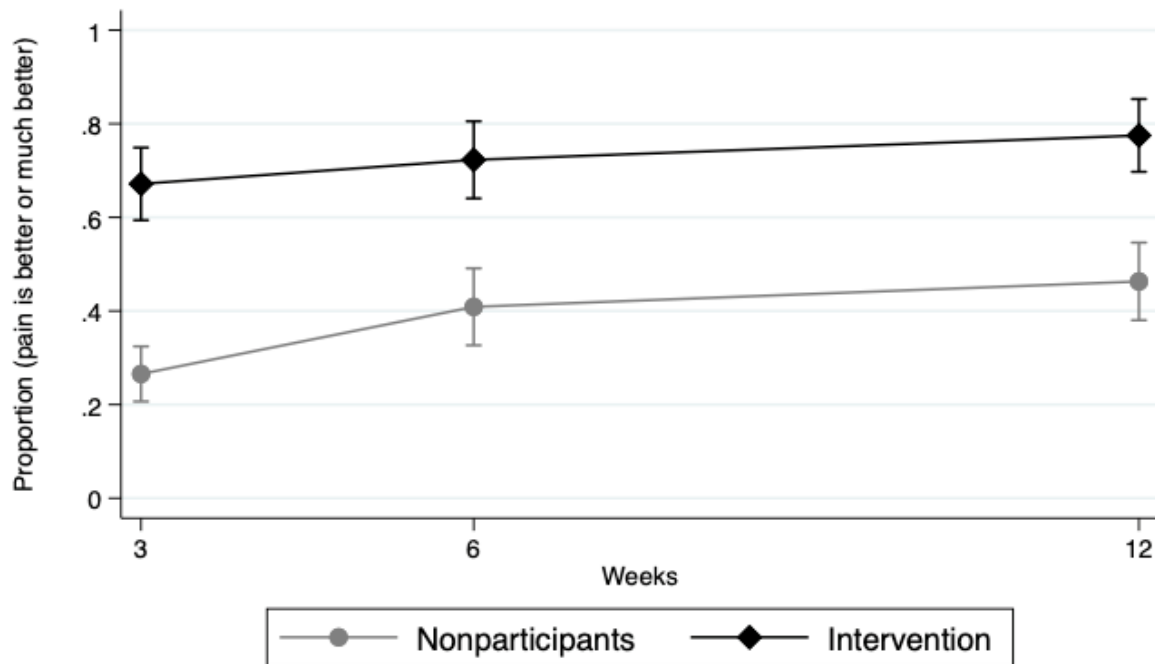
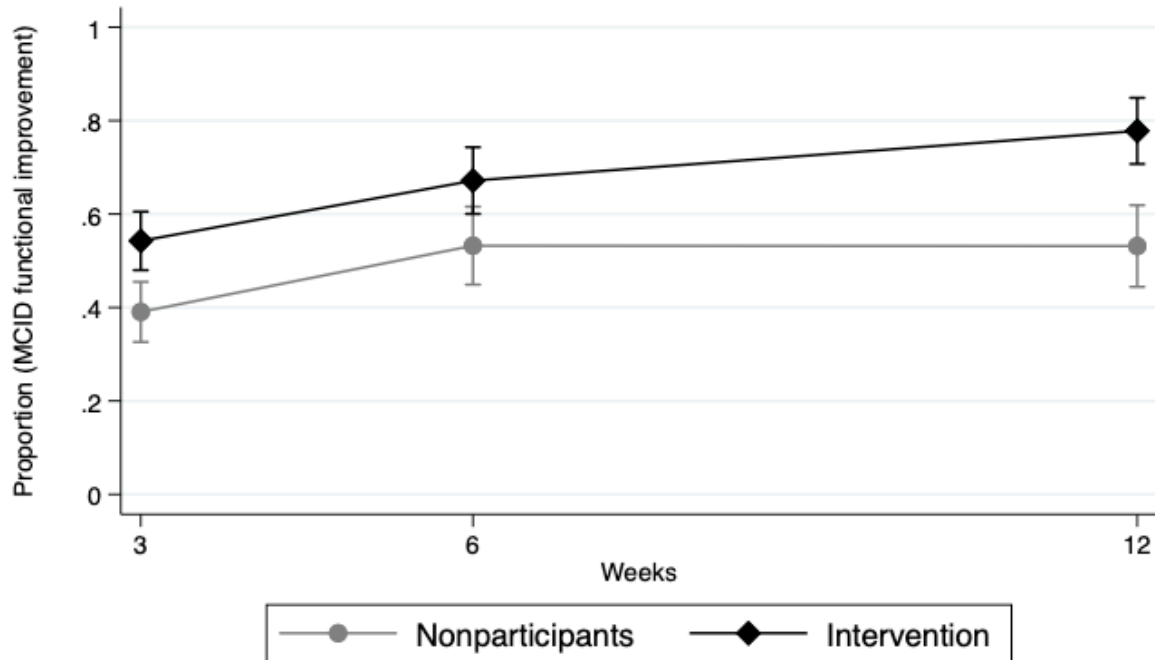


Figure 4. Adjusted proportion of participants with MCID in functional improvement over time. Results adjusted for age, baseline pain, pain region, registration month, health care service use, and time as fixed effects. MCID: minimal clinically important difference.



Engagement

By 12 weeks, the intervention group averaged 1.8 (SD 1.1; range 1-6) video visits and 17.7 (SD 21.2; median 10; range 0-103) exercise therapy sessions.

Discussion

Principal Results and Generalizability

This observational study examined pain and function at 3, 6, and 12 weeks after starting a digital MSK program for acute and subacute MSK conditions versus nonparticipants. We found significant associations between the intervention and both pain

improvement and PGIC at 3, 6, and 12 weeks. A significantly larger percentage of the intervention group also reported clinically meaningful functional improvement versus the nonparticipant group at 3 and 12 weeks.

As an observational study, we propose that findings are generalizable to the population of people with acute and subacute MSK pain with expressed interest in a digital acute MSK program. However, the study may not be generalizable to later adopters of health technology or all people with MSK pain.

Comparison to Prior Work

VAS pain scores improved from baseline to follow-up for nonparticipants and intervention group members. However, the magnitude of pain improvement was significantly greater for the intervention group. The intervention group's pain score improved from baseline by more than 10.9 points at 3 weeks, 10.1 points at 6 weeks, and 11.5 points at 12 weeks versus nonparticipants. This 10.1 to 11.5 point difference is similar to pain improvement shown in meta-analyses of spinal manipulative therapy (mean difference: 10; 95% CI 4-16) and exceeds that of nonsteroidal anti-inflammatory drugs for acute back pain (mean difference: 7; 95% CI 4-11) [27,28]. Our results are also consistent with recent meta-analyses reporting that exercise is an efficacious treatment for acute and subacute low back pain in the immediate term [9].

We detected statistically significant associations between the digital MSK program and meaningful functional improvement. In contrast, the effect of traditional services and medications on functional improvement have not been consistently demonstrated in acute MSK injuries [5]. Our study found that a significantly greater percentage of the intervention group reported meaningful functional improvement versus nonparticipants at 3 and 12 weeks, but not at 6 weeks. This may be due to the small sample size. We also suggest that nonparticipants' function improved over time but at a slower rate than the intervention group. Furthermore, the intervention group continued to make progress in function beyond the 6-week mark, whereas nonparticipants' functional improvement plateaued between 6 and 12 weeks. The ways that a digital acute MSK program changes the trajectory of functional improvement over time and in the long term are an area for additional research in the future.

We found that the intervention group averaged 1.8 video visits and 17.7 exercise therapy sessions by week 12. Although we did not collect self-reported information about exercises conducted without the app, this engagement data about completed exercise sessions demonstrated the feasibility of

using app-based data to monitor member adherence to recommended exercises. This objective measure of adherence may supplement self-reports about efficacy and confidence in doing exercises. Adherence to exercises delivered through digital health programs has been shown to match or exceed that of in-person programs, and improved adherence is associated with better treatment outcomes for MSK needs [29-32].

Strengths and Limitations

Study strengths include the use of data from 2 prospective cohorts who were similar in age, pain, and pain region at baseline. As a result, the study resulted in the longitudinal monitoring of a digital acute MSK program versus a nonparticipant group. Further, to our knowledge, our study is the first to evaluate a digital MSK program for acute and subacute needs against a nonparticipant group. The comparison group is essential given the natural history of acute and subacute MSK conditions. Improvement was assessed using 3 different outcomes, and we evaluated the program in real-world settings.

First, a study limitation is that this observational study cannot establish the causality of the intervention's effect on outcomes. Second, we may have omitted important confounding variables (eg, motivation) that attenuate outcome estimates. Furthermore, we did not document the types of medications that study participants took to address pain and function. To build on current findings, we recommend a randomized controlled trial to establish causality and account for the effect of unmeasured factors. Third, more granular follow-up timepoints (eg, weekly) could provide more insight into the longitudinal course of pain and function in an acute digital MSK program. Future studies could use daily diaries to document exercise adherence and changes in daily pain to show time to pain resolution in days or weeks. Fourth, the study examines acute and subacute needs as a whole, and we do not report on outcomes for each region (ie, back, knee, shoulder, hip, or neck) separately. It is possible that the outcomes vary from region to region, and positive outcomes in one region might mask neutral or even negative outcomes in another region. To address this concern, we controlled for region in the regression models. Future studies could examine outcomes for specific regions or present stratified results.

Conclusions

This study provided evidence that a digital acute MSK program may help improve pain and function in the short term among those with acute and subacute MSK needs. Future studies can build upon these results to further evaluate the extent to which digital health effectively manages a range of MSK needs, including acute and subacute needs.

Acknowledgments

Hinge Health, Inc provided the digital musculoskeletal program to participants.

Data Availability

The data sets generated during and/or analyzed during the current study are not publicly available because data are proprietary but are available from the corresponding author on reasonable request.

Authors' Contributions

GW, MY, MH, JK, and JFB designed the study. GW, MY, and MH analyzed the data. GW, MY, MH, JK, and JFB interpreted data and were major contributors in writing the manuscript. GW, MY, MH, JK, and JFB read and approved the final manuscript.

Conflicts of Interest

GW, MH, and JK are employees of Hinge Health, Inc and have equity interest in Hinge Health, Inc.

Multimedia Appendix 1

Unadjusted and adjusted models comparing the intervention group to nonparticipants for each outcome.

[[DOCX File, 14 KB - rehab_v9i2e38214_app1.docx](#)]

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Abbreviations

- HOOS-PS:** Hip disability and Osteoarthritis Outcome Score Physical Function Short form
KOOS-PS: Knee injury and Osteoarthritis Outcome Score Physical Function Short form

MCID: minimal clinically important difference
MSK: musculoskeletal
PGIC: patient's global impression of change
PT: physical therapist
RMDQ-11: 11-item Roland Morris Disability Questionnaire
sf-NPAD: Neck Pain and Disability Scale short form
SPADI: Shoulder Pain and Disability Index
VAS: visual analog scale

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Original Paper

The Current State of Remote Physiotherapy in Finland: Cross-sectional Web-Based Questionnaire Study

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Abstract

Background: The ongoing COVID-19 pandemic has required social, health, and rehabilitation organizations to implement remote physiotherapy (RP) as a part of physiotherapists' daily practice. RP may improve access to physiotherapy as it delivers physiotherapy services to rehabilitees through information and communications technology. Even if RP has already been introduced in this century, physiotherapists' opinion, amount of use, and form in daily practice have not been studied extensively.

Objective: This study aims to investigate physiotherapists' opinions of the current state of RP in Finland.

Methods: A quantitative, cross-sectional, web-based questionnaire was sent to working-aged members of the Finnish Association of Physiotherapists (n=5905) in March 2021 and to physiotherapists in a private physiotherapy organization (n=620) in May 2021. The questionnaire included questions on the suitability of RP in different diseases and the current state and implementation of RP in work among physiotherapists.

Results: Of the 6525 physiotherapists, a total of 9.9% (n=662; n=504, 76.1% female; mean age 46.1, SD 12 years) answered the questionnaire. The mean suitability "score" (0=not suitable at all to 10=fully suitable) of RP in different disease groups varied from 3.3 (neurological diseases) to 6.1 (lung diseases). Between early 2020 (ie, just before the COVID-19 pandemic) and spring 2021, the proportion of physiotherapists who used RP increased from 33.8% (21/62) to 75.4% (46/61; $P<.001$) in the public sector and from 19.7% (42/213) to 76.6% (163/213; $P<.001$) in the private sector. However, only 11.7% (32/274) of physiotherapists reported that they spent >20% of their practice time for RP in 2021. The real-time method was the most common RP method in both groups (public sector 46/66, 69.7% vs private sector 157/219, 71.7%; $P=.47$). The three most commonly used technical equipments were computers/tablets (229/290, 79%), smartphones (149/290, 51.4%), and phones (voice call 51/290, 17.6%). The proportion of physiotherapists who used computers/tablets in RP was higher in the private sector than in the public sector (183/221, 82.8% vs 46/68, 67.6%; $P=.01$). In contrast, a higher proportion of physiotherapists in the public sector than in the private sector used phones (18/68, 26.5% vs 33/221, 14.9%; $P=.04$).

Conclusions: During the COVID-19 pandemic, physiotherapists increased their use of RP in their everyday practice, although practice time in RP was still low. When planning RP for rehabilitees, it should be considered that the suitability of RP in different diseases seems to vary in the opinion of physiotherapists. Furthermore, our results brought up important new information for developing social, health, and rehabilitation education for information and communications technologies.

KEYWORDS

COVID-19; remote physiotherapy; COVID-19 pandemic; current state; suitability in disease groups; competence of physiotherapist

Introduction

Providing easy and equal access to physiotherapy services is a significant challenge due to the aging population; increasing prevalence of chronic diseases; and the concentration of health, rehabilitation, and social services to urban areas [1,2]. Physiotherapy is a profession with expertise in health, movement, mobility, and function [3,4]. Remote physiotherapy (RP), or alternatively telerehabilitation (this term was introduced in the late 90s in the scientific literature [5]), offers a means to improve the availability of physiotherapy as it delivers physiotherapy services to rehabilitees through information and communications technology (ICT) [5-11]. RP opens the possibility for new work tasks and new approaches for physiotherapists in examination, implementation, and follow-up, which affect their professional role [3]. While RP can involve direct online communication with a physiotherapist, such that the rehabilitee and the physiotherapist are physically in two different places, RP can also mean a digital application used in physiotherapy that provides automatic feedback and support for the rehabilitee [12]. In this paper, we use the term RP to describe how conventional physiotherapy is delivered remotely using ICT. The term rehabilitee is defined as a patient, client, customer, or group, and the real-time method describes direct online communication between the rehabilitee and physiotherapist.

The COVID-19 pandemic has required health care organizations to implement RP as a part of physiotherapists' daily practice [13]. RP has allowed physiotherapists to continue their daily clinical practice during the pandemic for those rehabilitees that need physiotherapy but are unable to visit a hospital or clinic. RP has also supported social distancing to reduce the spread of COVID-19 [13,14] and has been implemented in COVID-19 physiotherapy [15-17], although we have not focused on this in our study.

RP may be as effective as conventional physiotherapy in some disease groups, such as musculoskeletal diseases [2,18-20], heart and lung diseases [9,21], or neurological diseases [22]. Moreover, a major advantage over conventional physiotherapy is that the rehabilitee does not need to travel for RP, thus saving time and travel costs. Another positive consequence is that the rehabilitee can decide for themselves when to perform their therapeutic exercise, and it is easier to implement the exercise into their daily activity [12,20,23].

Despite the advantages of RP, physiotherapy is still typically practiced in person. There are several barriers that preclude the wider use of RP. These include the physiotherapist's competence in using technical equipment and resistance to RP; technical investment costs; and the age, degree of education, and computer literacy of the rehabilitee [24]. Environmental space and infrastructural challenges such as bandwidth capacity are other barriers to RP for both rehabilitees and physiotherapists [25].

There is some evidence that the COVID-19 pandemic has increased the use of RP in Switzerland [26] and in Kuwait [27]. However, our knowledge of the current state of RP in Finland is limited. Therefore, we conducted a study to determine how appropriate RP is for different disease groups, the proportion of practice time spent on RP before and during the COVID-19 pandemic, which method and what technology physiotherapists use on RP, and the difference between public and private sector use of RP.

Methods

Study Design

We used a quantitative, cross-sectional, web-based questionnaire study to answer the research questions. Physiotherapists responded to the questionnaire anonymously. This study adhered to the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) [28] and The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Statement [29].

The term RP was defined as a physiotherapy intervention that includes remote technology such as telephones, smartphones, computers, tablets, activity trackers, computer vision (CV), artificial intelligence (AI), virtual reality (VR), or robotics such that the physiotherapist is physically in a different place than the rehabilitee [7]. The terms real-time and not-tied-to-time methods were defined as follows: a real-time method is online communication between rehabilitee and physiotherapist; a method not tied to time means remote technology used in physiotherapy that provides automatic feedback and support for the rehabilitee [12].

The Finnish health care system consists of two complementary sectors that receive public funding, the public and private sector. There are substantial differences between these systems, such as scope of services provided, user fees, and waiting times. There are also differences in financing mechanisms. The public sector is financed based on taxes and the National Health Insurance (NHI); the private sector is partly (one-third) financed by NHI [30]. Therefore, we analyzed these sectors separate in our study. Although there are two different sectors, every rehabilitee has the right to good and equal quality health care and rehabilitation.

Subjects

We recruited physiotherapists of working age from the Finnish Association of Physiotherapists (n=5905) and from a private physiotherapy organization (n=620). A questionnaire was mailed to physiotherapists in March (Finnish Association of Physiotherapists) and May 2021 (private physiotherapy organization) via an information letter that included an electronic link to the questionnaire. The questionnaire had a 5-week deadline. Two reminders were sent during this period; the first reminder was sent after 1 week and the second reminder 2 weeks after the first.

The Questionnaire

A questionnaire was constructed that included items that were based on previous literature in the field [10,23,31-33] and on the opinions of the research teams and coworkers (that included experts such as medical doctors, physiotherapists, clinical specialists, researchers, and lecturers) working in a university hospital, city health station, university, university of applied sciences, and physiotherapy association. The questionnaire was piloted by 28 physiotherapists from different physiotherapy fields and geographical locations in Finland. In the pilot phase, we asked for feedback on the questionnaire, such as unclear questions and suggestions for corrections. Word choices were changed, and two questions were changed from compulsory to optional.

The questionnaire included 32 questions (31 closed and 1 open question). To study suitability of RP in different diseases and patients with pain, we used an 11-point numeric scale (0=not suitable at all, 10=fully suitable). While most of the patients with chronic pain are patients with musculoskeletal disorder [34], we inserted them into the category “musculoskeletal diseases.” The numeric rating scale was chosen as it is well understood and used in physiotherapy [35]. Other questions included were “how much of your practice time have you spent on RP in the month before the survey,” “how much of your practice time have you spent on RP just before the COVID-19 pandemic (early 2020),” “do you use real-time methods or methods not tied to time in RP,” and “which of the following technology solutions do you use weekly in RP.”

Statistical Methods

Statistical analyses were performed with SPSS (Version 27.0; IBM Corp). Frequency distributions, percentages, and means are given as descriptive statistics. Chi-square statistics and Student *t* test were applied to calculate statistical differences between the public and private groups. $P < .05$ (2-tailed) was considered as a statistically significant threshold.

Ethical Considerations

The study was granted ethical approval by the research ethics committee of the Faculty of Medicine at University of Helsinki in February 2021 (registration number 3/2021).

Results

Of the 6525 physiotherapists, a total of 9.9% ($n=662$) answered the questionnaire. Physiotherapy students and physiotherapists that were retired, lecturers, or researchers were excluded; the final study group included 579 (8.9%) physiotherapists. Of these 579 physiotherapists, 482 (83.2%) were females (mean age 49.3 SD 11.9 years), and 97 (16.8%) were males (mean age 46.2, SD 12.2 years). Of the physiotherapists, 423 (73.1%) worked in the private sector and 152 (26.3%) in the public sector; in addition to these, 3 did not answer this specific question, and 1 could not be classified to either group.

Physiotherapists in the public and private sector typically had extensive work experience. Almost four-fifths (440/579, 76%) had over 10 years of experience; there was no difference in work experience between the physiotherapists in these two sectors. However, the proportion of physiotherapists who reported that they do not have work experience in RP was higher in the public sector than in the private sector. Detailed characteristics of the physiotherapists are shown in Table 1.

There were minimal differences when the mean suitability “score” (0=not suitable at all to 10=fully suitable) of RP in different connected disease groups between public and private sectors were compared. However, the mean suitability “score” of lung diseases ($P=.02$) and in musculoskeletal diseases ($P=.01$) was higher in the public than private sector. The mean suitability “score” of RP in different diseases varied from 2.1 (memory disorder) to 6.6 (hip or knee osteoarthritis, asthma). Only 9.7% (40/411) considered asthma and 8.2% (37/452) considered hip or knee osteoarthritis as fully suitable (score 10) for RP; 32.2% (134/416) considered RP not suitable at all (score 0) for rehabilitees with memory disorder (Table 2).

Three-quarters of all physiotherapists reported that they did not spend any of their practice time in RP before the COVID-19 pandemic in early 2020. The proportion of such physiotherapists was higher in the private sector than in the public sector (171/213, 80.3%; vs 41/62, 66.1%; $P=.03$). Only a few physiotherapists spent more than 20% of their practice time for RP (Table 3).

Between early 2020 and spring 2021, the proportion of physiotherapists who used RP increased from 33.8% (21/62) to 75.4% (46/61; $P < .001$) in the public sector and from 19.7% (42/213) to 76.6% (163/213; $P < .001$) in the private sector. The proportion of physiotherapists who did not use RP in 2021 was only 24.6% (15/61) in the public sector and 23.5% (50/213) in the private sector with no statistically significant group difference ($P=.86$). However, the proportion of physiotherapists who used over 20% of their practice time on RP was still minimal. Detailed results are shown in Table 3.

When studying the methods and equipment used in individual RP, the real-time method was the most common method in the public (46/66, 69.7%) and the private (157/219, 71.7%) sector. In contrast, only a few physiotherapists used the method not tied to time (Table 4); a corresponding result was seen in group RP (data not shown). In the total group, the three most used technical equipment were computers/tablets (229/290, 79%), smartphones (149/290, 51.4%), and phones (51.290, 17.6%; voice call). The proportion of physiotherapists who used computers/tablets in RP was higher in the private sector than in the public sector (183/221, 82.8% vs 46/68, 67.6%; $P=.01$). However, a higher proportion of physiotherapists in the public sector than in the private sector used phones (18/68, 26.5% vs 33/221, 14.9%; $P=.04$). Other equipment such as VR, CV, or AI were rarely used (Table 4).

Table 1. Characteristics of the study physiotherapists.

	Total group (n=579)	Public sector (n= 152)	Private sector (n=423)	<i>P</i> value
Age (years), mean (SD)				
Total	48.8 (11.9)	48.6 (11.9)	49.0 (11.9)	.73 ^a
Female	49.3 (11.9)	49.3 (11.9)	49.3 (11.7)	.93 ^a
Male	46.2 (12.2)	42.3 (10.3)	47.3 (12.3)	.15 ^a
Time from physiotherapy degree (years), mean (SD)	22.3 (12.6)	21.4 (12.5)	22.7 (12.5)	.27 ^a
Work experience in physiotherapy, n (%)				
<1 year	18 (3.1)	7 (4.6)	10 (2.4)	.47 ^b
≥1 year and <5 years	65 (11.2)	17 (11.2)	47 (11.1)	
≥5 years and <10 years	56 (9.7)	12 (7.9)	43 (10.2)	
≥10 years	440 (76.0)	116 (76.3)	323 (76.4)	
Work experience in remote physiotherapy, n (%)				
No experience	210 (36.3)	77 (50.7)	130 (30.7)	<.001 ^b
<1 year	209 (36.1)	26 (30.3)	162 (38.3)	
1 year to 2 years	135 (23.3)	26 (17.1)	109 (25.8)	
>2 to 4 years	13 (2.2)	1 (0.7)	12 (2.8)	
>4 years	12 (2.1)	2 (1.3)	10 (2.4)	

^a*P* values are based on Student *t* test.

^b*P* values are based on chi-square test.

Table 2. Suitability score of remote physiotherapy in different disease groups^a.

Connected disease groups and subgroups	Total group, mean (SD)	Public sector, mean (SD)	Private sector, mean (SD)	Mean difference (95% CI)	<i>P</i> value ^b
Lung diseases	6.1 (2.4)	6.5 (2.1)	5.9 (2.5)	0.6 (0.1 to 1.1)	.02
Asthma	6.6 (2.5)	6.8 (2.3)	6.5 (2.5)	0.3 (−0.3 to 0.8)	.31
COPD ^c	5.6 (2.6)	6.2 (2.2)	5.4 (2.7)	0.8 (0.3 to 1.3)	.003
Musculoskeletal diseases	5.7 (2.2)	6.1 (1.9)	5.6 (2.3)	0.6 (0.1 to 1.0)	.01
Knee and hip osteoarthritis	6.6 (2.5)	7.2 (2.1)	6.4 (2.6)	0.8 (0.3 to 1.2)	.001
Low back pain	5.9 (2.6)	5.9 (2.5)	5.9 (2.6)	0.0 (−0.5 to 0.5)	.98
Repetitive strain injury of the hand and forearm	5.9 (2.8)	6.5 (2.7)	5.6 (2.8)	0.9 (0.3 to 1.5)	.002
Tendon disorder of the shoulder	5.8 (2.7)	6.0 (2.6)	5.7 (2.7)	0.4 (−0.2 to 0.9)	.19
Rheumatoid arthritis	5.7 (2.5)	6.1 (2.3)	5.5 (2.6)	0.6 (0.1 to 1.2)	.02
Pain patient	5.2 (2.7)	5.3 (2.6)	5.1 (2.7)	0.2 (−0.4 to 0.8)	.50
Neck pain	4.8 (2.7)	4.7 (2.6)	4.8 (2.7)	−0.1 (−0.7 to 0.5)	.75
Psychiatric diseases	4.9 (2.7)	5.3 (2.6)	4.7 (2.7)	0.6 (0.0 to 1.2)	.06
Anxiety disorder	5.2 (3.0)	5.6 (3.1)	5.0 (3.0)	0.6 (0.0 to 1.3)	.045
Depression	5.0 (2.9)	5.3 (2.8)	4.8 (2.9)	0.5 (−0.2 to 1.1)	.15
Personality disorder	4.7 (2.9)	4.9 (2.9)	4.6 (2.9)	0.4 (−0.2 to 1.0)	.23
Neurological diseases	3.3 (2.1)	3.3 (1.9)	3.3 (2.2)	0.1 (−0.5 to 0.4)	.81
Multiple sclerosis	4.4 (2.6)	4.3 (2.4)	4.4 (2.7)	−0.1 (−0.6 to 0.5)	.85
Parkinson disease	4.0 (2.6)	4.1 (2.5)	4.0 (2.6)	0.1 (−0.5 to 0.7)	.69
Cerebral infarction (eg, stroke)	3.3 (2.6)	3.1 (2.4)	3.4 (2.6)	−0.2 (−0.8 to 0.3)	.45
Spinal cord injury	3.2 (2.7)	2.9 (2.3)	3.3 (2.8)	−0.5 (−1.1 to 0.1)	.09
Brain injury	3.2 (2.5)	2.9 (2.4)	3.2 (2.6)	−0.3 (−0.8 to 0.2)	.25
Memory disorder	2.1 (2.2)	2.3 (2.3)	2.0 (2.2)	0.3 (−0.2 to 0.8)	.21
Other					
Heart disease/failure	5.8 (2.7)	6.1 (2.5)	5.7 (2.8)	0.4 (−0.1 to 1.0)	.14
Cancer	5.2 (2.8)	5.3 (2.7)	5.2 (2.8)	0.1 (−0.5 to 0.7)	.75
Multimorbid patient	3.6 (2.6)	3.7 (2.6)	3.5 (2.7)	0.2 (−0.4 to 0.8)	.46

^aSuitability score (0=not suitable at all to 10=fully suitable).

^b*P* values are based on Student *t* test.

^cCOPD: chronic obstructive pulmonary disease.

Table 3. Proportion of physiotherapists who used remote physiotherapy before (early 2020) and during the COVID-19 pandemic (spring 2021).

Proportion of practice time (%)	Total group, n (%)	Public sector, n (%)	Private sector, n (%)	<i>P</i> value ^a
Before COVID-19 pandemic				.03
0	212 (76.8)	41 (66.1)	171 (80.3)	
1-20	60 (21.7)	19 (30.6)	40 (18.8)	
>20	4 (1.4)	2 (3.2)	2 (0.9)	
During the COVID-19 pandemic				.20
0	65 (23.7)	15 (24.6)	50 (23.5)	
1-20	177 (64.6)	35 (57.4)	142 (66.7)	
>20	32 (11.7)	11 (18.0)	21 (9.9)	

^a*P* values are based on chi-square tests.

Table 4. Methods and equipment used in remote physiotherapy on a weekly basis.

	Total group, n (%)	Public sector, n (%)	Private sector, n (%)	<i>P</i> value ^a
Method				.47
Real-time method	203 (71.0)	46 (69.7)	157 (71.7)	
Method not tied to time	11 (3.8)	1 (1.5)	10 (4.6)	
Real-time method and method not tied to time	25 (8.7)	5 (7.6)	20 (9.1)	
Equipment				
Computer/tablet	229 (79.0)	46 (67.6)	183 (82.8)	.01
Smartphone	149 (51.4)	33 (48.5)	116 (52.5)	.58
Phone	51 (17.6)	18 (26.5)	33 (14.9)	.04
Activity tracker ^b	18 (6.2)	3 (4.4)	15 (6.8)	.58
Others ^c	10 (1.7)	1 (1.5)	9 (4.1)	.76

^a*P* values are based on chi-square tests.

^bFor example, pedometer and accelerometer.

^cExergame, television application, virtual reality, computer vision, artificial intelligence, robotics, smart textile, or augmented reality.

Discussion

Principal Findings

This study sought to investigate physiotherapists' opinion on the current state of RP in Finland. While the ongoing COVID-19 pandemic has increased the use of RP in everyday practice, practice time for RP was still minimal, as just 1 in 10 used >20% of practice time to conduct RP. The suitability of RP varied across different disease groups. According to the physiotherapists, RP is better suited for rehabilitees with lung, heart, or musculoskeletal diseases than for rehabilitees with neurological diseases. RP was most commonly performed with a computer/tablet or a smartphone and with real-time methods. Less than 2% of physiotherapists used other technological equipment (eg, VR, AI, or CV).

The COVID-19 pandemic has led to the rapid adoption of RP by hospitals and clinics. RP has enabled physiotherapists to continue to provide therapy to rehabilitees during the pandemic, prevent further transmission of the virus, and decrease the burden of the health system during this period [14,36]. Rapid implementation of RP was also observed in our study; however,

we did not assess the use of RP with rehabilitators due to the COVID-19 pandemic. Although still low, the number of physiotherapists who reported use of RP in their practice during the study period increased. One explanation for the rapid implementation of RP at the beginning of the COVID-19 pandemic may be that the Social Insurance Institution of Finland temporarily restricted conventional physiotherapy, and clinics and hospitals were thus required to use RP. Prior to the pandemic, RP was used more in the public sector than in the private sector, which may be due to strategic decisions in the public organizations. On the other hand, private sector companies are usually smaller and more dynamic, and this may partly explain the rapid implementation of RP in the private sector. Data security and protection systems are usually more complex in the public sector, which may have also affected implementation of RP.

In the private sector, 4 in 5 physiotherapists did not use RP at all prior to the COVID-19 pandemic, in contrast to 2 in 3 in the public sector. During the study period, the proportion of physiotherapists who reported that they do not use RP has decreased to slightly over 20% in both sectors. This increased use of RP observed in our study is consistent with the findings

of Rausch et al [26] who observed that RP increased from 4.9% (prior to the COVID-19 pandemic) to 44.6% (during the COVID-19 pandemic). In their study, physiotherapists aged <45 years used RP more than the older ones [23]. A corresponding relationship between age and RP use was not observed in our study (data not shown).

Previous studies indicate that RP is comparable to conventional physiotherapy for rehabilitees with stroke [22,37], hip and knee osteoarthritis [38], chronic respiratory disease [11], and multiple sclerosis [22]. In our study, the suitability “score” of RP seemed to be higher among certain diseases (eg, asthma or knee and hip osteoarthritis) in which verbal communication, such as guidance and advice, is a key element. Similarly, Rausch et al [26] concluded that RP is used the most in guidance and advice for rehabilitees. In contrast, RP seems to be poorly suitable for rehabilitees with memory disorders and spinal cord injuries. However, the current disease state should be considered when planning physiotherapy. It may be that RP is suitable in the early phase of, for example, neurological diseases, when hands-on therapy is not essential. Overall, knowledge on RP as an alternative or as a part of conventional physiotherapy in different diseases is still limited.

Physiotherapy has traditionally been a hands-on profession, and thereby physiotherapist may find it challenging to reach the standard of conventional physiotherapy with RP. RP may require changes in work routines and skills, as well as a greater workload and changes in interaction with rehabilitees [39]. RP cannot be used as replacement for the necessary contact between the rehabilitee and the physiotherapist [21] and should not replace conventional physiotherapy [26,32]. Further, barriers for RP that have been presented are demands in communication through a screen, lack of physical contact with rehabilitee, short of appropriate rehabilitation equipment in rehabilitees environment, digital literacy [32,40], and appropriate financial compensation [26]. In some countries, insurance companies hesitate to cover RP; however, it is not an issue in Finland where physiotherapists can decide what method to use, conventional physiotherapy or RP. It should be noted that real-time methods, which are the most used form of RP, still offer real-time contact between the rehabilitee and physiotherapist even if the medium is digital. In our study, 71% (203/286) of the physiotherapists reported having used real-time methods, 3.8% (11/286) methods not tied to time, and 8.7% (25/286) both methods. RP may offer opportunities to work more effectively with methods that are not tied to time, but the use of these methods is rare. However, the advantages and disadvantages of such methods should be tested in high-quality interventional studies.

A computer or tablet was the most chosen communication medium. This is comparable with previous findings that reported that physiotherapists preferred real-time methods with video technologies over other mediums [26,36,41,42]. Moreover, the possibilities that the technology provides to the physiotherapy process, rather than the method or technology itself, are important. Rehabilitees who are not interested in or are unfamiliar with the technology require more conventional physiotherapy than enthusiastic rehabilitees who see advantages on the use of technology and feel that RP could offer sufficient support [8].

In this study, almost three-quarters of the physiotherapists had no experience or had <1 year experience of RP, which can affect the use of RP. A previous study revealed that work experience is associated with the perception of how convenient RP is in clinical practice [41]. The willingness to use RP among physiotherapists has been reported to be high [27]. For easy implementation of RP in everyday practice, attention should be paid to not only professional education and skill training [26,32] but also common technical problems [43]. On the other hand, hardware and software costs are decreasing, ICT speeds are increasing, and the technology is continuously developing, which collectively have a positive effect on the use of RP [44]. The use of RP is still rare, but appropriate technology coupled with professional education in RP for undergraduate and recently graduated physiotherapists allows for an increase in the implementation of RP.

Strengths and Limitations

A strength of this study is the number of physiotherapists ($n=662$) who answered the survey, even if only a total of 9.9% (662/6525) answered. The physiotherapists were recruited from all municipalities in Finland and included physiotherapists with short and long clinical experience. Our physiotherapists could somehow be generalizable to the broader Finnish physiotherapy workforce, where 82% of employed physiotherapists are female with a mean age of 44.8 years, and the physiotherapists have relatively long clinical experience.

Our study also had some limitations. Our survey data were collected in Finland, and our findings may not be generalizable to other countries where physiotherapists may have more experience in RP and with a different health care system. The proportion of physiotherapists in the private sector who answered the questionnaire was higher than the corresponding proportion in the overall Finnish physiotherapy workforce in the private sector. Some of the physiotherapists in the private physiotherapy organization are also members of the Finnish Association of Physiotherapists and had the possibility to respond twice to the questionnaire. To avoid such an overlap, we recommended in the information letter not to respond twice. Furthermore, we do not know the reasons for overrepresentation of physiotherapists from the private sector in our study, but we analyzed the private and public sector separately.

Further, one limitation of our study may be nonparticipation bias. We recruited the study physiotherapists from the Finnish Association of Physiotherapists and from a private physiotherapy organization, but we had to collect the data anonymously. Therefore, it was not possible to analyze whether responders were significantly different from nonresponders and how these possible differences influenced the results of the study. Lastly, the use of a scientifically unvalidated questionnaire can be seen as a limitation. However, the questionnaire was based on consensus in a broad expert group, essential literature in the field, and was pilot-tested.

Conclusions

Based on our results, the suitability of RP for different diseases varies. During the COVID-19 pandemic, physiotherapists increased use of RP in their clinical practice, but use is still rare.

To conduct RP, physiotherapists use a computer/tablet or a smartphone and use a real-time method. Other technological equipment and methods are used infrequently. These results may help physiotherapists and organizations in planning and implementing RP in everyday work and in the development of physiotherapy education of ICT.

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Authors' Contributions

TH, JA, and JK contributed to designing the research. All authors were involved in constructing the questionnaire and edited, reviewed, and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence

CHERRIES: Checklist for Reporting Results of Internet E-Surveys

CV: computer vision

ICT: information and communications technology

NHI: National Health Insurance

RP: remote physiotherapy

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

VR: virtual reality

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